MoonLake Immunotherapeutics Announces Positive Outcome from Type B Meeting with U.S. FDA and Announces Investor Day

January 8, 2026

- *MoonLake requested a Type B meeting with the U.S. Food and Drug Administration (FDA) to obtain regulatory clarity and discuss the clinical evidence strategy for submission of a Biologic License Application (BLA) for Sonelokimab (SLK) in Hidradenitis Suppurativa (HS)*
- *FDA feedback confirms that the Company may establish substantial evidence of effectiveness (SEE), without additional clinical trials in HS, with a BLA consisting of data from its existing VELA-1, VELA-2 and MIRA trials*
- *The FDA specifically advised the Company to include the results of the MIRA trial in the submission and to submit the results of the VELA-2 trial for the marketing application to inform the safety profile of SLK, regardless of decisions on its utility in establishing SEE*
- *Based on the positive final official records of this Type B meeting MoonLake will continue its plans for BLA submission for SLK in HS in H2 2026*
- *An Investor Day to further discuss FDA feedback and value opportunities for SLK in HS and to share new clinical data, in HS and other indications, will be held on February 23rd, 2026*

ZUG, Switzerland, January 8, 2026 – MoonLake Immunotherapeutics (NASDAQ:MLTX) ("MoonLake" or the "Company"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today provided an update following the positive feedback received from the U.S. Food and Drug Administration (FDA) regarding the clinical evidence strategy for SLK in HS, based on the Type B meeting requested by MoonLake.

SLK was associated with significant improvements across different key outcomes in over 1,000 patients with HS enrolled in the MIRA, VELA-1 and VELA-2 trials. MIRA was the first placebo-controlled randomized clinical trial in HS using HiSCR75 as the primary endpoint and demonstrated a 43% response with 120mg SLK, and a 29 ppt delta vs placebo ($p < 0.001$) at week 12. VELA-1 met all primary and key secondary endpoints with statistical significance across all pre-specified analysis strategies (HiSCR75 at Week 16, 35% response with 120mg SLK, delta to placebo of 17ppt, $p < 0.001$). In VELA-2, using the pre-specified treatment policy strategy, SLK achieved statistical significance (HiSCR75 at Week 16, 36% response with 120mg SLK, delta to placebo of 10ppt, $p = 0.033$). A higher-than-expected placebo response precluded this study from achieving statistical significance using the primary composite analysis method (delta to placebo of 9%, $p=0.053$). All trials consistently suggested a favorable safety profile of SLK in HS patients.

To obtain regulatory clarity following the VELA readout and to continue the preparation of the BLA, MoonLake requested a Type B meeting with the FDA. The Company submitted a detailed briefing book with several additional analysis of the VELA data. The FDA indicated that MoonLake may establish substantial evidence of effectiveness (SEE) without additional clinical trials in HS, with an application consisting of data from its existing VELA-1, VELA-2 and MIRA trials. This supports the Company's perspective regarding the relevance of MIRA results for the HS BLA submission. In addition, the FDA advised the Company that the results of VELA-2 trial should be submitted for the marketing application to inform the safety of SLK, regardless of decisions on its utility in establishing SEE. The FDA further excluded using mechanistic evidence as confirmatory evidence, in combination with results from a single clinical trial, to establish SEE for the HS indication. Based on the final official records of this Type B meeting, MoonLake will continue its planned preparations for BLA submission.

Dr. Jorge Santos da Silva, Founder and Chief Executive Officer at MoonLake Immunotherapeutics, said: *"The positive outcome of our Type B meeting with the FDA provides the clarity needed to support a pathway to approval for our existing HS program, with no additional clinical trials required. In addition, the fact that we can prepare the BLA with the wealth of data across the VELA and MIRA trials provides us and the FDA with flexibility to determine the best label possible, so that SLK, if approved, can have the most positive impact for HS patients. Overall, this also provides a strong base for MoonLake to continue the broader development of SLK in other indications."*

Prof. Kristian Reich, Founder and Chief Scientific Officer at MoonLake Immunotherapeutics, said: *"The FDA has provided us with clear and helpful feedback indicating that the MIRA and VELA trials, which together enrolled more than 1000 patients with moderate-to-severe HS and tested sonelokimab using similar study designs, provide a basis for BLA submission. The FDA recognizes that MIRA and VELA-1, which met their primary and important key secondary endpoints, together with VELA-2, can be used to establish substantial evidence of effectiveness, and that VELA-2 provides a key source of evidence to inform, for example, the safety of sonelokimab. The encouraging feedback matches our view of the strong performance of sonelokimab in HS across three trials and we are looking forward to further engaging with the FDA prior to the BLA submission."*

The preparations for the submission of the BLA continue as planned and are on track for submission in H2 2026.

