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- MoonLake announces FDA clearance for Phase 2 clinical study of the Nanobody® sonelokimab in active psoriatic arthritis
- Expected to enroll approximately 200 patients to assess the efficacy and safety of sonelokimab compared to placebo, with adalimumab as an active reference arm; recruitment expected to commence shortly in the United States and Europe
- This Phase 2 study represents an important step in psoriatic arthritis clinical development, assessing high threshold outcomes across joint and skin domains of this multi-faceted disease
- Sonelokimab is an investigational Nanobody® designed to treat inflammatory diseases by inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation, directly target sites of inflammation and penetrate difficult-to-reach inflamed tissues

ZUG, Switzerland, September 26, 2022 – MoonLake Immunotherapeutics AG ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced U.S. Food and Drug Administration ("FDA") clearance for a Phase 2 clinical study of the nanobody sonelokimab in patients with active psoriatic arthritis ("PsA"). This is a global clinical study that also includes several European countries.

This new study is subsequent to the completion of a global Phase 2b study in moderate-to-severe psoriasis (NCT03384745) and the initiation of the Phase 2 "MIRA" study in moderate-to-severe hidradenitis suppurativa (NCT05322473).

The global, randomized, double-blind, placebo-controlled study (M1095-PSA-201, "ARGO") is designed to evaluate the efficacy and safety of different doses of sonelokimab compared to placebo, with adalimumab as an active reference arm, in approximately 200 patients with active PsA. The primary endpoint of the study is the American College of Rheumatology (ACR) 50 response defined as the percentage of participants achieving ≥50% improvement in signs and symptoms of disease from baseline, compared to placebo. This study is the first in PsA to use the Nanobody®.

The study will also include a range of secondary endpoints reflecting the heterogeneous and multi-faceted nature of the disease, including the assessment of skin clearance (including Psoriasis Area and Severity Index (PASI) 100), disability, enthesitis, pain, as well as other levels of ACR response (including ACR70). Patient enrollment is expected to begin in 2022, with the first sites being initiated in Europe and in the United States.

Sonelokimab (M1095) is an investigational Nanobody® designed to treat inflammatory disease by inhibiting the 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, Co-founder and Chief Scientific Officer at MoonLake, said: "The initiation of the ARGO study represents an important milestone in the development of the IL-17A and IL-17F inhibiting Nanobody sonelokimab for the treatment of inflammatory skin and joint conditions. I am particularly excited to see how the small size and albumin-binding properties of sonelokimab will further elevate the anti-inflammatory potential of IL-17A and IL-17F inhibition to improve treatment outcomes across various disease domains of PsA including arthritis, enthesitis and psoriasis."

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About the ARGO study

The ARGO study (M1095-PSA-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 psoriatic arthritis. The study will comprise approximately 200 patients, and will evaluate different doses of sonelokimab, with placebo control and adalimumab as an active reference arm. The primary endpoint of the study is the percentage of participants achieving ≥50% improvement in signs and symptoms of disease from baseline, compared to placebo, as measured by the American College of Rheumatology (ACR) 50 response. The study will also evaluate a number of secondary endpoints, including improvement compared to placebo in ACR70, complete skin clearance as measured by at least a 100 percent improvement in the Psoriasis Area and Severity Index (PASI100), physical function as measured by the Health Assessment Questionnaire-Disability Index (HAQ-DI), enthesitis as measured by the Leeds Enthesitis Index and pain as measured by the Patients Assessment of Arthritis Pain (PtAAP).

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 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 phase 2 trial in hidradenitis suppurativa (NCT05322473, M1095-PSA-201,"MIRA") including multiple arms and over 200 patients has been initiated (announced on May 5, 2022).

Sonelokimab is not yet approved for use in any indication.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic and progressive inflammatory arthritis associated with psoriasis primarily affecting the peripheral joints. The clinical features of PsA are diverse, involving pain, swelling, and stiffness of the joints, which can result in restricted mobility and fatigue. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. The symptom burden of PsA can have a substantial negative impact on patient quality of life. Although the exact mechanism of disease is not fully understood, evidence suggests that activation of the IL-17 pathway plays an important role in the disease pathophysiology.

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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