Phase 2 MIRA primary analysis trial results (12-week) for MoonLake's Nanobody® sonelokimab in hidradenitis suppurativa to be presented at a late-breaking session at the European Academy of Dermatology and Venereology Congress

October 4, 2023

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ZUG, Switzerland, October 4, 2023 – MoonLake Immunotherapeutics AG ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announces that 12-week Phase 2 MIRA trial data for the Nanobody® sonelokimab in hidradenitis suppurativa will be presented at the European Academy of Dermatology and Venereology Congress taking place from October 11-14 in Berlin, Germany**.**

In June 2023, MoonLake announced positive topline 12-week Phase 2 MIRA trial results, achieving a landmark milestone as the first placebo-controlled randomized trial in HS to report positive top-line results using HiSCR75 as the primary endpoint.

Professor Brian Kirby MD, FRCPI, Charles Department of Dermatology, St. Vincent's University Hospital and Charles Institute of Dermatology, University College Dublin, Dublin, Ireland will be presenting the results in a late-breaking news presentation, details of which are included below.

Session code and title: D1T01.1: Late breaking news
Location: Hall B
Date and time: Wednesday, 11 October**;** session 14.15 - 17.30 CEST, presentation 16.15 - 16.30 CEST
Presentation title: Efficacy and safety of the IL-17A- and IL-17F-inhibiting Nanobody® sonelokimab in patients with active, moderate-to-severe hidradenitis suppurativa: Results from the global, randomized, double-blind, placebo-controlled Phase 2 MIRA trial

The 24-week Phase 2 MIRA trial data for Nanobody® sonelokimab in hidradenitis suppurativa is anticipated imminently.

In addition, top-line 12-week results for MoonLake's Phase 2 ARGO trial with Nanobody ® sonelokimab in psoriatic arthritis (PsA) are expected in the first half of November 2023, ahead of the American College of Rheumatology Conference, November 10-15.

- 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 HS. The trial recruited 234 patients, with the aim to evaluate two different doses of sonelokimab, 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 evaluates 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

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 also 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). Recently, a

global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, “ARGO”) including multiple arms and over 200 patients has been initiated.

Sonelokimab is not yet approved for use in any indication.

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.

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 and timing of clinical trials, including expectations regarding the timing and outcome of the MIRA and ARGO trials, and clinical trials and the anticipated timing of the results from those trials. 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 regarding the timing and outcome of the MIRA and ARGO trials; positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical studies; 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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