

16724512.5

CONSOLIDATED LIST - KONSOLIDIERTE LISTE - LISTE RÉCAPITULATIVE

P: Bristol-Myers Squibb Company
1: Ulrich Dörries
2: Lederer & Keller Patentanwälte Partnerschaft mbB
3: Pajaro Limited
4: Elisabeth Greiner
5: Sandra Pohlman

 CITATIONS-ENTGEGENHALTUNGEN-CITATIONS		Opponent numbering						
Document numbers used in these submissions		O1	O2	O3	O4	O5	PP	EPO
D1	WO 2016/168716	D1						D1
D2	WO 2015/042246	D2			D10			D2
D3	Tsai et al., Human Vaccines & Immunotherapeutics, 10(11):3111- 3116, 2014	D3	D7					D3
D4	WO 2013/173223	D4			D21			D4
D5	Weber et al., Lancet Oncology, 16(4):375384, March 2015	D5						D5
D6	Scott, Drugs, 75(12):1413-1424, July 2015	D6						D6
D7	BMS Press Release, 6 April 2016	D7						D7
D8	Brahmer et al., NEJM, 373:123-135, May 2015	D8						D8
D9	EMA, Opdivo Assessment report, EMN682492/2015, December 2015	D9						D9
D10	Topalian et al., NEJM, 366(26):2443-2454, 2012	D10			D14			D10
D11	WO 2015/176033	D11			D13			D11
D12a	Protocol of clinical trial NCT02713867, version 6 of 26 April 2016	D12			D5			D12
D12b	Protocol of clinical trial NCT02713867, version 1 of 15 March 2016					D16		D71

Document numbers used in these submissions		Opponent numbering					PP	EPO
		O1	O2	O3	O4	O5		
D13	Zhao et al., Annals of Oncology, 28:2002-2008, 2017	D13			D3			D13
D13b	Zhao X. et al., Annals Oncol 2017 ; 28(8):2002-208, Supplementary Data				D13b			
D14a	Larkin et al., NEJM, 373(1): 23-34, July 2015		D1		D4			D14
D14b	Larkin et al., NEJM, 373(1): 23-34, July 2015 (HHS Public Access Author Manuscript)			B13		D29		D35
D14c	Larkin et al., NEJM, 373(1): 23-34, July 2015 (Supplementary Appendix)			B14				D36
D14d	Larkin et al., NEJM, 373(1): 23-34, July 2015 (Evidence of online publication date)			B15				D37
D15	Wang et al., Journal of Clinical Pharmacology, 49: 1012-1024, 2009		D2			D5		D15
D16	Bai et al., Clinical Pharmacokinetics, 51: 119-135, 2012		D3			D4		D16
D17	Wang et al., Clinical Pharmacology & Therapeutics, 97(S1), S42, Abstract PI-073, February 2015		D4					D17
D18a	Protocol of clinical trial NCT01844505, version 36 of 20 April 2015		D6					D18
D18b	Protocol of clinical trial NCT01844505, version 1 of 30 April 2013					D8		D63
D19	Opdivo (nivolumab) injection, for intravenous use, FDA label, September 2015		D8					D19
D20	FDA Guidance for Industry, "Exposure Response Relationship - Study Design, Data Analysis and Regulatory Applications", 2003		D9					D20
D21	Condeelis et al., Cold Spring Harbor Perspectives in Biology, 2:a003848, 2010		D10					D21
D22	McCabe et al., Cancer Biotherapy and Radiopharmaceuticals, 25(3): 253-261, 2010		D11					D22
D23	Olafsen et al., Protein Engineering, Design & Selection, 23(4): 243-249, 2010		D12					D23
D24	Prichard, Archives of Pathology & Laboratory Medicine, 138(12): 1578-82, 2014					D31		D85
D25a	Protocol of clinical trial NCT01721772, version 54 of 2 August 2021			B3, B7				D25
D25b	Protocol of clinical trial NCT01721772, version 1 of 2 November 2012					D7		-

