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Global Strategic Partners Merck KGaA, Darmstadt, Germany, and Pfizer Initiate Phase III Study with Avelumab in Patients with Stage IIIb/IV Non-Small Cell Lung Cancer

- **First of several registration trials expected to start in 2015 for the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer**
- **Initiation and first patient treated in Phase III clinical study recruiting across approximately 290 sites in more than 30 countries**
- **The primary endpoint of the study is overall survival (OS) in patients with programmed death-ligand 1 positive (PD-L1+) stage IIIb/IV non-small cell lung cancer (NSCLC) who have experienced disease progression after receiving a prior platinum-containing doublet therapy**

Darmstadt, Germany, and New York, US, April 20, 2015 – Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, today announced the initiation and first patient treated in the international Phase III study (EMR 100070-004) designed to assess the efficacy and safety of the investigational cancer immunotherapy avelumab* (MSB0010718C), compared with docetaxel, in patients with stage IIIb/IV non-small cell lung cancer (NSCLC) who have experienced disease progression after receiving a prior platinum-containing doublet therapy.

The Phase III study is an open-label, multicenter, 1:1 randomized clinical trial where patients with stage IIIb/IV NSCLC will receive either avelumab or docetaxel, regardless

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of PD-L1 status. Approximately 650 patients will participate across 290 sites in more than 30 countries in North America, South America, Asia, Africa and Europe. In North America, clinical trials on behalf of Merck KGaA, Darmstadt, Germany, will be conducted by EMD Serono, the company's US and Canadian biopharmaceutical businesses. The study is part of the JAVELIN clinical trial program for avelumab.

The primary endpoint of the study is overall survival (OS) in patients with programmed death-ligand 1 positive (PD-L1+) stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy. Secondary endpoints will be assessed across the entire study population regardless of PD-L1 status and include OS; overall response rate (ORR); progression-free survival (PFS); and patient-reported outcomes.

"New and innovative treatment strategies are urgently needed to improve overall survival for patients with NSCLC, and we are investigating avelumab as a potential treatment option for patients with this very difficult-to-treat disease," said Dr. Luciano Rossetti, Global Head of R&D of the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "The treatment of the first patient in the Phase III trial is an important milestone for our immuno-oncology alliance."

"This trial marks the first of several registration studies we are planning to initiate this year together, and underscores our commitment to accelerating the development of medications for patients with cancer," said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. "Through this alliance, we will have the opportunity to combine the promising anti-PD-L1 antibody, avelumab, with our combined portfolios of approved and investigational oncology therapies, which may provide an exciting opportunity to potentially broaden the use of immunotherapy for patients with cancer."

The JAVELIN clinical trial program also includes an international Phase II trial to investigate avelumab in patients with metastatic Merkel cell carcinoma; an international Phase I trial to investigate avelumab in patients with metastatic or locally advanced solid tumors, 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

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cancer. The Phase I program for avelumab includes more than 840 patients treated across multiple tumor types, including NSCLC, breast cancer, gastric cancer, ovarian cancer, bladder cancer, melanoma and mesothelioma.

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

References

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About Non-Small Cell Lung Cancer

Globally, lung cancer is the most common cause of cancer-related deaths in men and the second most common in women, responsible for almost twice as many deaths as both breast and prostate cancer combined[1]. NSCLC is the most common type of lung cancer, accounting for 85 to 90 percent of all lung cancers[2]. Locally advanced and metastatic disease account for approximately 35 to 40 percent[3] and 70 percent[4] of patients, respectively with NSCLC.

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 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 expansive 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 designed to assess the efficacy and safety of avelumab compared with docetaxel in patients with stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy; an international Phase II open-label multicenter trial to investigate the clinical activity and safety of avelumab in patients with metastatic Merkel cell carcinoma; 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; 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 with an expansion part in Asian patients with gastric cancer.

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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 healthcare 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.

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 April 20, 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 Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies, clinical development plans and a target indication for avelumab (MSB0010718C) for treatment of patients with stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy (the "Target Indication") 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 product candidates or combination therapies, including the Target Indication; 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, including the Target Indication; 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 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.