MoonLake Immunotherapeutics Reports First Quarter 2025 Financial Results and Provides a Business Update

May 12, 2025

MoonLake Immunotherapeutics Reports First Quarter 2025 Financial Results and Provides a Business Update

- *Continued to make significant progress with the development of the Nanobody® sonelokimab across portfolio of indications, including Phase 3 studies in hidradenitis suppurativa (HS), psoriatic Arthritis (PsA) and adolescent HS, as well as Phase 2 studies in palmoplantar pustulosis (PPP) and axial spondyloarthritis (axSpA)*
- *Announced completion of enrollment of patients in the Phase 3 program in HS (the VELA program) and disclosed baseline characteristics, replicating the Phase 2 MIRA trial*
- *Presented an interim readout of the Phase 2 LEDA study in PPP, highlighting the potential of sonelokimab in an indication with currently no approved therapeutics in the US and Europe, and further derisking the overall development of sonelokimab*
- *Ended the first quarter with $480.1 million in cash, cash equivalents and short-term marketable debt securities and announced closing of a debt facility, providing up to $500 million in non-dilutive funds and extending expected cash runway into 2028*

ZUG, Switzerland, May 12, 2025 – MoonLake Immunotherapeutics (NASDAQ:MLTX) ("MoonLake" or the "Company"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced its financial results for the first quarter of 2025.

Matthias Bodenstedt, Chief Financial Officer of MoonLake Immunotherapeutics, said: *"We continue executing across our portfolio of indications with quality, speed and efficiency. Having enrolled our Phase 3 VELA program with a patient population that mirrors our Phase 2 MIRA trial further increases our confidence in the primary endpoint data which we expect to present around September 2025. The interim readout in PPP opens up another potential blockbuster indication in dermatology with a significant unmet need, and also our trials in rheumatology are progressing well. The non-dilutive facility with Hercules Capital of up to $500 million in committed capital adds to our already strong balance sheet and extends our projected cash runway into 2028, which is expected to provide us with protection from a currently volatile market and retain value for existing shareholders."*

Q1 highlights (including post-period end):

- Initiated three new trials in the beginning of 2025 with the Nanobody® sonelokimab: Phase 3 VELA-TEEN trial in adolescent HS, Phase 2 LEDA trial in PPP and Phase 2 S-OLARIS trial in axSpA.
- Announced up to $500 million non-dilutive financing agreement with Hercules Capital Inc. (NYSE:HTGC), a leader in customized debt financing for companies in the life sciences and technology-related markets, for up to $500 million in non-dilutive capital, of which $75 million was drawn down at close and additional tranches will become available upon achievement of certain pre-specified milestones that are aligned with MoonLake's strategy and funding needs.
- Held an in-person and virtual Capital Markets Update in New York on Tuesday, April 29, 2025 where we:
  - Confirmed the baseline characteristics of the VELA program with the Nanobody® sonelokimab in HS and its comparability to Phase 2 MIRA and other competitor trials following the conclusion of patient recruitment and provided narrowed guidance with respect to the timing of the primary endpoint readout
  - Announced an earlier-than-expected interim readout of the LEDA study, highlighting the potential of sonelokimab in the evolving PPP market and further derisking the overall development of the asset

First quarter 2025 financial results

As of March 31, 2025, MoonLake held cash, cash equivalents and short-term marketable debt securities of $480.1 million. Research and development expenses for the quarter ended March 31, 2025, were $36.5 million, similar to the $40.4 million in the previous quarter. General and administrative expenses for the quarter ended March 31, 2025 were $11.0 million, compared to the $9.2 million incurred in the previous quarter. The increase was primarily due to personnel-related costs to support organizational growth and legal and advisory fees incurred to negotiate the non-dilutive debt facility.

Important upcoming anticipated milestones for MoonLake:

- Initiation of Phase 2 P-OLARIS trial of Nanobody® sonelokimab in PsA and axSpA (mid 2025)
- Top line results for Phase 3 VELA program for the Nanobody® sonelokimab in HS (around September 2025)
- Primary end point readout from the Phase 2 LEDA trial, the first clinical trial in PPP for an IL-17A and IL-17F inhibitor (2H 2025)

Upcoming investor and medical conferences:

- Jefferies Global Healthcare Conference, June 3-5, New York
- Goldman Sachs Annual Global Healthcare Conference, June 10-13, Miami
- EULAR 2025 (European Congress of Rheumatology), June 11-14, Barcelona
- Leerink Partners Therapeutics Forum, July 8-9, Boston
- GRAPPA Annual Meeting, July, 10-12, Bogotá, Colombia

-Ends-

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.

