MoonLake In-licensing and launch

May 3, 2021

MoonLake Immunotherapeutics in-licenses potentially best-in-class Tri-specific Nanobody®,6 Sonelokimab (M1095/ALX 0761) from Merck KGaA, Darmstadt, Germany, with goal of transforming treatment of inflammatory diseases driven by IL-17A and F

- Clinically demonstrated efficacy and "pipeline within a product" potential to drive disease modification in dermatology and rheumatology patients with major unmet need
- Planned acceleration of clinical development program in multiple indications, building on unique data set from Merck KGaA, Darmstadt, Germany, and Ablynx
- MoonLake Immunotherapeutics led by internationally experienced immunology specialists and backed by lead investor BVF Partners LP

ZUG, Switzerland, May 3, 2021 – MoonLake Immunotherapeutics AG, a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory skin and joint diseases, today announced that it has in-licensed the Tri-specific Nanobody® Sonelokimab (M1095/ALX 0761) from Merck KGaA, Darmstadt, Germany.

MoonLake Immunotherapeutics has been established by an international team of immunology specialists to leverage revolutionary Nanobody® (single-domain antibody) technology in multiple indications. It will accelerate the clinical development of Sonelokimab, building on robust clinical data generated by Merck KGaA, Darmstadt, Germany, and by Ablynx, a Sanofi company, which discovered the molecule. Sonelokimab has clinically demonstrated potential to drive disease modification in dermatology and rheumatology patients. Sonelokimab is a Tri-specific, balanced IL-17A/F inhibitor with an albumin binding site, which has the potential to facilitate deep tissue penetration in the skin and joints[1].

Kristian Reich MD, PhD, Chief Scientific Officer and co-founder of MoonLake Immunotherapeutics, commented: *"Sonelokimab is a remarkable Nanobody with game-changing potential in the treatment of a range of IL-17A/F-driven inflammatory diseases. As a dermatologist with over 25 years of experimental and clinical experience in immunology, I believe MoonLake Immunotherapeutics has a unique opportunity to build on the excellent development work of Merck KGaA and Ablynx. Our goal is to unlock the full potential of Sonelokimab, giving millions of patients with skin and joint diseases a chance of better disease control."*

Spike Loy, Managing Director of BVF Partners LP, commented: *"We believe the expert immunology team at MoonLake Immunotherapeutics has the depth and breadth of experience to ensure Sonelokimab achieves its full potential in a range of inflammatory skin and joint diseases, where there is substantial need for new treatment options. Building on positive Phase 2 data, we look forward to MoonLake Immunotherapeutics rapidly bringing this promising new therapy to patients."*

Sonelokimab was previously studied in a robust Phase 2b clinical trial in n=313 moderate-to-severe psoriasis patients. Sonelokimab showed impressive efficacy and safety, and numerically outperformed active control secukinumab. Secukinumab is marketed under the trade name Cosentyx® by Novartis. The study highlights Sonelokimab's promise as a treatment of inflammatory diseases where the cytokines IL-17A and IL-17F play a major role. 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.

MoonLake Immunotherapeutics plans to accelerate the development of Sonelokimab in multiple inflammatory diseases in dermatology and rheumatology driven by IL-17A and IL-17F. This group of IL-17A/F Inflammatory Diseases (introducing the novel concept of AFID) include psoriatic arthritis, ankylosing spondylitis, and hidradenitis suppurativa – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake Immunotherapeutics plans to initiate multiple Phase 2 trials soon.

MoonLake Immunotherapeutics AG was founded in 2021, backed by a Series A financing led by BVF Partners LP. Other investors include Merck KGaA, Darmstadt, Germany. The Company has been founded by a highly expert executive leadership team with decades of experience in immunology, including discovery, clinical development, regulatory affairs, product launch, commercialization & business development. The team includes:

- **Arnout Ploos van Amstel MSc. Econ**, co-founder and Chief Operating Officer, who has more than 25 years of experience as a global executive leader in biopharma, including at Novartis.
- **Prof Kristian Reich MD, PhD**, co-founder and Chief Scientific Officer, who has more than 25 years of experience as a global clinical leader in dermatology and immunology.
- Other members of the executive team and Board of Directors will be announced soon.

