

EXHIBIT 9

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [pre]	Merck's Keytruda (Pembrolizumab)
A method of treating cancer in a human patient, the method comprising:	Merck's FDA-approved label for Keytruda ("Keytruda Label")¹ instructs physicians to use Keytruda to treat cancer in a patient. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7)² and MSI-H or dMMR endometrial cancer (Indication 1.15)³. <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

¹ While the March 2021, April 2023, and August 2023 Keytruda Labels are cited herein, Hopkins hereby incorporates all Keytruda Labels existing from the earliest issuance date of the asserted patents (March 2021) to present, which have substantially the same relevant information.

² Unless specified otherwise, the Indication No. provided corresponds to the Indication No. of the current Keytruda Label (*i.e.*, 08/2023 Keytruda Label).

³ The revisions in the November 2023 Keytruda Label changed the indication of endometrial carcinoma from Indication 1.15 to Indication 1.16.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [pre]	Merck's Keytruda (Pembrolizumab)
	[03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1[a]	Merck's Keytruda (Pembrolizumab)
testing or having tested a biological sample obtained from a patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer, thereby determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient; and	The Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient after testing or having tested a biological sample obtained from the patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer to determine that the patient's solid tumor exhibits at least one marker for high microsatellite instability (MSI-H) or DNA mismatch repair deficiency (dMMR). For example, the Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is either MSI-H or dMMR for treatment with Keytruda according to Indications 1.7 and 1.15 based on the MSI-H/dMMR status in a biological sample (<i>e.g.</i>, tumor specimen). 2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.4)</i>]. • metastatic urothelial carcinoma [see <i>Clinical Studies (14.7)</i>]. • metastatic gastric cancer [see <i>Clinical Studies (14.10)</i>]. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.11)</i>]. • recurrent or metastatic cervical cancer [see <i>Clinical Studies (14.12)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.8, 14.9)</i>].

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1[a]	Merck's Keytruda (Pembrolizumab)
	[03/2021 Keytruda Label at 7.] 2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is MSI-H or dMMR. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1[a]	Merck's Keytruda (Pembrolizumab)
	Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status via local PCR, IHC, or third-party tests such as <i>e.g.</i>, FoundationOne[®]CDx and VENTANA MMR RxDx Panel. The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available MSI-H and dMMR biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda			Export Excel		Show	10 entries
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite instability-High (MSI-H)	P170019/S029 (02/18/2022)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001 (03/21/2022)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002 (06/16/2022)	

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

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	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] For example, the “FoundationOne[®]CDx (F1CDx) is a qualitative next generation sequencing based <i>in vitro</i> diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI)” See SSED PMA P170019/S029 at 2; see also SSED PMA P170019/S016 at 2. To determine a patient's MSI status, F1CDx employs a fraction based (FB) MSI algorithm to categorize a tumor specimen as MSI-High (MSI-H) or microsatellite stable (MSS). The FB-MSI algorithm calculates the fraction of microsatellite loci determined to be altered or unstable (i.e., the fraction unstable loci score) based on a genome-wide analysis across >2000 microsatellite loci. For a given microsatellite locus, non-somatic alleles are discarded, and the microsatellite is categorized as unstable if remaining alleles differ from the reference genome. The final fraction unstable loci score is calculated as the number of unstable microsatellite loci divided by the number of evaluable microsatellite loci. Two FB-MSI score thresholds are applied to classify a tumor specimen as having MSI-H or MSS status. MSI-H status is reported for patients with solid tumors whose samples have FB-MSI scores ≥ 0.0124 while MSS status is reported for patients with solid tumors whose samples have FB-MSI scores ≤ 0.0041. Per the F1CDx assay, a patient whose tumor has an MSI-H score ≥ 0.0124 is reported as eligible for treatment with KEYTRUDA. For patients with solid tumors whose samples have FB-MSI scores >0.0041 and <0.0124, an MSI “Cannot be Determined” result is reported. Patients with this result should be re-tested with a validated orthogonal (alternative) method as these MSI scores represent a range of scores with low reliability. Patients with solid tumors may also receive an MSI status reported as MSI-Cannot Be Determined due to a quality control (QC) failure. Patients with this result should consider re-testing with FoundationOneCDx or an orthogonal (alternative) method, if clinically appropriate.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1[a]	Merck's Keytruda (Pembrolizumab)
	[SSED PMA P170019/S029 at 10; <i>see also</i> SSED PMA P170019/S016 at 9.] <i>See also, e.g.,</i> “VENTANA MMR RxDx Panel,” generically known as “[i]mmunohistochemistry test, DNA mismatch repair (MMR) [p]rotein assay,” which is used for “identifying patients with solid tumors with dMMR status who may benefit from treatment with KEYTRUDA.” [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210001S001 (last visited 11/14/2023).] At the time of the Keytruda Label, numerous biomarker assays for determining MSI-H/dMMR status were available, including the Promega OncoMate® MSI Dx Analysis System. <i>See, e.g.,</i> https://www.promega.com/products/microsatellite-instability-msi-testing/clinical-msi-testing-ivd/oncomate-msi-dx-analysis-system/. Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these microsatellite and MMR markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
in response to determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient, treating the patient determined to have microsatellite instability high or DNA mismatch repair deficient cancer with a therapeutically effective amount	The Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to treat a patient with a therapeutically effective amount of Keytruda in response to determining that the patient's cancer is MSI-H or dMMR. For example, the Keytruda Label discloses that Keytruda is a pembrolizumab injection. KEYTRUDA® (pembrolizumab) injection, for intravenous use Initial U.S. Approval: 2014 [03/2021 Keytruda Label at 1; 04/2023 Keytruda Label at 1; 08/2023 Keytruda Label at 1.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
of pembrolizumab.	The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Recommended Dosage section of the Keytruda Label provides the recommended dosages of Keytruda, as well as the duration/timing of treatment based on the indication, wherein the indication is directed to cancers confirmed to be MSI-H or dMMR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)																					
	2.2 Recommended Dosage Table 1: Recommended Dosage <table><tr><th>Indication</th><th>Recommended Dosage of KEYTRUDA</th><th>Duration/Timing of Treatment</th></tr><tr><td colspan="3">Monotherapy</td></tr><tr><td>Adult patients with unresectable or metastatic melanoma</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease progression or unacceptable toxicity</td></tr><tr><td>Adjuvant treatment of adult patients with melanoma</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease recurrence, unacceptable toxicity, or up to 12 months</td></tr><tr><td>Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease progression, unacceptable toxicity, or up to 24 months</td></tr><tr><td>Adult patients with high-risk BCG-unresponsive NMIBC</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months</td></tr><tr><td>Pediatric patients with cHL, PMBCL, MSI-H Cancer, MCC, or TMB-H Cancer</td><td>2 mg/kg every 3 weeks (up to a maximum of 200 mg)*</td><td>Until disease progression, unacceptable toxicity, or up to 24 months</td></tr></table> * 30-minute intravenous infusion † Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate. ‡ When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer. [03/2021 Keytruda Label at 8.]	Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment	Monotherapy			Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity	Adjuvant treatment of adult patients with melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months	Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months	Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months	Pediatric patients with cHL, PMBCL, MSI-H Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease progression, unacceptable toxicity, or up to 24 months
Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment																				
Monotherapy																						
Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity																				
Adjuvant treatment of adult patients with melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months																				
Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months																				
Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months																				
Pediatric patients with cHL, PMBCL, MSI-H Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease progression, unacceptable toxicity, or up to 24 months																				

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]

Merck's Keytruda (Pembrolizumab)

2.2 Recommended Dosage

Table 1: Recommended Dosage

Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment
Monotherapy		
Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity
Adjuvant treatment of adult patients with melanoma, NSCLC, or RCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months
Adult patients with NSCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, MSI-H or dMMR Endometrial Carcinoma, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months
Pediatric patients with cHL, PMBCL, MSI-H or dMMR Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease progression, unacceptable toxicity, or up to 24 months
Pediatric patients (12 years and older) for adjuvant treatment of melanoma	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease recurrence, unacceptable toxicity, or up to 12 months

* 30-minute intravenous infusion

† Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

‡ When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer.

§ Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent KEYTRUDA.

[08/2023 Keytruda Label at 8-9; see also 04/2023 Keytruda Label at 8-9.]

