MoonLake Immunotherapeutics reports on week 16 results of the VELA Phase 3 hidradenitis suppurativa program with the Nanobody® sonelokimab

- *VELA-1 and VELA-2 are two identical trials to evaluate the efficacy and safety of sonelokimab in adult participants with moderate to severe hidradenitis suppurativa (HS) and the first Phase 3 program using the higher clinical response level of HS Clinical Response (HiSCR) 75 as primary endpoint at week 16*
- *Data was analyzed, as per protocol and in accordance with regulatory agency feedback, using a composite strategy as the primary analysis and a treatment policy strategy to test the robustness of the results: difference between the two methods relates to the statistical handling of intercurrent events*
- *In the combined VELA program, patients treated with sonelokimab 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, sonelokimab 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%, $p=0.053$)*
- *The pre-specified treatment policy strategy provides for the analysis of data irrespective of intercurrent events; using this analysis, a statistically significant HiSCR75 at week 16 in VELA-1 and VELA-2 was achieved with sonelokimab (35% and 36%, respectively) vs placebo (18% and 26%, respectively); clinically meaningful and statistically significant benefit was also observed for all key secondary endpoints (Table 2)*
- *Sonelokimab continued to show a favourable safety profile with no new safety signals detected, including an absence of key events of interest such as suicidal ideation and behavior*
- *VELA progresses to its pre-specified week 52 readout and the Company will now seek to confirm the path to registration in HS with the appropriate regulatory authorities*
- *Other clinical studies with sonelokimab, including the Phase 3 VELA-TEEN trial in adolescent HS, the Phase 3 IZAR program and the Phase 2 P-OLARIS trial in psoriatic arthritis (PsA), the Phase 2 LEDA trial in palmoplantar pustulosis (PPP), and the Phase 2 S-OLARIS trial in axial spondyloarthritis (*axSpA*), continue as planned and are expected to support a catalyst-rich roadmap*
- *The Company will hold a webcast on Monday, September 29 at 2pm CET / 8am EDT (link below)*

ZUG, Switzerland, September 28, 2025 – MoonLake Immunotherapeutics (NASDAQ: MLTX) ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced the week 16 results of the Phase 3 VELA-1 and VELA-2 trials of its registrational global program in patients with moderate-to-severe hidradenitis suppurativa (HS).

The VELA program used 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. Key secondary endpoints included the percentage of participants achieving HiSCR50 and the percentage of patients achieving a Dermatology Quality of Life Index (DLQI) total score reduction of $\geq$4 (minimal clinically important difference), among participants with a baseline DLQI $\geq$4, as well as other scores that reflect the evolving needs of HS patients, treating physicians and regulators. These included the percentage of participants achieving at least a 55% reduction in the International HS Severity Scoring System (IHS4-55), the percentage of participants achieving at least a 3 point improvement from baseline in the worst pain Numerical Rating Scale (NRS) among participants with a baseline score of at least 3 points, and the change from baseline in the HS-specific Quality of Life score (HiSQOL). A total of 838 patients were enrolled across both trials. The trials were identical in design comparing a single 120mg dose of sonelokimab to placebo with

HiSCR75 reading out at week 16. From week 16, all patients receive the 120mg dose of sonelokimab through to 48 weeks, with a last assessment at week 52, followed by an open-label extension for up to two years. The Phase 3 program used a protocol design consistent with the Phase 2 MIRA trial, which identified the optimal dose of sonelokimab for HS. 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 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. Data in this press release is presented using the aforementioned analysis strategies, as indicated throughout. The baseline characteristics for VELA-1 and VELA-2 are shown in Table 1.