The company will hold an Investor Day on February 23rd, 2026 at 8 am EST / 2pm CET, to further discuss the outcomes of this Type B FDA Meeting and to present new clinical data for SLK across indications. The Company will also provide further details on the catalyst calendar for 2026 and beyond. The details for this Investor Day will be announced in due course.

Other clinical trials of SLK are progressing and are expected to support a catalyst-rich roadmap over the next 12 months, including data releases from the Phase 2 S-OLARIS trial in Axial Spondyloarthritis (axSpA) and the Phase 3 IZAR trials in Psoriatic Arthritis (PsA), among others.

Important upcoming anticipated milestones for MoonLake:

- Q1 2026: Primary endpoint readout of the Phase 2 S-OLARIS trial in axSpA
- Q2 2026: 52 weeks data of the VELA-1 and VELA-2 trials in HS
- Mid 2026: Primary endpoint readout of the Phase 3 IZAR-1 trial in PsA
- Mid 2026: Primary endpoint readout of Phase 3 VELA-TEEN trial in adolescent HS
- H2 2026: Submission of a BLA
- H2 2026: Primary endpoint readout of the Phase 3 IZAR-2 trial in PsA

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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, psoriatic arthritis, axial spondyloarthritis and palmoplantar pustulosis – 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 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 Sonelokimab
Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHHs 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 lead indications, hidradenitis suppurativa (HS) and psoriatic arthritis (PsA), and the Company is pursuing other indications in dermatology and rheumatology, including adolescent HS, palmoplantar pustulosis (PPP) and axial spondyloarthritis (axSpA).

For adults with HS, sonelokimab is being assessed in two identical Phase 3 trials, the VELA-1 and VELA-2 trials, using the higher clinical response level of HS Clinical Response (HiSCR) 75 as the primary endpoint, which defines a response as an at least 75% reduction in abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count. In September 2025, the primary endpoint data from the VELA-1 and VELA-2 clinical trials were announced. In the combined VELA program, patients treated with SLK experienced a clinically meaningful and statistically significant improvement across all primary and key secondary endpoints using both pre-specified strategies ($p<0.001$). In VELA-1, SLK achieved statistical significance for all primary and key secondary endpoints using both pre-specified strategies (HiSCR75, delta to placebo of 17%, $p<0.001$). In VELA-2, intercurrent events in the higher-than-expected placebo arm precluded the study from achieving statistical significance in the week 16 primary endpoint using the composite strategy (HiSCR75, delta to placebo of 9%, $p=0.053$). From week 16, all patients are expected to continue to receive the 120mg dose of SLK through to 48 weeks, with a last assessment planned at week 52, followed by an open-label extension for up to two years. The safety profile of sonelokimab in the VELA trials was consistent with previous trials with no new safety signals detected.

Sonelokimab is currently undergoing evaluation in the VELA-TEEN Phase 3 trial, which is the first clinical study specifically focused on adolescent patients with moderate-to-severe HS.

For PsA, sonelokimab is being assessed in the Phase 3 trials, IZAR-1 and IZAR-2, following the announcement in March 2024 of the full dataset from the global Phase 2 ARGO trial (M1095-PSA-201) evaluating the efficacy and safety of the Nanobody® sonelokimab over 24 weeks in patients with active PsA. Significant improvements were observed across all key outcomes, including approximately 60% of patients treated with sonelokimab achieving an American College of Rheumatology (ACR) 50 response and Minimal Disease Activity (MDA) at week 24. This followed the positive top-line results in November 2023, where the trial met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an ACR50 response compared to those on placebo at week 12. All key secondary endpoints in the trial were met for the 60mg and 120mg doses with induction. The safety profile of sonelokimab in the ARGO trial was consistent with previous trials with no new safety signals detected.

Sonelokimab is also being assessed in the Phase 2 LEDA trial, which is ongoing for PPP, a debilitating inflammatory skin condition affecting a significant number of patients.