The Preparation and Administration section of the Keytruda Label provides instructions for

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
	preparing and administering Keytruda (pembrolizumab) to patients: 2.4 Preparation and Administration <u>Preparation for Intravenous Infusion</u> • Visually inspect the solution for particulate matter and discoloration. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial if visible particles are observed. • Dilute KEYTRUDA injection (solution) prior to intravenous administration. • Withdraw the required volume from the vial(s) of KEYTRUDA and transfer into an intravenous (IV) bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake. The final concentration of the diluted solution should be between 1 mg/mL to 10 mg/mL. • Discard any unused portion left in the vial. <u>Storage of Diluted Solution</u> The product does not contain a preservative. Store the diluted solution from the KEYTRUDA 100 mg/4 mL vial either: • At room temperature for no more than 6 hours from the time of dilution. This includes room temperature storage of the diluted solution, and the duration of infusion. • Under refrigeration at 2°C to 8°C (36°F to 46°F) for no more than 96 hours from the time of dilution. If refrigerated, allow the diluted solution to come to room temperature prior to administration. Do not shake. Discard after 6 hours at room temperature or after 96 hours under refrigeration. Do not freeze. <u>Administration</u> • Administer diluted solution intravenously over 30 minutes through an intravenous line containing a sterile, non-pyrogenic, low-protein binding 0.2 micron to 5 micron in-line or add-on filter. • Do not co-administer other drugs through the same infusion line. [03/2021 Label at 10-11; 04/2023 Keytruda Label at 11; 08/2023 Keytruda Label at 11.] The Keytruda Label includes clinical trial results showing that the recommended dosages of Keytruda are therapeutically effective among patients with MSI-H or dMMR solid tumors relevant to Indication 1.7 (or Indication 1.8 for 03/2021 Keytruda Label):

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
	14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)																																																
	<table><tr><th colspan="6">Table 57: MSI-H Trials</th></tr><tr><th>Study</th><th>Design and Patient Population</th><th>Number of Patients</th><th>MSI-H/dMMR Testing</th><th>Dosage</th><th>Prior Therapy</th></tr><tr><td>KEYNOTE-016 NCT01876511</td><td> - prospective, investigator-initiated 6 sites - patients with CRC and other tumors </td><td>28 CRC 30 non-CRC</td><td>local PCR or IHC</td><td>10 mg/kg every 2 weeks</td><td> - CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen </td></tr><tr><td>KEYNOTE-164 NCT02460198</td><td> - prospective international multi-center - CRC </td><td>61</td><td>local PCR or IHC</td><td>200 mg every 3 weeks</td><td>Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb</td></tr><tr><td>KEYNOTE-012 NCT01848834</td><td> - retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer </td><td>6</td><td>central PCR</td><td>10 mg/kg every 2 weeks</td><td>≥1 prior regimen</td></tr><tr><td>KEYNOTE-028 NCT02054806</td><td> - retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC </td><td>5</td><td>central PCR</td><td>10 mg/kg every 2 weeks</td><td>≥1 prior regimen</td></tr><tr><td>KEYNOTE-158 NCT02628067</td><td> - prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts </td><td>19</td><td>local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)</td><td>200 mg every 3 weeks</td><td>≥1 prior regimen</td></tr><tr><td>Total</td><td></td><td>149</td><td></td><td></td><td></td></tr></table> CRC = colorectal cancer PCR = polymerase chain reaction IHC = immunohistochemistry	Table 57: MSI-H Trials						Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy	KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen	KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb	KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen	KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen	KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥1 prior regimen	Total		149			
Table 57: MSI-H Trials																																																	
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy																																												
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen																																												
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KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥1 prior regimen																																												
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	[03/2021 Keytruda Label at 82-83.]																																																

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Efficacy results are summarized in Tables 69 and 70.

Table 69: Efficacy Results for Patients with MSI-H/dMMR Cancer

Endpoint	KEYTRUDA n=504*
Objective Response Rate	
ORR (95% CI)†	33.3% (29.2, 37.6)
Complete response rate	10.3%
Partial response rate	23.0%
Duration of Response	n=168
Median in months (range)	63.2 (1.9+, 63.9+)
% with duration ≥12 months	77%
% with duration ≥36 months	39%

* Median follow-up time of 20.1 months (range 0.1 to 71.4 months)

† Of the 7 pediatric patients from KEYNOTE-051, 1 patient had a radiographic complete response after initial growth of their tumor but is not reflected in the results.

* Denotes ongoing response

Table 70: Response by Tumor Type

	N	Objective Response Rate n (%)	95% CI	Duration of Response range (months)
CRC	124	42 (34%)	(26%, 43%)	(4.4, 58.5+)
Non-CRC*	380	126 (33%)	(28%, 38%)	(1.9+, 63.9+)
Endometrial cancer	94	47 (50%)	(40%, 61%)	(2.9, 63.2)
Gastric or GE junction cancer	51	20 (39%)	(26%, 54%)	(1.9+, 63.0+)
Small intestinal cancer	27	16 (59%)	(39%, 78%)	(3.7+, 57.3+)
Brain cancer	27†	1 (4%)‡	(0%, 19%)	18.9
Ovarian cancer	25	8 (32%)	(15%, 54%)	(4.2, 56.6+)
Biliary cancer	22	9 (41%)	(21%, 64%)	(6.2, 49.0+)
Pancreatic cancer	22	4 (18%)	(5%, 40%)	(8.1, 24.3+)
Sarcoma	14	3 (21%)	(5%, 51%)	(35.4+, 57.2+)
Breast cancer	13	1 (8%)	(0%, 36%)	24.3+
Other§	13	4 (31%)	(9%, 61%)	(6.2+, 32.3+)
Cervical cancer	11	1 (9%)	(0%, 41%)	63.9+
Neuroendocrine cancer	11	1 (9%)	(0%, 41%)	13.3
Prostate cancer	8	1 (13%)	(0%, 53%)	24.5+
Adrenocortical cancer	7	1 (14%)	(0%, 58%)	4.2
Mesothelioma	7	0 (0%)	(0%, 41%)	
Thyroid cancer	7	1 (14%)	(0%, 58%)	8.2
Small cell lung cancer	6	2 (33%)	(4%, 78%)	(20.0, 47.5)
Bladder cancer	6	3 (50%)	(12%, 88%)	(35.6+, 57.5+)
Salivary cancer	5	2 (40%)	(5%, 85%)	(42.6+, 57.8+)
Renal cell cancer	4	1 (25%)	(0%, 81%)	22.0

* Results include patients in Cohort K of KEYNOTE-158 that were later determined to be pMMR or not MSI-H by central testing

† Includes 6 pediatric patients with brain cancer

‡ In addition to the 1 adult responder, 1 pediatric patient had a radiographic complete response after initial growth of their tumor.

§ Includes tumor type (n): anal (3), HNSCC (1), nasopharyngeal (1), retroperitoneal (1), testicular (1), vaginal (1), vulvar (1), appendiceal adenocarcinoma, NOS (1), hepatocellular carcinoma (1), and carcinoma of unknown origin (1). Includes 1 pediatric patient with abdominal adenocarcinoma.

* Denotes ongoing response

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 1 [b]	Merck's Keytruda (Pembrolizumab)																		
	[04/2023 Keytruda Label at 97-98; 08/2023 Keytruda Label at 98-99.] The Keytruda Label also includes clinical trial results showing that the recommended dosages of Keytruda are therapeutically effective in patients with MSI-H or dMMR endometrial cancers relevant to Indication 1.15. As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Table 83: Efficacy Results in Patients with Advanced MSI-H or dMMR Endometrial Carcinoma in KEYNOTE-158 <table> <tr> <th>Endpoint</th><th>KEYTRUDA n=90*</th></tr> <tr> <td>Objective Response Rate</td><td></td></tr> <tr> <td>ORR (95% CI)</td><td>46% (35, 56)</td></tr> <tr> <td>Complete response rate</td><td>12%</td></tr> <tr> <td>Partial response rate</td><td>33%</td></tr> <tr> <td>Duration of Response</td><td>n=41</td></tr> <tr> <td>Median in months (range)</td><td>NR (2.9, 55.7+)</td></tr> <tr> <td>% with duration ≥12 months</td><td>68%</td></tr> <tr> <td>% with duration ≥24 months</td><td>44%</td></tr> </table> * Median follow-up time of 16.0 months (range 0.5 to 62.1 months) + Denotes ongoing response NR = not reached [04/2023 Keytruda Label at 122-123; <i>see also</i> 08/2023 Keytruda Label at 123-124.]	Endpoint	KEYTRUDA n=90*	Objective Response Rate		ORR (95% CI)	46% (35, 56)	Complete response rate	12%	Partial response rate	33%	Duration of Response	n=41	Median in months (range)	NR (2.9, 55.7+)	% with duration ≥12 months	68%	% with duration ≥24 months	44%
Endpoint	KEYTRUDA n=90*																		
Objective Response Rate																			
ORR (95% CI)	46% (35, 56)																		
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% with duration ≥24 months	44%																		

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 4	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer or cholangiocarcinoma.	<i>See claim 1.</i> In addition, the Keytruda Label instructs physicians to use Keytruda to treat a patient having a cancer selected from the group of claim 1, wherein the cancer is endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer or cholangiocarcinoma. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 4	Merck's Keytruda (Pembrolizumab)
	1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.]
Claim 5	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer,	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to treat a patient having a cancer selected from the group of claim 1, wherein the cancer is pancreatic cancer, prostate

