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Merck KGaA, Darmstadt, Germany and GSK Announce Global Alliance to Jointly Develop and Commercialize M7824, a Novel Immunotherapy with Potential in Multiple Difficult-to-Treat Cancers

- **Eight high priority immuno-oncology clinical development studies ongoing or expected to commence in 2019, including studies in non-small cell lung and biliary tract cancers**
- **Merck KGaA, Darmstadt, Germany will receive an upfront payment of €300 million and is eligible for potential development milestone payments of up to €500 million triggered by data from the M7824 lung cancer program, plus future approval and commercial milestones of up to €2.9 billion for a total potential deal value of up to €3.7 billion**

Darmstadt, Germany, February 5, 2019 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, and GSK, a science-led global healthcare company, today announced that the companies have entered into a global strategic alliance to jointly develop and commercialize M7824 (bintrafusp alfa*). M7824 is an investigational bifunctional fusion protein immunotherapy that is currently in clinical development, including potential registration studies, for multiple difficult-to-treat cancers. This includes a Phase II trial to investigate M7824 compared with pembrolizumab as a first-line treatment in patients with PD-L1 expressing advanced non-small cell lung cancer (NSCLC).



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M7824 is designed to simultaneously target two immuno-suppressive pathways, transforming growth factor- β (TGF- β) trap and an anti-programmed cell death ligand-1 (PD-L1), that are commonly used by cancer cells to evade the immune system. Bifunctional antibodies aim to increase efficacy above and beyond that achieved with individual therapies or combinations of individual therapies.¹ M7824 has the potential to offer new ways to fight difficult-to-treat cancers beyond the established PD-1/PD-L1 class. In addition to use as a single agent, M7824 is also being considered for use in combination with other assets from the pipelines of both companies.

“Our bifunctional fusion protein M7824 has the potential to bring new answers to patients living with cancer. Together with GSK we aim to drive a paradigm shift in the treatment of cancer as the leader in this novel class of immunotherapies,” said Belén Garijo, Member of the Executive Board and CEO Healthcare of Merck KGaA, Darmstadt, Germany. “GSK clearly emerged as the ideal partner due to their strong commitment to oncology, and the complementary talent and capabilities they will bring to our alliance. We now look forward to harnessing the full potential of M7824 across a broad range of cancer indications as we continue to advance our oncology portfolio.”

“Despite recent medical advances, many patients with difficult-to-treat cancers don’t currently benefit from immuno-oncology therapies leaving them with limited treatment options. M7824 brings together two different biological functions in a single molecule and we have observed encouraging clinical results in treating certain cancer patients, particularly those people with non-small cell lung cancer,” said Hal Barron, Chief Scientific Officer and President R&D, GSK. “I’m excited by the potential impact this first-in-class immunotherapy could have on the lives of cancer patients.”

Merck KGaA, Darmstadt, Germany will receive an upfront payment of €300 million and is eligible for potential development milestone payments of up to €500 million triggered by data from the M7824 lung cancer program. Merck KGaA, Darmstadt, Germany will also be eligible for further payments upon successfully achieving future approval and commercial milestones of up to €2.9 billion. The total potential deal value is up to €3.7 billion. Both companies will jointly conduct development and

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commercialization with all profits and costs from the collaboration being shared equally on a global basis.

This alliance reflects the strategic approach of Merck KGaA, Darmstadt, Germany to oncology R&D, identifying those opportunities that can progress the company's highly promising clinical stage assets as efficiently and rapidly as possible, whether through internal expertise and capabilities or external collaborations.

For GSK, this alliance is a further step in the company's priority to strengthen its pharmaceuticals pipeline. This follows the company's recent acquisition of TESARO, an oncology-focused company based in Waltham, Massachusetts. GSK's approach to oncology is focused on innovation in the areas of immuno-oncology, cell therapy, cancer epigenetics and, most recently, genetic medicine.

With this alliance, both companies have the leadership position in this new class of immunotherapies, specifically leveraging TGF- β biology.

**Bintrafusp alfa is the proposed International Nonproprietary Name (INN) for the bifunctional immunotherapy M7824. Bintrafusp alfa is currently under clinical investigation and not approved for any use anywhere in the world.*

About M7824 (also now known as bintrafusp alfa)

M7824 is an investigational bifunctional immunotherapy that is designed to combine a TGF- β trap with the anti-PD-L1 mechanism in one fusion protein. M7824 is designed to combine co-localized blocking of the two immuno-suppressive pathways – targeting both pathways aims to control tumor growth by potentially restoring and enhancing anti-tumor responses. M7824 is currently in Phase I studies for solid tumors, as well as a randomized Phase II trial to investigate M7824 compared with pembrolizumab as a first-line treatment in patients with PD-L1 expressing advanced NSCLC. The multicenter, randomized, open-label, controlled study is evaluating the safety and efficacy of M7824 versus pembrolizumab as a monotherapy treatment.

To-date, nearly 700 patients have been treated with M7824 across more than 10 tumor types in Phase I studies. Encouraging data from the ongoing Phase I studies indicates M7824's potential safety and clinical anti-tumor activity across multiple types of difficult-to-treat cancers, including advanced NSCLC, human papillomavirus-associated cancers, biliary tract cancer (BTC) and gastric cancer. In addition, in pre-clinical studies M7824 demonstrated superior anti-tumor activity, compared with anti-PD-L1 alone or with anti-PD-L1 and TGF- β trap when co-administered. In total, eight high priority immuno-oncology clinical development studies are ongoing or expected to commence in 2019, including studies in non-small cell lung and biliary tract cancers.

References

1. Lan Y, et al. Enhanced preclinical antitumor activity of M7824, a bifunctional fusion protein simultaneously targeting PD-L1 and TGF- β . *Science Translational Medicine*. 2018 Jan; 10(424).

GSK – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 51,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From advancing gene editing technologies and discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2017, Merck KGaA, Darmstadt, Germany, generated sales of € 15.3 billion in 66 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials. Since its founding 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.