TABLE 1

Baseline Characteristics	**Trials**			
	VELA 1		**VELA 2**	
	Placebo (n=138)	SLK (n=283)	Placebo (n=141)	SLK (n=276)
Age [years], mean	36.1	37.2	38.0	37.2
Female, %	62.3	61.5	49.6	53.6
Race, %				
White	76.1	77.7	85.1	81.5
Black or African American	15.2	12.0	10.6	9.4
BMI, mean	33.6	33.5	32.7	33.0
Current smoker, %	41.3	43.8	56.0	51.8
Hurley Stage, %				
II	63.8	64.0	67.4	63.0
III	36.2	36.0	32.6	37.0
Years since diagnosis, mean	8.4	8.1	7.7	7.5
Lesions, mean				
AN count	13.3	13.5	13.8	14.5
DT count	2.8	3.2	3.5	3.9
DLQI Total, mean	11.8	11.7	11.3	12.6
HiSQOL Total, mean	27.6	26.5	23.8	28.0
Patient Global Assessment of Skin Pain NRS, mean	4.9	4.7	5.0	4.9
Prior biologic use, %	15.9	15.5	22.0	19.6
Concomitant antibiotics, %	8.7	6.7	7.8	10.5

In the combined Phase 3 VELA program, all endpoints reached statistical significance with p-values below 0.001, including lesion counts and patient reported outcomes (PROs), as per Table 2. Sonelokimab demonstrated the expected profile of response over time, with statistically significant HiSCR75 for both studies achieved as early as week 4 (Table 3). A preliminary analysis suggests that responses continue to improve beyond week 16 and that placebo patients crossing over at week 16 achieve similar responses to those originally randomized to the sonelokimab 120mg arm, as of week 20 (pre-specified analysis, data not shown).

Using the treatment policy strategy as per protocol, both VELA-1 and VELA-2 showed a statistically significant increase in the percentage of participants achieving HiSCR75 at week 16 and provided a clinically meaningful benefit (Table 2). Response rates for sonelokimab 120mg were consistent between the two trials, with 34.8% and 35.9% of patients in VELA-1 and VELA-2 achieving HiSCR75 at week 16, respectively. The placebo response rate in VELA-1 of 17.5% at week 16 was within the historical Phase 3 range of 13% to 18%. The placebo response rate in VELA-2 of 25.6% at week 16 was higher than expected.

Both VELA-1 and VELA-2 achieved statistical significance for all key secondary endpoints (Table 2). This includes other lesion count based endpoints (HiSCR50 and IHS4-55). It also includes relevant PROs in HS. Around 30% of patients experienced a marked reduction of pain, as measured by an at least 3-point improvement in the worst pain

NRS, in both VELA-1 and VELA-2 (p≤0.002). Sonelokimab showed a significant improvement of HiSQOL score at week 16 (p<0.001), which was consistent between VELA-1 and VELA-2. Almost 60% of patients achieved a meaningful (4 points or more) improvement of DLQI, an approximately 20 percentage-point benefit over placebo (p≤0.001).

Overall, the week 16 endpoint results using the treatment policy strategy were as follows:

TABLE 2

Endpoint			Trial								
Class	**Type**	**Score**	**VELA combined**			**VELA-1**			**VELA-2**		
			Placebo (n=279)	SLK 120mg (n=559)	p-value	Placebo (n=138)	SLK 120mg (n=283)	p-value	Placebo (n=141)	SLK 120mg (n=276)	p-value
Primary	Lesion count	HiSCR75 (%)	21.6	35.4	<0.001	17.5	34.8	<0.001	25.6	35.9	0.033
Key secondary		HiSCR50 (%)	36.7	55.1	<0.001	30.3	51.6	<0.001	43.0	58.7	0.003
		IHS4-55 (%)	39.4	55.7	<0.001	34.2	54.4	<0.001	44.7	56.9	0.021
	Patient-reported outcome (PRO)	Pain NRS 3pt (%)	13.9	29.1	<0.001	12.7	28.4	0.001	14.9	29.8	0.002
		HiSQOL (CFB)	-3.5	-9.1	<0.001	-3.8	-9.4	<0.001	-3.5	-9.0	<0.001
		DLQI (MCID, %)	38.3	58.6	<0.001	37.8	59.0	<0.001	39.0	58.1	0.001

