MoonLake Immunotherapeutics completes patient enrollment and randomization ahead of schedule in a Phase 2 trial of the Nanobody® sonelokimab in moderate-to-severe hidradenitis suppurativa

February 2, 2023

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- Enrollment target of 210 patients randomized completed ahead of schedule
- Top line results on the primary endpoint, for the novel IL-17A and IL-17F inhibitor Nanobody® sonelokimab, expected mid-2023
- First registered randomized trial in HS to use HiSCR75 as the primary endpoint; trial also includes adalimumab as an active reference arm
- The trial will proceed to its 24-week completion, including placebo patients re-randomized to sonelokimab and adalimumab patients switched to sonelokimab, with final read out expected, as planned, by Q4 2023

ZUG, Switzerland, February 2, 2023 – MoonLake Immunotherapeutics AG ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that it has completed enrollment of the target 210 patients randomized ahead of schedule in its global Phase 2 clinical trial evaluating sonelokimab in moderate-to-severe hidradenitis suppurativa (HS).

The MIRA trial (M1095-HS-201) is the first global, randomized, double-blind, placebo-controlled trial using Hidradenitis Suppurativa Clinical Response (HiSCR) 75, a higher measure of clinical response, as its primary endpoint. It is evaluating different doses of sonelokimab, compared with placebo, with adalimumab as an active control reference arm, in patients with HS, a severely debilitating chronic skin condition, that results in irreversible tissue destruction.

Sonelokimab (M1095) is a Nanobody® designed to directly target sites of inflammation by inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers and to penetrate difficult-to-reach inflamed tissues. HiSCR75 is 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 use of HiSCR75 as a primary endpoint in an HS clinical trial is a reflection of MoonLake's confidence in sonelokimab and the Company's ambition to revolutionize patient outcomes by seeking a greater reduction in disease markers than is typically tested in clinical trials. The trial also includes a range of secondary endpoints reflecting the heterogeneous clinical phenotypes of the disease, including inflammatory lesions and draining tunnels, as well as a number of patient-reported outcome measures such as pain and quality of life assessments.

Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented: "The rapid completion of enrollment and randomization for our Phase 2 trial reflects the need for new treatment options and the clinical interest in evaluating the Nanobody® sonelokimab in hidradenitis suppurativa. In our view, and based on competitive data, sonelokimab's ability to efficiently inhibit IL-17F in addition to IL-17A could represent a major improvement in treating inflammation for this devastating disease. Sonelokimab's smaller size versus traditional antibodies and albumin-binding domain provide an opportunity for further efficacy. We thank patients and investigators for their participation in this important trial, and remain on schedule to announce top line results on the primary endpoint by mid-2023."

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 and recruitment is ongoing.

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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

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 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 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). Recently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, "ARGO") including multiple arms and over 200 patients has been initiated (announced on Dec 14, 2022).

Sonelokimab is not yet approved for use in any indication.

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 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 Current Report on Form 8-K filed on April 11, 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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