

News Release

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Merck KGaA, Darmstadt, Germany, Announces Out-Licensing Agreement for Phase II-ready Anti-ADAMTS5 Nanobody for Osteoarthritis

- **Merck KGaA, Darmstadt, Germany, out-licenses promising clinical-stage program to Novartis**
- **Anti-ADAMTS5 Nanobody® program is Phase II-ready with novel MoA which could protect against cartilage damage and reduce joint pain**
- **Merck KGaA, Darmstadt, Germany, receives upfront payment of € 50 million with the potential of receiving a further € 400 million related to delivering on certain development and commercial milestones**

Darmstadt, Germany, October 6, 2020 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that it has entered into an out-licensing agreement with Novartis, for the development of M6495, an anti-ADAMTS5 Nanobody® for the potential treatment of osteoarthritis (OA).

The Phase II-ready program represents potential for a disease modifying osteoarthritis drug (DMOAD). M6495 is being developed with the aim to be self-administered via subcutaneous injections to maintain structural integrity of knee joint and reduce pain.



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“With this deal we have found the right solution for this asset designed to present an innovative mechanism of action for the potential treatment of osteoarthritis, as we prioritize our pipeline to deliver the greatest impact for patients across our internal areas of expertise,” says Luciano Rossetti, Head of Global Research & Development for the Biopharma business of Merck KGaA, Darmstadt, Germany. “This agreement underscores our commitment to ensure this molecule, which has promise in many different types of OA, makes it to patients as quickly as possible.”

As part of the agreement, Merck KGaA, Darmstadt, Germany, will out-license to Novartis the Phase II-ready asset M6495 for further evaluation in OA patients. Merck KGaA, Darmstadt, Germany, will receive an upfront payment of € 50 million with the potential of receiving a further € 400 million related to delivering on certain development and commercial milestones and royalties on future net sales. Novartis will assume full responsibility for the development and commercialization of the M6495 program.

Two Phase I studies were completed with M6495: [one study](#) in healthy volunteers demonstrated M6495 safety and tolerability and a meaningful reduction of ARGS (a neoepitope from cleaved aggrecan, found in the synovial fluid and serum of OA patients) levels at single doses (n=54); [one study](#) targets inhibition of ARGS with dosing every other week in OA patients. Novartis will continue to characterize M6495 in future studies with the goal of bringing it to market for osteoarthritis patients.

M6495 was originally jointly developed by Merck KGaA, Darmstadt, Germany, and Ablynx (now Ablynx, a Sanofi company) as part of a joint discovery and development agreement in 2011; the asset was later solely developed by Merck KGaA, Darmstadt, Germany, up until the out-licensing agreement with Novartis.

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Merck KGaA, Darmstadt, Germany, in Neurology and Immunology

Merck KGaA, Darmstadt, Germany, has a long-standing legacy in neurology and immunology, with significant R&D and commercial experience in multiple sclerosis (MS). The company's current MS portfolio includes two products for the treatment of relapsing MS, with a robust pipeline focusing on discovering new therapies that have the potential to modulate key pathogenic mechanisms in MS. Merck KGaA, Darmstadt, Germany, aims to improve the lives of those living with MS, by addressing areas of unmet medical needs.

The company's robust immunology pipeline focuses on discovering new therapies that have the potential to modulate key pathogenic mechanisms in chronic diseases such as MS and systemic lupus erythematosus.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across healthcare, life science and performance materials. Around 57,000 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 2019, Merck KGaA, Darmstadt, Germany, generated sales of € 16.2 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.