MoonLake Immunotherapeutics announces landmark Phase 2 results for Nanobody® sonelokimab in active psoriatic arthritis

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- First placebo-controlled randomized trial in active psoriatic arthritis (PsA) using a Nanobody® to report positive topline results in support of potential best-in-class profile
- Primary endpoint ACR50 met with up to 47% ($p<0.01$ versus placebo) of patients on sonelokimab achieving ACR50 as early as week 12
- All key secondary endpoints met including up to 77% ($p<0.001$ versus placebo) of patients on sonelokimab achieving PASI90 as early as week 12
- Other secondary endpoints also reached statistical significance at week 12, including endpoints focused on deep tissue inflammation, Minimal Disease Activity (MDA) and patient reported outcomes
- High threshold outcomes, including ACR70 and PASI100, continue to improve beyond week 12, consistent with previous studies of sonelokimab
- Discontinuation rate below 4% and safety results of sonelokimab consistent with previously reported studies with no new safety signals
- The top-line data will be discussed on Monday 6 November, at 2pm CET/8am ET, via webcast (registration link below)

ZUG, Switzerland, November 5, 2023 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive top-line results from its global Phase 2 ARGO trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis (PsA).

The ARGO trial (M1095-PSA-201), which enrolled 207 patients, met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an American College of Rheumatology (ACR) 50 response compared to those on placebo at
week 12. Specifically, for the 60mg and 120mg doses with induction, respectively, 46% and 47% of patients treated with sonelokimab achieved ACR50 ($p<0.01$ versus placebo); 78% and 72% of patients achieved ACR20; and 29% and 26% achieved ACR70. The primary analyses were based on the most stringent type of analysis for such trials, intention-to-treat with non-responder imputation (ITT-NRI). As expected, the 60mg dose without induction did not reach statistical significance, confirming the 60mg and 120mg with induction as the potential dose regimens to carry forward into Phase 3.

All key secondary endpoints were met for the 60mg and 120mg doses with induction. The key secondary endpoint Psoriasis Area and Severity Index (PASI) 90 was met for all doses with induction; 77% of patients responding at week 12 to the 60mg dose (ITT-NRI, $p<0.001$ versus placebo). For this dose, 58% of patients achieved complete skin clearance (PASI100) at week 12. PASI responses across dose arms were consistent with the previously reported Phase 2b data of sonelokimab in moderate-to-severe plaque-type psoriasis, with the 120mg dose achieving the highest responses for PASI100 (close to 60% of patients at week 12, ITT-NRI) in patients with more severe skin lesions (PASI score ≥ 10 at baseline).

Other clinically relevant secondary endpoints, such as Minimal Disease Activity (MDA), the modified Nail Psoriasis Severity Index (mNAPSI), the Leeds Enthesitis Index (LEI) and the patient self-reported Psoriatic Arthritis Impact of Disease (PsAID-12), each show promising levels of response at week 12.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"As part of our efforts to elevate outcomes for patients, we set ambitious goals for our Nanobody® sonelokimab. ARGO is MoonLake's third Phase 2 trial and the first trial in psoriatic arthritis using a Nanobody ® to report positive topline results, setting another landmark milestone. Again, we met the objectives we set out for ourselves, in this case for PsA. As with our hidradenitis suppurativa program, the preparation of our Phase 3 program in PsA is rapidly advancing and expected timing of end-of-Phase 2 regulatory meetings will be announced in due course."*

Adalimumab was used as an active reference to validate responses across arms (not powered for statistical comparisons to active treatment). Sonelokimab 60mg and 120mg (with induction) numerically outperformed adalimumab on the primary endpoint and all key secondary endpoints, with

the observed deltas further supporting the potential for sonelokimab as a future leading therapy.

The patient discontinuation rate in the ARGO trial was low at week 12 (less than 4%), similar to what was observed in previous trials of sonelokimab in psoriasis and hidradenitis suppurativa. The safety profile of sonelokimab in ARGO was consistent with previously reported studies with no new safety signals. Specifically, oral candidiasis was observed in less than 2% of patients on sonelokimab, with no case leading to discontinuation. No cases of inflammatory bowel disease (IBD), major adverse cardiovascular events (MACE) or suicidal ideation and behavior (SI/B) were observed. Overall, sonelokimab continues to show a favorable safety profile. Across the sonelokimab clinical program to date, the company has not seen any signal of SI/B or liver enzyme elevations related to sonelokimab treatment.