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 5	Merck's Keytruda (Pembrolizumab)
testicular cancer or oral cancer.	cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is determined to be microsatellite instability high.	<i>See claim 1.</i> In addition, the Keytruda Label instructs physicians to use Keytruda to treat a patient having a cancer selected from the group of claim 1, wherein the cancer is determined to be microsatellite instability high (MSI-H). For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H solid tumors (Indication 1.7) and MSI-H endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is MSI-H for treatment with Keytruda according to Indications 1.7 and 1.15 based on the MSI-H status in a biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation <i>[see Clinical Studies (14.2)]</i>. • metastatic NSCLC <i>[see Clinical Studies (14.2)]</i>. • first-line treatment of metastatic or unresectable, recurrent HNSCC <i>[see Clinical Studies (14.4)]</i>. • metastatic urothelial carcinoma <i>[see Clinical Studies (14.7)]</i>. • metastatic gastric cancer <i>[see Clinical Studies (14.10)]</i>. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. • previously treated recurrent locally advanced or metastatic esophageal cancer <i>[see Clinical Studies (14.11)]</i>. • recurrent or metastatic cervical cancer <i>[see Clinical Studies (14.12)]</i>. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens <i>[see Clinical Studies (14.8, 14.9)]</i>. [03/2021 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is MSI-H. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's MSI-H status via local PCR, IHC, or third-party tests such as <i>e.g.</i>, FoundationOne®CDx.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available MSI-H biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda		Export Excel		Show	10	entries
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016	(06/16/2020)
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite instability-High (MSI-H)	P170019/S029	(02/18/2022)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013	(10/02/2015)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009	(06/12/2018)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014	(06/10/2019)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016	(07/30/2019)
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020	(11/13/2020)
Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001	(03/21/2022)
Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002	(06/16/2022)

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] For example, the “FoundationOne[®]CDx (F1CDx) is a qualitative next generation sequencing based <i>in vitro</i> diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI)” See SSED PMA P170019/S029 at 2; see also SSED PMA P170019/S016 at 2. To determine a patient's MSI status, F1CDx employs a fraction based (FB) MSI algorithm to categorize a tumor specimen as MSI-High (MSI-H) or microsatellite stable (MSS). The FB-MSI algorithm calculates the fraction of microsatellite loci determined to be altered or unstable (i.e., the fraction unstable loci score) based on a genome-wide analysis across >2000 microsatellite loci. For a given microsatellite locus, non-somatic alleles are discarded, and the microsatellite is categorized as unstable if remaining alleles differ from the reference genome. The final fraction unstable loci score is calculated as the number of unstable microsatellite loci divided by the number of evaluable microsatellite loci. Two FB-MSI score thresholds are applied to classify a tumor specimen as having MSI-H or MSS status. MSI-H status is reported for patients with solid tumors whose samples have FB-MSI scores ≥ 0.0124 while MSS status is reported for patients with solid tumors whose samples have FB-MSI scores ≤ 0.0041. Per the F1CDx assay, a patient whose tumor has an MSI-H score ≥ 0.0124 is reported as eligible for treatment with KEYTRUDA. For patients with solid tumors whose samples have FB-MSI scores >0.0041 and <0.0124, an MSI “Cannot be Determined” result is reported. Patients with this result should be re-tested with a validated orthogonal (alternative) method as these MSI scores represent a range of scores with low reliability. Patients with solid tumors may also receive an MSI status reported as MSI-Cannot Be Determined due to a quality control (QC) failure. Patients with this result should consider re-testing with FoundationOneCDx or an orthogonal (alternative) method, if clinically appropriate.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 6	Merck's Keytruda (Pembrolizumab)
	[SSED PMA P170019/S029 at 10; <i>see also</i> SSED PMA P170019/S016 at 9.] At the time of the Keytruda Label, numerous biomarker assays for determining MSI-H status were available, including the Promega OncoMate® MSI Dx Analysis System. <i>See, e.g.</i>, https://www.promega.com/products/microsatellite-instability-msi-testing/clinical-msi-testing-ivd/oncomate-msi-dx-analysis-system/. Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these microsatellite markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 7	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is determined to be mismatch repair deficient.	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to treat a patient having a cancer selected from the group of claim 1, wherein the cancer is determined to be mismatch repair deficient (dMMR). For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having dMMR solid tumors (Indication 1.7) and dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is dMMR for treatment with Keytruda according to Indications 1.7 and 1.15 based on the dMMR status in a biological sample (<i>e.g.</i>, tumor specimen).

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation <i>[see Clinical Studies (14.2)]</i>. • metastatic NSCLC <i>[see Clinical Studies (14.2)]</i>. • first-line treatment of metastatic or unresectable, recurrent HNSCC <i>[see Clinical Studies (14.4)]</i>. • metastatic urothelial carcinoma <i>[see Clinical Studies (14.7)]</i>. • metastatic gastric cancer <i>[see Clinical Studies (14.10)]</i>. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. • previously treated recurrent locally advanced or metastatic esophageal cancer <i>[see Clinical Studies (14.11)]</i>. • recurrent or metastatic cervical cancer <i>[see Clinical Studies (14.12)]</i>. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens <i>[see Clinical Studies (14.8, 14.9)]</i>. [03/2021 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is dMMR. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's dMMR status via local PCR, IHC, or third-

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	party tests such as <i>e.g.</i>, VENTANA MMR RxDx Panel. The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available dMMR biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda		Export Excel		Show 10 entries		
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite Instability-High (MSI-H)	P170019/S029 (02/18/2022)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001 (03/21/2022)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002 (06/16/2022)	

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 7	Merck's Keytruda (Pembrolizumab)
	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] <i>See, e.g.</i>, “VENTANA MMR RxDx Panel,” generically known as “[i]mmunohistochemistry test, DNA mismatch repair (MMR) [p]rotein assay,” and is used for “identifying patients with solid tumors with dMMR status who may benefit from treatment with KEYTRUDA.” [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210001S001 (last visited 11/14/2023).] Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these MMR markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 12	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is small bowel cancer.	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to treat a patient having a cancer selected from the group of claim 1, wherein the cancer is small bowel cancer. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) (<i>e.g.</i>, small bowel cancer). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 12	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) - solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or - colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.]
Claim 13	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to treat a patient having a cancer selected from the group of claim 1, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 13	Merck's Keytruda (Pembrolizumab)
patient was treated with the prior cancer therapy drug.	progressed after the patient was treated with the prior cancer therapy drug. The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15) that has progressed after the patient was treated with the prior cancer therapy drug. <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 13	Merck's Keytruda (Pembrolizumab)
	<u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] <i>See also, e.g.,</i> Section 14.7 of the Keytruda Label (Section 14.8 of the 03/2021 Keytruda Label) instructing physicians to use Keytruda to treat of MSI-H/dMMR cancers that have progressed following prior cancer treatment. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 13

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥ 1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥ 1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Kevtruda Label at 82-83.]

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 13	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] <i>See also, e.g.,</i> Section 14.15 of the Keytruda Label instructing physicians to use Keytruda to treat of MSI-H/dMMR endometrial cancer that has progressed following prior cancer treatment.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 13	Merck's Keytruda (Pembrolizumab)
	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Among the 90 patients evaluated, the baseline characteristics were: median age of 64 years (range: 42 to 86); 83% White, 8% Asian, and 3% Black; 12% Hispanic or Latino; 39% ECOG PS of 0 and 61% ECOG PS of 1; 96% had M1 disease and 4% had M0 disease at study entry; and 51% had one and 48% had two or more prior lines of therapy. Nine patients received only adjuvant therapy and one patient received only neoadjuvant and adjuvant therapy before participating in the study. Efficacy results are summarized in Table 83. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
Claim 14	Merck's Keytruda (Pembrolizumab)
The method of claim 1 further comprising testing or having tested the patient for progression of the cancer after the treatment.	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient having a cancer selected from the group of claim 1, wherein treatment further comprises testing or having tested the patient for progression of the cancer after the treatment. For example, the Keytruda Label instructs physicians to assess progression of the cancer of MSI-H or dMMR tumors treated with Keytruda in accordance with Indication 1.7 (or 1.8 of

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 14	Merck's Keytruda (Pembrolizumab)
	the 03/2021 Keytruda Label) every 8 or 9 or 12 weeks. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 14

