MoonLake Announces Week 52 Results of Sonelokimab from its Phase 3 VELA Program in Hidradenitis Suppurativa and Confirms Investor Day on June 22, 2026

June 21, 2026

- *Results from the Phase 3 VELA clinical trials at Week 52 in adults with moderate-to-severe hidradenitis suppurativa (HS) demonstrate sonelokimab's (SLK) potential best-in-class and best-in-disease profile, with consistent responses that are higher than those observed in trials of competing agents at the end of their respective parental trials*
- *Namely, ~67% of patients treated with SLK achieved HiSCR75 at the one-year mark, with more than one quarter of patients achieving inflammatory remission (IHS4-100), and around one third reaching HiSCR100*
- *Patients treated with SLK likewise showed substantial improvement in HiSQOL at Week 52, with a mean score difference between end of trial and baseline of -15.0 points, indicating an average change from "severe" to "mild" impairment of the HS-related quality of life*
- *Almost half of the patients experienced a marked reduction in pain (at least a 3-point improvement from baseline in the worst skin pain Numerical Rating Scale (NRS))*
- *No new safety signals were detected in the VELA trials to date, supporting a consistent safety profile through Week 52*
- *Data from the VELA-TEEN trial in adolescent HS patients show strong therapeutic response and no new safety signals in adolescent patients, with nearly 70% of patients achieving HiSCR75 at Week 24 and almost half of patients reaching HiSCR100*
- *Submission of the Biologics License Application (BLA) for SLK in HS, including data from adolescent patients, is expected at the end of September 2026, and will follow previous agency guidance on the label strategy*
- *An Investor Day webcast will be held on June 22, 2026, 8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET), to discuss these data and provide guidance on upcoming events*

ZUG, Switzerland, June 21, 2026 – MoonLake Immunotherapeutics (NASDAQ: MLTX) (MoonLake or the Company), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced the Week 52 results of the Phase 3 VELA-1 and VELA-2 clinical trials of its registrational global program in patients with moderate-to-severe HS. The Company also announced that it will host an Investor Day webcast on June 22, 2026, 8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET), including an open Q&A session.

Results from the Phase 3 VELA clinical trials at Week 52

Week 52 data for SLK showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with SLK achieved HiSCR75 and 33.1% of patients achieved HiSCR100 at Week 52 (n=396). The results were consistent across both trials (VELA-1: 68.3% HiSCR75, 31.2% HiSCR100; VELA-2: 66.0% HiSCR75, 35.1% HiSCR100). At Week 52, 26.0% of patients (n=396) achieved an IHS4-100 response (VELA-1: 24.4%, VELA-2: 27.7%), reflecting inflammatory remission, defined as a 100% reduction in abscesses (A100), nodules (N100) and draining tunnels (DT100). The long-term results of the VELA program are higher than in previous Phase 3 HS programs with competing agents (using the same pooled, as observed, end of parental trial data analysis). Relative to the competitor IL-17-A & F inhibitor monoclonal antibody, the SLK Nanobody®, for example, showed responses with over ~10% more responding patients for HiSCR75, HiSCR100 or IHS4-100.

The strong long-term clinical responses observed with SLK were accompanied by sustained improvements in Patient-Reported Outcomes, which are considered to matter most to patients living with HS and their treating physicians. Patients treated with SLK consistently showed the largest reductions in the HS-specific Quality of Life score (HiSQOL) at Week 52, with a -15.3 mean score difference between end of trial and baseline in VELA-1, and -14.8 in VELA-2 (as observed, n=395). The broader skin DLQI score confirmed the HiSQOL results and showed clinically meaningful response (≥4-point improvement from baseline) in 75.0% (VELA-1) and 69.4% (VELA-2) of patients (as observed, in patients with baseline DLQI ≥4, n=363). Responses for both these quality of life metrics were higher than previously demonstrated in competitor pivotal HS studies. In line with these data, 46.5% of patients experienced a marked reduction in pain, measured as at least a 3-point reduction from baseline in the worst skin pain NRS (VELA-1: 48.4%, VELA-2: 44.3%; as observed, in patients with baseline worst skin pain score of ≥3, n=241).

These findings demonstrate leading and durable improvements across outcomes of key relevance for patients, including quality of life, pain and long-term disease control.

