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Merck Announces Out-Licensing Agreement for Investigational Atacicept with Vera Therapeutics

Darmstadt, Germany (ots/PRNewswire) - Not intended for UK and US based media

- Merck out-licenses Phase IIb-ready atacicept to Vera Therapeutics

- Phase IIa trial conducted by Merck shows promising results in IgA nephropathy (IgAN), also known as "Berger's disease"

- Out-licencing deal includes 10% equity in Vera Therapeutics and up to EUR 605 million in development and commercial milestones, plus royalties on any future net sales

Merck, a leading science and technology company, today announced that it, through its subsidiary Ares Trading S.A., has entered into an out-licensing agreement with biotechnology company Vera Therapeutics, South San Francisco, USA, for the further development of investigational therapy atacicept. Vera Therapeutics will first prioritize to take atacicept into a Phase IIb study in IgA nephropathy (IgAN), an autoimmune kidney disease also known as "Berger's disease".

"The positive results from our Phase IIa study in IgA nephropathy reinforce the potential of this compound, and we are pleased to see Vera Therapeutics take it into the next phase of development," says Andreas Stickler, Chief Financial Officer and Head of Strategy, Business Development and Portfolio Management of the healthcare business sector of Merck. "This agreement shows how we are executing on our strategy to focus on our priority assets and areas of expertise, while underscoring our commitment to ensure promising molecules from our immunology pipeline have the opportunity to make it to patients as quickly as possible."

Atacicept is a recombinant fusion protein that contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL. These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases such as IgAN. IgAN is one of the most common kidney diseases worldwide, with a remaining high unmet medical

need for efficacious new medications to treat the disease.

As part of the agreement, Merck will receive 10% equity in Vera Therapeutics, up to a total of EUR 605 million related to delivering on certain development and commercial milestones, plus royalties on any future net sales. Vera Therapeutics will assume full responsibility for the development and commercialization of the atacicept program in all indications. A Phase IIb study in IgAN is planned to start in the second quarter of 2021.

JANUS, a Phase IIa, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of atacicept in IgA nephropathy showed a dose dependent effect of atacicept on key biomarkers, i.e. serum immunoglobulin levels and proteinuria, and at the same time a favourable safety profile. These data were awarded to be among the "Absolute Best Abstracts" at the annual meeting of the European Renal Association (ERA-EDTA) in June and were recently presented by Dr. Jonathan Barratt, University of Leicester, UK, in an encore virtual talk during the American Society of Nephrology (ASN) Kidney week, October 20-25, 2020.

Merck acquired exclusive worldwide development and commercialization rights for atacicept from Zymogenetics in 2008 (Zymogenetics was acquired by Bristol-Myers Squibb in 2010). The asset has since then been solely developed by Merck.

About atacicept

Atacicept is a recombinant fusion protein that contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL. These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases, including IGA nephropathy, also known as "Berger's disease", and systemic lupus erythematosus (SLE). Merck acquired exclusive worldwide development and commercialization rights for atacicept from Zymogenetics in 2008. Zymogenetics has since then been acquired by Bristol-Myers Squibb (BMS). Atacicept is currently under clinical investigation and not approved for use anywhere in the world.

Merck in Neurology and Immunology

Merck 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 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.

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About Merck

Merck, 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 generated sales of EUR 16.2 billion in 66 countries.

Scientific exploration and responsible entrepreneurship have been key to Merck's technological and scientific advances. This is how Merck has thrived since its founding in 1668. The founding family remains the majority owner of the publicly listed company. Merck holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the business sectors of Merck operate as EMD Serono in healthcare, MilliporeSigma in life science, and EMD Performance Materials.

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