



Your Contacts

Merck KGaA, Darmstadt, Germany

Media: Gangolf Schrimpf
US Media: Lisa Buffington
Investor Relations:
+49 6151 72 9591
+1 781 681 2340
+49 6151 72 3321

Pfizer Inc, New York, USA

Media: Lisa O'Neil +44 7929 339560 Investor Relations: Ryan Crowe +1 212 733 8160

News Release

September 24, 2015

Merck KGaA, Darmstadt, Germany, and Pfizer Collaborate with Dako, an Agilent Technologies Company, on Development of Companion Diagnostic for Investigational anti-PD-L1 Antibody, Avelumab

 Merck KGaA, Darmstadt, Germany, and Pfizer collaborate with Dako in developing an immunohistochemistry (IHC)-based companion diagnostic (CDx) in immuno-oncology

Darmstadt, Germany, and New York, US, September 24, 2015 – As part of the global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer to jointly develop and commercialize avelumab*, an investigational immune checkpoint inhibitor, the companies have announced today that they have a collaboration agreement in place with Dako, an Agilent Technologies company, for the development of a potential companion diagnostic test (CDx).

The three-party agreement, signed recently, enables Dako, Merck KGaA, Darmstadt, Germany, and Pfizer to work to develop the CDx to assess programmed death-ligand 1 (PD-L1) protein expression levels in tumor tissue, and its microenvironment, including tumor-associated immune cells. The investigational CDx is part of the protocols in ongoing clinical trials of avelumab, some of which will be reported at upcoming scientific congresses.

The financial terms of the agreement were not disclosed.





News Release

*Avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C).

Avelumab is currently under clinical investigation and has not been approved for use in the U.S., E.U., Canada, or elsewhere. All investigational products have not yet been proven to be either safe or effective and any claims of safety and effectiveness can be made only after regulatory review of the data and approval of the labeled claims.

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.





News Release

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 US or Canada, please go to http://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

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses − Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials − and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company − since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the "Merck" name and brand. The only exceptions are Canada and the United States, 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 September 24, 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), the potential of immuno-oncology, 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 and www.pfizer.com.