

## News Release

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May 2, 2018

### **Merck KGaA, Darmstadt, Germany to Develop Abituzumab in Metastatic Colorectal Cancer with SFJ Pharmaceuticals Group**

- **Agreement enables Merck KGaA, Darmstadt, Germany, to further develop abituzumab through a novel risk-sharing collaboration agreement**
- **SFJ Pharmaceuticals Group to develop abituzumab as a first-line treatment for metastatic colorectal cancer (mCRC) in combination with Erbitux® and chemotherapy**
- **Clinical program will concentrate on patients with RAS wild-type left-sided tumors with high  $\alpha\beta6$  integrin expression**

Darmstadt, Germany, May 2, 2018 – Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its healthcare business in the U.S. and Canada as EMD Serono, today announced a development agreement for investigational molecule abituzumab with SFJ Pharmaceuticals Group (SFJ), a US-based company focused on increasing R&D output and productivity through innovative models.

“Our collaboration with SFJ illustrates Merck KGaA, Darmstadt, Germany’s increasing focus on strategic partnering in order to further diversify our development risks as well as enable a more efficient pipeline prioritization,” said Belén Garijo, member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO Healthcare. “Together with SFJ, we aim to progress the understanding of the potential of abituzumab as a targeted treatment for patients suffering from mCRC.”



Merck KGaA, Darmstadt, Germany, has completed Phase II development of abituzumab in combination with Erbitux<sup>®</sup> and chemotherapy in a second line all-comer patient population with KRAS wild-type mCRC. In this Phase II study, a subgroup of patients with overexpression of integrin  $\alpha\beta6$  was identified as potentially benefiting from this treatment.<sup>1</sup> With the evolving understanding of the relationship between mCRC tumor location and treatment outcomes in recent years, SFJ will pursue the combination of abituzumab, Erbitux<sup>®</sup> and chemotherapy in a first-line setting in high  $\alpha\beta6$ -expressing patients who have RAS wild-type left-sided mCRC.<sup>2-3</sup>

In a novel innovation model recently emerging in the biopharma industry, SFJ – one of the pioneers of such collaborations – will finance and also be responsible for Phase II/III development of abituzumab. The agreement reflects Merck KGaA, Darmstadt, Germany's strategic approach to collaborations, identifying those opportunities that can progress the company's highly promising clinical stage assets through novel innovation models. Both Merck KGaA, Darmstadt, Germany, and SFJ have agreed not to disclose the terms of the deal.

"We are delighted to partner with Merck KGaA, Darmstadt, Germany, to pursue this new clinical development project," said Robert DeBenedetto, Chief Executive Officer of SFJ. "Our expertise in oncology and renowned ability to successfully carry out various late stage clinical development projects is gaining wider acceptance and enables industry players like Merck KGaA, Darmstadt, Germany, to develop their promising assets by risk-sharing with us."

#### **About Abituzumab**

Abituzumab is an investigational pan- $\alpha$  integrin inhibiting monoclonal antibody with activity against  $\alpha\beta1$ , 3, 5, 6 and 8 integrin heterodimers. By interfering with the TGF- $\beta$  latency associated peptide via inhibition of the  $\alpha\beta6$  integrin, it has a potential for treating solid tumors such as colorectal cancer.<sup>4</sup> Abituzumab is currently under clinical investigation and not approved for any use anywhere in the world.

#### **About Erbitux<sup>®</sup> (cetuximab)**

Erbitux<sup>®</sup> 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. Erbitux also targets cytotoxic immune effector cells towards EGFR expressing tumor cells (antibody dependent cell-mediated cytotoxicity, ADCC).

The most commonly reported side effect with Erbitux is an acne-like skin rash. 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 RAS wild-type metastatic 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, a registered trademark of ImClone LLC, outside the U.S. and Canada from ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company, in 1998.

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#### **About Merck KGaA, Darmstadt, Germany**

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Almost 53,000 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 2017, Merck KGaA, Darmstadt, Germany, generated sales of € 15.3 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" name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

#### **About the SFJ Pharmaceuticals Group**

The SFJ Pharmaceuticals Group, which was formed in 2008 is a global drug development group of companies, which provides a unique co-development partnering model for some of the world's top pharmaceutical and biotechnology companies. SFJ uses its financial strength and global team of pharmaceutical development experts to provide highly customized partnering models in which SFJ provides the funding and clinical development supervision, necessary to obtain regulatory approval for some of the most promising drug development programs of Pharmaceutical and Biotechnology companies. Some of SFJ's recent successful Co-Development Partnership's include the 2015 approval of Lenvima for thyroid cancer, the 2017 approval of Besponsa for Acute Lymphoblastic Leukemia and the 2017 approval of Mylotarg for Acute Myeloid Leukemia. Plus the anticipated 2018 approval of Dacomitinib for lung cancer.

#### **References.**

1. Elez E, et al. Abituzumab combined with cetuximab plus irinotecan versus cetuximab plus irinotecan alone for patients with KRAS wild-type metastatic colorectal cancer: the randomized Phase I/II POSEIDON trial. *Annals of Oncology*. 2015;26(1):132-140.
2. Lee B, et al. Left versus right sided colorectal cancer: Teasing out drivers of disparity in outcomes in metastatic disease. *Journal of Clinical Oncology*. 2017;35:4\_suppl, 682-682.
3. Arnold D, et al. Prognostic and predictive value of primary tumor side in patients with RAS wild-type metastatic colorectal cancer treated with chemotherapy and EGFR directed antibodies in six randomized trials. *Annals of Oncology*. 2017; 28(8):1713-1729.
4. Reed NI, et al. The  $\alpha$ V $\beta$ 1 integrin plays a critical in vivo role in tissue fibrosis. *Science Translation Medicine*. 2015;7(288).