

## Supplementary Online Content

D'Angelo SP, Russell J, Lebbé C, et al. Efficacy and safety of first-line avelumab treatment in patients with stage IV metastatic Merkel cell carcinoma: a preplanned interim analysis. *JAMA Oncol*. Published online March 22, 2018. doi:10.1001/jamaoncol.2018.0077

**eTable 1.** JAVELIN Merkel 200 Part B Study Group

**eTable 2.** Patient Demographics and Baseline Characteristics

**eTable 3.** Incidence of Treatment-Related Adverse Events

**eTable 4.** Immune-Related Adverse Events

This supplementary material has been provided by the authors to give readers additional information about their work.

**eTable 1. JAVELIN Merkel 200 Part B Study Group**

<b>Principal Investigator</b>	<b>Site – Country</b>	<b>Site – Institution</b>
Arance Fernandez, Ana M	Spain	Hospital Clinic i Provincial de Barcelona
Ascierto, Paolo	Italy	Istituto Nazionale Tumori Fondazione G.Pascale
Atkinson, Victoria	Australia	Princess Alexandra Hospital
Aubin, François	France	CHU Besançon - Hôpital Jean Minjoz
Bedane, Christophe	France	CHU de Limoges - Hôpital Dupuytren
Begbie, Stephen	Australia	Port Macquarie Base Hospital
Berrocal Jaime, Alfonso	Spain	Hospital General Universitario de Valencia
Bhatia, Shailender	United States	University of Washington - Seattle Cancer Care Alliance
Brownell, Isaac	United States	National Cancer Institute
Burgess, Melissa	United States	University of Pittsburgh
Buzzoni, Roberto	Italy	Fondazione IRCCS Istituto Nazionale dei Tumori
Capdevila Castillon, Jaume	Spain	Hospital Universitari Vall d'Hebron
Chiarion Sileni, Vanna	Italy	IOV - Istituto Oncologico Veneto IRCCS
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Dalac-Rat, Sophie	France	CHU de Dijon - Hôpital du Bocage
D'Angelo, Sandra P	United States	Memorial Sloan Kettering Cancer Center
Dreno, Brigitte	France	CHU Nantes - Hôtel Dieu
Dutriaux, Caroline	France	Groupe Hospitalier Saint André - Hôpital Saint André
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Fazio, Nicola	Italy	IEO Istituto Europeo di Oncologia
Ferolla, Piero	Italy	Azienda Ospedaliera di Perugia Ospedale S. Maria della Misericordia
Fluck, Michael	Germany	Fachklinik Hornheide
Gambichler, Thilo	Germany	St. Josef-Hospital Universitaetsklinikum
Grignani, Giovanni	Italy	Fondazione del Piemonte per l'Oncologia IRCC Candiolo
Grob, Jean-Jacques	France	Hôpital de la Timone
Guminski, Alexander	Australia	Royal North Shore Hospital
Hamid, Omid	United States	The Angeles Clinic and Research Institute - West LA
Hassel, Jessica	Germany	Universitaetsklinikum Heidelberg
Herbst, Rudolf	Germany	Helios Klinikum Erfurt
Hernandez-Aya, Leonel	United States	Washington University
Hogg, David	Canada	Princess Margaret Hospital

<b>Principal Investigator</b>	<b>Site – Country</b>	<b>Site – Institution</b>
Kaehler, Katharina	Germany	Universitaetsklinikum Schleswig-Holstein
Kaufmann, Roland	Germany	Klinikum der Johann Wolfgang Goethe-Universitaet
Kiecker, Felix	Germany	Charite Universitaetsmedizin Berlin - Campus Charite Mitte
Kiyohara, Yoshio	Japan	Shizuoka Cancer Center
Lacour, Jean-Philippe	France	CHU Nice - Hopital de l Archet 2
Lebbé, Céleste	France	Hôpital Saint-Louis
Leccia, Marie-Thérèse	France	CHU de Grenoble - Hôpital André Michallon
Lewis, Karl	United States	University of Colorado Health
Lopez Martin, Jose Antonio	Spain	Hospital Universitario 12 de Octubre
Maio, Michele	Italy	A.O.U. Senese Policlinico Santa Maria alle Scotte
Marquez Rodas, Ivan	Spain	Hospital General Universitario Gregorio Marañon
Mauch, Cornelia	Germany	Universitaetsklinikum Koeln
Meier, Friedegund	Germany	Universitaetsklinikum Carl Gustav Carus TU Dresden
Meyer, Nicolas	France	CHU de Toulouse - Hôpital Larrey
Milella, Michele	Italy	Istituto Nazionale Tumori Regina Elena IRCCS
Mortier, Laurent	France	Hopital Claude Huriez - CHU Lille
Olszanski, Anthony	United States	Fox Chase Cancer Center
Pinto, Carmine	Italy	Arcispedale S. Maria Nuova Azienda Ospedaliera di Reggio Emilia
Rabinowits, Guilherme	United States	Dana Farber Cancer Institute
Robert, Caroline	France	Institut Gustave Roussy
Russel, Jeffrey	United States	H. Lee Moffitt Cancer Center and Research Institute, Inc
Saiag, Philippe	France	Hôpital Ambroise Paré - Boulogne-Billancourt
Samimi, Mahtab	France	CHU Tours - Hôpital Trousseau
Sandhu, Shahneen	Australia	Peter MacCallum Cancer Centre
Staub, Janina	Germany	Universitaetsklinikum Hamburg-Eppendorf
Terheyden, Patrick	Germany	Universitaetsklinikum Schleswig Holstein - Campus Luebeck
Thomas, Luc	France	Centre Hospitalier Lyon Sud
Van Hagen, Thomas	Australia	St John of God Subiaco Hospital
Walker, John	Canada	Cross Cancer Institute
Yamazaki, Naoya	Japan	National Cancer Center Hospital

