MoonLake Immunotherapeutics Reports Fourth Quarter and Year-End 2022 Financial Results and Provides a Business Update

March 20, 2023

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- *Strong financial position: year-end cash, cash equivalents and short-term marketable debt securities of $72.1 million, expected to provide runway well into 2H 2024 and at least 12 months beyond expected key data readouts*
- *Recent clinical data announced at the 81st Annual Meeting of the American Academy of Dermatology on the novel IL-17A and IL-17F inhibition further reinforces MoonLake's competitive position with sonelokimab in the Hidradenitis Suppurativa ("HS") landscape*
- *Patient enrollment and randomization completed ahead of schedule in a global Phase 2 trial of sonelokimab in HS with top-line results expected around the end of June 2023 and final read-out by Q4 2023*
- *Patient enrollment on schedule in a global Phase 2 trial in Psoriatic Arthritis ("PsA") with primary end-point readout expected at the end of 2023*
- *Capital Markets Day to be held on Wednesday, April 19th, 2023, 10:30am EST to 12.30pm EST – live in New York and via webcast – to discuss recent progress and upcoming catalysts for MoonLake – see details below*

ZUG, Switzerland, March 20, 2023 – MoonLake Immunotherapeutics (NASDAQ:MLTX) ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced its financial results for the fourth quarter and year ended December 31, 2022, and provided a business update.

MoonLake continues to make good progress with the clinical development of sonelokimab in multiple inflammatory diseases in dermatology and rheumatology where the pathophysiology is known to be driven by IL-17A and IL-17F. Sonelokimab's ability to efficiently inhibit IL-17F in addition to IL-17A could represent a major improvement in treating inflammation in these diseases. Sonelokimab'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: *"2022 was an excellent year for MoonLake. We went public on Nasdaq, raised $150 million, and initiated two global Phase 2 clinical trials. 2023 looks even more important with results from our two global trials expected during the year. The first Phase 2 trial anticipated to read out is for sonelokimab in HS, a devastating skin disease that can seriously alter the daily lives and emotional well-being of those affected. Recent clinical evidence reported for competitor programs including bimekizumab, secukinumab and izokibep provide us with even greater confidence in our approach and we look forward to announcing the top-line data around the end of June 2023. Our second global Phase 2 trial to read out this year will be for sonelokimab in PsA. This remains on schedule, with top-line results expected at the end of the year. Together with Psoriasis, where we already have data from a large Phase 2 study, we are now looking at Phase 3 readiness in several multi-billion dollar markets."*

Q4 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. 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.
- First patients screened and enrollment is on schedule in ongoing global Phase 2 study of sonelokimab in active psoriatic arthritis. This is the first known trial in PsA to use a Nanobody®.

Fourth quarter and year-end financial results

As of December 31, 2022, MoonLake held cash, cash equivalents and short-term marketable debt securities of $72.1 million, compared to $83.5 million as of September 30, 2022, corresponding to a cash burn of $11.4 million in the fourth quarter which was primarily driven by net cash used in operating activities.

Research and development expenses for the fourth quarter ended December 31, 2022 were $11.4 million, compared to $9.0 million in the previous quarter. The increase was due to a milestone expense of $2.7 million. Research and development expense for the year ended December 31, 2022 were $42.0 million.

General and administrative expenses for the fourth quarter ended December 31, 2022 were $5.3 million, compared to $5.7 million in the previous quarter. General and administrative expense for the year ended December 31, 2022 were $23.0 million.

Net loss for the year ended December 31, 2022 was $64.5 million compared to $53.6 million for the period from March 10, 2021 (inception) to December 31, 2021.

As of December 31, 2022, there were 53.3 million fully diluted ordinary shares outstanding.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *"2022 provided us with a very strong financial platform to rapidly and efficiently pursue the clinical development of sonelokimab, building on the promising results already observed in the Phase 2b psoriasis trial. We remain in excellent financial health with a strong balance sheet providing a cash runway into 2H 2024 and at least 12 months beyond expected key readouts. This is on plan with our financial roadmap. MoonLake remains lean, efficient, and well-funded to deliver its goals."*

Industry update underlines our approach

Over the past year, there has been a groundswell of innovation in the development of new therapeutics to treat HS. Recent clinical data from peers reinforce our confidence in the competitive positioning for sonelokimab in the HS landscape. These data announced at leading medical conferences such as the 81st Annual Meeting of the American Academy of Dermatology and published in peer-reviewed scientific journals provide increasing evidence to support IL-17, in general, and IL-17A- and IL-17F-mediated inflammation in particular, as a key driver of HS.

Data presented recently for secukinumab, a IL-17A only inhibitor, suggest IL-17 inhibition in general presents a more durable therapeutic option for patients, versus the current TNF-alpha standard. In turn, we believe that data shown for bimekizumab firmly establishes dual inhibition of IL-17A and IL-17F as a leading therapeutic solution in HS. Early data for the non-biologic izokibep IL-17A/A only inhibitor, based on open-labelled, non-placebo controlled work, further suggest that small size and penetration ability may provide an additional desirable characteristic in addressing deep-tissue inflammation in HS. Emerging early data from orals targeting non-IL-17 specific pathways show some level of efficacy and safety but not at the level seen with biologics. Altogether, the data demonstrate the importance of targeting IL-17F in addition to IL-17A and of having a small molecule size to aid tissue penetration, both characteristics uniquely combined in our Nanobody® sonelokimab.