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 14	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The Keytruda Label also instructs physicians to assess the objective response rate in patients with MSI-H or dMMR endometrial tumors treated with Keytruda in accordance with Indication 1.15 every 9 or 12 weeks.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 14	Merck's Keytruda (Pembrolizumab)
	As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
Claim 15	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is metastatic.	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient having a cancer selected from the group of claim 1, wherein the cancer is metastatic. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having metastatic MSI-H or dMMR solid tumors (Indication 1.7). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 15	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)
A method of reducing the risk of cancer progression or increasing overall survival in a human	Merck's FDA-approved label for Keytruda ("Keytruda Label") instructs physicians to use Keytruda to reduce the risk of cancer progression or increase the overall survival in a human patient.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)
patient, the method comprising:	For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Keytruda Label includes clinical trial results showing that the recommended dosages of Keytruda are a therapeutically effective to reduce the risk of progression amount among patients with MSI-H or dMMR solid tumors relevant to Indication 1.7. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)																																																
	<table><tr><th colspan="6">Table 57: MSI-H Trials</th></tr><tr><th>Study</th><th>Design and Patient Population</th><th>Number of Patients</th><th>MSI-H/dMMR Testing</th><th>Dosage</th><th>Prior Therapy</th></tr><tr><td>KEYNOTE-016 NCT01876511</td><td> - prospective, investigator-initiated 6 sites - patients with CRC and other tumors </td><td>28 CRC 30 non-CRC</td><td>local PCR or IHC</td><td>10 mg/kg every 2 weeks</td><td> - CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen </td></tr><tr><td>KEYNOTE-164 NCT02460198</td><td> - prospective international multi-center - CRC </td><td>61</td><td>local PCR or IHC</td><td>200 mg every 3 weeks</td><td>Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb</td></tr><tr><td>KEYNOTE-012 NCT01848834</td><td> - retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer </td><td>6</td><td>central PCR</td><td>10 mg/kg every 2 weeks</td><td>≥1 prior regimen</td></tr><tr><td>KEYNOTE-028 NCT02054806</td><td> - retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC </td><td>5</td><td>central PCR</td><td>10 mg/kg every 2 weeks</td><td>≥1 prior regimen</td></tr><tr><td>KEYNOTE-158 NCT02628067</td><td> - prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts </td><td>19</td><td>local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)</td><td>200 mg every 3 weeks</td><td>≥1 prior regimen</td></tr><tr><td>Total</td><td></td><td>149</td><td></td><td></td><td></td></tr></table> CRC = colorectal cancer PCR = polymerase chain reaction IHC = immunohistochemistry	Table 57: MSI-H Trials						Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy	KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen	KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb	KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen	KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen	KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥1 prior regimen	Total		149			
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	[03/2021 Keytruda Label at 82-83.]																																																

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EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Efficacy results are summarized in Tables 69 and 70.

Table 69: Efficacy Results for Patients with MSI-H/dMMR Cancer

Endpoint	KEYTRUDA n=504*
Objective Response Rate	
ORR (95% CI)†	33.3% (29.2, 37.6)
Complete response rate	10.3%
Partial response rate	23.0%
Duration of Response	n=168
Median in months (range)	63.2 (1.9+, 63.9+)
% with duration ≥12 months	77%
% with duration ≥36 months	39%

* Median follow-up time of 20.1 months (range 0.1 to 71.4 months)

† Of the 7 pediatric patients from KEYNOTE-051, 1 patient had a radiographic complete response after initial growth of their tumor but is not reflected in the results.

+ Denotes ongoing response

Table 70: Response by Tumor Type

	N	Objective Response Rate n (%)	95% CI	Duration of Response range (months)
CRC	124	42 (34%)	(26%, 43%)	(4.4, 58.5+)
Non-CRC‡	380	126 (33%)	(28%, 38%)	(1.9+, 63.9+)
Endometrial cancer	94	47 (50%)	(40%, 61%)	(2.9, 63.2)
Gastric or GE junction cancer	51	20 (39%)	(26%, 54%)	(1.9+, 63.0+)
Small intestinal cancer	27	16 (59%)	(39%, 78%)	(3.7+, 57.3+)
Brain cancer	27†	1 (4%)‡	(0%, 19%)	18.9
Ovarian cancer	25	8 (32%)	(15%, 54%)	(4.2, 56.6+)
Biliary cancer	22	9 (41%)	(21%, 64%)	(6.2, 49.0+)
Pancreatic cancer	22	4 (18%)	(5%, 40%)	(8.1, 24.3+)
Sarcoma	14	3 (21%)	(5%, 51%)	(35.4+, 57.2+)
Breast cancer	13	1 (8%)	(0%, 36%)	24.3+
Other§	13	4 (31%)	(9%, 61%)	(6.2+, 32.3+)
Cervical cancer	11	1 (9%)	(0%, 41%)	63.9+
Neuroendocrine cancer	11	1 (9%)	(0%, 41%)	13.3
Prostate cancer	8	1 (13%)	(0%, 53%)	24.5+
Adrenocortical cancer	7	1 (14%)	(0%, 58%)	4.2
Mesothelioma	7	0 (0%)	(0%, 41%)	
Thyroid cancer	7	1 (14%)	(0%, 58%)	8.2
Small cell lung cancer	6	2 (33%)	(4%, 78%)	(20.0, 47.5)
Bladder cancer	6	3 (50%)	(12%, 88%)	(35.6+, 57.5+)
Salivary cancer	5	2 (40%)	(5%, 85%)	(42.6+, 57.8+)
Renal cell cancer	4	1 (25%)	(0%, 81%)	22.0

* Results include patients in Cohort K of KEYNOTE-158 that were later determined to be pMMR or not MSI-H by central testing

† Includes 6 pediatric patients with brain cancer

‡ In addition to the 1 adult responder, 1 pediatric patient had a radiographic complete response after initial growth of their tumor.

§ Includes tumor type (n): anal (3), HNSCC (1), nasopharyngeal (1), retroperitoneal (1), testicular (1), vaginal (1), vulvar (1), appendiceal adenocarcinoma, NOS (1), hepatocellular carcinoma (1), and carcinoma of unknown origin (1). Includes 1 pediatric patient with abdominal adenocarcinoma.

+ Denotes ongoing response

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)																		
	[04/2023 Keytruda Label at 97-98; 08/2023 Keytruda Label at 98-99.] <i>See also</i> NEJM Article at <i>e.g.</i>, Figure 2 and Tables 1 and 2 (discussing reducing risk of progression of MSI-H/dMMR cancers in patients following treatment with Keytruda). The Keytruda Label also includes clinical trial results showing that the recommended dosages of Keytruda are therapeutically effective in patients with MSI-H or dMMR endometrial cancers relevant to Indication 1.15 to reduce the risk of cancer progression. As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Table 83: Efficacy Results in Patients with Advanced MSI-H or dMMR Endometrial Carcinoma in KEYNOTE-158 <table> <tr> <th>Endpoint</th><th>KEYTRUDA n=90*</th></tr> <tr> <td>Objective Response Rate</td><td></td></tr> <tr> <td>ORR (95% CI)</td><td>46% (35, 56)</td></tr> <tr> <td>Complete response rate</td><td>12%</td></tr> <tr> <td>Partial response rate</td><td>33%</td></tr> <tr> <td>Duration of Response</td><td>n=41</td></tr> <tr> <td>Median in months (range)</td><td>NR (2.9, 55.7+)</td></tr> <tr> <td>% with duration ≥12 months</td><td>68%</td></tr> <tr> <td>% with duration ≥24 months</td><td>44%</td></tr> </table> * Median follow-up time of 16.0 months (range 0.5 to 62.1 months) + Denotes ongoing response NR = not reached	Endpoint	KEYTRUDA n=90*	Objective Response Rate		ORR (95% CI)	46% (35, 56)	Complete response rate	12%	Partial response rate	33%	Duration of Response	n=41	Median in months (range)	NR (2.9, 55.7+)	% with duration ≥12 months	68%	% with duration ≥24 months	44%
Endpoint	KEYTRUDA n=90*																		
Objective Response Rate																			
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INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [pre]	Merck's Keytruda (Pembrolizumab)
	[04/2023 Keytruda Label at 122-123; 08/2023 Keytruda Label at 123-124.]

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
testing, or having tested, a biological sample obtained from a patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer, thereby determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient; and	The Keytruda Label instructs physicians to use Keytruda to reduce the risk of cancer progression or increase the overall survival of a patient wherein the biological sample obtained from the patient having endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer is tested to determine that the patient's solid tumor exhibits at least one marker for high microsatellite instability (MSI-H) or DNA mismatch repair deficiency (dMMR). For example, the Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is either MSI-H or dMMR for treatment with Keytruda according to Indications 1.7, 1.8, and 1.15 based on the MSI-H/dMMR status in a biological sample (<i>e.g.</i>, tumor specimen).

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: - stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation <i>[see Clinical Studies (14.2)]</i>. - metastatic NSCLC <i>[see Clinical Studies (14.2)]</i>. - first-line treatment of metastatic or unresectable, recurrent HNSCC <i>[see Clinical Studies (14.4)]</i>. - metastatic urothelial carcinoma <i>[see Clinical Studies (14.7)]</i>. - metastatic gastric cancer <i>[see Clinical Studies (14.10)]</i>. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. - previously treated recurrent locally advanced or metastatic esophageal cancer <i>[see Clinical Studies (14.11)]</i>. - recurrent or metastatic cervical cancer <i>[see Clinical Studies (14.12)]</i>. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens <i>[see Clinical Studies (14.8, 14.9)]</i>. [03/2021 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is MSI-H or dMMR. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics . [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
	Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status via local PCR, IHC, or third-party tests such as <i>e.g.</i>, FoundationOne[®]CDx and VENTANA MMR RxDx Panel. The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available MSI-H and dMMR biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda		Export Excel		Show 10 entries		
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite instability-High (MSI-H)	P170019/S029 (02/18/2022)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001 (03/21/2022)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206247	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002 (06/16/2022)	

