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GSK collaborates with Merck for cancer immunotherapy

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Bifunctional antibodies aim to increase efficacy above and beyond that achieved with individual therapies or combinations of individual therapies

GlaxoSmithKline and Merck KGaA, Darmstadt, Germany have announced that they have entered into a global strategic alliance to jointly develop and commercialise 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).

M7824 is designed to simultaneously target two immuno-suppressive pathways, transforming growth factor-? (TGF-?) 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.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said, “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. I’m excited by the potential impact this first-in-class immunotherapy could have on the lives of cancer patients.”

Dr Belén Garijo, Member of the Executive Board and CEO Healthcare of Merck KGaA, Darmstadt, Germany said, “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. 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.”

Merck KGaA, Germany will receive an upfront payment of €300 million (£260 million) and is eligible for potential development milestone payments of up to €500 million (£440 million) triggered by data from the M7824 lung cancer programme. 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 (£2.5 billion). The total potential deal value is up to €3.7 billion (£3.2 billion). Both companies will jointly conduct development and commercialisation with all profits and costs from the collaboration being shared equally on a global basis.

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.

This alliance reflects Merck KGaA, Darmstadt, Germany’s strategic approach 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.

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