

Merck KGaA

Darmstadt, Germany

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COMPANY STATEMENT

Merck KGaA, Darmstadt, Germany Statement on the Out-licensing Agreement for Investigational sonelokimab (M1095)

Merck KGaA, Darmstadt, Germany has, through one of its subsidiaries, entered into an out-licensing agreement with MoonLake Immunotherapeutics AG, a newly founded clinical-stage biotechnology company focused on creating next-level therapies for inflammatory skin and joint diseases, for sonelokimab (M1095). Sonelokimab is 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.

MoonLake Immunotherapeutics will assume full responsibility for the research, development and commercialization of sonelokimab. The company plans to accelerate the development of the asset in multiple inflammatory diseases in dermatology and rheumatology driven by IL-17A and IL-17F, including psoriatic arthritis (PsA), ankylosing spondylitis (AS), and hidradenitis suppurativa (HS) – conditions affecting millions of people worldwide with a large need for improved treatment options. Phase II programs in PsA, AS and HS are expected to be initiated soon.

A Phase IIb clinical trial of sonelokimab in 303 patients with moderate to severe psoriasis was completed by Merck KGaA, Darmstadt, Germany through a co-development agreement with Avillion. The study met its primary endpoint of Investigator Global Assessment (IGA) response of at least 2 points reduction from baseline, and secondary endpoints of Psoriasis and Severity Index (PASI) with high statistical significance ($p < 0.001$). Results from this study were the subject of a late breaker presentation at the European Academy of Dermatology and Venereology (EADV) Congress in October 2020.

Merck KGaA, Darmstadt, Germany acquired full, exclusive rights to sonelokimab through a global development and commercialization agreement with Ablynx (now Ablynx, a Sanofi Company) in 2013. The out-licensing agreement with MoonLake Immunotherapeutics AG is a part of the strategic evolution of Merck KGaA, Darmstadt, Germany's immunology pipeline, allowing the company to focus its efforts on priority assets and areas of expertise to deliver the greatest impact for patients. The sonelokimab agreement follows other recently announced out-licensing agreements, including the [out-licensing of M6495](#) - an anti-ADAMTS5 Nanobody® for the potential treatment of Osteoarthritis - to Novartis, and the out-licensing of the Phase II-ready IgA nephropathy-candidate [atacept](#) to Vera Therapeutics.