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] For example, the “FoundationOne[®]CDx (F1CDx) is a qualitative next generation sequencing based <i>in vitro</i> diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI)” See SSED PMA P170019/S029 at 2; see also SSED PMA P170019/S016 at 2. To determine a patient's MSI status, F1CDx employs a fraction based (FB) MSI algorithm to categorize a tumor specimen as MSI-High (MSI-H) or microsatellite stable (MSS). The FB-MSI algorithm calculates the fraction of microsatellite loci determined to be altered or unstable (i.e., the fraction unstable loci score) based on a genome-wide analysis across >2000 microsatellite loci. For a given microsatellite locus, non-somatic alleles are discarded, and the microsatellite is categorized as unstable if remaining alleles differ from the reference genome. The final fraction unstable loci score is calculated as the number of unstable microsatellite loci divided by the number of evaluable microsatellite loci. Two FB-MSI score thresholds are applied to classify a tumor specimen as having MSI-H or MSS status. MSI-H status is reported for patients with solid tumors whose samples have FB-MSI scores ≥ 0.0124 while MSS status is reported for patients with solid tumors whose samples have FB-MSI scores ≤ 0.0041. Per the F1CDx assay, a patient whose tumor has an MSI-H score ≥ 0.0124 is reported as eligible for treatment with KEYTRUDA. For patients with solid tumors whose samples have FB-MSI scores >0.0041 and <0.0124, an MSI “Cannot be Determined” result is reported. Patients with this result should be re-tested with a validated orthogonal (alternative) method as these MSI scores represent a range of scores with low reliability. Patients with solid tumors may also receive an MSI status reported as MSI-Cannot Be Determined due to a quality control (QC) failure. Patients with this result should consider re-testing with FoundationOneCDx or an orthogonal (alternative) method, if clinically appropriate.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [a]	Merck's Keytruda (Pembrolizumab)
	[SSED PMA P170019/S029 at 10; <i>see also</i> SSED PMA P170019/S016 at 9.] <i>See also, e.g.,</i> “VENTANA MMR RxDx Panel,” generically known as “[i]mmunohistochemistry test, DNA mismatch repair (MMR) [p]rotein assay,” which is used for “identifying patients with solid tumors with dMMR status who may benefit from treatment with KEYTRUDA.” [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210001S001 (last visited 11/14/2023).] At the time of the Keytruda Label, numerous biomarker assays for determining MSI-H/dMMR status were available, including the Promega OncoMate® MSI Dx Analysis System. <i>See, e.g.,</i> https://www.promega.com/products/microsatellite-instability-msi-testing/clinical-msi-testing-ivd/oncomate-msi-dx-analysis-system/. Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these microsatellite and MMR markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
in response to determining that the patient's cancer is microsatellite instability high or DNA mismatch repair deficient, treating the patient determined to have microsatellite instability high or mismatch repair deficient cancer with a therapeutically effective amount of	The Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to reduce the risk of cancer progression or increase the overall survival of a patient determined to have a cancer that is MSI-H or dMMR with a therapeutically effective amount of Keytruda. For example, the Keytruda Label discloses that Keytruda is a pembrolizumab injection. KEYTRUDA® (pembrolizumab) injection, for intravenous use Initial U.S. Approval: 2014

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
pembrolizumab.	[03/2021 Keytruda Label at 1; 04/2023 Keytruda Label at 1; 08/2023 Keytruda Label at 1.] The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
	<u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Recommended Dosage section of the Keytruda Label provides the recommended dosages of Keytruda, as well as the duration/timing of treatment based on the indication, wherein the indication is directed to cancers confirmed to be MSI-H or dMMR to reduce the risk of cancer progression or increase the overall survival of the patient.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]

Merck's Keytruda (Pembrolizumab)

2.2 Recommended Dosage

Table 1: Recommended Dosage

Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment
Monotherapy		
Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity
Adjuvant treatment of adult patients with melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months
Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months
Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months
Pediatric patients with cHL, PMBCL, MSI-H Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)†	Until disease progression, unacceptable toxicity, or up to 24 months

* 30-minute intravenous infusion

† Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

‡ When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer.

[03/2021 Keytruda Label at 8.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)																								
	2.2 Recommended Dosage Table 1: Recommended Dosage <table><tr><th>Indication</th><th>Recommended Dosage of KEYTRUDA</th><th>Duration/Timing of Treatment</th></tr><tr><td colspan="3">Monotherapy</td></tr><tr><td>Adult patients with unresectable or metastatic melanoma</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease progression or unacceptable toxicity</td></tr><tr><td>Adjuvant treatment of adult patients with melanoma, NSCLC, or RCC</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease recurrence, unacceptable toxicity, or up to 12 months</td></tr><tr><td>Adult patients with NSCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, MSI-H or dMMR Endometrial Carcinoma, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until disease progression, unacceptable toxicity, or up to 24 months</td></tr><tr><td>Adult patients with high-risk BCG-unresponsive NMIBC</td><td>200 mg every 3 weeks* or 400 mg every 6 weeks*</td><td>Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months</td></tr><tr><td>Pediatric patients with cHL, PMBCL, MSI-H or dMMR Cancer, MCC, or TMB-H Cancer</td><td>2 mg/kg every 3 weeks (up to a maximum of 200 mg)*</td><td>Until disease progression, unacceptable toxicity, or up to 24 months</td></tr><tr><td>Pediatric patients (12 years and older) for adjuvant treatment of melanoma</td><td>2 mg/kg every 3 weeks (up to a maximum of 200 mg)*</td><td>Until disease recurrence, unacceptable toxicity, or up to 12 months</td></tr></table> * 30-minute intravenous infusion † Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate. ‡ When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer. § Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent KEYTRUDA. [08/2023 Keytruda Label at 8-9; see also 04/2023 Keytruda Label at 8-9.] The Preparation and Administration section of the Keytruda Label provides instructions for	Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment	Monotherapy			Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity	Adjuvant treatment of adult patients with melanoma, NSCLC, or RCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months	Adult patients with NSCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, MSI-H or dMMR Endometrial Carcinoma, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months	Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months	Pediatric patients with cHL, PMBCL, MSI-H or dMMR Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease progression, unacceptable toxicity, or up to 24 months	Pediatric patients (12 years and older) for adjuvant treatment of melanoma	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease recurrence, unacceptable toxicity, or up to 12 months
Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment																							
Monotherapy																									
Adult patients with unresectable or metastatic melanoma	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression or unacceptable toxicity																							
Adjuvant treatment of adult patients with melanoma, NSCLC, or RCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease recurrence, unacceptable toxicity, or up to 12 months																							
Adult patients with NSCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, MSI-H or dMMR Endometrial Carcinoma, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months																							
Adult patients with high-risk BCG-unresponsive NMIBC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months																							
Pediatric patients with cHL, PMBCL, MSI-H or dMMR Cancer, MCC, or TMB-H Cancer	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease progression, unacceptable toxicity, or up to 24 months																							
Pediatric patients (12 years and older) for adjuvant treatment of melanoma	2 mg/kg every 3 weeks (up to a maximum of 200 mg)*	Until disease recurrence, unacceptable toxicity, or up to 12 months																							

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
	preparing and administering Keytruda (pembrolizumab) to patients: 2.4 Preparation and Administration <u>Preparation for Intravenous Infusion</u> • Visually inspect the solution for particulate matter and discoloration. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial if visible particles are observed. • Dilute KEYTRUDA injection (solution) prior to intravenous administration. • Withdraw the required volume from the vial(s) of KEYTRUDA and transfer into an intravenous (IV) bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake. The final concentration of the diluted solution should be between 1 mg/mL to 10 mg/mL. • Discard any unused portion left in the vial. <u>Storage of Diluted Solution</u> The product does not contain a preservative. Store the diluted solution from the KEYTRUDA 100 mg/4 mL vial either: • At room temperature for no more than 6 hours from the time of dilution. This includes room temperature storage of the diluted solution, and the duration of infusion. • Under refrigeration at 2°C to 8°C (36°F to 46°F) for no more than 96 hours from the time of dilution. If refrigerated, allow the diluted solution to come to room temperature prior to administration. Do not shake. Discard after 6 hours at room temperature or after 96 hours under refrigeration. Do not freeze. <u>Administration</u> • Administer diluted solution intravenously over 30 minutes through an intravenous line containing a sterile, non-pyrogenic, low-protein binding 0.2 micron to 5 micron in-line or add-on filter. • Do not co-administer other drugs through the same infusion line. [03/2021 Keytruda Label at 10-11; 04/2023 Keytruda Label at 11; 08/2023 Keytruda Label at 11.] The Keytruda Label includes clinical trial results showing that the recommended dosages of Keytruda are therapeutically effective among patients with MSI-H or dMMR solid tumors relevant to Indication 1.7 (or Indication 1.8 for 03/2021 Keytruda Label) to reduce the risk of

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
	cancer progression and/or increase overall survival: 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Keytruda Label at 82-83.]

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Efficacy results are summarized in Tables 69 and 70.

Table 69: Efficacy Results for Patients with MSI-H/dMMR Cancer

Endpoint	KEYTRUDA n=504*
Objective Response Rate	
ORR (95% CI)†	33.3% (29.2, 37.6)
Complete response rate	10.3%
Partial response rate	23.0%
Duration of Response	n=168
Median in months (range)	63.2 (1.9+, 63.9+)
% with duration ≥12 months	77%
% with duration ≥36 months	39%

* Median follow-up time of 20.1 months (range 0.1 to 71.4 months)

† Of the 7 pediatric patients from KEYNOTE-051, 1 patient had a radiographic complete response after initial growth of their tumor but is not reflected in the results.