The results suggest that, as early as week 12, the Nanobody® sonelokimab reaches levels of clinical response at or above those seen with other therapies tested in similarly stringent trials. The high performance of sonelokimab and its favorable safety profile continue to support the potential of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases.

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: "*The positive topline results from the pivotal-like ARGO trial establish the Nanobody® sonelokimab as an innovative potential treatment in another chronic inflammatory disease, psoriatic arthritis. Importantly, the results confirm our expectations in terms of dosing, clinical responses and safety findings. We believe that we have elevated the therapeutic bar by reaching important clinical outcomes at week 12. The data also support sonelokimab's unique molecule characteristics and mode of action to effectively inhibit IL-17F in addition to IL-17A in deep tissue inflammation. The positive outcome of the ARGO trial would not have been possible without the support and participation of the patients and investigators to whom we are grateful.*"

Joseph F. Merola, MD, MMSc, Professor of Dermatology, Medicine and Rheumatology, Distinguished Chair of Dermatology at UT Southwestern Medical Center added: *"Psoriatic arthritis is a chronic, inflammatory, recurrent, and debilitating multidomain disease that has profound and wide-ranging impacts across many aspects of patients' lives. As a physician, I see tremendous need for new treatment options for people living with PsA, particularly for therapies that reach high thresholds of response (e.g., ACR70, PASI100) and that simultaneously improve the disease domains that matter most for patients. The positive high clinical responses across joint and skin endpoints and stringent composite measures such as minimal disease activity observed with sonelokimab as early as week 12 in the Phase 2 ARGO trial are encouraging, demonstrating its promise as a potential future treatment option."*

These topline data will be discussed on Monday November 6, 2023 at 2pm CET/8am ET before the Nasdaq market opens, via webcast at:

https://edge.media-server.com/mmc/p/bp43a4xr

A replay of the webcast and the presentation document will be made available at https://ir.moonlaketx.com.

The ARGO trial proceeds to week 24, with a 4-week safety follow-up. Important data is being collected regarding longer-term efficacy and safety of sonelokimab, as well as results from the cross-over of patients treated with placebo or adalimumab to sonelokimab and the continued monthly dosing of sonelokimab.

Today's top-line data announcement follows the announcement in July 2023 that the ARGO trial successfully completed randomization of its target 200 patients, several weeks ahead of schedule (read more here). Full results from the ARGO trial will be submitted for publication in a peer-reviewed medical journal and for presentation at an upcoming scientific meeting.

The positive top-line12-week results from the Phase 2 ARGO trial in PsA follows the positive top-line 12-week and 24-week results from the Phase 2 MIRA trial in hidradenitis suppurativa (HS) as announced in June 2023 (read more here) and October 2023 (read more here). The MIRA trial set a landmark milestone as the first placebo-controlled randomized trial in HS to report positive top-line results using HiSCR75 as the primary endpoint.

Sonelokimab is not yet approved for use in any indication.

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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 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 also evaluates a number of secondary endpoints, including improvement compared to placebo in ACR20, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index (PASI), 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 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 is being assessed in two trials, the Phase 2 ARGO trial in PsA (trial ongoing) and the Phase 2 MIRA trial in HS. In June 2023, topline

results of the MIRA trial (NCT05322473) at 12 weeks showed that the trial met its primary endpoint, the Hidradenitis Suppurativa Clinical Response (HiSCR)75, which is a higher measure of clinical response versus the HiSCR50 measure used in other clinical trials, setting a landmark milestone. In October 2023, the full dataset from the MIRA trial at 24 weeks showed that maintenance treatment with sonelokimab led to further improvements in HiSCR75 response rates and other clinically relevant outcomes.

Sonelokimab has also been assessed in a randomized, placebo-controlled Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis. Clinical response (considering the Investigator's Global Assessment Score 0 or 1, and the Psoriasis Area and Severity Index 90/100) was observed 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).

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 their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

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. The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

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.

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