Note 1: ITT, pre-specified treatment policy strategy
Note 2: Across the VELA program all deltas to placebo vary between treatment policy and composite strategy by less than 1.5 percentage points (HiSQOL varies by less than 0.5 points)
Note 3: For VELA-1 and VELA-2, using composite strategy, all primary and key secondary endpoints achieved p<0.025 except for VELA-2 primary endpoint (HiSCR75, p=0.053); control for multiple testing was only performed within the composite strategy testing for VELA-1 and VELA-2 individually. Statistical significance refers to analyses where p<0.05, in both multiplicity and non-multiplicity controlled strategies
Note 4: "Pain NRS 3pt " refers to Worst Pain NRS reduction of at least 3 points; "CFB" refers to mean change from baseline; "MCID" refers to minimally clinically important difference which reflects a reduction of at least 4 points in the score

The percentage of participants achieving HS Clinical Response (HiSCR) 75 at different timepoints was as follows:

TABLE 3

Trial	Arm	Time (weeks)					
		0	**2**	**4**	**8**	**12**	**16**
VELA combined	Placebo (n=279)	0	6.1	7.1	17.1	17.8	21.6
	SLK 120mg (n=559)	0	8.8	19.2	30.3	35.8	35.4
	Delta	*0*	*2.7*	*12.1*	*13.1*	*18.0*	*13.8*
	p-value		*0.157*	*<0.001*	*<0.001*	*<0.001*	*<0.001*
VELA-1	Placebo (n=138)	0	7.3	6.5	14.1	15.8	17.5
	SLK 120mg (n=283)	0	8.9	20.5	29.5	33.8	34.8
	Delta	*0*	*1.6*	*14.0*	*15.4*	*18.0*	*17.3*
	p-value		*0.570*	*<0.001*	*<0.001*	*<0.001*	*<0.001*
VELA-2	Placebo (n=141)	0	5.0	7.6	20.1	19.8	25.6
	SLK 120mg (n=276)	0	8.6	18.0	31.1	37.9	35.9
	Delta	*0*	*3.7*	*10.4*	*11.1*	*18.1*	*10.3*
	p-value		*0.145*	*0.002*	*0.011*	*<0.001*	*0.033*

Note 1: ITT, pre-specified treatment policy strategy (time points other than week 16 were pre-specified Other secondary endpoints)
Note 2: Multiplicity control was only applied for testing of the primary and key secondary endpoints at week 16 by composite strategy in VELA-1 and VELA-2 individually. Statistical significance refers to analyses where p<0.05, in both multiplicity and non-multiplicity controlled strategies

The safety profile of sonelokimab was consistent with previously reported studies with no new safety signals observed. This includes the absence of new signals in key events of interest with IL-17A and F therapies: Suicidal

Ideation and Behavior, hepatic events, IBD and non-infectious diarrhea, MACE and Eczema and Dermatitis (Table 4).

TABLE 4

Participants with event, n (%)	Placebo (n=279)	Sonelokimab 120 mg (n=559)
Any TEAE	155 (55.6)	376 (67.3)
Any serious TEAE	5 (1.8)	14 (2.5)
Any TEAE leading to treatment discontinuation	4 (1.4)	16 (2.9)
Most frequent TEAEs[1]		
Nasopharyngitis	28 (10.0)	48 (8.6)
Headache	14 (5.0)	27 (4.8)
Upper respiratory tract infection	21 (7.5)	24 (4.3)
Safety topics of interest		
IBD[2]	0	0
Diarrhea (non-infectious)[3]	1 (0.4)	2 (0.4)
Oral candidiasis[4]	1 (0.4)	41 (7.3)
Serious hypersensitivity	0	0
Dermatitis & Eczema[5]	7 (2.5)	20 (3.6)
Serious infections	2(0.7)	4 (0.7)
SI/B[6]	0	0
Hepatic events[7]	3 (1.1)	1 (0.2)
MACE[8]	0	0

