Merck KGaA, Darmstadt, Germany, and Pfizer to Present Avelumab Data in Seven Different Cancers at ASCO Annual Meeting

Wednesday, May 18, 2016 - 01:30pm

14 avelumab abstracts at ASCO 2016 highlight significant progress being made by the collaboration between Merck KGaA, Darmstadt, Germany, and Pfizer Two oral presentations: avelumab investigated as a second-line treatment for metastatic Merkel cell carcinoma and in advanced mesothelioma Data featured contributes to growing understanding of the potential role of avelumab in treating a broad range of cancers JAVELIN clinical program rapidly accelerating ASCO Abstract # 8503, 9508, 4009, 4514, 4516, 9036, TPS4134, TPS4135, TPS9105, 3055, TPS3106, 5533, TPS5600, TPS4580

“These data add to the growing body of evidence for avelumab, indicating efficacy and a favorable safety profile in multiple cancers, which supports ongoing development”

Merck KGaA, Darmstadt, Germany, and Pfizer today announced that avelumab* presentations across seven different tumor types, including two oral presentations, will be featured at the 52nd American Society of Clinical Oncology (ASCO) Annual Meeting being held June 3–7, 2016, in Chicago, IL. The avelumab presentations, from the rapidly accelerating JAVELIN clinical development program, include new study results from a number of difficult-to-treat cancers, including data from the pivotal Phase II trial of avelumab being investigated as second-line treatment for metastatic Merkel cell carcinoma (MCC). Additional data include highlights from mesothelioma, adrenocortical carcinoma, non-small cell lung cancer, and urothelial bladder, gastric and ovarian cancers, as well as updated safety data.

“One of our key highlights for ASCO will be the new avelumab data in second-line metastatic Merkel cell carcinoma,” said Luciano Rossetti, Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. “As there are currently no approved treatments for this rare and aggressive cancer, these clinically meaningful data represent a breakthrough for this difficult-to-treat tumor type.”

Since ASCO 2015, the collaboration between Merck KGaA, Darmstadt, Germany, and Pfizer has made significant progress. The JAVELIN development program for avelumab now includes 30 ongoing clinical programs and nine pivotal studies. As of May 2016, JAVELIN now includes approximately 2,200 patients, being treated across more than 15 tumor types.

"These data add to the growing body of evidence for avelumab, indicating efficacy and a favorable safety profile in multiple cancers, which supports ongoing development,” said Chris Boshoff, M.D., PhD., Vice President and Head of Early Development, Translational and Immuno-Oncology at Pfizer Oncology. “Through our comprehensive JAVELIN clinical development program for avelumab, we are making meaningful advances for a broad range of patients with cancer.”

Avelumab is an investigational, fully human antibody specific for a protein found on tumor cells called PD-L1, or programmed death ligand. As a checkpoint inhibitor, avelumab is thought to have a dual mechanism of action which is believed to enable the immune system to find and attack cancer cells. By binding to PD-L1, avelumab is thought to prevent tumor cells from using PD-L1 for protection against white blood cells such as T-cells, exposing them to anti-tumor responses. Avelumab is also thought to help white blood cells such as natural killer (NK) cells find and attack tumors in a process known as ADCC, or antibody-dependent cell-mediated cytotoxicity.

A list of accepted avelumab abstracts is included below. The abstracts are also available on the ASCO website.

Title Lead Author
Abstract ID / Poster No.

Presentation Date / Time

Session Oral Presentations

Mesothelioma Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced unresectable mesothelioma from the JAVELIN Solid Tumor Phase Ib trial: safety, clinical activity, and PD-L1 expression

Hassan R
Abstract ID: 8503

Sunday, June 5 8:00 a.m. CDT Arie Crown Theater

Lung Cancer – Metastatic Disease

Merkel Cell Carcinoma Avelumab (MSB0010718C; anti-PD-L1) in patients with metastatic Merkel cell carcinoma previously treated with chemotherapy: results of the Phase II JAVELIN Merkel 200 trial

Kaufman H
Abstract ID: 9508

Monday, June 6 1:15 p.m. CDT Arie Crown Theater

Melanoma/Skin Cancers

Poster Discussions
Gastric/Gastro-esophageal Junction Cancer Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced gastric or gastroesophageal junction cancer from the JAVELIN Solid Tumor Phase Ib trial: analysis of safety, clinical activity

Chung HC
Abstract ID: 4009 Poster No.: 1

Saturday, June 4 8:00 a.m. CDT Hall A

Gastrointestinal (Noncolorectal) Cancer

Urothelial Carcinoma Avelumab (MSB0010718C; anti-PD-L1) in patients with metastatic urothelial carcinoma from the JAVELIN Solid Tumor Phase Ib trial: analysis of safety, clinical activity, and PD-L1 expression

Apolo A
Abstract ID: 4514 Poster No.: 137

Monday, June 6 1:00 p.m. CDT Hall A

Genitourinary (Nonprostate) Cancer

Adrenocortical Carcinoma Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced adrenocortical carcinoma from the JAVELIN Solid Tumor Phase Ib trial: safety and clinical activity

