Compare

Completed

Study of Pembrolizumab (MK-3475) as Monotherapy in Participants With Previously-Treated Locally Advanced Unresectable or Metastatic Colorectal Cancer (MK-3475-164/KEYNOTE-164)

ClinicalTrials.gov ID NCT02460198

Sponsor Merck Sharp & Dohme LLC

Information provided by Merck Sharp & Dohme LLC (Responsible Party)

Last Update Posted 2023-07-27

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
  - To view one version of the study record, click the submitted date.
  - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

☐	1	2015-05-29	• None (earliest version on record)

Feedback

MERCK EX1148
Merck Sharp & Dohme LLC v. The Johns Hopkins University
IPR2024-00650

☐	2	2015-07-10	• Study Identification • Study Status
☐	3	2015-07-28	• Study Status
☐	4	2015-09-02	• Recruitment Status • Study Status • Contacts/Locations
☐	5	2015-09-14	• Study Status • Contacts/Locations
☐	6	2015-10-07	• Study Status • Contacts/Locations
☐	7	2015-10-14	• Study Status • Contacts/Locations
☐	8	2015-11-03	• Study Status • Eligibility • Contacts/Locations
☐	9	2015-12-31	• Study Status • Contacts/Locations
☐	10	2016-02-02	• Study Status • Contacts/Locations
☐	11	2016-02-11	• Study Status • Contacts/Locations
☐	12	2016-02-24	• Study Status • Contacts/Locations

☐	13	2016-02-26	• Recruitment Status • Study Status
☐	14	2016-03-29	• Study Identification
			• Study Status • Study Description • Conditions • Study Design • Arms and Interventions • Outcome Measures • Eligibility • Contacts/Locations
☐	16	2016-05-20	• Study Status • Contacts/Locations
☐	17	2016-06-28	• Study Status • Contacts/Locations
☐	18	2016-07-08	• Study Status • Contacts/Locations
☐	19	2016-07-22	• Study Status • Contacts/Locations
☐	20	2016-07-29	• Study Status • Contacts/Locations
☐	21	2016-08-19	• Study Status • Contacts/Locations
☐	22	2016-09-01	• Study Status • Contacts/Locations

☐	23	2016-09-08	• Study Status
☐	24	2016-09-13	• Study Status
☐	26	2016-11-11	• Study Status
☐	27	2017-02-16	• Study Status
☐	28	2017-09-25	• Study Status
☐	29	2018-01-11	• Study Identification • Study Status • Oversight • Study Description • Conditions • Study Design • Arms and Interventions • Outcome Measures • Eligibility
☐	30	2019-09-25	• Study Status
	Version	**Date submitted (YYYY-MM-DD)**	**Changes**
			• Study Status • Study Description • Conditions • Arms and Interventions • Eligibility
	Version	**Date submitted (YYYY-MM-DD)**	**Changes**

☐	33	2020-07-31	• Study Status • Study Description • Arms and Interventions • Outcome Measures
			• Participant Flow • Baseline Characteristics • Outcome Measures (Results) • Adverse Events
☐	35	2020-11-18	• Study Status
☐	36	2021-01-15	• Study Status
☐	37	2021-02-25	• Recruitment Status • Study Status • Eligibility
☐	38	2022-03-29	• Study Status • Arms and Interventions • Outcome Measures • Document Section • Participant Flow • Baseline Characteristics • Outcome Measures (Results) • Adverse Events
	Version	**Date submitted (YYYY-MM-DD)**	**Changes**
☐	40	2023-07-25	• Study Status

			• References

Version 1: 2015-05-29

Study Details

Study Identification

Unique Protocol ID
3475-164

Brief Title
Study of Pembrolizumab (MK-3475) as Monotherapy in Participants With Previously-Treated Locally Advanced Unresectable or Metastatic Colorectal Cancer (MK-3475-164/KEYNOTE-164)

Official Title
A Phase II Study of Pembrolizumab (MK-3475) as Monotherapy in Subjects With Previously Treated Locally Advanced Unresectable or Metastatic (Stage IV) Microsatellite Instability-High Colorectal Carcinoma

Version	Date submitted (YYYY-MM-DD)	Changes
2015-001852-32		

Study Status

Record Verification
2015-05

Overall Status
Not yet recruiting

Study Start
2015-08

Primary Completion
2017-09 [Estimated]

Study Completion
2017-09 [Estimated]

