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News Release

ECC Abstract #

Avelumab: 3090, 3110, 2749, 2398, 2630, 2364

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Merck KGaA, Darmstadt, Germany, and Pfizer to Present Updates for Avelumab at the European Cancer Congress 2015

- **Data from six abstracts, including new data in mesothelioma, urothelial (e.g. bladder), and gastric/gastroesophageal cancers to be presented at the European Cancer Congress (ECC)**
- **Additional findings for non-small cell lung cancer (NSCLC) and ovarian cancers build on previously presented data**

Darmstadt, Germany, and New York, US, September 11, 2015 – Merck KGaA, Darmstadt, Germany, and Pfizer today announced that six abstracts on studies evaluating the potential role of programmed death-ligand 1 (PD-L1) inhibition and the safety and efficacy of the investigational cancer immunotherapy avelumab* will be presented at this year's ECC in Vienna, Austria, September 25–29, 2015.

New data will be presented in urothelial (e.g. bladder), mesothelioma and gastric/gastroesophageal cancers. Additional NSCLC and ovarian cancer data from Phase Ib trials build on those previously presented at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO).[1-10] .As the promise of immuno-oncology

continues to grow, these new data help to further the understanding of the potential role of avelumab for patients suffering from cancers with high unmet need.

Despite continued progress in bringing new treatments to patients, there remains a significant unmet need across many types of cancer. For example, the incidence of gastric cancer remains a major public issue in Western and Asian countries, and there is a continued need to better understand the disease biology to provide patients with the most appropriate and effective treatment.[11] For some cancer types, such as mesothelioma, the incidence rates are rising worldwide,[12] with limited treatment options currently available for patients.

“Our clinical program for avelumab continues to accelerate, and we remain on-target to initiate up to six pivotal trials this year,” said Dr Luciano Rossetti, Head of Global Research & Development at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. “As we investigate avelumab across a broad range of tumor types, we and Pfizer are working together diligently to analyze and present data at important congresses like ECC, to share the latest knowledge and understanding of this immune checkpoint inhibitor with the medical community.”

Currently, more than 1,000 cancer patients have been treated with avelumab in the Phase I/Ib clinical program (JAVELIN Solid Tumor), and more than 15 tumor types are under investigation.

“This is an exciting time for our alliance. Working together, we have made substantial progress in advancing the clinical evaluation of avelumab as both a single agent and as part of combination therapy in patients with difficult-to-treat cancers,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. “We believe that the talent, resources, pipeline products, and commitment that each partner brings to this collaboration position us well to become potential leaders in the field of immuno-oncology.”

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The abstracts to be presented at ECC 2015 include:

Title	Lead Author	Abstract ID / Poster No.	Presentation Date / Time	Session
NSCLC: Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with metastatic or recurrent non-small-cell lung cancer progressing after platinum-based chemotherapy: a phase IB trial	Gulley J	Abstract ID: 3090 Poster board No.: 342	Date: September 27 Time: 09:15–11:15 Location: Hall C	Lung Cancer - Metastatic Disease
Mesothelioma: Safety and clinical activity of avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with advanced, unresectable mesothelioma: a phase IB trial	Hassan R	Abstract ID: 3110 Poster board No.: 326	Date: September 27 Time: 09:15–11:15 Location: Hall C	Lung Cancer – Metastatic Disease
			Date: September 27 Time: 09:45–10:45 Location: Hall C	Poster spotlight session: Lung cancer
Ovarian Cancer: Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with recurrent or refractory ovarian cancer: a phase Ib trial reporting safety and clinical activity	Disis M	Abstract ID: 2749 Poster board No.: 412	Date: September 28 Time: 09:15–11:15 Location: Hall C	Gynaecological Cancer
Esophageal Cancer: Prognostic significance of tumor-infiltrating immune cells and PD-L1 expression in esophageal	Jiang Y	Abstract ID: 2398 Poster board No.: 360	Date: September 28 Time: 09:15–11:15 Location: Hall C	Gastrointestinal Malignancies - Noncolorectal Cancer

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squamous cell carcinoma in Chinese patients				
Urothelial Cancer: Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with locally advanced or metastatic urothelial carcinoma: a phase IB trial	Apolo A	Abstract ID: 2630 Poster board No.: 121	Date: September 28 Time: 16:45–18:45 Location: Hall C	Genitourinary Malignancies - Nonprostate Cancer
Gastric Cancer/GEJ: Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with advanced gastric or gastroesophageal junction cancer: a phase IB trial in second-line and switch maintenance settings	Chung HC	Abstract ID: 2364 Poster board No.: 326	Date: September 28 Time: 16:45–18:45 Location: Hall C	Genitourinary Malignancies - Nonprostate Cancer

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.

Data to be presented at ECC are part of the JAVELIN clinical trial program, an extensive international program exploring the use of PD-L1 inhibition with avelumab to treat multiple types of cancer.