Anticipated Upcoming Milestones 2023

- Top-line results for a Phase 2 trial of sonelokimab in moderate-to-severe HS expected around the end of June 2023 with final read-out by Q4 2023
- Completion of patient enrollment and randomization for the ongoing Phase 2 trial of sonelokimab in active PsA expected in Q3 2023
- Top-line results for a Phase 2 trial of sonelokimab in active PsA anticipated on schedule at the end of the year

Capital Markets Day on 19 April

MoonLake will be hosting a Capital Markets Day for investors and analysts on Wednesday, April 19 from 10:30 am -12:30 pm EDT in New York, US and via webcast to look ahead at the near-term news catalysts, and provide a clinical trial and research update. Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin will provide an update on the treatment landscape and reflect on data from the recent AAD conference. Register for the event and webcast in advance. The registration link and additional details are available in the *Events & Presentations* section of the Company's website at www.ir.moonlaketx.com.

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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 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

CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	December 31, 2022	September 30, 2022 (Unaudited)
Current assets		
Cash and cash equivalents	$ 39,505,627	$ 41,204,667
Short-term marketable debt securities	32,609,108	42,254,788
Other receivables	217,129	600,536
Prepaid expenses	4,179,468	4,479,194
Total current assets	**76,511,332**	**88,539,185**
Non-current assets		
Operating lease right-of-use assets	282,580	—
Property and equipment, net	49,389	52,679
Total non-current assets	**331,969**	**52,679**
Total assets	**$ 76,843,301**	**$ 88,591,864**
Current liabilities		
Trade and other payables	$ 254,972	$ 1,056,253
Short-term portion of operating lease liabilities	153,629	—
Accrued expenses and other current liabilities	7,256,845	4,962,470
Total current liabilities	**7,665,446**	**6,018,723**
Non-current liabilities		
Long-term portion of operating lease liabilities	128,951	—
Pension liability	282,206	4,985
Total non-current liabilities	**411,157**	**4,985**
Total liabilities	**8,076,603**	**6,023,708**
Commitments and contingencies (Note 16)		
Equity (deficit)		
Series A Preferred Shares, CHF 0.10 par value; 22,880,908 authorized; 22,880,908 shares issued and outstanding as of December 31, 2021 (liquidation preference of $33.4 million);	—	—
Common Shares, CHF 0.10 par value; 13,119,092 authorized; 12,161,331 shares issued and 10,218,495 shares outstanding as of December 31, 2021	—	—
Treasury Shares, 1,942,837 as of December 31, 2021	—	—
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 38,977,600 shares issued and outstanding as of December 31, 2022	3,898	3,693
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 13,723,511 shares issued and outstanding as of December 31, 2022	1,373	1,578
Additional paid-in capital	129,192,291	123,825,896
Accumulated deficit	(80,650,212)	(68,788,276)
Accumulated other comprehensive income (loss)	350,946	245,283
Total shareholders' equity (deficit)	**48,898,296**	**55,288,174**
Noncontrolling interests	19,868,402	27,279,982
Total equity (deficit)	**68,766,698**	**82,568,156**
Total liabilities and equity (deficit)	**$ 76,843,301**	**$ 88,591,864**

MOONLAKE IMMUNOTHERAPEUTICS

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

	Three Months Period Ended December 31, 2022	Three Months Period Ended September 30, 2022 (Unaudited)	Year Ended December 31, 2022	Nine Months Period Ended September 30, 2022 (Unaudited)
Operating expenses				

Research and development	$ (11,369,112)	$ (9,024,437)	$ (42,048,954)	$ (30,679,842)
General and administrative	(5,327,311)	(5,746,064)	(23,012,463)	(17,685,152)
Total operating expenses	**(16,696,423)**	**(14,770,501)**	**(65,061,417)**	**(48,364,994)**
Operating loss	**(16,696,423)**	**(14,770,501)**	**(65,061,417)**	**(48,364,994)**
Other income (expense), net	239,505	37,593	591,732	352,227
Loss before income tax	**(16,456,918)**	**(14,732,908)**	**(64,469,685)**	**(48,012,767)**
Income tax expense	(11,012)	(8,740)	(36,366)	(25,354)
Net loss	**$ (16,467,930)**	**$ (14,741,648)**	**$ (64,506,051)**	**$ (48,038,121)**
Of which: net loss attributable to controlling interests shareholders	*(11,861,934)*	*(10,110,452)*	*(49,973,249)*	*(32,865,429)*
Of which: net loss attributable to noncontrolling interests shareholders	*(4,605,996)*	*(4,631,196)*	*(14,532,802)*	*(15,172,692)*
Net unrealized gain on marketable securities and short-term investments	313,747	77,006	390,753	77,006
Actuarial income (loss) on employee benefit plans[1]	(187,557)	89,586	269,893	457,450
Other comprehensive income (loss)	126,190	166,592	660,646	534,456
Comprehensive loss	**$ (16,341,740)**	**$ (14,575,056)**	**$ (63,845,405)**	**$ (47,503,665)**
Comprehensive loss attributable to controlling interests shareholders	*(11,772,007)*	*(9,998,892)*	*(49,437,461)*	*(32,507,526)*
Comprehensive loss attributable to noncontrolling interests	*(4,569,733)*	*(4,576,164)*	*(14,407,944)*	*(14,996,139)*
Weighted-average number of Class A Ordinary Shares, basic and diluted[2]	38,843,776	36,925,639	29,361,353	25,830,560
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.31)**	**$ (0.27)**	**$ (1.70)**	**$ (1.27)**

[1] USD 567 previously presented as *foreign currency translation* in other comprehensive income for the nine months period ended September 30, 2022, has been reclassified to *actuarial income (loss) on employee benefit plans*

[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.