MoonLake Immunotherapeutics presents positive 12-week data from the Phase 2 MIRA trial with Nanobody® Sonelokimab for Hidradenitis Suppurativa at the European Academy of Dermatology and Venereology Congress

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- Peer reviewed data presented during a late-breaking session at the European Academy of Dermatology and Venereology Congress (EADV) confirms the strong profile of sonelokimab in HS announced at MLTX's R&D Day on June 26, 2023
- HiSCR75 primary endpoint met with a significantly higher proportion of patients on sonelokimab 120mg (43.3%) compared to placebo (14.7%) achieving HiSCR75 at week 12; a 29 percentage points (ppt) delta ($p<0.001$)
- HiSCR50 secondary endpoint met with a significantly higher proportion of patients on sonelokimab 120mg (65.7%) compared to placebo (27.9%) achieving HiSCR50 at week 12; a 38 ppt delta ($p<0.001$)
- Sonelokimab rapidly achieved high levels of response across HiSCR thresholds, including HiSCR 90 and IHS4, and significant resolution of draining tunnels (DT 100) compared to placebo
- Sonelokimab also led to significant improvements in patient-reported quality of life, skin pain, and HS symptoms compared with placebo, with additional depth of response reported following additional analysis after the June R&D Day
- Safety results of sonelokimab were consistent with previously reported studies with no new observed signals, and included additional insight following further analysis after the June R&D Day
- 24-week data from the Phase 2 MIRA trial is anticipated imminently

ZUG, Switzerland, October 11, 2023 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, announced that positive 12-week results from its global Phase 2 MIRA trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with moderate-to-severe hidradenitis suppurativa ("HS") were presented today during a late-breaking session at the European Academy of Dermatology and Venereology Congress ("EADV") held in Berlin, Germany.

The EADV presentation follows the announcement, in June 2023, of the positive topline 12-week results from the trial in 234 patients, which marked a landmark milestone as the first placebo-controlled randomized trial in HS to report results using HiSCR75 as the primary endpoint. The primary analysis was based on the most stringent type of analysis for such trials, intent-to-treat non-responder imputation ("ITT-NRI").

The MIRA trial met its primary endpoint with a significantly higher proportion of patients treated with both sonelokimab 120mg (43.3%) and 240mg (34.8%) achieving HiSCR75 compared to those on placebo (14.7%) at week 12. Sonelokimab also met the key secondary endpoint with a significantly higher proportion of patients treated with both sonelokimab 120mg (65.7%) and 240mg (53.0%) achieving HiSCR50 compared to those on placebo (27.9%) at week 12. Both doses performed similarly, with the 120mg dose providing the highest delta on HiSCR75 and HiSCR50. The 120mg dose achieved a 29 percentage points (ppt) delta to placebo on HiSCR75 ($p<0.001$) and a 38 ppt delta to placebo on HiSCR50 ($p<0.01$). As early as week 8, a significant difference in response between sonelokimab and placebo was observed across HiSCR thresholds, including HiSCR90.

In addition, other clinically relevant secondary endpoints also reached statistical significance at week 12 with sonelokimab compared with placebo. This included improvements in International Hidradenitis Suppurativa Severity Score System ("IHS") 4, significantly greater complete resolution of draining tunnels (DT 100) as well as significant improvements in patient reported quality of life, skin pain, and HS symptoms.

The safety profile of sonelokimab was consistent with previously reported studies with no new safety signals observed. Overall, sonelokimab continues to show a favorable safety profile, in line with the known profile of IL-17 inhibitors.

Professor Brian Kirby MD, FRCPI, Charles Department of Dermatology, St. Vincent's University Hospital and Charles Institute of Dermatology, University College Dublin, Dublin, Ireland, commented: "*Hidradenitis suppurativa is a severely debilitating chronic skin condition resulting in irreversible tissue destruction and scarring. Patients often suffer great pain and become socially isolated. There is an urgent need for effective new treatments to help patients manage their disease. The positive 12-week data presented at EADV today with sonelokimab are highly encouraging and I look forward to seeing further data and the start of the Phase III clinical program."*

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, added: *"We observed maximum clinical responses of our Nanobody® sonelokimab at the lower 120mg dose tested, demonstrating the advantage of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F. We now look forward to reporting the 24-week data imminently which will provide important insights on the depth and breadth of efficacy of sonelokimab and further data on safety."*

Full results from the MIRA trial will be submitted for publication in a peer-reviewed medical journal and for presentation at an upcoming scientific meeting.

Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis in which it demonstrated a rapid and durable skin clearance (PASI100) with no unexpected safety findings.

Sonelokimab is currently being evaluated in a Phase 2 trial (NCT05640245), 'ARGO', in patients with active psoriatic arthritis. The top-line 12-week results are expected in the first half of November 2023, ahead of the American College of Rheumatology Conference, November 10-15.

Sonelokimab is not yet approved for use in any indication.

- Ends –

About Hidradenitis Suppurativa

Hidradenitis suppurativa is a severely debilitating chronic skin condition resulting in irreversible tissue destruction. HS manifests as painful inflammatory skin lesions, typically around the armpits, groin, and buttocks. Over time, uncontrolled and inadequately treated inflammation can result in irreversible tissue destruction and scarring. The disease affects 0.05–4.1% of the global population, with three times more females affected than males. Onset typically occurs in early adulthood and HS has a profound negative impact on quality of life, with a higher morbidity than other dermatologic conditions. There is increasing scientific evidence to support IL-17A- and IL-17F-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

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 recruited 234 patients, with the aim to evaluate two different doses of sonelokimab (120mg and 240mg) with placebo control and adalimumab as an active 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 also evaluated 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 at: https://www.clinicaltrials.gov/ct2/show/NCT05322473 .

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 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 is currently being assessed in two ongoing trials, the Phase 2 MIRA trial in HS and the Phase 2 ARGO trial in PsA. The MIRA trial met its primary endpoint, the Hidradenitis Suppurativa Clinical Response (HiSCR) 75 which is a higher measure of clinical response versus the HiSCR50 measure used in other clinical trials. A significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieved HiSCR75 compared to those on placebo at week 12. The positive results suggest that, as early as week 12, sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials. The trial proceeds to week 24, with a 4-week safety follow-up.

Sonelokimab has been assessed in a randomized, placebo-controlled Phase 2b study 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 study 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). Currently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, "ARGO") including multiple arms and over 200 patients is ongoing (announced on Dec 14, 2022).

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 their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

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

About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics 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 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 and psoriatic arthritis – 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.

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: plans for clinical trials and research and development programs; and the anticipated timing of the results from those trials, including completing the MIRA trial and the ARGO trial; and the efficacy of our products, if approved, including in relation to other products. 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 such 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, and reliance on third parties to conduct and support its clinical trials, and the other risks described in or incorporated by reference into MoonLake’s Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the Securities and Exchange Commission.

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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