MoonLake Immunotherapeutics achieves landmark milestone with positive Phase 2 results for Nanobody® sonelokimab in hidradenitis suppurativa

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- First placebo-controlled randomized trial in HS to report positive topline results using HiSCR75 as the primary endpoint
- Primary endpoint HiSCR75 met with 29 percentage points (ppt) delta vs placebo (p=0.0002) at week 12, setting a new bar in HS
- HiSCR50 met with 38 ppt delta vs placebo (p<0.0001), greater delta than observed for any other molecules
- Other secondary endpoints also reached statistical significance with clinically meaningful improvements at week 12, including HiSCR90, IHS4 and various patient reported outcomes
- Safety results of sonelokimab consistent with previously reported studies with no new observed safety signals
- These topline data will be discussed on Monday 26th June, at 2pm CEST/8am EDT, via webcast (registration link below)

ZUG, Switzerland, June 25, 2023 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive top-line 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).

The MIRA trial (M1095-HS-201), which recruited 234 patients, is the first randomized, double-blind, placebo-controlled trial to use Hidradenitis Suppurativa Clinical Response (HiSCR) 75 as its primary endpoint, a higher measure of clinical response versus the HiSCR50 measure used in other clinical trials, therefore representing a landmark milestone in HS clinical development.

The trial met its primary endpoint with a significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieving HiSCR75 compared to those on placebo at week 12. The primary analysis was based on the most stringent type of analysis for such trials, intent-to-treat non-responder imputation (ITT-NRI). Both doses performed similarly, with the 120mg dose providing the highest delta on HiSCR75 and HiSCR50. The 120mg dose achieved a 29 ppt delta to placebo on HiSCR75 (p=0.0002) and a 38ppt delta to placebo on HiSCR50 (p<0.0001). The results suggest that, as early as week 12, the Nanobody® sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials.

In addition, other clinically relevant secondary endpoints, such as HiSCR90, improvements in International Hidradenitis Suppurativa Severity Score System (IHS) 4, abscess/nodule and draining tunnel counts as well as patient reported pain and quality of life outcomes also reached statistical significance at week 12. The high performance of the Nanobody® at 120mg, the dose found to be optimal in psoriasis, demonstrates the advantage of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases.

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.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"As part of our efforts to elevate outcomes for patients, we set an ambitious goal for our Nanobody® sonelokimab to 'meet or beat' the best results shown in pivotal-like trials of competitors. We have achieved our 'beat' goal with the positive outcome of the Phase 2 MIRA trial. In doing so, we have raised the bar for what can be accomplished for HS and these positive topline data provide us with even greater confidence as we look forward to our next steps and our aspiration to become a leader in the inflammation and immunology space."*

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: "*The positive topline results from the MIRA trial establish a new era in the treatment of chronic inflammatory diseases, as our Nanobody® sonelokimab indicates a new bar versus what was achieved previously with monoclonal antibodies. Importantly, the results confirm the advantage of the Nanobody's smaller size versus traditional antibodies in the treatment of diseases in which high-level improvements depend on optimal tissue penetration such as hidradenitis suppurativa and likely psoriatic arthritis. The data also validate sonelokimab's unique mode of action to efficiently inhibit IL-17F in addition to IL-17A. The positive outcome of the MIRA trial would not have been possible without the support and participation of the patients and investigators to whom we are grateful."*

Alexa B. Kimball, MD, MPH, lead investigator of the MIRA trial, investigator at Beth Israel Deaconess Medical Center, Massachusetts, US, and Professor of Dermatology at Harvard Medical School, added: "*Hidradenitis suppurativa is a chronic, inflammatory, recurrent, and debilitating skin disease that has profound and wide-ranging impacts across many aspects of patient's lives. As a physician, I see tremendous need for new treatment options for people living with HS, particularly for treatments to reach high thresholds of response in clinical trials (e.g., HiSCR75 and beyond). The positive high clinical responses observed with sonelokimab in the Phase 2 MIRA trial are encouraging, demonstrating its promise as a potential future treatment option."*

These topline data will be discussed on Monday June 26, 2023 at 2pm CEST/8am EDT before the Nasdaq market opens, via webcast at:

https://onlinexperiences.com/Launch/QReg/ShowUUID=AF1A77F1-F560-4D58-AE3B-00698698C741&LangLocaleID=1033&GroupID=Onyx

A replay of the webcast and the presentation document will be made available at https://ir.moonlaketx.com.

The MIRA trial proceeds to week 24, with a 4-week safety follow-up. Important data is being collected regarding longer-term efficacy and safety of sonelokimab, as well as results from switching to sonelokimab from the placebo and the adalimumab arms. 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 with the primary end-point readout expected in Q4 this year.

Sonelokimab is not yet approved for use in any indication.

- Ends -

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 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.

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 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 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 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.

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 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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