+ Denotes ongoing response

Table 70: Response by Tumor Type

	N	Objective Response Rate n (%)	95% CI	Duration of Response range (months)
CRC	124	42 (34%)	(26%, 43%)	(4.4, 58.5+)
Non-CRC‡	380	126 (33%)	(28%, 38%)	(1.9+, 63.9+)
Endometrial cancer	94	47 (50%)	(40%, 61%)	(2.9, 63.2)
Gastric or GE junction cancer	51	20 (39%)	(26%, 54%)	(1.9+, 63.0+)
Small intestinal cancer	27	16 (59%)	(39%, 78%)	(3.7+, 57.3+)
Brain cancer	27†	1 (4%)‡	(0%, 19%)	18.9
Ovarian cancer	25	8 (32%)	(15%, 54%)	(4.2, 56.6+)
Biliary cancer	22	9 (41%)	(21%, 64%)	(6.2, 49.0+)
Pancreatic cancer	22	4 (18%)	(5%, 40%)	(8.1, 24.3+)
Sarcoma	14	3 (21%)	(5%, 51%)	(35.4+, 57.2+)
Breast cancer	13	1 (8%)	(0%, 36%)	24.3+
Other§	13	4 (31%)	(9%, 61%)	(6.2+, 32.3+)
Cervical cancer	11	1 (9%)	(0%, 41%)	63.9+
Neuroendocrine cancer	11	1 (9%)	(0%, 41%)	13.3
Prostate cancer	8	1 (13%)	(0%, 53%)	24.5+
Adrenocortical cancer	7	1 (14%)	(0%, 58%)	4.2
Mesothelioma	7	0 (0%)	(0%, 41%)	
Thyroid cancer	7	1 (14%)	(0%, 58%)	8.2
Small cell lung cancer	6	2 (33%)	(4%, 78%)	(20.0, 47.5)
Bladder cancer	6	3 (50%)	(12%, 88%)	(35.6+, 57.5+)
Salivary cancer	5	2 (40%)	(5%, 85%)	(42.6+, 57.8+)
Renal cell cancer	4	1 (25%)	(0%, 81%)	22.0

* Results include patients in Cohort K of KEYNOTE-158 that were later determined to be pMMR or not MSI-H by central testing

† Includes 6 pediatric patients with brain cancer

‡ In addition to the 1 adult responder, 1 pediatric patient had a radiographic complete response after initial growth of their tumor.

§ Includes tumor type (n): anal (3), HNSCC (1), nasopharyngeal (1), retroperitoneal (1), testicular (1), vaginal (1), vulvar (1), appendiceal adenocarcinoma, NOS (1), hepatocellular carcinoma (1), and carcinoma of unknown origin (1). Includes 1 pediatric patient with abdominal adenocarcinoma.

+ Denotes ongoing response

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)
	[04/2023 Keytruda Label at 97-98; 08/2023 Keytruda Label at 98-99.] <i>See also</i> NEJM Article at <i>e.g.</i>, Figure 2 and Tables 1 and 2 (discussing reducing risk of progression of MSI-H/dMMR cancers in patients following treatment with Keytruda). The Keytruda Label also includes clinical trial results showing that the recommended dosages of Keytruda are therapeutically effective in patients with MSI-H or dMMR endometrial cancers relevant to Indication 1.15 to reduce the risk of cancer progression and/or increase overall survival. <u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 16 [b]	Merck's Keytruda (Pembrolizumab)																		
	Table 83: Efficacy Results in Patients with Advanced MSI-H or dMMR Endometrial Carcinoma in KEYNOTE-158 <table border="1"> <thead> <tr> <th>Endpoint</th><th>KEYTRUDA n=90*</th></tr> </thead> <tbody> <tr> <td>Objective Response Rate</td><td></td></tr> <tr> <td>ORR (95% CI)</td><td>46% (35, 56)</td></tr> <tr> <td>Complete response rate</td><td>12%</td></tr> <tr> <td>Partial response rate</td><td>33%</td></tr> <tr> <td>Duration of Response</td><td>n=41</td></tr> <tr> <td>Median in months (range)</td><td>NR (2.9, 55.7+)</td></tr> <tr> <td>% with duration ≥12 months</td><td>68%</td></tr> <tr> <td>% with duration ≥24 months</td><td>44%</td></tr> </tbody> </table> * Median follow-up time of 16.0 months (range 0.5 to 62.1 months) + Denotes ongoing response NR = not reached [04/2023 Keytruda Label at 122-123; 08/2023 Keytruda Label at 123-124.]	Endpoint	KEYTRUDA n=90*	Objective Response Rate		ORR (95% CI)	46% (35, 56)	Complete response rate	12%	Partial response rate	33%	Duration of Response	n=41	Median in months (range)	NR (2.9, 55.7+)	% with duration ≥12 months	68%	% with duration ≥24 months	44%
Endpoint	KEYTRUDA n=90*																		
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Claim 19	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer or cholangiocarcinoma.	<i>See claim 16.</i> In addition, the Keytruda Label instructs physicians to use Keytruda to reduce the cancer progression or increase the overall survival of a patient having a cancer selected from the group of claim 16, wherein the cancer is endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer or cholangiocarcinoma. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) (<i>e.g.</i>, small bowel cancer, gastric cancer) and MSI-H or dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 19	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 19	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.]
Claim 20	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer.	<i>See</i> claim 16. In addition, the Keytruda Label instructs physicians to use Keytruda to reduce the cancer progression or increase the overall survival of a patient having a cancer selected from the group of claim 16, wherein the cancer is pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer or oral cancer. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
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Claim 21	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is determined to be microsatellite instability high.	<i>See</i> claim 16. In addition, the Keytruda Label instructs physicians to use Keytruda reduce cancer progression or increase the overall survival of a patient having a cancer selected from the group of claim 16, wherein the cancer is determined to be microsatellite instability high (MSI-H). For example, the Keytruda Label indicates that Keytruda is approved for the treatment of

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	cancer in patients having MSI-H solid tumors (Indication 1.7), MSI-H colorectal cancer (Indication 1.8), and MSI-H endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is MSI-H for treatment with Keytruda according to Indications 1.7 and 1.15 based on the MSI-H status in a biological sample to reduce cancer progression and/or increase the overall survival of the patient.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.4)</i>]. • metastatic urothelial carcinoma [see <i>Clinical Studies (14.7)</i>]. • metastatic gastric cancer [see <i>Clinical Studies (14.10)</i>]. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.11)</i>]. • recurrent or metastatic cervical cancer [see <i>Clinical Studies (14.12)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.8, 14.9)</i>]. [03/2021 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is MSI-H. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's MSI-H status via local PCR, IHC, or third-party tests such as <i>e.g.</i>, FoundationOne®CDx.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available MSI-H biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda		Export Excel		Show 10 entries		
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite Instability-High (MSI-H)	P170019/S029 (02/18/2022)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)	
Ventana MMR RdX Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001 (03/21/2022)	
Ventana MMR RdX Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002 (06/16/2022)	