**eTable 2. Patient Demographic and Baseline Characteristics**

<b>Characteristic</b>	<b>N = 39</b>
Age, No. (%) < 65 years ≥ 65 years Median (range), years	8 (20.5) 31 (79.5) 75.0 (47-88)
Sex, No. (%) Male Female	30 (76.9) 9 (23.1)
Race, No. (%) White Black or African American Not collected at the site Unknown	33 (84.6) 1 (2.6) 4 (10.3) 1 (2.6)
Eastern Cooperative Oncology Group performance status, No. (%) 0 1	31 (79.5) 8 (20.5)
Site of primary tumor, No. (%) <sup>a</sup> Skin	39 (100.0)
Visceral metastases at baseline, No, (%) Present Absent Missing <sup>b</sup>	26 (66.7) 8 (20.5) 5 (12.8)
Time from initial diagnosis to study entry, months Median Range	13.0 0.7-120.9
Time since first metastatic disease diagnosis, months Median Range	3.1 0.6-27.7
Prior chemotherapy, No. (%) Yes No	5 (12.8) 34 (87.2)
Receiving prior chemotherapy, per disease state, No. (%) Neoadjuvant Adjuvant Locally advanced Metastatic	0 3 (7.7) 2 (5.1) 0

<sup>a</sup> There were no cases of unknown primary tumor.

<sup>b</sup> Tumor assessment per independent review committee was not available at the time of data cutoff.

**eTable 3. Incidence of Treatment-Related Adverse Events**

<b>Treatment-Related Adverse Event</b>	<b>Any Grade, n (%)</b>	<b>Grade ≥3, n (%)</b>
Any	28 (71.8)	8 (20.5)
Fatigue	9 (23.1)	0
Infusion-related reaction	9 (23.1)	1 (2.6)
Asthenia	3 (7.7)	0
Lipase increased	3 (7.7)	1 (2.6)
Elevated ALT	3 (7.7)	1 (2.6)
Arthralgia	2 (5.1)	0
Blood CPK increased	2 (5.1)	1 (2.6)
Chills	2 (5.1)	0
Diarrhea	2 (5.1)	0
Dry mouth	2 (5.1)	0
Dyspnea	2 (5.1)	0
Eosinophilia	2 (5.1)	0
Nausea	2 (5.1)	0
Pruritus <sup>a</sup>	2 (5.1)	0
Pyrexia	2 (5.1)	0
Rash maculo-papular <sup>a</sup>	2 (5.1)	0
Weight decreased	2 (5.1)	0
Autoimmune nephritis	1 (2.6)	1 (2.6)
Cholangitis	1 (2.6)	1 (2.6)
Elevated AST	1 (2.6)	1 (2.6)
Gait disturbance	1 (2.6)	1 (2.6)
Paraneoplastic encephalomyelitis	1 (2.6)	1 (2.6)
Polyneuropathy	1 (2.6)	1 (2.6)
Paraneoplastic syndrome	1 (2.6)	1 (2.6)
Troponin increased	1 (2.6)	1 (2.6)

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CPK, creatine phosphokinase.

Adverse events of any grade in at least 5% of patients or any grade 3 adverse event.

<sup>a</sup> One event of pruritus and 2 events of rash maculo-papular were also considered immune-related adverse events.

**eTable 4. Immune-Related Adverse Events**

<b>Event</b>	<b>CTCAE grade</b>	<b>Action Taken With Study Treatment</b>	<b>Outcome<sup>a</sup></b>	<b>Serious Adverse Event?</b>
Rash	1	Dose not changed	Recovered/resolved	No
Pruritus	1	Dose not changed	Not recovered/not resolved	No
Pruritus	1	Dose not changed	Recovered/resolved	No
Hypothyroidism	1	Not applicable	Recovered/resolved	No
Rash	1	Dose not changed	Not recovered/not resolved	No
Pruritus	1	Dose not changed	Recovered/resolved	No

<sup>a</sup> This is an interim analysis and events may have resolved subsequent to the data cutoff.