



MoonLake Immunotherapeutics Reports First Quarter 2023 Financial Results and Provides a Business Update

May 12, 2023

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- *Capital Markets Day held in April highlighted the differentiating features of sonelokimab and strong competitive position following competitor data in moderate-to-severe hidradenitis suppurativa (HS)*
- *Preparations are well underway for the announcement of top-line results from a Phase 2 trial of sonelokimab in moderate-to-severe HS around the end of June with final read-out of 24-week data by Q4 this year*
- *Patient enrollment in a global Phase 2 trial in active psoriatic arthritis (PsA) is on schedule with primary end-point readout expected in Q4 this year*
- *Expected cash runway extended to the end of 2024*

ZUG, Switzerland, May 12, 2023 – MoonLake Immunotherapeutics (NASDAQ:MLTX) (“MoonLake”), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today provided a business update, following the filing of its first quarter financial results on May 11.

MoonLake continues to make substantial progress with the clinical development of sonelokimab, which is currently being investigated in two Phase II clinical trials: the first, ‘MIRA’, in moderate-to-severe HS and the second, ‘ARGO’, in PsA. Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial in 313 patients with moderate-to-severe plaque-type psoriasis in which it demonstrated a rapid and durable skin clearance (PASI100). Sonelokimab efficiently inhibits IL-17F in addition to IL-17A and therefore could represent a major improvement in treating inflammation in these dermatological and rheumatological diseases. The Nanobody’s[®] smaller size versus traditional antibodies and albumin-binding domain provide an opportunity for further efficacy.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *“2023 has started off very strongly for MoonLake. Patient enrollment and randomization were completed ahead of schedule in our global Phase 2 trial of sonelokimab in moderate-to-severe HS and we are now anticipating announcement of the top-line results next month. We were delighted to reflect on the pivotal design of the trial and the baseline characteristics of enrolled patients in our Capital Markets Day in April together with Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, and believe that our study is most comparable to the Phase 3 trials of competitors. Based on sonelokimab’s mechanism of action and unique characteristics, we are confident that we can ‘meet or beat’ the best results shown in such trials, which would translate into a greater than 20 percentage point delta on HiSCR 75 compared to placebo and represent a meaningful difference to the lives of patients with HS, an estimated \$10bn market opportunity in the United States alone. Patient enrollment in our second global Phase 2 trial, in active PsA, is progressing well with primary end-point readout expected in Q4 of this year.”*

Q1 highlights (including post-period end)

- Patient enrollment and randomization completed ahead of schedule in a global Phase 2 trial of sonelokimab in moderate-to-severe HS (MIRA). This is the first global, randomized, double-blind, placebo-controlled trial using Hidradenitis Suppurativa Clinical Response (HiSCR) 75, a higher measure of clinical response, as its primary endpoint with top-line results anticipated next month.
- Capital Markets Day hosted in New York on April 19th featured a series of presentations from MoonLake’s executive team who provided a financial update and look to the year ahead at near-term catalysts and the Company’s publication roadmap. The event program highlighted key features of sonelokimab and included a clinical trial progress update. The program also referenced the release of important competitor data at the American Academy of Dermatology (AAD) Annual Meeting in March. In addition, external speaker Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, provided an update on the treatment landscape and pipeline, reflecting on data and key takeaways from AAD.
- Collaboration agreement signed with SHL Medical, a world-leading provider of advanced drug delivery solutions, to develop an autoinjector for clinical and potential subsequent commercial supply of MoonLake’s Nanobody[®] sonelokimab.

First quarter 2023 financial results

As of March 31, 2023, MoonLake held cash, cash equivalents and short-term marketable debt securities of \$63.1 million, compared to \$72.1 million as of December 31, 2022, corresponding to a cash burn of \$9.1 million¹ in the first quarter.

Research and development expenses for the quarter ended March 31, 2023, were \$7.4 million, compared to \$11.4 million in the previous quarter. The decrease was primarily due to a milestone expense under MoonLake’s in-license agreement of sonelokimab that was recognized in the previous

quarter. General and administrative expenses for the quarter ended March 31, 2023 were \$5.5 million, compared to \$5.3 million in the previous quarter.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *“MoonLake is in a very solid financial position with a strong balance sheet. As a result of careful financial management, planning and operating efficiently, we have extended our expected cash runway to the end of 2024 which is 18 months beyond our upcoming readout in HS. This robust cash position also covers our other mid-stage PsA clinical readout, as well as the ongoing preparations for our Phase 3 programs, and thereby gives us a lot of financial flexibility and optionality. We have a unique asset in sonelokimab, which we expect to soon be Phase 3 ready in three multi-billion dollar indications.”*

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 on 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 the ability to design multivalent therapeutic molecules with bespoke target combinations.

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 has been assessed in a randomized, placebo-controlled Phase 2b study in 313 patients with moderate-to-severe plaque-type psoriasis. Sonelokimab demonstrated a rapid and durable clinical response (Investigator’s Global Assessment Score 0 or 1, Psoriasis Area and Severity Index 90/100) 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 Phase 1 study 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). Recently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, “ARGO”) including multiple arms and over 200 patients has been initiated (announced on Dec 14, 2022).

Sonelokimab is not yet approved for use in any indication.