First Submitted
2015-05-29

First Submitted that Met QC Criteria
2015-05-29

First Posted
2015-06-02 [Estimated]

Last Update Submitted that Met QC Criteria
2015-05-29

Last Update Posted
2015-06-02 [Estimated]

Version	Date submitted (YYYY-MM-DD)	Changes

Sponsor
Merck Sharp & Dohme LLC

Responsible Party

Sponsor

Collaborators

Oversight

U.S. FDA-regulated Drug

U.S. FDA-regulated Device

Data Monitoring
No

Study Description

Brief Summary
In this study, participants with previously-treated locally advanced unresectable or metastatic microsatellite-instability high colorectal carcinoma (MSI-H CRC) will be treated with pembrolizumab (MK-3475) monotherapy. The primary study hypothesis is that pembrolizumab will provide a clinically meaningful overall response.

Detailed Description

Version	Date submitted (YYYY-MM-DD)	Changes

Colorectal Carcinoma

Keywords
PD1

PDL1 PD-L1

Study Design

Study Type
Interventional

Primary Purpose
Treatment

Study Phase
Phase 2

Interventional Study Model
Single Group Assignment

Number of Arms
1

Masking
None (Open Label)

Allocation
N/A

Enrollment
60 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Pembrolizumab Participants receive pembrolizumab 200 mg intravenously (IV) on Day 1 of every	Biological: Pembrolizumab • Other Names: ◦ MK-3475

21-day cycle (Q3W) for up to 2 years	

Outcome Measures

Primary Outcome Measures
1. Overall Response Rate (ORR) [Time Frame: Up to 2 years]

Secondary Outcome Measures
1. Disease Control Rate (DCR) [Time Frame: Up to 2 years]

Eligibility

Minimum Age
18 Years

Maximum Age

Sex
All

Gender-based Eligibility

Gender Eligibility Description

Accepts Healthy Volunteers
No

Criteria
Inclusion criteria:

- Histologically-proven locally advanced unresectable or metastatic CRC
- Blood sample and available tumor tissue for confirmation of MSI-H CRC by the Sponsor
- Previously treated with at least two lines of approved standard therapies, which must include fluoropyrimidine, oxaliplatin, irinotecan, bevacizumab, and cetuximab or panitumumab
- Eastern Cooperative Oncology Group performance status of 0 or 1
- Life expectancy of greater than 3 months
- At least one measureable lesion
- Female participants of childbearing potential should be willing to use 2 methods of birth control or be surgically sterile, or abstain from heterosexual activity for the course of the study through 120 days after the last dose of study medication
- Male participants should agree to use an adequate method of contraception starting with the first dose of study therapy through 120 days after the last dose of study medication
- Adequate organ function

Exclusion criteria:

- Currently participating in another study and receiving trial treatment, participated in a study of an investigational agent and received trial treatment within 4 weeks of the first dose of medication in this study, or used an investigational device within 4 weeks of the first dose of medication in this study
- Active autoimmune disease that has required systemic treatment in past 2 years
- Diagnosis of immunodeficiency or receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication
- Known active central nervous system (CNS) metastases and/or carcinomatous meningitis
- Prior monoclonal antibody (mAb), chemotherapy, targeted small molecule therapy, or radiation therapy within 2 weeks prior to study Day 1 or not recovered (i.e., ≤ Grade 1 or at baseline) from adverse events due to a previously administered agent
- Prior therapy with an anti-programmed cell death (PD)-1, anti-PD-L1, or anti-PD-L2 agent, or participant has previously participated in Merck pembrolizumab (MK-3475) clinical trial
- Known additional malignancy that is progressing or requires active treatment with the exception of basal cell carcinoma of the skin or

squamous cell carcinoma of the skin that has undergone potentially curative therapy, or in situ cervical cancer
- Received a live vaccine within 30 days of planned start of study medication
- Known history of human immunodeficiency virus (HIV)
- Known active Hepatitis B or C
- Known history or any evidence of interstitial lung disease or active, non-infectious pneumonitis
- Active infection requiring systemic therapy
- Known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial
- Pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of trial medication

Contacts/Locations

Central Contact Person

Study Officials

- Name
  Medical Director

  Role
  Study Director

  Affiliation
  Merck Sharp & Dohme LLC

Location

IPD Sharing

IPD information

References

Citations

Links

Available IPD/Information

Document Section