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March 3, 2016

Merck KGaA, Darmstadt, Germany, Pfizer and Verastem Announce Combination Trial of Avelumab and VS-6063 in Ovarian Cancer

- **Collaboration will focus on a Phase I/Ib clinical trial expected to begin in the second half of 2016**

Darmstadt, Germany, New York, US and Boston, US, March 3, 2016 – Merck KGaA, Darmstadt, Germany, Pfizer and Verastem announced today that they have entered into an agreement to evaluate avelumab*, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, in combination with Verastem’s VS-6063**, an investigational focal adhesion kinase (FAK) inhibitor, in patients with advanced ovarian cancer. Avelumab is currently under clinical investigation across a broad range of tumor types. The Phase I/Ib clinical trial is expected to begin in the second half of 2016. Financial terms of the agreement have not been disclosed.

“Combination strategies in immuno-oncology offer significant promise for patients in need. Through our collaboration with Verastem, we hope to accelerate our understanding of avelumab and its potential as a combination therapy with FAK inhibition for patients fighting ovarian cancer,” said Dr. Alise Reicin, Head of Global Clinical Development at Merck KGaA, Darmstadt, Germany’s biopharma business, which in the US and Canada operates as EMD Serono.

“Through this collaboration, we hope to advance our understanding of how FAK inhibition may complement our development program for avelumab, with the



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ultimate goal of potentially achieving better outcomes for women with ovarian cancer,” said Chris Boshoff, Vice President and Head of Early Development, Translational and Immuno-Oncology at Pfizer Oncology.

“Recent research shows that FAK inhibitors could be beneficial in combination with immuno-oncology agents.¹ We are excited to be working with Merck KGaA, Darmstadt, Germany, and Pfizer to build upon the early clinical signals observed in patients with ovarian cancer receiving combination therapy with VS-6063,” said Robert Forrester, Verastem President and Chief Executive Officer.

FAK is a protein which is often overproduced in tumors, enabling cancer cells to evade attack by the immune system. As reported in the September 24, 2015, edition of *Cell*, pre-clinical research shows that FAK inhibition can modulate the balance of immune cells in the tumor, increasing the presence of cytotoxic T cells in the tumor and decreasing the presence of immunosuppressive T regulatory cells.¹

*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.

**VS-6063 (defactinib) 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. Serrels A et al. FAK Controls Chemokine Transcription, Tregs, and Evasion of Anti-tumor Immunity. *Cell* 2015; 163 (1): 160–73
2. Ferlay J et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>. Accessed December 2015.
3. World Cancer Research Fund International. Ovarian Cancer Statistics. Available from: <http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/ovarian-cancer-statistics>. Accessed November 2015.
4. NICE. Ovarian Cancer: Recognition and Initial Management. Available from: <https://www.nice.org.uk/guidance/cg122>. Accessed November 2015.
5. National Cancer Institute. Ovarian Epithelial, Fallopian Tube, and Primary Peritoneal Cancer Treatment (PDQ®). Available from: <http://www.cancer.gov/types/ovarian/patient/ovarian-epithelial-treatment-pdq> Accessed November 2015.
6. Ledermann JA et al. Newly diagnosed and relapsed epithelial ovarian carcinoma: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Ann Oncol* 2013; 24(Suppl 6): vi24–32.
7. Ojalvo LS et al. Emerging immunotherapies in ovarian cancer. *Discov Med* 2015; 20(109): 97–109.

About Ovarian Cancer

Globally, ovarian cancer is the seventh most common cancer in women.² Annually, nearly 239,000 cases are diagnosed worldwide.³ Ovarian cancer may be difficult to diagnose, as symptoms may appear only in the later stages, when the disease has spread beyond the ovaries.³ Outcomes for women with ovarian cancer are generally poor due to most patients presenting with advanced disease.⁴ The 5-year prevalence of women globally living with ovarian cancer is 22.6 per 100,000.³ Current treatment options for epithelial ovarian cancer may include surgery, radiotherapy, chemotherapy and targeted



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therapies.⁵ 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.⁶ Platinum-refractory ovarian cancer is defined as ovarian cancer that progresses during treatment with a platinum-based chemotherapy regimen.⁶ There is still a clear unmet need in ovarian cancer in relation to general disease awareness,³ improving initial investigations in primary and secondary care and novel therapies with demonstrable efficacy.⁷

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.

About Verastem, Inc.

Verastem, Inc. (NASDAQ:VSTM) is a biopharmaceutical company focused on discovering and developing drugs to improve outcomes for patients with cancer. Our product candidates utilize a multi-faceted approach to treat cancer by reducing cancer stem cells, enhancing anti-tumor immunity, and modulating the local tumor microenvironment. Our most advanced clinical product candidates are the Focal Adhesion Kinase inhibitors, VS-6063 and VS-4718, and the dual PI3K/mTOR inhibitor, VS-5584. For more information, please visit www.verastem.com.

About Focal Adhesion Kinase

Focal Adhesion Kinase (FAK) is a non-receptor tyrosine kinase encoded by the PTK-2 gene that is involved in cellular adhesion and, in cancer, metastatic capability. VS-6063 (defactinib) and VS-4718 are orally available compounds that are potent inhibitors of FAK. VS-6063 and VS-4718 utilize a multi-faceted approach to treat cancer by reducing cancer stem cells, enhancing anti-tumor immunity, and modulating the local tumor microenvironment. VS-6063 and VS-4718 are currently being studied in multiple clinical trials for their ability to improve patient survival.

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.

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. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, [LinkedIn](#), and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

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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.

Verastem forward-looking statements notice

This press release includes forward-looking statements about the Verastem's strategy, future plans and prospects, including statements regarding the development and activity of the Verastem's product candidates, VS-6063 and VS-4718, Verastem's FAK program generally, and the potential for combination of FAK inhibitors with immuno-oncology agents, including a potential indication for avelumab in combination with VS-6063 for advanced ovarian cancer. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that the preclinical testing of Verastem's product candidates and preliminary or interim data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that data may not be available when we expect it to be, that enrollment of clinical trials may take longer than expected, that our product candidates will cause unexpected safety events, that Verastem will be unable to successfully initiate or complete the clinical development of its product candidates, that the development of the Company's product candidates will take longer or cost more than planned, and that Verastem's product candidates will not receive regulatory approval or become commercially successful products. Other risks and uncertainties include those identified under the heading "Risk Factors" in Verastem's Annual Report on Form 10-K for the year ended December 31, 2014 and in any subsequent SEC filings. The forward-looking statements contained in this press release reflect Verastem's current views with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Pfizer Disclosure Notice

The information contained in this release is as of March 3, 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 Verastem, Inc. (Verastem) to evaluate avelumab in combination with Verastem's VS-6063, an investigational focal adhesion kinase inhibitor, in patients with advanced 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, 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.