MoonLake Immunotherapeutics Reports Third Quarter 2024 Financial Results and Provides a Business Update

November 7, 2024

MoonLake Immunotherapeutics Reports Third Quarter 2024 Financial Results and Provides a Business Update

- *Ended the third quarter with $493.9 million in cash, cash equivalents and short-term marketable debt securities, expected to support a roadmap rich in potential catalysts and a cash runway to the end of 2026*
- *Strong market performance of other IL-17 inhibitors in hidradenitis suppurativa (HS) and other inflammatory indications validating large market opportunity for sonelokimab*
- *Phase 3 clinical program in HS is progressing as per plan with primary endpoint readout anticipated as of mid-2025*
- *Preparations for Phase 3 clinical program in psoriatic arthritis (PsA) completed with patient enrollment expected to commence imminently*
- *Additional Phase 2 programs, including trials in palmoplantar pustulosis (PPP) and axial spondyloarthritis (axSpA), and Phase 3 trial in adolescent HS, on track to commence around year-end*

ZUG, Switzerland, November 7, 2024 – 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 third quarter of 2024.

During this period, MoonLake has made significant progress with the clinical development of its Nanobody® sonelokimab, which targets IL-17A and IL-17F dimers and are heavily implicated in the pathology of several Type 3 dermatological and rheumatological inflammatory conditions.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"MoonLake continued to make good clinical progress with sonelokimab in the third quarter across several large dermatology and rheumatology indications, with multiple Phase 3 and Phase 2 trials either underway or starting soon. The strong clinical data that we continue to build on suggests that the ability to inhibit all IL-17A and IL-17F containing dimers, together with the molecular advantages of our Nanobody®, translate into higher clinical responses for patients, and provide ample opportunity for differentiation of sonelokimab versus all competitors. We look forward to 2025 with multiple data catalysts, including the expected primary readout of our Phase 3 VELA program in HS as of mid-year."*

Q3 highlights:

- Phase 3 HS program progressing well: clinical study sites across North America and Europe are actively enrolling patients into the identical VELA-1 and VELA-2 studies, to enable the anticipated primary endpoint readout as of mid-2025
- Preparations for the Phase 3 PsA program completed: imminent enrollment of first patients into the IZAR-1 study for bio-naïve* patients and into the IZAR-2 study for TNF-IR** patients, the first study including an IL-23 inhibitor as an active reference arm
- Preparation for first ever dedicated clinical trial in adolescent HS on track: Phase 3 VELA TEEN clinical trial scheduled to commence around year-end
- Preparations for three additional Phase 2 trials advancing well: the LEDA trial in PPP and the S-OLARIS trial in axSpA anticipated to start around year-end, and the P-OLARIS trial in patients with seronegative spondylarthritis scheduled to start in early 2025
- Strong commercial performance of other IL-17 inhibitors in both HS and other inflammatory indications continues to outperform "street" expectations, leading to greater awareness and diagnosis, driving market growth and further validating the significant commercial opportunity for sonelokimab with its highly differentiated molecular characteristics (small Nanobody® size and both IL17A and IL-17F dimer binding) and potentially best in class clinical data to date

* Patients without previous exposure to biologics

** Patients with an inadequate response to TNF inhibitors

Third quarter 2024 financial results

As of September 30, 2024, MoonLake held cash, cash equivalents and short-term marketable debt securities of $493.9 million. Research and development expenses for the quarter ended September 30, 2024, were $35.7 million, compared to $23.7 million in the previous quarter. The increase was primarily due to expenses pertaining to the ramp-up of the Phase 3 VELA program in HS and to prepare for the start of the new clinical trials in PsA, PPP and axSpA. General and administrative expenses for the quarter ended September 30, 2024 were $7.4 million, compared to the $6.9 million incurred in the previous quarter. The increase was primarily due to personnel-related costs to support organizational growth.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *"MoonLake delivered a solid financial performance in Q3, with a strong cash position to at least the end of 2026. We continue to maintain a tight control of costs with a laser focus on value and delivery of our core company goals. We are incredibly fortunate to be custodians of sonelokimab which, as a pipeline-in-a-product across multiple large indications, could be worth over $8bn in sales by 2035 across the indications we are currently targeting. To optimally capture this opportunity, we continue to invest into our large clinical development programs (enrolling over 2,500 patients globally) whilst ramping up preparations for regulatory filings, and other pre-commercial activities."*

Upcoming investor and medical conferences:

- American College of Rheumatology (ACR) Conference, November 14-19 Washington DC, US
- Jefferies London Healthcare Conference, November 19-21, 2024, London, UK
- Citi's 19 th Annual BioPharma Conference, December 3-5, Miami, US
- JP Morgan Annual Healthcare Conference, January 13-16, San Francisco, US
- 14th Conference of the European Hidradenitis Suppurativa Foundation e.V., Vilnius, Lithuania, February 12-14
- American Academy of Dermatology 2025 Annual Meeting, 7-11 March, Orlando, Florida

-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 IL17F/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 Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

Sonelokimab is being assessed in two lead indications, HS and PSA, and MoonLake is pursuing other indications in dermatology and rheumatology.

For 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.

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 up to 61% 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 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.

A Phase 2 trial is expected to be initiated in 2024 for palmo-plantar pustulosis (PPP), a debilitating inflammatory skin condition affecting a significant number of patients. In addition, in 2024, a Phase 3 trial is expected to be initiated in adolescent HS, a condition that typically manifests at this early stage of a patient's life, and the period in which irreversible damage and inflammatory remission is most critical.

