MoonLake completes patient randomization ahead of schedule for its Phase 2 trial in active psoriatic arthritis (PsA) and provides calendar of next readouts

July 25, 2023

MoonLake completes patient randomization ahead of schedule for its Phase 2 trial in active psoriatic arthritis (PsA) and provides calendar of next readouts

- Randomization target of 200 patients completed ahead of schedule in the ARGO PsA trial
- Top-line 12-week results of the ARGO trial in PsA for the novel IL-17A and IL-17F inhibiting Nanobody® sonelokimab, are now expected in the first half of November 2023, ahead of the American College of Rheumatology Conference, November 10-15th
- A Capital Markets Day will be held on September 11th 2023 to discuss the PsA market and share expectations on the ARGO readout and an update on the MIRA trial in Hidradenitis Suppurativa (HS) top-line 24-week data readout, now expected in mid-October 2023, following the recent successful top-line 12-week data readout
- The Company also announces a calendar of upcoming events and data readouts

ZUG, Switzerland, July 25, 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 successfully completed randomization of the target 200 patients, several weeks ahead of schedule, in its global Phase 2 ARGO clinical trial evaluating Nanobody® sonelokimab in active psoriatic arthritis (PsA).

MoonLake also announced a Capital Markets Day to be held in New York at NASDAQ, including a virtual webcast format, on September 11th 2023. This session will be used to discuss the PsA market and share expectations on the top-line 12-week ARGO data readout, as well as an update on the MIRA trial in Hidradenitis Suppurativa (HS) 24-week data readout, expected in mid-October 2023, following the successful top-line 12-week data readout.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"ARGO is MoonLake's second trial to have achieved faster completion of recruitment and randomization than expected. Reaching this stage well ahead of schedule for active psoriatic arthritis is an encouraging reflection of the interest in our clinical development programs. We are looking forward to all of the upcoming key MoonLake readouts and events and are excited about updating investors with our progress in due course."*

The ARGO trial in PsA

The ARGO trial (NCT05640245) commenced patient screening in December 2022 with the aim to evaluate the clinical efficacy and safety of Nanobody® sonelokimab at 120mg and 60mg dosed every 4 weeks (after bi-weekly induction dosing) and 60mg dosed every 4 weeks (with no induction dosing) compared with placebo. The trial also includes adalimumab, the current standard of care for PsA, as an active reference arm. The purpose of including this arm, which is not statistically powered, was to validate the study and to guide the design of the Phase 3 trial.

PsA is a complex, chronic and progressive inflammatory disease. The clinical features of PsA are diverse, comprising both musculoskeletal (such as enthesitis, a type of inflammation of the joints) and non-musculoskeletal (skin and nail psoriasis) manifestations. Patient burden is high with many patients presenting with more than one clinical manifestation. Both IL-17F and IL-17A are implicated in disease pathophysiology and inhibition shows promise for patients and their treating physicians in concurrently elevating treatment outcomes for joint and skin inflammation.

Sonelokimab (M1095) is an investigational Nanobody® designed to inhibit IL-17F in addition to IL-17A and therefore could potentially represent a major improvement in treating PsA. The Nanobody's ® smaller size versus traditional antibodies and albumin-binding domain provide an opportunity for further efficacy as determined by American College of Rheumatology (ACR)50 and Psoriasis Area and Severity Index (PASI)90. These and other clinically relevant endpoints are being tested in the ARGO trial.

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.

Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented: *"We are looking forward to announcing top-line data from the psoriatic arthritis trial ahead of the American College of Rheumatology meeting this year and hope to demonstrate elevation of treatment outcomes across various facets of this complex and debilitating disease. Our programs aim to develop an improved treatment option for patients with chronic inflammatory diseases. Considering the type of inflammation in PsA with involvement of penetration-sensitive tissues, such as the peripheral and spinal entheses, we consider our IL-17A and F inhibiting Nanobody® sonelokimab a promising potential therapeutic option, both from a mode of action as well as from a molecule perspective. PsA patients also have psoriasis and our Nanobody® has previously shown leading clinical activity in reaching complete skin clearance with a favorable benefit-risk profile."*

Status update on the MIRA trial in HS

In February 2023, the Phase 2 MIRA trial (NCT05322473) of the Nanobody® sonelokimab in moderate-to-severe hidradenitis suppurativa (HS) completed its target enrollment ahead of schedule (to a total of 234 patients). Following this, in June 2023, MoonLake announced positive top-line

results from the trial which met its primary endpoint with a significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieving HiSCR75 compared to those on placebo at week 12. The 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. Further data on the trial can be found online in the press release here and in the R&D Day presentation and webcast on our website here.

The trial continues beyond week 12, and week 24 results (including a subsequent 4-week safety follow-up period) will be available in mid-October 2023. These will include data on the additional duration of response across all endpoints, improvement of response over time with maintenance dosing, as well as additional information on dose selection for Phase 3. An update on the top-line 24-week data readout from the MIRA trial in Hidradenitis Suppurativa (HS) will be discussed at the September 2023 Capital Markets Day, including sharing expectations on the results.

Important upcoming events and next data readouts for MoonLake:

September:

- Capital Markets Day in New York in person at NASDAQ, and virtually via webcast, on September 11th from 11:30 am – 13:00pm EDT/17:30 – 19:00 pm CEST to discuss the PsA market and expectations ahead of the top-line 12-week results for the ARGO trial and an update on the 24-week data readout from the MIRA trial in Hidradenitis Suppurativa (HS), now expected in mid-October 2023

October:

- MIRA trial top-line 12-week data will be presented at a scientific meeting
- R&D Day virtual webcast in mid-October 2023, where the top-line 24-week data of the MIRA trial will be first unveiled, together with Phase 3 trial plans in HS

November:

- R&D Day virtual webcast in early November, ahead of the American College of Rheumatology (ACR) Conference where top-line results for the PsA ARGO trial will be first presented

December:

- End of Phase 2 meeting with the FDA is expected in mid-December 2023, to discuss Phase 2 HS data and define plan for Phase 3 clinical trial final designs and clinical operations

Early 2024:

- R&D Day to communicate the final Phase 3 plans as well as other clinical and business catalysts in 2024 and beyond

Sonelokimab is not yet approved for use in any indication.

- ends -

About the ARGO trial

The ARGO trial (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 PsA. The trial is designed to evaluate 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 ≥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 trial 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% improvement in the Psoriasis Area and Severity Index, physical function as measured by the Health Assessment Questionnaire-Disability Index, enthesitis as measured by the Leeds Enthesitis Index and pain as measured by the Patients Assessment of Arthritis Pain. Further details are available on: https://clinicaltrials.gov/ct2/show/NCT05640245

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.

On June 25th 2023, MoonLake announced positive top-line results from the Phase 2 MIRA trial in HS, which met its primary endpoint with a significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieving HiSCR75 compared to those on placebo at week 12.

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 (announced on Dec 14, 2022).

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.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) 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 top-line data from the ARGO 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 Annual Report on Form 10-K for the year ended December 31, 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.

Contacts:

MoonLake Immunotherapeutics Investors Matthias Bodenstedt, CFO info@moonlaketx.com

MoonLake Immunotherapeutics Media

Patricia Sousa media@moonlaketx.com

Consilium Strategic Communications Mary-Jane Elliott, Ashley Tapp,
Namrata Taak
Tel: +44 (0) 20 3709 5700
media@moonlaketx.com MoonLake@consilium-comms.com