Document numbers used in these submissions		Opponent numbering					PP	EPO
		O1	O2	O3	O4	O5		
D25c	Protocol of clinical trial NCT01721772, version 42 of 27 January 2016						D25c	
<i>D25d</i>	<i>Protocol of clinical trial NCT01721772, version 43 of 25 October 2016</i>						<i>D25d</i>	
D26	Dako Autostainer, User Guide, 2007 (page 9).			B4				D26
<i>D27</i>	<i>Long et al., Annals of Oncology 29: 2208-2213, 2018.</i>			<i>B5</i>	<i>D2</i>			<i>D27</i>
<i>D28</i>	<i>Long et al., Annals of Oncology 29: 2208-2213, 2018, supplementary Figure S1</i>			<i>B6</i>				<i>D28</i>
<i>D29</i>	<i>Protocol of clinical trial NCT01668784, version 76 of 7 August 2020</i>			<i>B8</i>				<i>D30</i>
<i>D30</i>	<i>Protocol of clinical trial NCT01673867, version 67 of 21 August 2020</i>			<i>B9</i>				<i>D31</i>
D30a	Protocol of clinical trial NCT01673867, version 55 of 29 January 2016						D30a	
<i>D31</i>	<i>Protocol of clinical trial NCT01642004, version 52 of 24 June 2020</i>			<i>B10</i>				<i>D32</i>
D31a	Protocol of clinical trial NCT01642004, version 41 of 16 March 2016						D31a	
D32	Spranger & Gajewski, Journal for ImmunoTherapy of Cancer, 1:16, 2013			B11				D33
D33	Topalian et al., Journal of Clinical Oncology, 30(18 suppl.): Abstract CRA2509, 2012			B12				D34
<i>D34</i>	<i>Protocol of clinical trial NCT02648997, version 11 of 30 January 2021 (presumed)</i>			<i>B16</i>				<i>D38</i>
D34a	Protocol of clinical trial NCT02648997, version 2 of 7 March 2016						D34a	
<i>D35</i>	<i>Protocol of clinical trial NCT01928576, version 13 of 3 June 2021 (presumed)</i>			<i>B17</i>				<i>D39</i>
D35a	Protocol of clinical trial NCT01928576, version 4 of 20 April 2016						D35a	
<i>D36</i>	<i>EMA approval annexes for Yervoy, 2021 version (presumed)</i>			<i>B18</i>				<i>D40</i>
D36a	EMA approval annexes for Yervoy, version of 25 April 2016						D36a	
<i>D36b</i>	<i>Summary of updates to EMA approval for Yervoy</i>						<i>D36b</i>	

Document numbers used in these submissions		Opponent numbering					PP	EPO
		O1	O2	O3	O4	O5		
D37	Byrum et al., Journal of Cutaneous Pathology, 38(11): 933-936, 2011			B19				D41
D38	Hamanishi et al., PNAS, 104(9): 3360-3365, 2007			B20				D42
D39	Gadiot et al., Cancer, 117(10): 2192-2201, 2011			B21				D43
D40	Philips & Atkins, International Immunology, 27(1): 39-46, 2014				D1	D23		D44
D41	Barbee et al., Annals of Pharmacotherapy, 49(8): 907-937, May 2015				D6			D45
D42	Belum et al., European Journal of Cancer, 60: 12-25, 1 April 2016				D7			D46
D43	Postow et al., Journal of Clinical Oncology, 33(17): 1974-1982, January 2015				D8			D47
D44	Mahoney et al., Clinical Therapeutics, 37(4): 764-782, March 2015				D9			D48
D45	Ott et al., Clinical Cancer Research, 19(19): 5300-5309, 2013				D11			D49
D46	Ascierto et al., Clinical Cancer Research, 19(5): 1009-1020, 2013				D12			D50
D47	Topalian et al., Journal of Clinical Oncology, 32(10): 1020-1030, 2014				D15			D52
D48	<i>Bi et al., Annals of Oncology, 30(4): 644-651, 2019</i>				D16			D53
D49	<i>Zhao et al., Annals of Oncology, 31(2): 302-309, 2020</i>				D17			D54
D50	Meng et al., Cancer Treatment Reviews, 41(10): 868-76, November 2015				D18			D55
D51	Dong et al., Nature Medicine, 8(8): 793-800, 2002				D19			D56
D52	Postow et al., NEJM, 372: 2006-2017, 20 April 2015				D20			D57
D53	EMA Opdivo Assessment Report, Procedure No.: EMEA/H/C/003985/0000, 16 July 2015					D1		D58
D54a	FDA "Clinical Pharmacology and Biopharmaceutics Review(s)" for Opdivo, Application No.: 125554, January 2015					D2		D59

