MoonLake Immunotherapeutics announces the publication of new long-term disease control data from a Phase 2b Psoriasis trial of the Nanobody® sonelokimab

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- Higher rates of complete skin clearance were observed in psoriasis patients treated with the IL-17A and IL-17F-inhibiting Nanobody® sonelokimab versus the IL-17A-only inhibiting antibody secukinumab
- A substantial proportion of patients treated with the Nanobody® sonelokimab maintained complete skin clearance after treatment withdrawal
- Complete skin clearance was rapidly re-achieved in patients who experienced some reoccurrence of disease
- In many patients with remaining disease activity at week 24, continuous treatment with sonelokimab was able to induce complete skin clearance over time
- Inhibition of IL-17A and IL-17F with the Nanobody® sonelokimab may modify the disease pathways underlying psoriasis

ZUG, Switzerland, May 9, 2022 – MoonLake Immunotherapeutics AG (Nasdaq: MLTX) (MoonLake, or the Company), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that the *British Journal of Dermatology* (BJD) has published a new data analysis, which can be accessed in the BJD online library, from the Phase 2b clinical trial assessing the effect of sonelokimab on moderate to severe plaque type psoriasis over 48 weeks (NCT03384745). Sonelokimab is an investigational Nanobody® that selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the naturally occurring IL-17A/A, IL 17A/F, and IL-17F/F dimers.

The dataset shows that with the optimal dose of sonelokimab (120mg Q4W) more patients achieved complete skin clearance at week 24 than in patients treated with the IL-17A inhibiting antibody secukinumab (56.9% vs. 34.0% respectively, exploratory $P = 0.019$).

Among patients treated with sonelokimab (120mg Q4W) who had complete skin clearance at week 24 (IGA=0) and were withdrawn from sonelokimab, 20% maintained complete skin clearance for 24 weeks after the last dose with no further treatment. The remaining patients in this group, rapidly re-established complete skin clearance, often with only one additional dose after treatment was withdrawn. Comparable rates of complete skin clearance at week 48 were observed between patients in the sonelokimab withdrawal/retreatment group (72%) and those treated with secukinumab continuously (74%).

Among patients who had not achieved complete skin clearance by week 24, 50% of patients with continuous sonelokimab treatment achieved complete skin clearance by week 48, a numerically higher response rate than that seen for those patients treated with secukinumab (30%).

The impact of sonelokimab in the treatment of other inflammatory diseases with important unmet needs for both patients and their treating physicians is being further tested in different clinical trials led by MoonLake. For example, the “MIRA” clinical trial (M1095-HS-201; NCT05322473) represents a landmark milestone in hidradenitis suppurativa clinical development as it is the first to use Hidradenitis Suppurativa Clinical Response (HiSCR) 75 as its primary endpoint (defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline). This is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of different doses of sonelokimab, compared with placebo, with adalimumab as an active control reference arm, in over 200 patients with HS.

Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented:
“The new data we have now published continues to solidify the potential of sonelokimab’s IL-17A and IL-17F inhibition as a new mechanism of action to provide long-term disease control in inflammatory diseases including phenomena currently discussed as disease modification. We believe the data hint at several related clinical effects with sonelokimab treatment. Prolonged maintenance of complete skin clearance was observed in a substantial proportion of patients after they had achieved complete skin clearance without further treatment and after pharmacological clearance of the drug. It is also interesting to see that more and more patients with remaining skin lesions after the first months of therapy achieved a deep clinical response and complete skin clearance with continuous treatment over time. In addition, the data confirm rapid re-achievement of complete skin clearance upon re-initiation of sonelokimab after treatment withdrawal, a highly relevant drug characteristic in daily patient management.
We are reassured that sonelokimab has the potential to elevate patient outcomes due to its ability to inhibit the IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation in many inflammatory diseases, and its Nanobody® characteristics should additionally improve tissue penetration, helping the molecule to target difficult-to-reach inflammatory lesions.”

MoonLake will continue to pursue its scientific program, in parallel with its clinical program, and will share important finds regarding other diseases and other characteristics of the Nanobody® shortly.

About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics AG is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational Nanobody® for the treatment of inflammatory disease, to revolutionize outcomes for patients. Sonelokimab inhibits IL-17A and IL-17F by inhibiting the naturally occurring IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation. The company’s focus is on inflammatory diseases with a major unmet need, including hidradenitis suppurativa, psoriatic arthritis, and ankylosing spondylitis (also known as radiographic axial spondyloarthritis) – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake was founded in 2021 and is headquartered in Zug, Switzerland. Further information is available at www.moonlaketx.com.

About Nanobodies®

Nanobodies® represent a new generation of antibody-derived targeted therapies. They consist of one or more domains based on the small antigen-binding variable regions of heavy-chain-only antibodies (VHH). Nanobodies® have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and the ability to design multivalent therapeutic molecules with bespoke target combinations.

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

About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the naturally occurring IL-17A/A, IL 17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

Sonelokimab has been assessed in a randomized, placebo-controlled Phase 2b trial in 313 patients with moderate-to-severe plaque-type psoriasis. Sonelokimab demonstrated a rapid and durable clinical response (Investigator's Global Assessment Score 0 or 1, Psoriasis Area and Severity Index 90/100) in patients with moderate-to-severe plaque-type psoriasis. Sonelokimab was generally well tolerated, with a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

In an earlier Phase 1 trial in patients with moderate-to-severe plaque-type psoriasis, sonelokimab has been shown to decrease (to normal skin levels) the cutaneous gene expression of pro-inflammatory cytokines and chemokines (Svecova D. J Am Acad Dermatol. 2019;81:196–203).

Sonelokimab is not yet approved for use in any indication.

About the MIRA trial

The MIRA trial (M1095-HS-201) is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in the treatment of adult patients with active moderate to severe hidradenitis suppurativa. The trial will comprise over 200 patients, and will evaluate two different doses of sonelokimab, with placebo control and adalimumab as an active control reference arm. The primary endpoint of the trial is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial will also evaluate a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total score of ≤5, and **the proportion of patients achieving at least 30% reduction from baseline** in Numerical Rating Scale (NRS30) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain).

Further details are available on: https://www.clinicaltrials.gov/ct2/show/NCT05322473

Cautionary Statement Regarding Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding MoonLake's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: the anticipated outcomes for patients in clinical trials of sonelokimab for various indications. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Forward-looking statements are based on current expectations and assumptions that, while considered reasonable by MoonLake and its management, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with MoonLake's business in general and limited operating history, difficulty enrolling patients in clinical trials, the safety and tolerability of sonelokimab and its ultimate therapeutic effect, and reliance on third parties to conduct and support its preclinical studies and clinical trials.

Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. MoonLake does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or in the events, conditions or circumstances on which any such statement is based.

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