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 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 is expected to enroll 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 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). 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, including initiation of the Phase 2 P-OLARIS trial; 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, including timing of topline results from the Phase 3 VELA program and primary endpoint readout from the Phase 2 LEDA trial; 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, 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, the impact of general economic, health, industrial or political conditions in the United States or internationally, including recently announced tariffs and potential additional tariffs, FDA and comparable foreign regulatory authorities changes in leadership or policies or issuing additional regulations or revising existing regulations, 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, including MoonLake's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025.

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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MOONLAKE IMMUNOTHERAPEUTICS

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	**March 31, 2025 (Unaudited)**	**December 31, 2024**
Current assets		
Cash and cash equivalents	$ 271,566	$ 180,426
Short-term marketable debt securities	208,564	267,601
Other receivables	2,988	2,844
Prepaid expenses	23,146	23,418
Total current assets	**506,264**	**474,289**
Non-current assets		
Operating lease right-of-use assets	2,589	2,922
Property and equipment, net	711	722
Other non-current assets	1,698	—
Total non-current assets	**4,998**	**3,644**
Total assets	**$ 511,262**	**$ 477,933**
Current liabilities		
Trade and other payables	$ 12,006	$ 8,992

Accrued expenses and other current liabilities	10,543	12,099
Short-term portion of operating lease liabilities	1,432	1,372
Total current liabilities	**23,981**	**22,463**
Non-current liabilities		
Long-term debt	73,022	—
Long-term portion of operating lease liabilities	1,142	1,458
Pension liability	536	621
Total non-current liabilities	**74,700**	**2,079**
Total liabilities	**98,681**	**24,542**
Commitments and contingencies (Note 16)		
Equity		
Class A Ordinary Shares: $0.0001 par value per share; 500,000,000 shares authorized; 63,474,253 shares issued and outstanding as of March 31, 2025; 63,077,431 shares issued and outstanding as of December 31, 2024	6	6
Class C Ordinary Shares: $0.0001 par value per share; 100,000,000 shares authorized; 729,320 shares issued and outstanding as of March 31, 2025; 841,269 shares issued and outstanding as of December 31, 2024	—	—
Additional paid-in capital	680,664	677,415
Accumulated deficit	(275,537)	(235,593)
Accumulated other comprehensive income	2,387	4,997
Total shareholders' equity	**407,520**	**446,825**
Noncontrolling interests	5,061	6,566
Total equity	**412,581**	**453,391**
Total liabilities and equity	**$ 511,262**	**$ 477,933**

MOONLAKE IMMUNOTHERAPEUTICS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
(in thousands, except share and per share data)	**2025**	**2024**
Operating expenses		
Research and development	$ (36,459)	$ (13,014)
General and administrative	(11,026)	(6,806)
Total operating expenses	**(47,485)**	**(19,820)**
Operating loss	**(47,485)**	**(19,820)**
Interest expense	(18)	–
Other income, net	7,097	5,915
Loss before income tax	**(40,406)**	**(13,905)**
Income tax expense	(153)	(70)
Net loss	**$ (40,559)**	**$ (13,975)**
Of which: net loss attributable to controlling interests shareholders	*(39,944)*	*(13,673)*
Of which: net loss attributable to noncontrolling interests shareholders	*(615)*	*(302)*
Net unrealized gain (loss) on marketable securities and short-term investments	(2,756)	182
Actuarial income on employee benefit plans	95	81
Other comprehensive income (loss)	(2,661)	263
Comprehensive loss	**$ (43,220)**	**$ (13,712)**
Comprehensive loss attributable to controlling interests shareholders	*(42,564)*	*(13,416)*
Comprehensive loss attributable to noncontrolling interests	*(656)*	*(296)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	63,233,788	62,637,212
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.63)**	**$ (0.22)**