



# Merck KGaA, Darmstadt, Germany, and Pfizer to Present Data at ASCO for Avelumab, an Investigational Anti-PD-L1 Antibody

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Early data demonstrates advances in the understanding of investigational immunology therapy avelumab across multiple tumor types First presentations at a major global medical meeting since the formation of the alliance between Merck KGaA, Darmstadt, Germany and Pfizer

Merck KGaA, Darmstadt, Germany, and Pfizer today announced multiple presentations on studies evaluating the preliminary safety and efficacy of avelumab\* at the 2015 American Society of Clinical Oncology (ASCO) annual meeting.

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. Further, by retaining a native Fc-region, avelumab is thought to engage the innate immune system and may induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November, 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to jointly develop and commercialize avelumab.

“Immuno-oncology continues to be an exciting area of clinical investigation, and we are eager to share the latest early data for avelumab at ASCO,” said Dr. Luciano Rossetti, Global Head of Research and Development for the biopharmaceuticals business of Merck KGaA, Darmstadt, Germany. “This is the first time we will be presenting data on avelumab as an alliance. Our ovarian data represent the largest reported dataset of patients with recurrent ovarian cancer treated with an anti-PD-L1 therapy, underscoring

our commitment as an alliance to bring new therapies in difficult-to-treat tumor types.”

Avelumab presentations at ASCO provide the latest clinical updates available across various tumor types, including an oral presentation on ovarian cancer and posters on gastric cancer, non-small cell lung cancer (NSCLC) and several other studies in a range of patient populations.

“The field of immuno-oncology offers a vast opportunity for the development of new therapies that have the potential to change the way cancer is treated, and we believe the combined assets of our alliance allow us to further the science in this space,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology, adding, “By leveraging the combined strengths of our two companies in oncology, we will advance the clinical trial program for avelumab, further the understanding of anti-PD-L1 in the treatment of cancer, and look to bring treatments to market that have the potential to improve the lives of people with cancer.”

The presentations for avelumab at ASCO 2015 are:

Title	Lead Author	Abstract Number	Presentation Date/Time (CDT)	
Session Solid Tumors: Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with metastatic or locally advanced solid tumors: assessment of safety and tolerability in a Phase I, open-label expansion study				
Kelly K	3044	Saturday, May 30, 8:00-11:30 am	Poster Session: Developmental Therapeutics - Immunotherapy Solid Tumors:	
Phase I, open-label, multi-ascending dose trial of avelumab (MSB0010718C), an anti-PD-L1 monoclonal antibody, in Japanese patients with advanced solid tumors				
Shitara K	3023	Saturday, May 30, 8:00-11:30 am	Poster Session: Developmental Therapeutics - Immunotherapy Solid Tumors:	

Phase I expansion cohort trial to investigate the safety and clinical activity of avelumab (MSB0010718C) in patients with metastatic or locally advanced solid tumors

Heery C TPS3101 Saturday, May 30, 8:00-11:30 am Poster Session: Developmental Therapeutics - Immunotherapy ADCC:

Antibody dependent cellular cytotoxicity activity of a novel anti-PD-L1 antibody, avelumab (MSB0010718C), on human tumor cells (Independent)

Tsang K 3038 Saturday, May 30, 8:00-11:30 am Poster Session: Developmental Therapeutics - Immunotherapy Pharmacokinetic profile and receptor occupancy of avelumab (MSB0010718C), an anti-PD-L1 monoclonal antibody, in a Phase I, open-label, dose escalation trial in patients with advanced solid tumors Heery C 3055 Saturday, May 30, 8:00-11:30 am Poster Session: Developmental Therapeutics - Immunotherapy Ovarian Cancer:

Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with previously treated, recurrent or refractory ovarian cancer: a Phase Ib, open-label expansion trial

Disis M 5509 Monday, June 1, 3:00-3:12 pm  
Oral Presentation - Clinical Science Symposium:

Intersection of the Mutanome and the Immunome

NSCLC:

Avelumab (MSB0010718C), an anti-PD-L1 antibody, in advanced NSCLC patients: a Phase 1b, open-label expansion trial in patients progressing after platinum-based chemotherapy

Gulley J 8034 Monday, June 1, 8:00-11:30 am Poster Session: Lung Cancer Non-Small Cell Metastatic Gastric Cancer:

Prognostic significance of tumor infiltrating immune cells and PD-L1 expression in gastric carcinoma in Chinese patients

Geng R 4042 Monday, June 1, 8:00-11:30 am Poster Session: Gastrointestinal (Noncolorectal) Cancer Gastric Cancer:

A Phase I dose expansion trial of avelumab (MSB0010718C), an anti-PD-L1 antibody, in Japanese patients with advanced gastric cancer

Yamada Y 4047 Monday, June 1, 8:00-11:30 am Poster Session: Gastrointestinal (Noncolorectal) Cancer Merkel Cell Carcinoma:

A Phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in patients with metastatic Merkel cell carcinoma (TIP)

Kaufman H TPS9086 Monday, June 1, 1:15-4:45 pm Poster Session: Melanoma/Skin Cancers

Avelumab is under clinical investigation and has not been proven to be safe and effective. There is no guarantee any product will be approved in the sought-after indication by any health authority worldwide.

The data to be presented are based on the international Phase I trial to investigate avelumab in patients with metastatic or locally advanced solid tumors in which more than 840 patients have been treated across multiple solid tumor types. The Phase I trial is part of the expansive international clinical trial program for avelumab, JAVELIN, which is exploring the use of PD-L1 inhibition with avelumab to treat multiple types of cancer.

The JAVELIN program also includes an international Phase III trial to investigate avelumab in patients with non-small cell lung cancer, an international Phase II trial to investigate avelumab in patients with metastatic Merkel cell carcinoma and a Phase I trial to investigate avelumab in Japanese patients with metastatic or locally advanced solid tumors with an expansion part in Asian patients with gastric cancer.

#### Avelumab

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to engage the innate immune system and may induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November, 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

#### Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an investigational anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The companies will collaborate on up to 20 high priority immuno-oncology clinical development programs, including combination trials, many of which are expected to commence in 2015.

Pfizer Inc: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the US or Canada, please go to <http://www.emdgroup.com/subscribe> to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

Pfizer Disclosure Notice

The information contained in this release is as of May 13, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about avelumab (MSB0010718C), the potential of immuno-oncology, Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies and clinical development plans, including their potential benefits that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results; risks associated with interim data, including the risk that the final results of the Phase 1 study for avelumab and/or additional clinical trials may be different from (including less favorable than) the interim data results and may not support further clinical development; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any jurisdictions for any potential product candidates or combination therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of any of such product candidates or combination therapies; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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\*avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C)

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