Additionally, Sonelokimab is being assessed in the ongoing Phase 2 S-OLARIS and P-OLARIS trials for active axSpA and PsA, respectively. Both trials feature an innovative design complementing traditional clinical outcomes with cellular imaging techniques.

Sonelokimab has also been assessed in a randomized, placebo-controlled third-party Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis. High threshold clinical responses (Investigator's Global Assessment Score 0 or 1, and Psoriasis Area and Severity Index 90/100) were observed in patients with moderate-to-severe plaque-type psoriasis. Sonelokimab generally presented a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

In an earlier third-party Phase 1 trial in patients with moderate-to-severe plaque-type psoriasis, sonelokimab decreased (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 the VELA program
The Phase 3 VELA program has enrolled over 800 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, and placebo-

controlled trials are identical in design evaluating the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in adult patients with active moderate-to-severe hidradenitis suppurativa. Similar to the design of the landmark Phase 2 MIRA trial, the primary endpoint is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response (HiSCR) 75, 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 trials 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 reduction of ≥4, the proportion of patients achieving at least 50% reduction from baseline in Numerical Rating Scale (NRS50) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain) and complete resolution of Draining Tunnels (DT100). The VELA protocols and statistical analysis plans were prepared in accordance with regulatory agency advice and include two analysis strategies. The composite strategy for the VELA trials (also referred to as the primary estimand) is the primary statistical analysis. The protocol specifies the treatment policy strategy as the alternative method of handling intercurrent events to test the robustness of the VELA data. The trials compare a single 120mg dose of sonelokimab to placebo with HiSCR75 reading out at week 16. Results of the week 16 data were announced in September 2025. Further details are available under NCT06411899 and NCT06411379 at www.clinicaltrials.gov.

About the MIRA trial

The MIRA trial (M1095-HS-201) is a global, randomized, double-blind, placebo-controlled Phase 2 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 recruited 234 patients, with the aim to evaluate two different doses of sonelokimab (120mg and 240mg) with placebo control and adalimumab as an active 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 also evaluated 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 under NCT05322473 at www.clinicaltrials.gov.

About the VELA-TEEN trial

The Phase 3 VELA-TEEN trial is an open-label, single-arm trial designed to evaluate sonelokimab 120mg administered subcutaneously once every two weeks (Q2W) until week six and once every four weeks (Q4W) from week eight onwards. The trial aims to enroll 30-35 adolescents, aged 12-17, with moderate-to-severe hidradenitis suppurativa, from U.S. sites experienced in clinical trials and pediatric dermatology. The primary trial phase will be 24 weeks with a primary endpoint evaluating the pharmacokinetics, safety, and tolerability of sonelokimab. VELA-TEEN will also evaluate several secondary endpoints, including the proportion of patients achieving the higher clinical response measure of the Hidradenitis Suppurativa Clinical Response Score (HiSCR) 75, in addition to HiSCR50. Other outcomes are the change from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4), which includes the quantitative measure of draining tunnels, and the proportion of patients achieving a meaningful reduction of the Children's Dermatology Life Quality Index (CDLQI) and the Patients Global Assessment of Skin Pain (PGA Skin Pain). Further details are available under NCT06768671 at www.clinicaltrials.gov.

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 an estimated 2% of the population, with three times more females affected than males. Real-world data in the United States indicates that at least 2 million unique patients have been diagnosed with and treated for HS between 2016 and 2023 alone, highlighting a significant unmet need and impact on healthcare systems, and a market opportunity projected to reach $15bn by 2035. 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.

About the IZAR Program

IZAR-1 (NCT06641076) and IZAR-2 (NCT06641089) are global, randomized, double-blind, placebo-controlled Phase 3 trials designed to evaluate the efficacy and safety of sonelokimab compared with placebo in a total of approximately 1,500 adults with active psoriatic arthritis (PsA), with a primary endpoint of superiority to placebo in American College of Rheumatology (ACR) 50 response at Week 16. IZAR-1 is expected to enroll biologic-naïve patients and include an evaluation of radiographic progression, while IZAR-2 is expected to enroll patients with an inadequate response to tumor necrosis factor-α inhibitors (TNF-IR) — reflecting patients commonly seen in clinical practice — and is the first PsA trial to include a risankizumab active reference arm. Both trials will also assess a range of secondary endpoints reflecting the multiple disease manifestations characteristic of PsA. These include skin and nail outcomes, multidomain outcomes, and patient-reported outcome measures such as pain and quality of life assessments. Further details are available under NCT06641076 and NCT06641089 at www.clinicaltrials.gov.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive and complex inflammatory disease that manifests across multiple domains, leading to substantial functional impairment and decreased quality of life. The clinical features of PsA are diverse, comprising both musculoskeletal (peripheral arthritis, spondylitis, dactylitis, and enthesitis) and non-musculoskeletal (skin and nail disease) domains. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. 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 S-OLARIS trial

