

News Release

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Merck KGaA, Darmstadt, Germany, Decides Not to Pursue Evofosfamide Further in Soft Tissue Sarcoma and Pancreatic Cancer

- **Despite signs of activity in locally advanced and metastatic pancreatic cancer, two Phase III studies did not meet pre-specified primary endpoints**
- **Merck KGaA, Darmstadt Germany, focus efforts on more promising candidates in pipeline**

Darmstadt, Germany, December 7, 2015 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that it is not planning to file for approval of evofosfamide in advanced soft tissue sarcoma and advanced pancreatic adenocarcinoma. The decision was made in light of results from two Phase III studies of evofosfamide in combination with chemotherapy in these two types of cancer, as reported by Threshold Pharmaceuticals Inc. today. Merck KGaA, Darmstadt, Germany, will now be redeploying its resources into high-profile future products, such as avelumab* and all other priority programs in oncology, immunoncology and immunology.

“Despite seeing signs of activity in pancreatic cancer, pre-specified primary endpoints were not met in both studies and therefore the data do not support filing in these indications,” said Luciano Rossetti, Head of Global Research and Development at the biopharma business of Merck KGaA, Darmstadt, Germany. “We decided today not to pursue investigation of evofosfamide in soft tissue sarcoma and pancreatic cancer, and we will be making a quick decision on the future of the ongoing evofosfamide clinical program.”

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Merck KGaA

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Details of the two Phase III studies will be shared with the scientific community once the data have been further analyzed.

“Today’s results are disappointing for patients. Yet we are confident in our pipeline and will reallocate evofosfamide resources to accelerate other key programs in oncology and immuno-oncology,” said Rossetti.

The pharmaceutical pipeline of Merck KGaA, Darmstadt, Germany, is focusing on oncology, immuno-oncology and immunology. In immuno-oncology, the company, together with Pfizer, is researching avelumab, an investigational anti-PD-L1 antibody, in more than 15 tumor types.

*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 any product will be approved in the sought-after indication by any health authority worldwide.

About Evofosfamide

Evofosfamide (previously known as TH-302) is an investigational hypoxia-activated prodrug of a bis-alkylating agent that is preferentially activated under severe tumor hypoxic conditions, a feature of many solid tumors. Areas of low oxygen levels (hypoxia) in solid tumors are due to insufficient blood vessel supply. Similarly, the bone marrow of patients with hematological malignancies has also been shown, in some cases, to be severely hypoxic.

Merck KGaA, Darmstadt, Germany, signed a global license and co-development agreement for evofosfamide with Threshold Pharmaceuticals, Inc. in February 2012, with an option for Threshold to co-commercialize in the U.S.

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Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 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 2014, Merck KGaA, Darmstadt, Germany, generated sales of € 11.3 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 KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.