Responses seen in patients crossing over from placebo (switch to SLK at Week 16) confirm and validate these findings. After 4 Weeks of SLK treatment, HiSCR75 rates increased by ~20 percentage points across both studies. At the end of the VELA program (i.e., after 36 weeks of SLK treatment), cross-over patients ("Placebo-to-SLK") showed HiSCR75 rates similar to those observed after 36 weeks of treatment in the "SLK-to-SLK" arms (~60%, as observed).

The high acceptance rate and good tolerability of SLK across the VELA program was confirmed by the rate of patients rolling over into the VELA-OLE (two-year open-label extension) following the parental trials (~90% across all arms) further validating the convenience of the 120mg Q4W (once every four weeks) dosing regimen.

Interim Week 24 data from the Phase 3 VELA-TEEN trial

Furthermore, data from the VELA-TEEN clinical trial showed rapid onset and high response rates in adolescent patients with HS. Interim analysis of Week 24 data show that ~68% of patients treated with SLK achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, n=22). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. SLK was generally well tolerated in this vulnerable patient population, and no new safety signals were observed. These promising results highlight the relevance and opportunity of an early treatment of HS with the goal to slow down the progression to irreversible tissue damage.

The safety profile of SLK in the VELA clinical programs including VELA-TEEN remains consistent over time, with no new safety signals detected.

Dr. Jorge Santos da Silva, Founder and Chief Executive Officer of MoonLake Immunotherapeutics, said: *"The final Week 52 data from the VELA program confirm the strength of SLK across most, if not all, metrics that matter in HS: strong early efficacy, sustained and leading improvement over time, a consistent safety profile and great convenience in dosing. All this, not just for adult patients but also for adolescent patients. Together with the alignment we have reached with the FDA on our HS label strategy, these data support the potential for a highly differentiated label profile and reinforce our conviction that SLK has the potential to become a best-in-class and best-in-disease therapy for those living with HS."*

Prof. Kristian Reich, Founder and Chief Scientific Officer of MoonLake Immunotherapeutics, added: *"What is particularly compelling in the final Week 52 dataset is how consistently the strong clinical efficacy of SLK is reflected in Patient-Reported Outcomes. The sustained improvements we observed across HiSQOL, pain and broader quality of life measures are highly meaningful in HS, where the burden of disease extends far beyond lesion counts. In our view, these data highlight the potential of SLK to redefine long-term outcomes in HS by delivering durable disease control and meaningful improvements of the daily lives of patients combined with a favourable safety profile."*

Next steps and anticipated BLA submission

MoonLake plans to submit the BLA for HS to the FDA at the end of September 2026. The pre-BLA process is concluded and no more regulatory meetings with the FDA will take place. Clarity on the Prescription Drug User Fee Act (PDUFA) date is currently expected by the end of November 2026, concurrent with the FDA's acceptance of the BLA. The Company plans to submit a request for Priority Review for this BLA based on SLK's potential best-in-class profile as well as its VELA-TEEN adolescent data; the FDA's decision on the Priority Review request would be included in the application's PDUFA date allocation/filing letter. Priority Review remains an upside scenario for MoonLake, subject to FDA resource and capacity considerations. If Priority Review is not granted, MoonLake expects a third or fourth quarter 2027 launch for SLK. Should Priority Review be granted, it is estimated that the time-to-market for SLK may be reduced by approximately one quarter.

Investor Day, June 22, 2026

The Company will hold an Investor Day for investors and analysts on **June 22, 2026**. The webcast will take place from **8:00 – 9:30 a.m. EST (2:00 – 3:30 p.m. CET),** including an open Q&A session. A recording will be made available post-event. **Webcast Access:** https://edge.media-server.com/mmc/p/ke4wbinp

In this session, MoonLake's CEO, Jorge Santos da Silva, CSO, Kristian Reich, and CFO, Matthias Bodenstedt, will present the final Week 52 data from the Phase 3 VELA program in HS and provide an update on the VELA-TEEN clinical trial in adolescent HS, a recap of the proposed label, the Company's view on its commercialization plan, as well as an outlook on H2 2026 events, including the readout of IZAR-1 Phase 3 trial in psoriatic arthritis (PsA).

