MoonLake Immunotherapeutics to initiate global Phase 2 study of the Nanobody® Sonelokimab in patients with moderate-to-severe hidradenitis suppurativa with HiSCR75 as the primary endpoint

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- Expected to enroll over 200 patients with moderate-to-severe HS to assess the efficacy and safety of sonelokimab, with recruitment expected to commence imminently, with the first sites to be initiated in the United States
- Sonelokimab is an investigational Nanobody® designed to treat inflammatory disease by selectively binding 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

ZUG, Switzerland, March 24, 2022 /PRNewswire/ -- MoonLake Immunotherapeutics AG ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that it is proceeding with a global Phase 2 clinical study to evaluate sonelokimab in patients with moderate-to-severe hidradenitis suppurativa ("HS").

Subsequent to the completion of a global Phase 2b clinical study in moderate-to-severe psoriasis (NCT03384745), the new protocol for HS was filed as part of MoonLake's Investigational New Drug ("IND") with the U.S. Food and Drug Administration. The review process was inclusive of a Type C meeting, as well as the statutory 30-day review period during which no additional comments were received. Approval for the protocol was obtained from the central Institutional Review Board.

The global, randomized, double-blind, placebo-controlled study (M1095-HS-201, "MIRA") is designed 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. This study represents a landmark in HS clinical development, as it will be 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.

The study 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. Patient enrollment is expected to start imminently in 2022, with the first sites being initiated in the United States.

Sonelokimab (M1095) is an investigational Nanobody® designed to treat inflammatory disease by inhibiting 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.

Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented: "We believe this is a landmark moment for patients with such a devastating disease as HS. Using an at least 75% improvement of HiSCR as the primary endpoint reflects our goal to reach for a greater reduction in disease markers than is typically tested in clinical trials. By binding to IL-17A and IL-17F, sonelokimab inhibits the naturally occurring IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation in HS. Furthermore, the Nanobody® characteristics of sonelokimab should improve its tissue penetration, helping the molecule to target difficult-to-reach inflammatory lesions such as deep abscesses and tunnels, which are hallmarks of HS. We are excited to continue development of the first IL-17A- and IL-17F-targeting Nanobody® as a potential novel treatment for chronic inflammatory conditions such as HS, with the aim of elevating outcomes for patients."

About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics AG 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 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).

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 preclinical studies, clinical trials and research and development programs; and the anticipated timing of the results from those studies and 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 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 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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