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Merck KGaA, Darmstadt, Germany, and Pfizer Initiate Phase III Trial to Evaluate Avelumab as First-line Treatment for Ovarian Cancer

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First Phase III trial evaluating the addition of an immune checkpoint inhibitor to standard of care in first-line ovarian cancer New investigational regimen will evaluate avelumab in extending progression-free survival in treatment-naïve women

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Merck KGaA, Darmstadt, Germany, and Pfizer (NYSE: PFE) today announced the initiation of a Phase III study, JAVELIN Ovarian 100, to evaluate the efficacy and safety of avelumab* in combination with, and/or as follow-on (maintenance) treatment to, platinum-based chemotherapy in patients with locally advanced or metastatic disease (Stage III or Stage IV) with previously untreated epithelial ovarian cancer. JAVELIN Ovarian 100 is the first Phase III study evaluating the addition of an immune checkpoint inhibitor to standard-of-care in first-line treatment for this aggressive disease.

“In an early ongoing study, avelumab showed encouraging tumor response rates in patients with recurrent or refractory ovarian cancer,” said Alise Reicin, M.D., Head of Global Clinical Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. “Historically, ovarian cancer presents as an advanced disease with poor survival rates. The hope is that avelumab can change the natural history of the disease and potentially take the survival rate beyond the current five year estimate.”

JAVELIN Ovarian 100 is an open-label, international, multi-center, randomized (1:1:1) Phase III trial in treatment naïve patients with locally advanced or metastatic ovarian cancer (Stage III or Stage IV). This study is designed to evaluate the potential superiority of two first-line therapies with avelumab and platinum-based chemotherapy versus platinum-based chemotherapy alone, as assessed by progression-free survival. The study will enroll approximately 950 patients, who will receive concurrent avelumab and chemotherapy, avelumab following chemotherapy, or chemotherapy alone.

“Patients with ovarian cancer need additional treatment options. We believe there could be synergistic activity in the combination of avelumab and established treatments such as platinum-based chemotherapy,” said Chris Boshoff, M.D., Ph.D., Head of Early Development, Translational and Immuno-Oncology, Oncology in Pfizer Global Product Development. “With two studies now underway of avelumab in ovarian cancer, we look forward to receiving the results from these trials and continuing to break ground in this hard-to-treat cancer.”

The alliance aims to build a strong foundation in ovarian cancer. In December 2015, Merck KGaA, Darmstadt, Germany, and Pfizer announced the initiation of an international Phase III study of avelumab as a treatment for platinum-resistant/refractory ovarian cancer. As of May 2016, the complete JAVELIN clinical development program for avelumab includes approximately 2,200 patients enrolled, being treated across more than 15 tumor types.

For more information about avelumab, please visit www.powerofcombination.com.

*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.

References

1. GLOBOCAN2012. International Agency for Research on Cancer. World Health Organization. http://globocan.iarc.fr/Default.aspx. Last accessed June 1, 2016.

2. Ovarian Cancer Statistics. World Cancer Research Fund International. http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/ovarian-cancer-statistics. Last accessed June 1, 2016.

About Ovarian Cancer

Ovarian cancer causes more deaths than any other gynecologic cancer globally. Each year, nearly a quarter of a million women will be diagnosed with ovarian cancer worldwide.1 Women in Europe and Northern America have the highest incidence rates of ovarian cancer.2 Patients are said to have 'platinum-resistant' disease if the disease worsens within 6 months of completing platinum-based chemotherapy. One quarter of those who relapse after initial treatment, more than 4,300 women, will have platinum-resistant cancer, the most difficult-to-treat form of the disease.

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.

About Merck KGaA, Darmstadt, Germany

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 to www.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.

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.

For further details and press materials about Merck KGaA, Darmstadt, Germany products please visit http://www.emdgroup.com/emd/media/media_center_oncology.html.

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Pfizer Disclosure Notice

The information contained in this release is as of July 6, 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), including a potential indication for avelumab in combination with, and as follow-on treatment to, platinum-based chemotherapy in patients with previously untreated epithelial ovarian 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; 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.

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