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Merck KGaA, Darmstadt, Germany, and Pfizer Announce Investigational Immunotherapy Avelumab Receives FDA Fast Track Designation for Metastatic Merkel Cell Carcinoma

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Fast Track milestone for avelumab builds upon recent Orphan Drug designation in this aggressive skin cancer
Fast Track designation highlights the serious, unmet medical need that exists for patients with this disease

Merck KGaA, Darmstadt, Germany, and Pfizer today announced that the US Food and Drug Administration (FDA) has granted avelumab*, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, Fast Track designation for the treatment of metastatic Merkel cell carcinoma (MCC), a rare and aggressive type of skin cancer.1,2 This announcement builds on the recent FDA Orphan Drug designation that was granted for avelumab on September 21, 2015 for the treatment of MCC. The Fast Track designation is designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and address an unmet medical need.

“We are pleased that the FDA continues to acknowledge the current high unmet needs for patients with metastatic Merkel cell carcinoma through these recent regulatory designations for avelumab,” said Dr. Luciano Rossetti, Global Head of Research & Development of the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. “We look forward to working closely with the FDA on an expedited review process for avelumab, and we hope to be able to provide a potential new treatment option for patients with this difficult-to-treat cancer in the future.”

“We look forward to working with our partners at Merck KGaA, Darmstadt, Germany, on the development of avelumab in patients with relapsed and refractory Merkel cell carcinoma,” said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. “Fast Track designation will enable us to coordinate these efforts more closely with the FDA.”

The designation relates to the clinical development program for avelumab in metastatic MCC, which includes the Phase II study, JAVELIN Merkel 200, to assess the safety and efficacy of avelumab in patients with metastatic MCC who have progressed after at least one prior chemotherapy regimen. In this study, the primary endpoint is objective response rate, and secondary endpoints include duration of response, progression-free survival, overall survival and safety. The study, which exceeded its expected enrollment of 84 patients with 88 patients enrolled, is being conducted in sites across Asia Pacific, Australia, Europe and North America.

The clinical development program for avelumab now includes more than 1,000 patients who have been treated across more than 15 tumor types, including breast cancer, gastric/gastroesophageal cancer, head and neck cancer, MCC, mesothelioma, melanoma, non-small cell lung cancer, ovarian cancer, renal cell carcinoma and urothelial (e.g. bladder) cancer.

About the FDA Designations

FDA's granting of the Fast Track and Orphan Drug designations for metastatic MCC does not alter the standard regulatory requirement to establish the safety and effectiveness of a drug through adequate and well-controlled studies to support approval.

Fast Track is designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and address an unmet medical need. Once a drug receives F*ast Track* designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication can help resolve questions and issues quickly, often leading to earlier drug approval and patient access to important new therapies. Fast Track designated products are eligible for accelerated approval and priority review, if relevant criteria are met, and rolling FDA review of marketing applications.

FDA Orphan Drug designation is granted to drugs intended to treat rare diseases or disorders that affect fewer than 200,000 people in the US, or those that affect more than 200,000 people, but are unlikely to recover the costs of developing and marketing the drug.

*Avelumab is the proposed International 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 that avelumab will be approved in the sought-after indication by any health authority worldwide.

References

1. Hughes MP et al. Merkel cell carcinoma: epidemiology, target, and therapy. Curr Dermatol Rep 2014;3:46–53.
2. Kaae J et al. Merkel cell carcinoma: incidence, mortality, and risk of other cancers. J Natl Cancer Inst 2010;102(11):793–801.

Avelumab is currently under clinical investigation and has not been approved for use in the US, EU, 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.

About Merkel Cell Carcinoma (MCC)

MCC is a rare and aggressive disease in which cancer cells form in the top layer of the skin, close to nerve endings. MCC, which is also known as neuroendocrine carcinoma of the skin or trabecular cancer, often starts in those areas of skin that are most often exposed to the sun, including the head and neck, arms, legs, and trunk. Risk factors for MCC include sun exposure and having a weak immune system (i.e., solid organ transplant recipients, people with HIV/AIDS and people with other cancers, such as chronic lymphocytic leukemia, are at higher risk). Caucasian males over age 50 are at increased risk. MCC tends to metastasize at an early stage, spreading initially to nearby lymph nodes, and then potentially to more distant areas in the body, including other lymph nodes or areas of skin, lungs, brain, bones or other organs. Current treatment options for MCC include surgery, radiation and chemotherapy. Treatment for metastatic or Stage IV MCC is generally palliative.

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.

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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 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.

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.

Pfizer Disclosure Notice

The information contained in this release is as of October 7, 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 MCC, 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.

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