For further information please visit our website www.moonlaketx.com

Notes to Editors

MoonLake Immunotherapeutics AG

Arnout Ploos van Amstel
Kristian Reich MD PhD

Mo PR Advisory

Mo Noonan/Jonathan Birt

E: info@moonlaketx.com

Tel: +44 (0) 7876 444977 / (0) 7860 361746

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About AFID (Il17A/F Inflammatory Diseases)

AFID is a novel concept aiming to classify inflammatory diseases in which over-expression of the cytokines IL-17A and IL-17F is a major driver of the pathophysiology. Millions of people are suffering from AFIDs and there are limited treatment options for high-level clinical improvement. AFIDs include:

- Psoriatic arthritis (PsA) (prevalence: up to 0.5% and ~20% of patients with psoriasis); up to 40% of patients with PsA have axial disease[2,3]
- Axial spondyloarthritis (axSpA) (prevalence up to 1.6%); split into non-radiographic axial SpA (nr-axSpA) and ankylosing spondylitis (AS, r-axSpa; prevalence: up to 0.3%)[4]
- Hidradenitis suppurativa (HS) (prevalence: up to 1.2%); currently underdiagnosed/undertreated with limited effective treatment options available[5]
- Psoriasis (prevalence: ~2.5%); more than 1/3 of patients living with psoriasis have psoriatic arthritis or other persistent manifestations, such as nail disease[2]
- Other potential AFIDs include palmoplantar pustulosis (PPP), generalized pustular psoriasis (GPP) and pyoderma gangrenosum (PG)

About Nanobodies®(single-domain antibodies) A single-domain antibody (sdAb), also known as a Nanobody®, is an antibody fragment consisting of a single monomeric variable antibody domain. Like antibodies, Nanobodies® are able to bind selectively to a specific antigen with high affinity.

Whole antibodies are composed of two immunoglobulin heavy chains and two light chains. The first single-domain antibodies were engineered from heavy-chain only antibodies to create an antibody fragment – a Nanobody®. Nanobodies® have the same or higher affinity and specificity compared to traditional antibodies yet have approximately 1/10th of the molecular weight. They offer a number of potential advantages including an easier manufacturing process, a higher thermostability, and the potential to create multivalent molecules with enhanced ability to penetrate inflamed tissue, especially when containing an additional albumin binding domain such as Sonelokimab[1].

The terms Nanbody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics AG, founded in 2021, is a clinical-stage biopharmaceutical company leveraging Nanobody® technology to develop next-level medicines for immunologic diseases, including inflammatory skin and joint diseases. MoonLake Immunotherapeutics has a portfolio of therapeutic programs based on Sonelokimab (M1095/ALX-0761), a biologic molecule potentially capable of driving disease modification in dermatology and rheumatology patients.

About the in-licensing of Solenokimab

Under the terms of the license agreement, Merck KGaA will receive an upfront payment as well as a minority equity stake in MoonLake Immunotherapeutics. Merck KGaA is eligible for potential development and commercial milestone payments as well as industry-standard royalties on net sales.

1) Coppieters K et al., Arthritis Rheum 2006; 54:1856-66; Tijink BM, et al. Mol Cancer Ther. 2008; 7:2288-97

2) Reich K, et al. Br J Dermatol. 2009; 160:1040-1047

3) Alinaghi F, et al. J Am Acad Dermatol. 2019; 80:251-265

4) Dean LE et al. Rheumatology 2014; 53:650–657

5) Nguyen TV, et al. J Eur Acad Dermatol Venereol. 2021; 35:50-61

6) The terms Nanbody ® and Nanobodies ® are trademarks of Ablynx, a Sanofi company