Sonelokimab also is also planned to be assessed for seronegative spondyloarthritis with a Phase 2 trial in radiographic and non-radiographic axial spondyloarthritis (axSpA) expected to start by end of 2024, and a Phase 2 trial in axSpA with PsA in 2025. The trials are expected to feature an innovative design complementing traditional clinical outcomes with modern 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 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 the VELA program

The VELA program is expected to enroll 800 patients across two similarly designed Phase 3 trials (VELA-1 and VELA-2) with the aim to evaluate 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 of the program 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 will also evaluate a number of secondary endpoints, including the proportion of patients achieving Hidradenitis Suppurative Clinical Response (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 NCT06411379 and NCT06411899 at www.clinicaltrials.gov.

About IZAR

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 PsA, with a primary endpoint of superiority to placebo in ACR 50 response at Week 16. IZAR-1 will enroll biologic-naïve patients and include an evaluation of radiographic progression, while IZAR-2 will enroll patients with an inadequate response to tumor necrosis factor-α inhibitors (TNF-IR) — reflecting patients commonly seen in clinical practice — and will be 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.

About Hidradenitis Suppurativa

Hidradenitis suppurativa 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 0.05–4.1% of the global 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 exceeding $10bn 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-17-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

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.

Cautionary Statement Regarding Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding MoonLake's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for and timing of clinical trials, including initiation of Phase 3 VELA TEEN trial of sonelokimab in adolescents with HS, commencement of clinical trials of sonelokimab in PPP, axSpA and seronegative spondylarthritis, topline results of the Phase 3 VELA program of sonelokimab in HS and enrollment of first patents into Phase 3 IZAR-1 and IZAR-2 trials, the efficacy and safety of sonelokimab for the treatment of HS, PsA, PPP, axSpA and seronegative spondylarthritis, including in comparison to existing standards or care or other competing therapies, clinical trials and research and development programs and the anticipated timing of the results from those studies and trials, potential market opportunities for sonelokimab and our anticipated cash usage and the period of time we anticipate such cash to be available. 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 and reliance on third parties to conduct and support its preclinical studies and clinical trials and the other risks described in or incorporated by reference into MoonLake's Annual Report on Form 10-K for the year ended December 31, 2023 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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MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	September 30, 2024 (Unaudited)	December 31.2023
Current assets		
Cash and cash equivalents	$ 375,656,291	$ 451,169,337
Short-term marketable debt securities	118,268,400	59,838,900
Other receivables	2,407,062	1,056,862
Prepaid expenses - current	15,984,425	2,102,203
Total current assets	**512,316,178**	**514,167,302**
Non-current assets		
Operating lease right-of-use assets	3,251,197	3,628,480
Property and equipment, net	581,378	320,865
Prepaid expenses - non-current	2,064,575	8,423,468
Total non-current assets	**5,897,150**	**12,372,813**
Total assets	**$ 518,213,328**	**$ 526,540,115**
Current liabilities		
Trade and other payables	$ 10,710,603	$ 1,837,684
Short-term portion of operating lease liabilities	1,444,893	1,197,876
Accrued expenses and other current liabilities	7,925,524	6,930,120
Total current liabilities	**20,081,020**	**9,965,680**
Non-current liabilities		
Long-term portion of operating lease liabilities	1,935,709	2,499,990
Pension liability	694,959	583,426
Total non-current liabilities	**2,630,668**	**3,083,416**
Total liabilities	**22,711,688**	**13,049,096**
Commitments and contingencies (Note 15)		
Equity		
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 63,046,025 shares issued and outstanding as of September 30, 2024; 60,466,453 shares issued and outstanding as of December 31, 2023	6,305	6,047
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 841,269 shares issued and outstanding as of September 30, 2024; 2,505,476 shares issued and outstanding as of December 31, 2023	84	251
Additional paid-in capital	675,343,443	609,969,236
Accumulated deficit	(189,988,477)	(116,657,472)
Accumulated other comprehensive income	2,833,970	2,357,621
Total shareholders' equity	**488,195,325**	**495,675,683**

Noncontrolling interests	7,306,315	17,815,336
Total equity	**495,501,640**	**513,491,019**
Total liabilities and equity	**$ 518,213,328**	**$ 526,540,115**

MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(Amounts in USD, except share and per share data)

	For the Three Months Period Ended	
	September 30, 2024	**June 30, 2024**
Operating expenses		
Research and development	$ (35,735,514)	$ (23,662,147)
General and administrative	(7,376,495)	(6,916,054)
Total operating expenses	**(43,112,009)**	**(30,578,201)**
Operating loss	**(43,112,009)**	**(30,578,201)**
Other income, net	7,089,691	5,898,148
Loss before income tax	**(36,022,318)**	**(24,680,053)**
Income tax expense	(92,106)	(78,701)
Net loss	**$ (36,114,424)**	**$ (24,758,754)**
Of which: net loss attributable to controlling interests shareholders	*(35,390,337)*	*(24,267,012)*
Of which: net loss attributable to noncontrolling interests shareholders	*(724,087)*	*(491,742)*
Net unrealized gain (loss) on marketable securities and short term investments	(325,510)	652,097
Actuarial gain (loss) on employee benefit plans	(115,629)	(76,479)
Other comprehensive income (loss)	(441,139)	575,618
Comprehensive loss	**$ (36,555,563)**	**$ (24,183,136)**
Comprehensive loss attributable to controlling interests shareholders	*(35,822,526)*	*(23,703,201*
Comprehensive loss attributable to noncontrolling interests	*(733,037)*	*(479,935)*
Weighted-average number of Class A Ordinary Shares, basic and diluted	62,896,782	62,874,637
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.56)**	**$ (0.39)**