S-OLARIS is an open-label Phase 2 proof-of-concept trial aiming to investigate sonelokimab 60mg administered subcutaneously in approximately 25 patients with active axial spondyloarthritis (axSpA). The primary endpoint is the change from baseline (CfB) at week 12 in the uptake of 18F-NaF in the sacroiliac joints and spine using PET in combination with MRI imaging. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes (e.g., ASAS), scores related to physical function, spinal mobility, and enthesitis as well as patient reported outcomes. The trial also includes an exploratory peripheral blood and tissue biomarker program.

About Axial Spondyloarthritis

Axial Spondyloarthritis (axSpA) typically impacts young people, with diagnosis based on chronic inflammatory back pain lasting more than three months with onset under 45 years of age. Advanced disease can lead to progressive and pathologic bone formation and joint fusion, severely limiting spinal mobility. Global reported prevalence of axSpA ranges from 0.5% to 1.5%. AxSpA can be categorized by disease progression into two subtypes:

non-radiographic axSpA and ankylosing spondylitis (AS), also known as radiographic axSpA, which is diagnosed based on radiographic evidence of structural changes to the sacroiliac joints. Patients with axSpA experience fatigue, persistent morning stiffness, and pain that worsens at night and can disrupt sleep. Many patients also face the burden of comorbidities such as psoriatic arthritis and psoriasis. Studies have found elevated IL-17 levels in the blood and synovial fluid of patients with axSpA, and IL-17A and IL-17F are both thought to be key contributors to pathogenesis across the spondyloarthropathies.

About the LEDA Trial
The LEDA trial (M1095-PPP-201) is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 120mg administered subcutaneously in adult patients with palmoplantar pustulosis (PPP). The trial recruited 32 patients. The primary endpoint of the trial is percent change from baseline in Palmoplantar Psoriasis Area and Severity Index (ppPASI) with important secondary endpoints including ppPASI75 (at least 75% improvement in the ppPASI). The LEDA trial features an innovative translational research program using peripheral blood and tissue biomarkers as trial controls.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 MIRA trial in hidradenitis suppurativa, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513305-32-00 at https://euclinicaltrials.eu.

About Palmoplantar Pustulosis
Palmoplantar Pustulosis (PPP) is characterized by the development of blister-like pustules within erythematous, scaly plaques on the palms and the soles of the feet. PPP typically develops in adulthood, more frequently impacts females. Patients frequently experience significant pain, burning, and itching sensations on the palms and soles of the feet which can be debilitating and impair their ability to work, sleep, or perform other activities of daily living. Currently, the treatment of PPP is challenging with a significant unmet need for novel therapies to reduce the symptom burden for patients. Evidence suggests that activation of the IL-17 pathway has an important role in 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: the anticipated timing of clinical trials and timing of the results from those trials, the anticipated timing of filing of a BLA in the United States; outcomes of discussions with regulatory authorities, including whether an application consisting of data from its existing VELA-1, VELA-2 and MIRA trials may establish substantial evidence of effectiveness (SEE) without additional clinical trials in HS; the efficacy and safety of sonelokimab for the treatment of adult HS, adolescent HS, axSpA, PsA and PPP, including in comparison to existing standards or care or other competing therapies, clinical trials and research and development programs; potential market opportunities for sonelokimab; and MoonLake's anticipated cash position. 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, the risk that interim data analyses conducted prior to database lock and based on a limited number of patients having reached the relevant time point are not consistent with final data, risks and uncertainties associated with MoonLake's business in general and limited operating history, difficulty enrolling patients in clinical trials, state and federal healthcare reform measures that could result in reduced demand for MoonLake's product candidates and reliance on third parties to conduct and support its preclinical studies and 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, 2024 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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