MoonLake Immunotherapeutics starts Phase 2 trial of the Nanobody® Sonelokimab in patients with moderate-to-severe hidradenitis suppurativa

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- First Phase 2 trial in hidradenitis suppurativa using the higher clinical response level of HiSCR75 as the primary endpoint
- Trial evaluates sonelokimab, an investigational Nanobody® with an innovative mode of action designed to treat and elevate patient outcomes for inflammatory disease

ZUG, Switzerland, May 12, 2022 – MoonLake Immunotherapeutics AG (MoonLake; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that the first patient has been randomized and dosed, in a U.S. site, in its global Phase 2 clinical trial evaluating sonelokimab, an investigational Nanobody® designed to treat inflammatory disease, in patients with moderate-to-severe hidradenitis suppurativa (HS).

HS is a severely debilitating chronic skin condition, with a prevalence of approximately 1% globally, that results in irreversible tissue destruction. Sonelokimab (M1095) inhibits the naturally occurring IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation. In addition, sonelokimab is designed to directly target sites of inflammation and penetrate difficult-to-reach inflamed tissues.

The MIRA trial (M1095-HS-201) 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.

This trial represents a landmark milestone in HS clinical development as it is the first to use Hidradenitis Suppurativa Clinical Response (HiSCR) 75 as its primary endpoint. 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. Using an at least 75% improvement of HiSCR as the primary endpoint reflects MoonLake's goal to revolutionize patient outcomes by seeking a greater reduction in disease markers than is typically tested in clinical trials.

The trial will also include a range of secondary endpoints reflecting the heterogeneous clinical phenotypes of the disease, including inflammatory lesions and tunnels, as well as a number of patient-reported outcome measures such as pain and quality of life assessments. The first sites of this global trial have been initiated in the United States.

Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented: "There remains an urgent need for novel treatments for hidradenitis suppurativa, a devastating skin disease that impacts approximately 1% of people globally. The commencement of our Phase 2 trial with sonelokimab is a landmark moment for HS as it is the first to use an endpoint that aims for a higher clinical response level. We believe that sonelokimab has the potential to elevate patient outcomes due to its ability to inhibit the naturally occurring IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation in HS, and its Nanobody® characteristics should improve its tissue penetration, helping the molecule to target difficult-to-reach inflammatory lesions such as deep abscesses and tunnels."

The initiation of this Phase 2 trial follows the announcement in March 2022 that approval of trial protocol was obtained from the central Institutional Review Board as part of MoonLake's Investigational New Drug (IND) filing with the U.S. Food and Drug Administration. The trial is expected to complete by the end of 2023.

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 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 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 anticipated markets for products, if approved. 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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