Document numbers used in these submissions		Opponent numbering					PP	EPO
		O1	O2	O3	O4	O5		
D54b	Evidence of D54a's publication date					D2a		D59
D55	Brahmer et al., Journal of Clinical Oncology, 28(19): 3167-3175, 2010					D3		D60
D56	Protocol of clinical trial NCT01721746, version 1 of 2 November 2012					D6		D62
D57	Protocol of clinical trial NCT02156804, version 1 of 2 June 2014					D9		D64
D58	Protocol of clinical trial NCT02374242, version 1 of 26 February 2015					D10		D65
D59a	Protocol of clinical trial NCT01968109, version 1 of 18 October 2013					D11		D66
D59b	Protocol of clinical trial NCT01968109, comparison of version 8 of 6 October 2014 with version 1 of 18 October 2013					D12		D67
D60	Flies et al., Yale Journal of Biology and Medicine, 84(4): 409-421, 2011					D13		D68
D61	Toutain & Bousquet-Mélou, Journal of Veterinary Pharmacology and Therapeutics, 27(6):427-439, 2004					D14		D69
D62	Protocol of clinical trial NCT02046733, comparison of version 6 of 6 October 2015 with version 1 of 24 January 2014					D15		D70
D63	Protocol of clinical trial NCT02335918, comparison of version 17 of 15 April 2016 with version 1 of 7 January 2015					D17		D72
D64	<i>Opdivo FDA Label (Revised: 3/2018)</i>					D18		D73
D65a	Expert declaration by Professor Robert Leonard					D19		D74
D65b	CV of Professor Robert Leonard					D19a		D74
D66	Grosso et al., Journal of Clinical Oncology, 31(15 suppl.): Abstract 3016, 2013					D20		D75
D67	Patel & Kurzrock, Molecular Cancer Therapeutics, 14(4): 847-856, February 2015					D21		D76
D68	Patentee's reply to the 1st examination report					D22		D77

Document numbers used in these submissions		Opponent numbering					PP	EPO
		O1	O2	O3	O4	O5		
D69a	"CheckMate 067: Nivo + Ipi and Nivo Alone Superior to Ipi in Previously Untreated Advanced Melanoma" Clinical Care Options slide set from the 2015 ASCO Annual Meeting, June 2015					D24		D79
D69b	Evidence of D69a's publication date					D24a		D79
D70	Berking, Trillium Krebsmedizin: 24(4):214-217, 2015					D25		D80
D71	Helwick, "CheckMate 067: Dual Checkpoint Blockade Proves Effective in Advanced Melanoma", The ASCO Post, June 2015					D26		D81
D72	Hughes, "Nivolumab Significantly Improves Outcomes in Advanced Melanoma", Cancer Therapy Advisor, May 2015					D27		D82
D73	The ASCO post, "ASCO 2015: Phase III Study Finds Nivolumab Improves Progression-Free Survival, Especially When Combined With Ipilimumab, in Advanced Melanoma", May 2015					D28		D83
D74	EPO Communication dated 16 December 2019, issued in response to the Applicant's reply submitted herewith as D68					D30		D84
D75	Simeone et al., Journal of Clinical Oncology, 38(15 suppl.): Abstract e22008, 2020						D75	
D76	Expert opinion from Prof. Dr. P. Langguth			BB22				
D77	Mallardo D. et al., J. Immunother. Cancer 2022, 10:e005132				D76			
P1	US 62/153,954 (priority document)			B2	P1	P1		D24
WO	WO 2016/176504 A1 (application as filed)			B1	WO	OA		
EP	EP 3288980 B1 (granted patent)				B1			