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] For example, the “FoundationOne[®]CDx (F1CDx) is a qualitative next generation sequencing based <i>in vitro</i> diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels) and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI)” See SSED PMA P170019/S029 at 2; see also SSED PMA P170019/S016 at 2. To determine a patient's MSI status, F1CDx employs a fraction based (FB) MSI algorithm to categorize a tumor specimen as MSI-High (MSI-H) or microsatellite stable (MSS). The FB-MSI algorithm calculates the fraction of microsatellite loci determined to be altered or unstable (i.e., the fraction unstable loci score) based on a genome-wide analysis across >2000 microsatellite loci. For a given microsatellite locus, non-somatic alleles are discarded, and the microsatellite is categorized as unstable if remaining alleles differ from the reference genome. The final fraction unstable loci score is calculated as the number of unstable microsatellite loci divided by the number of evaluable microsatellite loci. Two FB-MSI score thresholds are applied to classify a tumor specimen as having MSI-H or MSS status. MSI-H status is reported for patients with solid tumors whose samples have FB-MSI scores ≥ 0.0124 while MSS status is reported for patients with solid tumors whose samples have FB-MSI scores ≤ 0.0041. Per the F1CDx assay, a patient whose tumor has an MSI-H score ≥ 0.0124 is reported as eligible for treatment with KEYTRUDA. For patients with solid tumors whose samples have FB-MSI scores >0.0041 and <0.0124, an MSI “Cannot be Determined” result is reported. Patients with this result should be re-tested with a validated orthogonal (alternative) method as these MSI scores represent a range of scores with low reliability. Patients with solid tumors may also receive an MSI status reported as MSI-Cannot Be Determined due to a quality control (QC) failure. Patients with this result should consider re-testing with FoundationOneCDx or an orthogonal (alternative) method, if clinically appropriate.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 21	Merck's Keytruda (Pembrolizumab)
	[SSED PMA P170019/S029 at 10; <i>see also</i> SSED PMA P170019/S016 at 9.] At the time of the Keytruda Label, numerous biomarker assays for determining MSI-H/dMMR status were available, including the Promega OncoMate® MSI Dx Analysis System. <i>See, e.g.,</i> https://www.promega.com/products/microsatellite-instability-msi-testing/clinical-msi-testing-ivd/oncomate-msi-dx-analysis-system/. Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these microsatellite markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 22	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is determined to be mismatch repair deficient.	<i>See</i> claim 1. In addition, the Keytruda Label instructs physicians to use Keytruda to reduce cancer progression or increase overall survival of a patient having a cancer selected from the group of claim 1, wherein the cancer is determined to be mismatch repair deficient (dMMR). For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having dMMR solid tumors (Indication 1.7) and dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is dMMR for treatment with Keytruda according to Indications 1.7 and 1.15 based on the dMMR status in a biological sample (<i>e.g.</i>, tumor specimen) to reduce cancer progression and/or increase overall survival of the patient.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, TMB-H Cancer, or TNBC Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation <i>[see Clinical Studies (14.2)]</i>. • metastatic NSCLC <i>[see Clinical Studies (14.2)]</i>. • first-line treatment of metastatic or unresectable, recurrent HNSCC <i>[see Clinical Studies (14.4)]</i>. • metastatic urothelial carcinoma <i>[see Clinical Studies (14.7)]</i>. • metastatic gastric cancer <i>[see Clinical Studies (14.10)]</i>. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing. • previously treated recurrent locally advanced or metastatic esophageal cancer <i>[see Clinical Studies (14.11)]</i>. • recurrent or metastatic cervical cancer <i>[see Clinical Studies (14.12)]</i>. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens <i>[see Clinical Studies (14.8, 14.9)]</i>. [03/2021 Keytruda Label at 7.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	2 DOSAGE AND ADMINISTRATION 2.1 Patient Selection Information on FDA-approved tests for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. <u>Patient Selection for Single-Agent Treatment</u> Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in: • Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see <i>Clinical Studies (14.2)</i>]. • metastatic NSCLC [see <i>Clinical Studies (14.2)</i>]. • first-line treatment of metastatic or unresectable, recurrent HNSCC [see <i>Clinical Studies (14.3)</i>]. • previously treated recurrent locally advanced or metastatic esophageal cancer [see <i>Clinical Studies (14.10)</i>]. • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy [see <i>Clinical Studies (14.11)</i>]. For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see <i>Clinical Studies (14.7, 14.8)</i>]. [04/2023 Keytruda Label at 7; see also 08/2023 Keytruda Label at 7.] The Dosage and Administration section of the Keytruda Label also refers physicians to FDA's website to find information necessary to test or have tested a biological sample obtained from a patient to determine whether the cancer is dMMR. Information on FDA-approved tests used for patient selection is available at: http://www.fda.gov/CompanionDiagnostics. [04/2023 Keytruda Label at 7; 08/2023 Keytruda Label at 7.] Moreover, Clinical Studies sections 14.7 (or 14.8 in the 03/2021 Keytruda Label) instructs physicians to test or have tested the patient tumor's dMMR status via local PCR, IHC, or third-party tests such as <i>e.g.</i>, VENTANA MMR RxDx Panel.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests. [03/2021 Keytruda Label at 83.] 14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] The FDA's website has a "List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)," from which a physician can select and use or direct the use of a commercially available dMMR biomarker assay to test a patient's biological sample.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)						
Search: keytruda		Export Excel		Show 10 entries		
Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA	Biomarker(s)	Biomarker(s) (Details)	PMA / 510(k) / 513(f)(2) / HDE (Approval / Clearance / Grant Date)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	TMB	TMB ≥ 10 mutations per megabase	P170019/S016 (06/16/2020)	
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514	MSI-High	Microsatellite instability-High (MSI-H)	P170019/S029 (02/18/2022)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013 (10/02/2015)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S009 (06/12/2018)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S014 (06/10/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S016 (07/30/2019)	
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514	PD-L1	PD-L1 protein expression	P150013/S020 (11/13/2020)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Keytruda (pembrolizumab) BLA 125514	deficient mismatch repair (dMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S001 (03/21/2022)	
Ventana MMR Rx Dx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947	proficient mismatch repair (pMMR) proteins	MLH1, PMS2, MSH2 and MSH6	P210001/S002 (06/16/2022)	

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 22	Merck's Keytruda (Pembrolizumab)
	[https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools (last visited on 11/14/2023).] <i>See also, e.g.,</i> “VENTANA MMR RxDx Panel,” generically known as “[i]mmunohistochemistry test, DNA mismatch repair (MMR) [p]rotein assay,” which is used for “identifying patients with solid tumors with dMMR status who may benefit from treatment with KEYTRUDA.” [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210001S001 (last visited 11/14/2023).] Physicians prescribing Keytruda in accordance with the Keytruda Label would have been aware of these MMR markers and would have understood how to test for them in accordance with the Keytruda Label.
Claim 27	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is small bowel cancer.	<i>See</i> claim 16. In addition, the Keytruda Label instructs physicians to use Keytruda to reduce cancer progression or increase the overall survival of a patient having a cancer selected from the group of claim 16, wherein the cancer is small bowel cancer. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) (<i>e.g.</i>, small bowel cancer). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 27	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) - solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or - colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
Claim 28	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior	See claim 16. In addition, the Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to reduce cancer progression or increase overall survival of a patient having a cancer selected from the group of claim 16, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 28	Merck's Keytruda (Pembrolizumab)
cancer therapy drug.	cancer therapy drug. The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15) that has progressed after the patient was treated with the prior cancer therapy drug. <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 28	Merck's Keytruda (Pembrolizumab)
	<u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.] <i>See also, e.g.,</i> Section 14.7 of the Keytruda Label (Section 14.8 of the 03/2021 Keytruda Label) instructing physicians to use Keytruda to treat of MSI-H/dMMR cancers that have progressed following prior cancer treatment. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 28

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥ 1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥ 1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 28	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] <i>See also, e.g.,</i> Section 14.15 of the Keytruda Label instructing physicians to use Keytruda to treat of MSI-H/dMMR endometrial cancer that has progressed following prior cancer treatment.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 28	Merck's Keytruda (Pembrolizumab)
	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Among the 90 patients evaluated, the baseline characteristics were: median age of 64 years (range: 42 to 86); 83% White, 8% Asian, and 3% Black; 12% Hispanic or Latino; 39% ECOG PS of 0 and 61% ECOG PS of 1; 96% had M1 disease and 4% had M0 disease at study entry; and 51% had one and 48% had two or more prior lines of therapy. Nine patients received only adjuvant therapy and one patient received only neoadjuvant and adjuvant therapy before participating in the study. Efficacy results are summarized in Table 83. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
Claim 30	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is metastatic cancer.	<i>See</i> claim 16. In addition, the Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient having a cancer selected from the group of claim 16, wherein the cancer is metastatic. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having metastatic MSI-H or dMMR solid tumors (Indication 1.7).

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 30	Merck's Keytruda (Pembrolizumab)
	<u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
Claim 31	Merck's Keytruda (Pembrolizumab)
The method of claim 1, wherein the cancer is endometrial cancer.	<i>See claim 1.</i> In addition, the Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient having a cancer selected from the group of claim 1, wherein the cancer is endometrial cancer.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>
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EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 6; <i>see also</i> 08/2023 Keytruda Label at 6.]
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EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32	Merck's Keytruda (Pembrolizumab)
The method of claim 31, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior cancer therapy drug.	<i>See claim 31.</i> In addition, the Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to treat a patient having endometrial cancer wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior cancer therapy drug. The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15) that has progressed after the patient was treated with the prior cancer therapy drug. <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32	Merck's Keytruda (Pembrolizumab)
	1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 6; 08/2023 Keytruda Label at 6.] <i>See also, e.g.,</i> Section 14.7 of the Keytruda Label (Section 14.8 of the 03/2021 Keytruda Label) instructing physicians to use Keytruda to treat of MSI-H/dMMR cancers that have progressed following prior cancer treatment.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32	Merck's Keytruda (Pembrolizumab)
	14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥ 1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥ 1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] <i>See also, e.g.,</i> Section 14.15 of the Keytruda Label instructing physicians to use Keytruda to treat of MSI-H/dMMR endometrial cancer that has progressed following prior cancer treatment.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 32	Merck's Keytruda (Pembrolizumab)
	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Among the 90 patients evaluated, the baseline characteristics were: median age of 64 years (range: 42 to 86); 83% White, 8% Asian, and 3% Black; 12% Hispanic or Latino; 39% ECOG PS of 0 and 61% ECOG PS of 1; 96% had M1 disease and 4% had M0 disease at study entry; and 51% had one and 48% had two or more prior lines of therapy. Nine patients received only adjuvant therapy and one patient received only neoadjuvant and adjuvant therapy before participating in the study. Efficacy results are summarized in Table 83. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
Claim 33	Merck's Keytruda (Pembrolizumab)
The method of claim 31 further comprising testing or having tested the patient for progression of the cancer after the treatment.	<i>See</i> claim 31. In addition, the Keytruda Label instructs physicians to use Keytruda to treat endometrial cancer in a patient, wherein treatment further comprises testing or having tested the patient for progression of the cancer after the treatment. For example, the Keytruda Label instructs physicians to test the progression of the cancer in patients with MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	endometrial tumors (Indication 1.15) treated with Keytruda every 8 or 9 or 12 weeks. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR. [03/2021 Keytruda Label at 82.]
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EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively.

- KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy.
- KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J).
- KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers.

Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051.

[08/2023 Keytruda Label at 98; *see also* 04/2023 Keytruda Label at 97.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
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Claim 34	Merck's Keytruda (Pembrolizumab)
The method of claim 31, wherein the cancer is metastatic.	<i>See</i> claim 31. In addition, the Keytruda Label instructs physicians to use Keytruda to treat cancer in a patient having endometrial cancer, wherein the endometrial cancer is metastatic. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR metastatic solid tumors (Indication 1.7). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 34	Merck's Keytruda (Pembrolizumab)
	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
Claim 35	Merck's Keytruda (Pembrolizumab)
The method of claim 16, wherein the cancer is endometrial cancer.	See claim 16.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 35	Merck's Keytruda (Pembrolizumab)
	In addition, the Keytruda Label instructs physicians to use Keytruda to reduce cancer progression or increase overall survival in a patient having a cancer selected from the group of claim 1, wherein the cancer is endometrial cancer. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial cancer (Indication 1.15). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)].

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 35	Merck's Keytruda (Pembrolizumab)
	[04/2023 Keytruda Label at 5; <i>see also</i> 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u> 1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation <i>[see Dosage and Administration (2.1)]</i>. [04/2023 Keytruda Label at 6; 08/2023 Keytruda Label at 6.]
Claim 36	Merck's Keytruda (Pembrolizumab)
The method of claim 35, wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior cancer therapy drug.	<i>See</i> claim 35. In addition, the Keytruda Label instructs physicians to use Keytruda (pembrolizumab) to reduce cancer progression or increase overall survival of a patient having endometrial cancer wherein the patient had previously been treated with a prior cancer therapy drug and the patient's cancer had progressed after the patient was treated with the prior cancer therapy drug. The Indications and Usage Section of the Keytruda Label indicates that Keytruda is approved for the treatment of MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR endometrial carcinoma (Indication 1.15) that has progressed after the patient was treated with the prior cancer therapy drug.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 36	Merck's Keytruda (Pembrolizumab)
	<u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u> 1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.] <u>Indication 1.15</u>

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 36	Merck's Keytruda (Pembrolizumab)
	1.15 Endometrial Carcinoma KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) as determined by an FDA-approved test or not MSI-H, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see Dosage and Administration (2.1)]. KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see Dosage and Administration (2.1)]. [04/2023 Keytruda Label at 6; 08/2023 Keytruda Label at 6.] <i>See also, e.g.,</i> Section 14.7 of the Keytruda Label (Section 14.8 of the 03/2021 Keytruda Label) instructing physicians to use Keytruda to treat of MSI-H/dMMR cancers that have progressed following prior cancer treatment. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 36

Merck's Keytruda (Pembrolizumab)

Table 57: MSI-H Trials					
Study	Design and Patient Population	Number of Patients	MSI-H/dMMR Testing	Dosage	Prior Therapy
KEYNOTE-016 NCT01876511	- prospective, investigator-initiated 6 sites - patients with CRC and other tumors	28 CRC 30 non-CRC	local PCR or IHC	10 mg/kg every 2 weeks	- CRC: ≥ 2 prior regimens - Non-CRC: ≥ 1 prior regimen
KEYNOTE-164 NCT02460198	- prospective international multi-center - CRC	61	local PCR or IHC	200 mg every 3 weeks	Prior fluoropyrimidine, oxaliplatin, and irinotecan +/- anti-VEGF/EGFR mAb
KEYNOTE-012 NCT01848834	retrospectively identified patients with PD-L1-positive gastric, bladder, or triple-negative breast cancer	6	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-028 NCT02054806	retrospectively identified patients with PD-L1-positive esophageal, biliary, breast, endometrial, or CRC	5	central PCR	10 mg/kg every 2 weeks	≥ 1 prior regimen
KEYNOTE-158 NCT02628067	- prospective international multi-center enrollment of patients with MSI-H/dMMR non-CRC - retrospectively identified patients who were enrolled in specific rare tumor non-CRC cohorts	19	local PCR or IHC (central PCR for patients in rare tumor non-CRC cohorts)	200 mg every 3 weeks	≥ 1 prior regimen
Total		149			

CRC = colorectal cancer
PCR = polymerase chain reaction
IHC = immunohistochemistry

[03/2021 Keytruda Label at 82-83.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 36	Merck's Keytruda (Pembrolizumab)
	14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively. - KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy. - KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J). - KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers. Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051. [04/2023 Keytruda Label at 97; <i>see also</i> 08/2023 Keytruda Label at 98.] <i>See also, e.g.,</i> Section 14.15 of the Keytruda Label instructing physicians to use Keytruda to treat of MSI-H/dMMR endometrial cancer that has progressed following prior cancer treatment.

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

Claim 36	Merck's Keytruda (Pembrolizumab)
	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. Among the 90 patients evaluated, the baseline characteristics were: median age of 64 years (range: 42 to 86); 83% White, 8% Asian, and 3% Black; 12% Hispanic or Latino; 39% ECOG PS of 0 and 61% ECOG PS of 1; 96% had M1 disease and 4% had M0 disease at study entry; and 51% had one and 48% had two or more prior lines of therapy. Nine patients received only adjuvant therapy and one patient received only neoadjuvant and adjuvant therapy before participating in the study. Efficacy results are summarized in Table 83. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
Claim 37	Merck's Keytruda (Pembrolizumab)
The method of claim 35 further comprising testing or having tested the patient for progression of the cancer after the treatment.	<i>See</i> claim 35. In addition, the Keytruda Label instructs physicians to use Keytruda to reduce cancer progression or increase overall survival in a patient having endometrial cancer, wherein treatment further comprises testing or having tested the patient for progression of the cancer after the treatment. For example, the Keytruda Label instructs physicians to test the progression of the cancer in patients with MSI-H or dMMR solid tumors (Indication 1.7) and MSI-H or dMMR

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	endometrial tumors (Indication 1.15) treated with Keytruda every 8 or 9 or 12 weeks. 14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR. [03/2021 Keytruda Label at 82.]
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EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

14.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in 504 patients with MSI-H or dMMR cancers enrolled in three multicenter, non-randomized, open-label, multi-cohort trials: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067), and KEYNOTE-051 (NCT02332668). All trials excluded patients with autoimmune disease or a medical condition that required immunosuppression. Regardless of histology, MSI or MMR tumor status was determined using polymerase chain reaction (PCR; local or central) or immunohistochemistry (IHC; local or central), respectively.

- KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy.
- KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancers (non-CRC) who had disease progression following prior therapy. Patients were either prospectively enrolled with MSI-H/dMMR tumors (Cohort K) or retrospectively identified in one of 10 solid tumor cohorts (Cohorts A-J).
- KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers.

Adult patients received KEYTRUDA 200 mg every 3 weeks (pediatric patients received 2 mg/kg every 3 weeks) until unacceptable toxicity, disease progression, or a maximum of 24 months. In KEYNOTE-164 and KEYNOTE-158, assessment of tumor status was performed every 9 weeks through the first year, then every 12 weeks thereafter. In KEYNOTE-051, assessment of tumor status was performed every 8 weeks for 24 weeks, and then every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1 (modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ in KEYNOTE-158) and as assessed by the investigator according to RECIST v1.1 in KEYNOTE-051.

[08/2023 Keytruda Label at 98; *see also* 04/2023 Keytruda Label at 97.]

EXHIBIT 9

INFRINGEMENT OF U.S. PATENT NO. 11,634,491 BY KEYTRUDA

	<u>As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma</u> The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ. [04/2023 Keytruda Label at 122; <i>see also</i> 08/2023 Keytruda Label at 123.]
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Claim 38	Merck's Keytruda (Pembrolizumab)
The method of claim 35, wherein the cancer is metastatic.	<i>See</i> claim 35. In addition, the Keytruda Label instructs physicians to use Keytruda to reduce cancer progression or increase overall survival in a patient having endometrial cancer, wherein the endometrial cancer is metastatic. For example, the Keytruda Label indicates that Keytruda is approved for the treatment of cancer in patients having MSI-H or dMMR metastatic solid tumors (Indication 1.7). <u>Indication 1.7 (1.8 in the March 2021 Keytruda Label)</u>

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	1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or • colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. This indication is approved under accelerated approval based on tumor response rate and durability of response [see <i>Clinical Studies</i> (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. <u>Limitations of Use:</u> The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established. [03/2021 Keytruda Label at 5.] 1.7 Microsatellite Instability-High or Mismatch Repair Deficient Cancer KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options [see <i>Dosage and Administration</i> (2.1)]. [04/2023 Keytruda Label at 5; see also 08/2023 Keytruda Label at 5.]
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