Le Tourneau C
Abstract ID: 4516 Poster No.: 138

Monday, June 6 1:00 p.m. CDT Hall A

Genitourinary (Nonprostate) Cancer

Poster Presentations
NSCLC Avelumab (MSB0010718C; anti-PD-L1) as a first-line treatment for patients with advanced NSCLC from the JAVELIN Solid Tumor Phase Ib trial: safety, clinical activity, and PD-L1 expression

Verschraegen C
Abstract ID: 9036 Poster No.: 359

Saturday, June 4 8:00 a.m. CDT Hall A

Lung Cancer – Non-Small Cell Metastatic

Gastric Cancer Maintenance therapy with avelumab (MSB0010718C; anti-PD-L1) vs continuation of first-line chemotherapy in patients with unresectable, locally advanced or metastatic gastric cancer: the Phase III JAVELIN Gastric 100 trial

Moehler M
Abstract ID: TPS4134 Poster No.: 124b

Saturday, June 4 8:00 a.m. CDT Hall A

Gastrointestinal (Noncolorectal) Cancer

Gastric Cancer Avelumab (MSB0010718C; anti-PD-L1) + best supportive care (BSC) vs BSC ± chemotherapy as third-line treatment for patients with unresectable, recurrent, or metastatic gastric cancer: the Phase III JAVELIN Gastric 300 trial

Bang Y-J
Abstract ID: TPS4135 Poster No.: 125a

Saturday, June 4 8:00 a.m. CDT Hall A

Gastrointestinal (Noncolorectal) Cancer

NSCLC Avelumab (MSB0010718C; anti-PD-L1) vs platinum-based doublet as first-line treatment for metastatic or recurrent PD-L1–positive non-small-cell lung cancer: the Phase III JAVELIN Lung 100 trial

Reck M
Abstract ID: TPS9105 Poster No.: 425a

Saturday, June 4 8:00 a.m. CDT Hall A

Lung Cancer— Non-Small Cell Metastatic

Advanced Cancer Avelumab (MSB0010718C; anti-PD-L1) in patients with advanced cancer: safety data from 1300 patients enrolled in the Phase Ib JAVELIN Solid Tumor trial

Kelly K
Abstract ID: 3055 Poster No.: 377

Sunday, June 5 8:00 a.m. CDT Hall A

Developmental Therapeutics— Immunotherapy

Advanced Malignancies Avelumab (MSB0010718C; anti-PD-L1) in combination with other cancer immunotherapies in patients with advanced malignancies: the Phase Ib/II JAVELIN Medley study

Ribas A
Abstract ID: TPS3106 Poster No.: 422b

Sunday, June 5 8:00 a.m. CDT Hall A

Developmental Therapeutics— Immunotherapy

Ovarian Cancer Avelumab (MSB0010718C; anti-PD-L1) in patients with recurrent/refractory ovarian cancer from the JAVELIN Solid Tumor Phase Ib trial: safety and clinical activity

Disis ML
Abstract ID: 5533 Poster No.: 356

Monday, June 6 1:00 p.m. CDT Hall A

Gynecologic Cancer

Ovarian Cancer Avelumab (MSB0010718C; anti-PD-L1) ± pegylated liposomal doxorubicin vs pegylated liposomal doxorubicin alone in patients with platinum-resistant/refractory ovarian cancer: the Phase III JAVELIN Ovarian 200 trial

Pujade Lauraine E

Abstract ID: TPS5600 Poster No.: 421b

Monday, June 6 1:00 p.m. CDT Hall A

Gynecologic Cancer

Renal Cell Carcinoma Avelumab (MSB0010718C; anti-PD-L1) in combination with axitinib as first-line treatment for patients with advanced renal cell carcinoma

Larkin J
Abstract ID: TPS4580 Poster No.: 199a

Monday, June 6 1:00 p.m. CDT Hall A

Genitourinary (Nonprostate) Cancer

*Avelumab is the proposed nonproprietary name for the anti-PD-L1 monoclonal antibody (MSB0010718C). 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.

About 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 potentially engage the innate immune system and 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 alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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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 healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare 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. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, and like us on Facebook at Facebook.com/Pfizer.

Merck KGaA, Darmstadt, Germany

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Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly

listed corporate group. Merck KGaA, Darmstadt, Germany operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada.

Pfizer Disclosure Notice

The information contained in this release is as of May 18, 2016. 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; 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 indications for avelumab, combination therapies or other product candidates; 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 avelumab, combination therapies or other product candidates; 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, 2015, 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Merck KGaA, Darmstadt, Germany Media: Gangolf Schrimpf, +49 6151 72 9591 or Investor Relations: +49 6151 72 3321 or Pfizer Inc., New York, USA Media: Sally Beatty, +1 212 733 6566 or Investor Relations: Ryan Crowe, +1 212 733 8160