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Merck KGaA, Darmstadt, Germany, and Pfizer Announce Initiation of Phase III First-Line Trial of Avelumab in Patients with Recurrent or Stage IV Non-Small Cell Lung Cancer

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Trial marks second Phase III study of avelumab in non-small cell lung cancer (NSCLC) initiated by Merck KGaA, Darmstadt, Germany, and Pfizer in just over six months Primary endpoint is progression-free survival in previously untreated patients with recurrent or Stage IV programmed death-ligand 1 positive (PD-L1+) NSCLC

Merck KGaA, Darmstadt, Germany, and Pfizer today announced the initiation of an international Phase III study of the investigational cancer immunotherapy avelumab* in a treatment naïve advanced NSCLC setting. The study, JAVELIN Lung 100, is designed to assess the safety and efficacy of avelumab compared with platinum-based doublet chemotherapy, in patients with late-stage NSCLC who have not previously received any treatment for their systemic lung cancer. Avelumab (previously known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody that potentially uses the body's own immune system to fight cancer.

The Phase III study is an open-label, multicenter, randomized clinical trial in which patients with recurrent or Stage IV PD-L1+ NSCLC will receive either avelumab or the investigator's choice of platinum-based chemotherapy, depending on the patient's histology (either squamous or non-squamous), as first-line treatment. Patients will be pre-screened for PD-L1+ status using an immunohistochemistry-based companion diagnostic test.

The study expects to enroll approximately 420 patients across more than 240 sites in Africa, America (North and South), Asia and Europe. Clinical trials in North America on behalf of Merck KGaA, Darmstadt, Germany, will be conducted by EMD Serono, the company's US and Canadian biopharma business.

"Through this Phase III trial, we hope to gain a better understanding of avelumab as a potential first-line treatment for non-small cell lung cancer – a prevalent and devastating disease," said Dr. Luciano Rossetti, Global Head of Research & Development of the biopharma business of Merck KGaA, Darmstadt, Germany. "We are working to help patients with this challenging cancer and will continue to develop our NSCLC program by evaluating avelumab as a potential monotherapy and in combination with our extensive portfolios of approved and investigational oncology therapies."

The primary endpoint of the study is progression-free survival in patients with PD-L1+ tumors. Secondary endpoints include progression-free survival in patients with strongly PD-L1 positive (PD-L1++) tumors, overall

survival, objective response rate, quality of life, tolerability and safety in patients treated with avelumab versus investigator-choice chemotherapy. This is the second randomized Phase III study of avelumab in NSCLC initiated in just over six months; the first study was initiated in April 2015 and is evaluating avelumab in patients whose disease has progressed after receiving a platinum-containing doublet chemotherapy compared with docetaxel.

“There is great promise for the use of immunotherapy in the treatment of non-small cell lung cancer and this new trial underscores our continuing commitment to investigating potential immune-based treatment options for this devastating disease,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. “The clinical development program for avelumab continues to accelerate, and the initiation of this Phase III study represents another important achievement in 2015 for the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer.”

The clinical development program for avelumab now includes more than 1,400 patients who have been treated across more than 15 tumor types, including breast cancer, gastric/gastro-esophageal (GEJ) cancers, head and neck cancer, Merkel cell carcinoma, melanoma, NSCLC, ovarian cancer, renal cell carcinoma and urothelial (e.g., bladder) cancer.

*Avelumab is the proposed International Non-proprietary 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.

References

1. American Cancer Society (2015) Global Facts & Figures Third Edition. Available from: www.cancer.org/acs/groups/content/@research/documents/document/acspc-044738.pdf. Accessed October 2015.

2. American Cancer Society (2015) Lung Cancer (Non-Small Cell) [Fact sheet]. Available from: www.cancer.org/acs/groups/cid/documents/webcontent/003115-pdf. Accessed October 2015.

3. Mayo Clinic (2015) Cancer survival rate: what it means for your prognosis: http://www.mayoclinic.org/diseases-conditions/cancer/in-depth/cancer/art-20044517. Accessed October 2015.

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,1 responsible for more deaths than colon, breast and prostate cancer combined2. NSCLC is the most common type of lung cancer, accounting for 85 to 90 percent of all lung cancers2. The five-year survival rate for people diagnosed with late-stage lung cancer that has spread (metastasized) to other areas of the body is 4 percent.3

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 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.

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 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.

Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 40,000 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 2014, Merck KGaA, Darmstadt, Germany, generated sales of € 11.3 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, holds the global rights to the Merck KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

Pfizer Disclosure Notice

The information contained in this release is as of November 4, 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), including a potential indication for the treatment of patients with late-stage NSCLC who have not previously received any treatment for their systemic lung cancer, 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 andwww.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