About the MIRA trial

The MIRA trial (M1095-HS-201) is a global, randomized, double-blind, placebo-controlled 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 will comprise over 200 patients, and will evaluate two different doses of sonelokimab, with placebo control and adalimumab as an active control 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 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 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 on: <https://www.clinicaltrials.gov/ct2/show/NCT05322473>

About the ARGO trial

The ARGO trial (M1095-PSA-201) is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of the sonelokimab, administered subcutaneously, in the treatment of adult patients with active PsA. The trial is expected to comprise of approximately 200 patients, and is designed to evaluate different doses of sonelokimab, with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving ≥50% improvement in signs and symptoms of disease from baseline, compared to placebo, as measured by the American College of Rheumatology (ACR) 50 response. The trial will also evaluate a number of secondary endpoints, including improvement compared to placebo in ACR70, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index, physical function as measured by the Health Assessment Questionnaire-Disability Index, enthesitis as measured by the Leeds Enthesitis Index and pain as measured by the Patients Assessment of Arthritis Pain. Further details are available on: <https://clinicaltrials.gov/ct2/show/NCT05640245>

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 patient enrollment in the MIRA and ARGO trials, the efficacy and safety of sonelokimab for the treatment of HS and PsA, 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, 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.

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)

	March 31, 2023	December 31, 2022
	(Unaudited)	
Current assets		
Cash and cash equivalents	\$ 50,129,197	\$ 39,505,627
Short-term marketable debt securities	12,920,960	32,609,108
Other receivables	378,445	217,129
Prepaid expenses	3,075,862	4,179,468
Total current assets	66,504,464	76,511,332
Non-current assets		
Operating lease right-of-use assets	246,256	282,580
Property and equipment, net	46,099	49,389
Total non-current assets	292,355	331,969
Total assets	\$ 66,796,819	\$ 76,843,301
Current liabilities		
Trade and other payables	\$ 3,827,403	\$ 254,972
Short-term portion of operating lease liabilities	155,173	153,629
Accrued expenses and other current liabilities	3,296,839	7,256,845
Total current liabilities	7,279,415	7,665,446
Non-current liabilities		
Long-term portion of operating lease liabilities	91,081	128,951
Pension liability	314,174	282,206

Total non-current liabilities	<u>405,255</u>	<u>411,157</u>
Total liabilities	<u>7,684,670</u>	<u>8,076,603</u>
Commitments and contingencies (Note 15)		
Equity (deficit)		
Class A Ordinary Shares: \$0.0001 par value; 500,000,000 shares authorized; 39,154,203 shares issued and outstanding as of March 31, 2023; 38,977,600 shares issued and outstanding as of December 31, 2022	3,916	3,898
Class C Ordinary Shares: \$0.0001 par value; 100,000,000 shares authorized; 13,546,908 shares issued and outstanding as of March 31, 2023; 13,723,511 shares issued and outstanding as of December 31, 2022	1,355	1,373
Additional paid-in capital	131,308,849	129,192,291
Accumulated deficit	(89,655,068)	(80,650,212)
Accumulated other comprehensive income (loss)	340,108	350,946
Total shareholders' equity (deficit)	<u>41,999,160</u>	<u>48,898,296</u>
Noncontrolling interests	17,112,989	19,868,402
Total equity (deficit)	<u>59,112,149</u>	<u>68,766,698</u>
Total liabilities and equity (deficit)	<u>\$ 66,796,819</u>	<u>\$ 76,843,301</u>

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		
	March 31, 2023	December 31, 2022	March 31, 2022
Operating expenses			
Research and development	\$ (7,415,097)	\$ (11,369,112)	\$ (10,454,948)
General and administrative	(5,516,469)	(5,327,311)	(5,487,368)
Total operating expenses	<u>(12,931,566)</u>	<u>(16,696,423)</u>	<u>(15,942,316)</u>
Operating loss	<u>(12,931,566)</u>	<u>(16,696,423)</u>	<u>(15,942,316)</u>
Other income (expense), net	723,589	239,505	69,506
Loss before income tax	<u>(12,207,977)</u>	<u>(16,456,918)</u>	<u>(15,872,810)</u>
Income tax expense	(11,010)	(11,012)	(7,332)
Net loss	<u>\$ (12,218,987)</u>	<u>\$ (16,467,930)</u>	<u>\$ (15,880,142)</u>
<i>Of which: net loss attributable to controlling interests shareholders</i>	(9,004,856)	(11,861,934)	(15,880,142)
<i>Of which: net loss attributable to noncontrolling interests shareholders</i>	(3,214,131)	(4,605,996)	—
Net unrealized gain on marketable securities and short term investments	24,472	313,747	—
Actuarial gain (loss) on employee benefit plans	(42,144)	(187,557)	266,269
Other comprehensive income (loss)	<u>(17,672)</u>	<u>126,190</u>	<u>266,269</u>
Comprehensive loss	<u>\$ (12,236,659)</u>	<u>\$ (16,341,740)</u>	<u>\$ (15,613,873)</u>
<i>Comprehensive loss attributable to controlling interests shareholders</i>	(9,017,481)	(11,772,007)	(15,613,873)
<i>Comprehensive loss attributable to noncontrolling interests</i>	(3,219,178)	(4,569,733)	—
Weighted-average number of Class A Ordinary Shares, basic and diluted	39,061,977	38,843,776	—
Basic and diluted net loss per share attributable to controlling interests shareholders	<u>\$ (0.23)</u>	<u>\$ (0.31)</u>	<u>\$ —</u>
Weighted-average number of Common Shares ²	—	—	5,013,646
Basic and diluted net loss per Common Share	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (3.17)</u>

² As a result of the Business Combination, the Company has retroactively restated the weighted average number of shares outstanding prior to April 5, 2022 to give effect to the Exchange Ratio. For definitions of capitalized terms, refer to the unaudited condensed consolidated financial statements filed on Form 10-Q for the quarter ended March 31, 2023.

¹ Values may not add up due to rounding.