

Merck KGaA

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News Release

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Merck KGaA, Darmstadt, Germany, Strengthens Presence as Leading Oncology Company by Taking Full Promotional Responsibility for Erbitux in Japan

 Merck KGaA, Darmstadt, Germany, and Bristol-Myers Squibb to end copromotion of Erbitux in Japan, with full promotional responsibilities transferring to Merck KGaA, Darmstadt, Germany

Darmstadt, Germany, February 13, 2015 – Merck KGaA, Darmstadt, Germany, a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials today announced that Merck KGaA, Darmstadt, Germany, and Bristol-Myers Squibb have agreed to transfer full responsibility for the promotion of Erbitux® (cetuximab) to Merck KGaA, Darmstadt, Germany, in Japan as of May 1, 2015.

"Expanding our oncology presence in Japan is of strategic importance to achieve our long term ambition to become a leading global player in oncology and immuno-oncology," said Belén Garijo, Member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO Healthcare.

The transfer of promotional responsibilities for Erbitux in Japan further increases the presence of Merck KGaA, Darmstadt, Germany, in this important strategic market, where the company has already positioned Japan as its regional Research and Development hub for South East Asia.

"With this agreement, Japan will increasingly become a key focus country for us as it complements our Asia-centric Research and Development strategies. As a result, we

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plan to work diligently to develop therapies that best suit the unmet need, and the epidemiological profiles of Asian patient populations," said Elcin Ergun, Head of Global Commercial at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany.

Erbitux was launched in collaboration with Bristol-Myers Squibb in Japan in September 2008 for the treatment of metastatic colorectal cancer, followed by an additional indication for the treatment of head and neck cancer, approved in December 2012.*

* Please refer to the local prescribing and product information for details.

About Erbitux

Erbitux® is a highly active IgG1 monoclonal antibody targeting the epidermal growth factor receptor (EGFR). As a monoclonal antibody, the mode of action of Erbitux is distinct from standard non-selective chemotherapy treatments in that it specifically targets and binds to the EGFR. This binding inhibits the activation of the receptor and the subsequent signal-transduction pathway, which results in reducing both the invasion of normal tissues by tumor cells and the spread of tumors to new sites. It is also believed to inhibit the ability of tumor cells to repair the damage caused by chemotherapy and radiotherapy and to inhibit the formation of new blood vessels inside tumors, which appears to lead to an overall suppression of tumor growth.

The most commonly reported side effect with Erbitux is an acne-like skin rash that seems to be correlated with a good response to therapy. In approximately 5% of patients, hypersensitivity reactions may occur during treatment with Erbitux; about half of these reactions are severe.

Erbitux has already obtained market authorization in over 90 countries world-wide for the treatment of colorectal cancer and for the treatment of squamous cell carcinoma of the head and neck (SCCHN). Merck KGaA, Darmstadt, Germany, licensed the right to market Erbitux outside the US and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998. Merck KGaA, Darmstadt, Germany, has an ongoing commitment to the advancement of oncology treatment and is currently investigating novel therapies in highly targeted areas.

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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 Tools and Performance Materials − and generated total revenues of € 11.1 billion in 2013. 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.