

# Avelumab

May 2015

## Avelumab\* (anti-PD-L1 MSB0010718C)

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 engage the innate immune system and may 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.

## JAVELIN clinical trial program

JAVELIN is an expansive international clinical trial program exploring the use of PD-L1 inhibition with avelumab to treat multiple types of cancer.

TRIAL	PHASE	GEOGRAPHY	TUMOR TYPES
<b>NCT01772004 (JAVELIN SOLID TUMOR)</b> Open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity of avelumab in subjects with metastatic or locally advanced solid tumors and expansion to selected indications	I	Global	Solid Tumors
<b>NCT01943461 (JAVELIN SOLID TUMOR JPN)</b> Open-label, dose-escalation trial to investigate the tolerability, safety, pharmacokinetics, biological and clinical activity of avelumab in Japanese subjects with metastatic or locally advanced solid tumors, with an expansion part in Asian subjects with gastric cancer	I	Asia	Solid Tumors, Gastric Cancer
<b>NCT02155647 (JAVELIN MERKEL 200)</b> Open-label, multicenter, single-arm trial to investigate the clinical activity and safety of avelumab in subjects with metastatic Merkel cell carcinoma (MCC) who have received one line of chemotherapy for the treatment of metastatic MCC	II	Global	Merkel Cell Carcinoma
<b>NCT02395172 (JAVELIN LUNG 200)</b> Open-label, multicenter, 1:1 randomized clinical trial to assess the efficacy and safety of avelumab, compared with docetaxel, in patients with stage IIIb/IV or recurrent non-small cell lung cancer (NSCLC) who have experienced disease progression after receiving a prior platinum-containing doublet therapy	III	Global	Non-Small Cell Lung Cancer

## Avelumab clinical development status

PHASE I	PHASE II	PHASE III
Bladder Cancer Gastric Cancer Head & Neck Cancer Mesothelioma NSCLC** Ovarian Cancer Renal Cancer	Merkel Cell Carcinoma	NSCLC

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.

\*avelumab = proposed International Non-proprietary Name (INN), formerly referred to as Anti-PD-L1 mAb (MSB0010718C)

\*\*NSCLC (Non-Small Cell Lung Cancer)

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## About the alliance

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The 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 health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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](http://www.pfizer.com).

## About 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.

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