1 Most frequent TEAEs excluding safety topics of interest (as presented separately in this table) and one TEAEs to maintain blinding of the ongoing VELA studies 2 AESI, events in adjudication; 3 AESI; 4 there were three cases of oesophageal candida and two cases of oropharyngeal candida on SLK; 5 PTs eczema and dermatitis; 6 Reported adverse events, 7 Hepatic events (all hepatic AEs and laboratory investigations in adjudication to possible DILI); 8 Events in adjudication

Overall, the Company believes that sonelokimab continues to show a favorable safety profile, with no new safety signals detected and a competitive outlook. The VELA program is conducted using a convenient sub-cutaneous dosing scheme with 1ml volume delivered every other week to week 6 in the induction phase (4 injections), and monthly from week 8 for maintenance, with no up-titration. This profile is matched by improvements of HS lesions, including draining tunnels, as well as in all key Patient Reported Outcomes (PROs), such as quality-of-life and pain scores, that are meaningful for HS patients and their treating physicians.

Prof. Kristian Reich, Founder and Chief Scientific Officer at MoonLake, commented: ***"****We are encouraged by the results of VELA-1, which follow the expected performance of sonelokimab in all the important metrics for patients and treating physicians. The higher-than-expected placebo response rate in VELA-2 is disappointing but we are encouraged by the consistent performance of sonelokimab arms across all endpoints in both studies. We are pleased to see a favorable safety profile consistent with previous studies, with no new safety signals. We believe that this, together with the convenient dosing, the efficacy data in the lesion-based metrics and the patient reported outcomes, shows the potential for a promising profile of sonelokimab in HS. Patients with HS are in desperate need of new treatment options and we remain committed to our path forward in HS."*

These interim results will now be discussed with the appropriate regulators, including the analytical strategies considering the higher-than-expected placebo response rate in VELA-2 at week 16 and path to submission of a Biologics License Application.

The Company continues to progress with the development of its Nanobody® sonelokimab across a portfolio of indications, including:

- Q4 2025: Primary endpoint readout of the Phase 2 LEDA trial in PPP
- 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
- H1 2026: Primary endpoint readout of Phase 3 VELA-TEEN trial in adolescent HS
- H1 2026: Primary endpoint readout of Phase 3 IZAR program in PsA

The Company will hold a webcast on Monday 29th of September at 2pm CET / 8am EDT. Link to the webcast, a replay of it and the presentation document will be made available at https://ir.moonlaketx.com.

Sonelokimab is not yet approved for use in any indication.

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

About Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three variable regions of heavy-chain-only antibodies domains (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 suppurative (HS) and psoriatic arthritis (PsA), and the Company is pursuing other indications in dermatology and rheumatology, including adolescent HS, palmo-plantar pustulosis (PPP) and axial spondyloarthritis (axSpA).

For adults with HS, sonelokimab is being assessed in the Phase 3 trials, VELA-1 and VELA-2, following the successful outcome of MoonLake's end-of-Phase 2 interactions with the FDA and as well as positive feedback from its interactions with the EMA announced in February 2024. 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 high threshold clinical and patient relevant outcomes. The safety profile of sonelokimab in the MIRA trial 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 trial for active axSpA. The trial features 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 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 third-party 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 the VELA program

The Phase 3 VELA program has enrolled over 800 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, 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 will 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. Data in this press release is presented using the aforementioned analysis strategies, as indicated throughout. Further details are available under NCT06411379 and NCT06411899 at 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 30-40 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 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 US 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 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 spondylarthritis (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 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 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.

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: trial design, plans for and timing of clinical trials; whether the regulatory agencies agree that the two statistical strategies, when reviewed together, provide substantial evidence of efficacy in the VELA program, recognizing that under the composite strategy, VELA-2 failed to show a statistically significant improvement over placebo at week 16 on the primary endpoint; enrollment for clinical trials, including the VELA-TEEN trial and the IZAR program; the efficacy and safety of sonelokimab for the treatment of adult HS, adolescent HS, PPP, PsA and axSpA, including in comparison to existing standards or care or other competing therapies, clinical trials and research and development programs; the anticipated timing of the results from those studies and trials, and 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 in the VELA trials are not consistent with the final 52-week 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 most recent Annual Report on Form 10-K 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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