Merck KGaA, Darmstadt, Germany, and Pfizer Initiate Two Phase III Studies of Investigational Immunotherapy Avelumab in Advanced Gastric and Gastro-esophageal Junction Cancers

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Trials mark third and fourth Phase III studies of avelumab initiated by Merck KGaA, Darmstadt, Germany, and Pfizer this year First-line study designed to evaluate superiority of avelumab immunotherapy as a maintenance treatment for advanced or metastatic gastric/gastro-esophageal junction cancers versus continuation of first-line platinum-based chemotherapy Third-line study designed to evaluate avelumab immunotherapy as a third-line treatment in advanced or metastatic gastric/gastro-esophageal junction cancers

Merck KGaA, Darmstadt, Germany, and Pfizer today announced the initiation of two Phase III studies of avelumab*, an investigational, fully human anti-PD-L1 IgG1 monoclonal antibody, in treating advanced or metastatic gastric/gastro-esophageal junction (GEJ) cancers, which are aggressive cancers with poor survival rates. These pivotal trials are investigating avelumab in the first-line and third-line settings, with overall survival (OS) as the primary endpoint in both trials.

JAVELIN Gastric 100, a study comparing the switch from first-line chemotherapy to maintenance therapy with avelumab versus continuation of chemotherapy, is a multicenter, international, randomized, open-label Phase III trial designed to evaluate the potential superiority (based on OS) of maintenance therapy with avelumab in patients with unresectable, locally advanced or metastatic gastric/GEJ cancers whose disease has

not progressed with first-line platinum-based chemotherapy. This is currently the only Phase III trial in gastric cancer that is designed to evaluate superiority of an immunotherapy compared with conventional platinum-based chemotherapy as a first-line maintenance treatment. The study will enroll 629 patients across more than 220 sites in Asia Pacific, Europe, North America and South America.

“The prognosis is generally poor for the majority of patients with advanced gastric cancers,” said Dr. Luciano Rossetti, Global Head of Research & Development of the biopharma business of Merck KGaA, Darmstadt, Germany. “By initiating these two Phase III trials in gastric and gastro-esophageal junction cancers, we are continuing the fight against cancer with an overarching goal of potentially improving survival for patients.”

The third-line study, JAVELIN Gastric 300, is a multicenter, international, randomized, open-label Phase III trial designed to evaluate the potential superiority (based on OS) of avelumab in patients with unresectable, recurrent or metastatic gastric/GEJ cancers, compared with investigator’s choice of chemotherapy from a pre-specified list of therapeutic options. The study will enroll approximately 330 patients, spanning approximately 170 sites in Asia, Australia, Europe, North America and South America.

“We are continuing to investigate avelumab in cancers with high unmet need and where there is a strong rationale for immunotherapeutic intervention,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. “Advanced gastric cancer is a challenging diagnosis to face as a patient, and we are dedicating significant resources to evaluate avelumab as a potential new treatment option for patients in multiple settings of this disease.”

The clinical development program for avelumab now includes more than 1,500 patients who have been treated across more than 15 tumor types, including breast cancer, gastric/GEJ cancers, head and neck cancer, Merkel cell carcinoma, melanoma, mesothelioma, non-small cell lung cancer, ovarian cancer, renal cell carcinoma and urothelial (e.g. bladder) cancer. Clinical trials for both of the gastric/GEJ Phase III trials in North America will be conducted on behalf of Merck KGaA, Darmstadt, Germany, by EMD Serono, the company’s US and Canadian biopharma business.

*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.

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About Gastric and Gastro-esophageal Junction (GEJ) Cancers

Gastric cancer is uncommon in the US and Western Europe.1,2 Each year, there are approximately 22,000 new cases of gastric cancer diagnosed in the US and 80,626 cases diagnosed in the EU.3 Gastric cancer is much more commonly diagnosed in East Asia, Eastern Europe, and parts of South America.4 For patients with advanced gastric cancer, the prognosis is poor. The 5-year survival rate in the US is <20 percent for Stage III gastric cancer and <5 percent for Stage IV gastric cancer.5 Current treatment options for gastric cancer may include surgery, radiotherapy, chemotherapy, chemoradiotherapy and targeted therapies.2,6

Reliable data on the global incidence of GEJ tumors are not available, due to the historically complicated classification system and the likelihood of misclassification.7 Current treatment options for GEJ cancer may include surgery, chemotherapy, radiation therapy and targeted therapy.8,9 Despite advances in the field of GEJ, there is no cure for patients with cancer that has spread.10 There is a clear unmet medical need for new treatment options.

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, MilliporeSigma 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 USA or Canada please go towww.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 December 9, 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 avelumab for gastric/gastro-esophageal junction cancers, 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, 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.

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