Important upcoming anticipated milestones for MoonLake:

- Mid 2026: Primary endpoint readout of the Phase 3 IZAR-1 trial in PsA
- Late Sep. 2026: Submission of a BLA for HS
- Late Nov. 2026: Expected PDUFA date allocation for HS BLA
- H2 2026: Primary endpoint readout of the Phase 3 IZAR-2 trial in PsA
- H2 2026: Interim readout of the Phase 2 P-OLARIS trial in PsA and axSpA

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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%, $p=0.053$). In June 2026, Week 52 Results of SLK from the VELA-1 and VELA-2 clinical trials were announced. Week 52 data for SLK showed consistent and further improvement in all clinical scores, compared to Week 16 data. Across both VELA-1 and VELA-2, 67.2% of patients treated with SLK achieved HiSCR75 and 33.1% of patients achieved HiSCR100 at Week 52 (as observed, n=396). 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. In June 2026, interim Week 24 data from the Phase 3 VELA-TEEN trial were announced. Interim analysis of Week 24 data show that ~68% of patients treated with SLK achieved HiSCR75, alongside ~86% achieving HiSCR50 and ~45% achieving HiSCR100 (as observed, n=22). HiSCR75 rates in VELA-TEEN were higher than those observed in the adult VELA program at comparable timepoints, indicating a pronounced clinical response in adolescent patients with earlier stage disease. SLK was generally well tolerated in this vulnerable patient population, and no new safety signals were observed.

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 PPP, a debilitating inflammatory skin condition affecting a significant number of patients, including in the completed Phase 2 LEDA program. In the Phase 2 LEDA clinical trial in PPP, SLK demonstrated clinically meaningful and statistically significant benefit. Patients treated with SLK achieved a mean percent change from baseline in the Palmoplantar Pustular Psoriasis Area and Severity Index (PPPASI) of 64% at Week 16, and 39% of patients achieved a ≥75% reduction in the PPPASI (PPPASI75), suggesting that SLK could provide clinically meaningful improvements in this disease for which there are currently no approved therapies. The safety profile of SLK in the LEDA trial was consistent with previous trials with no new safety signals detected.

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 recruited a total of 838 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. Results of the Week 52 data were announced in June 2026. Further details are available under NCT06411899 and NCT06411379 at www.clinicaltrials.gov.

About the MIRA trial

The MIRA trial 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 enrolled 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 (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 Patient's Global Assessment of Skin Pain (PGA Skin Pain). Results of the interim Week 24 data were announced in June 2026. 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 indicate 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 and IZAR-2 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 http://www.clinicaltrials.gov.

About the P-OLARIS trial

The P-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60mg administered subcutaneously in adult patients with active psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) with a focus on characterizing how sonelokimab affects markers of inflammation and tissue damage within joints. The trial aims to recruit approximately 20 patients with PsA and 10 patients with axSpA. The primary endpoint is the change in disease activity at Week 12, as measured by [68Ga]-fibroblast activation protein inhibitor (FAPI)-tracer uptake (SUVmax) on FAPI-positron emission tomography (PET)/low-dose computed tomography (CT) scans, a novel imaging modality able to detect inflammation and early tissue damage within joints. Throughout the trial, several other endpoints will be assessed including established clinical disease activity outcomes, as well as patient reported outcomes that assess the impact of disease signs and symptoms. The trial also features an innovative exploratory peripheral blood and tissue biomarker program.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in PsA as well as the Phase 2 S-OLARIS trial in axSpA which demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-514504-13-00 at https://euclinicaltrials.eu.

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

The S-OLARIS trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 60mg administered subcutaneously in adult patients with active axial spondyloarthritis (axSpA). The trial recruited 26 patients. The primary endpoint is the change from baseline (CfB) in 18F-NaF SUVmax signals at Week 12 in the sacroiliac joints and spine as detected by PET. 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 features an innovative exploratory peripheral blood and tissue biomarker program.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 ARGO trial in psoriatic arthritis, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively. Further details are available under EUCT number 2024-513498-36-00 at https://euclinicaltrials.eu.

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 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 and 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 efficacy and safety of sonelokimab for the treatment of moderate-to-severe HS; the anticipated interactions with regulatory authorities, including the FDA, and the anticipated BLA-submission, PDUFA date and request for Priority Review; the proposed label and labeling discussions with the FDA for sonelokimab in HS, including potential inclusion of clinical data from the MIRA trial; potential market opportunities for sonelokimab; upcoming anticipated clinical milestones, including the primary endpoint readouts of the Phase 3 IZAR-1 trial in PsA and Phase 3 IZAR-2 trial in PsA, interim endpoint readout of the Phase 2 P-OLARIS trial in PsA and axSPA and submission of a BLA for HS; the FDA's decision on Priority Review designation; and timing of first commercial launch in the United States. 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; state and federal healthcare reform measures that could result in reduced demand for MoonLake's product candidates; 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, 2025, Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, 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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