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Merck KGaA, Darmstadt, Germany Announces Positive Phase II Results for Investigational Sonelokimab (M1095) in Patients with Moderate to Severe Chronic Plaque-Type Psoriasis

- **Sonelokimab is an investigational IL-17 A/F Nanobody[®], which neutralizes both IL-17A and IL-17F**
- **Phase II study was facilitated by Avillion as part of an innovative co-development model**

Darmstadt, Germany, 10 September 2020 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced positive top-line results from a Phase II study of sonelokimab (M1095), an investigational anti-IL-17 A/F Nanobody[®], which neutralizes both IL-17A and IL-17F, in patients with moderate to severe chronic plaque-type psoriasis. Currently there are no approved IL-17 A/F nanobodies. The Phase II study was completed through a co-development agreement with Avillion, first announced in 2017.

“This Phase II study was conducted by Avillion as part of an innovative co-development model and we thank them for their partnership and successful completion of this trial with high quality data,” said Luciano Rossetti, Head of Global Research & Development for the biopharma business of Merck KGaA, Darmstadt, Germany. “Given the encouraging Phase II results we will explore partnership options to rapidly deliver this promising new therapy to patients living with psoriasis.”

The randomized, double-blind, placebo controlled, multi-centre, Phase IIb study was designed to assess efficacy, safety, and tolerability of sonelokimab in subjects with moderate to severe chronic plaque-type psoriasis. The trial enrolled 313 patients (age 18-75) with chronic plaque psoriasis for at least six months, with an



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Investigator Global Assessment (IGA) score ≥ 3 , involved body surface area $\geq 10\%$, and Psoriasis and Severity Index (PASI) ≥ 12 at screening and at baseline. Patients were randomized to one of four dose regimens of sonelokimab, or a placebo comparator arm, or a reference arm (secukinumab). The study met its primary endpoint of IGA response of at least 2 points reduction from baseline, and secondary endpoints of PASI with high statistical significance ($p < 0.001$). The data are being prepared for presentation at an upcoming international conference and for publication in a peer-reviewed medical journal.

“The Phase II study results for sonelokimab provide valuable insights. The onset of action and potential durable response of sonelokimab in psoriasis patients merits further characterization in a comprehensive Phase III program,” said Kim Papp, MD, PhD, FRCPC, Primary Investigator.

Merck KGaA, Darmstadt, Germany acquired full, exclusive rights to the anti-IL 17 A/F Nanobody[®] through a global development and commercialization deal with Ablynx (now Ablynx, a Sanofi Company) in 2013.

About sonelokimab (M1095)

The anti-IL-17 A/F Nanobody[®] sonelokimab is an investigational bi-specific half-life-extended Nanobody that is thought to neutralise both IL-17A and IL-17F with the potential to treat inflammatory diseases, including psoriasis. Currently there are no approved IL-17 A/F nanobodies. Merck KGaA, Darmstadt, Germany acquired full, exclusive rights to the anti-IL 17 A/F Nanobody[®] through a global development and commercialization deal with Ablynx (now Ablynx, a Sanofi Company) in 2013.

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, systemic lupus erythematosus, osteoarthritis and psoriasis.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 57,000 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 2019, Merck KGaA, Darmstadt, Germany, generated sales of € 16.2 billion in 66 countries.

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Scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. This is how Merck KGaA, Darmstadt, Germany, has thrived since its founding in 1668. The founding family remains the majority owner of the publicly listed company. Merck KGaA, Darmstadt, Germany, 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.