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Merck KGaA, Darmstadt, Germany, Pfizer and Syndax Announce Collaboration to Evaluate Combination of Avelumab and Entinostat in Ovarian Cancer

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Merck KGaA, Darmstadt, Germany, Pfizer and Syndax will collaborate to investigate safety, tolerability and preliminary efficacy of avelumab and entinostat in advanced ovarian cancer

Merck KGaA, Darmstadt, Germany, Pfizer and Syndax Pharmaceuticals, Inc. announced today that they have entered into a collaboration agreement to evaluate avelumab*, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, in combination with Syndax's entinostat, an investigational oral small molecule that targets immune regulatory cells (myeloid-derived suppressor cells and regulatory T-cells), in patients with heavily pre-treated, recurrent ovarian cancer. Avelumab is currently under clinical investigation across a broad range of tumor types by the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer. This is an exclusive agreement between the alliance and Syndax to study the combination of these two investigational agents in ovarian cancer. Syndax will be responsible for conducting the Phase Ib/II clinical trial in ovarian cancer.

"This collaboration with Syndax adds a new dimension to our quest to pursue combination immuno-oncology regimens based on compelling preclinical rationale and the potential to generate clinical results superior to those achieved with either agent alone," said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology.

"Combination therapy is the next frontier in immuno-oncology and a key strategy for the alliance," said Dr. Luciano Rossetti, Head of Global Research & Development of the biopharma business of Merck KGaA, Darmstadt, Germany. "Avelumab as a monotherapy has already shown promising early activity in ovarian cancer in a Phase Ib trial, and through our ongoing research and this collaboration with Syndax, we will hopefully be able to make a real difference to women fighting this complex cancer."

"We are delighted to be working with the alliance to explore the potential benefits of entinostat in combination with avelumab for ovarian cancer patients," said Dr. Briggs W. Morrison, Syndax's Chief Executive Officer. "The continued interest from leading companies in investigating the potential of entinostat in combination with checkpoint inhibitors reflects positively on the potential mechanism of action of the molecule, and also reinforces our clinical strategy to explore entinostat for the benefit of patients across a broad range of solid tumor indications."

Financial terms of the agreement were not disclosed.

*Avelumab is the proposed International Non-proprietary Name for the anti-PD-L1 IgG1 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.

About Ovarian Cancer

Globally, ovarian cancer is the seventh most common cancer in women.1 Annually, nearly 239,000 cases are diagnosed worldwide.2 Ovarian cancer may be difficult to diagnose, as symptoms may appear only in the later stages, when the disease has spread beyond the ovaries.2 Outcomes for women with ovarian cancer are generally poor due to most patients presenting with advanced disease.3 The 5-year prevalence of women globally living with ovarian cancer is 22.6 per 100,000.2 Current treatment options for epithelial ovarian cancer may include surgery, radiotherapy, chemotherapy and targeted therapies.4 Women who are unable to undergo treatment with platinum-based chemotherapy, due to resistance or refractory disease, currently have very limited treatment options. Platinum-resistant ovarian cancer is defined as ovarian cancer that recurs within six months of completing primary chemotherapy with a platinum-based medication.5 Platinum-refractory ovarian cancer is defined as ovarian cancer that progresses during treatment with a platinum-based chemotherapy regimen.5 There is still a clear unmet need in ovarian cancer in relation to general disease awareness,2 improving initial investigations in primary and secondary care and novel therapies with demonstrable efficacy.6

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.

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 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 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 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.

Pfizer Disclosure Notice

The information contained in this release is as of January 4, 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), Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies and clinical development plans and a collaboration agreement with Syndax Pharmaceuticals, Inc. (Syndax) to evaluate avelumab in combination with Syndax's entinostat, an investigational oral small molecule that targets immune regulatory cells (myeloid-derived suppressor cells and regulatory T-cells) in patients with ovarian cancer, 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 U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company developing entinostat as a combination therapy in multiple cancer indications with an initial focus on tumors that have shown sensitivity to immunotherapy, including lung cancer, ovarian cancer, melanoma and triple-negative breast cancer (TNBC). Entinostat is an oral, small molecule drug candidate that has direct effects on both cancer cells and immune regulatory cells, potentially enhancing the body's immune response to tumors. Entinostat is being evaluated as a combination therapeutic in Phase 1b/2 clinical trials with Merck & Co., Inc. for non-small cell lung cancer and melanoma and with Genentech, Inc. for TNBC, as well as in a Phase 3 clinical trial with ECOG-ACRIN for advanced hormone receptor positive breast cancer, an indication for which entinostat was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration. For more information on Syndax please visit www.syndax.com.

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements contained in this press include, without limitation, statements regarding a collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer to evaluate avelumab in combination with Syndax's entinostat in patients with ovarian cancer, including their potential benefits. Words such as "may," "believe," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance and involve a number of unknown risks, assumptions, uncertainties and factors that are beyond Syndax's control. All forward-looking statements are as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, Syndax expressly disclaims any responsibility to update any forward-looking statements contained herein, whether as a result of new information, future events or otherwise.

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