The JAVELIN clinical trial program includes a Phase III open-label, multicenter trial to investigate avelumab versus docetaxel in patients with Stage IIIb/IV or recurrent NSCLC that has progressed after platinum-based chemotherapy (JAVELIN Lung 200); an international Phase II trial to investigate avelumab in patients with metastatic Merkel cell carcinoma (JAVELIN Merkel 200); a Phase Ib, open-label, multicenter, multiple-dose trial designed to estimate the maximum tolerated dose and select the recommended Phase II dose of avelumab in combination with axitinib in patients with previously untreated advanced renal cell carcinoma (JAVELIN Renal 100); an international Phase I trial to

investigate avelumab in patients with metastatic or locally advanced solid tumors (JAVELIN Solid Tumor); and a Phase I trial to investigate avelumab in Japanese patients with metastatic or locally advanced solid tumors, with an expansion cohort in Asian patients with gastric cancer (JAVELIN Solid Tumor Japan). The clinical development program for avelumab now includes more than 1,000 patients treated across more than 15 tumor types, including NSCLC, breast cancer, gastric cancer, ovarian cancer, urothelial cancer, esophageal cancer, head and neck cancer, renal cell carcinoma, Merkel cell carcinoma, melanoma and mesothelioma.

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

References

1. Heery C et al. 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 (Abstract #3055). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
2. Kelly K et al. 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 (Abstract #3044). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
3. Shitara K et al. Phase I, open-label, multi-ascending dose trial of avelumab (MSB0010718C), an anti-PD-L1 monoclonal antibody, in Japanese patients with advanced solid tumors (Abstract #3023). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
4. Heery C et al. Trial in Progress: Phase I expansion cohort trial to investigate the safety and clinical activity of avelumab (MSB0010718C) in patients with metastatic or locally advanced solid tumors (Abstract #TPS3101). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
5. Gulley J et al. 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 (Abstract #8034). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
6. Disis M et al. Avelumab (MSB0010718C), an anti-PD-L1 antibody, in patients with previously treated, recurrent or refractory ovarian cancer: a phase Ib, open-label expansion trial (Abstract #5509). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
7. Yamada Y et al. A phase I dose expansion trial of avelumab (MSB0010718C), an anti-PD-L1 antibody, in Japanese patients with advanced gastric cancer (Abstract 4047). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
8. Kaufman H et al. Trial in Progress: A phase II, open-label, multicenter trial to investigate the clinical activity and safety of avelumab (MSB0010718C) in patients with metastatic Merkel cell carcinoma (Abstract #TPS9086). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.

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9. Geng R et al. Prognostic significance of tumor infiltrating immune cells and PD-L1 expression in gastric carcinoma in Chinese patients (Abstract #4042). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
10. Tsang K et al. Antibody dependent cellular cytotoxicity activity of a novel anti-PD-L1 antibody, avelumab (MSB0010718C), on human tumor cells (Abstract #3038). Presented at the 2015 Annual Meeting of the American Society of Clinical Oncology, May 29-June 2, 2015, Chicago, IL.
11. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.1, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2014. Available from: http://globocan.iarc.fr, Accessed on August 2015.
12. The Mesothelioma Center. Mesothelioma Cancer Trends. Available from: http://www.asbestos.com/mesothelioma/mesothelioma-trends/. Accessed August 2015.

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 potentially 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 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.

JAVELIN Clinical Trial Program for Avelumab
JAVELIN is an extensive international clinical trial program exploring the use of PD-L1 inhibition with avelumab to treat multiple types of cancer. The JAVELIN clinical trial program includes a Phase III study in stage IIIb/IV or recurrent NSCLC designed to assess the efficacy and safety of avelumab compared with docetaxel in patients who have experienced disease progression after receiving a prior platinum-containing doublet therapy (JAVELIN Lung 200). It also includes: a Phase Ib, open-label, multi-center, multiple-dose trial designed to estimate the maximum tolerated dose and select the recommended Phase II dose of avelumab in combination with axitinib in patients with previously untreated advanced renal cell carcinoma (JAVELIN Renal 100); an international Phase II open-label multicenter trial to investigate the clinical activity and safety of avelumab in patients with metastatic Merkel cell carcinoma (MCC) who must have received one line of chemotherapy for the treatment of metastatic MCC (JAVELIN Merkel 200); an international Phase I open-label, multiple ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity in patients with metastatic or locally advanced solid tumors (JAVELIN Solid Tumor); and a Phase I trial to investigate the tolerability, safety, pharmacokinetics, biological, and clinical activity of avelumab in Japanese patients with metastatic or locally advanced solid tumors (JAVELIN Solid Tumor Japan), with an expansion part in Asian patients with gastric cancer.

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.

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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 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.

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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.

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Pfizer Disclosure Notice

The information contained in this release is as of September 11, 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 I 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 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, 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 and www.pfizer.com.