MoonLake Immunotherapeutics Reports Third Quarter 2022 Financial Results and Provides Recent Business Update

November 14, 2022

MoonLake Immunotherapeutics Reports Third Quarter 2022 Financial Results and Provides Recent Business Update

- Global trial of sonelokimab in Hidradenitis Suppurativa (HS) has continued to meet recruitment targets with an expected primary endpoint readout in mid-2023
- Global Psoriatic Arthritis (PsA) trial received FDA clearance and US central IRB approval
- Quarter-end position of $83.5 million in cash, cash equivalents and short-term marketable debt securities, providing cash runway into 2H2024 and at least 12 months beyond expected key readouts

ZUG, Switzerland, November 14, 2022 – 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 quarter ended September 30, 2022, and provided a business update.

MoonLake continues to develop its novel IL-17A and IL-17F inhibiting Nanobody® sonelokimab ("SLK" or "sonelokimab") in multiple inflammatory diseases in dermatology and rheumatology where the pathophysiology is known to be driven by IL-17F and IL-17A. Sonelokimab is an investigational Nanobody® designed to treat inflammatory disease by inhibiting the IL-17A/A, IL-17A/F and IL-17F/F dimers that drive inflammation. In addition, being one third the size of a traditional monoclonal antibody and containing a human albumin-binding domain, SLK is designed to penetrate difficult-to-reach inflamed tissues and directly target sites of inflammation.

In May 2022, MoonLake initiated its Phase 2 global trial of sonelokimab in HS (M1095-HS-201) ("MIRA"), which has continued to meet recruitment targets with an expected primary endpoint readout in mid-2023. HS is a severely debilitating chronic skin condition, with a prevalence of approximately 1% globally, that results in irreversible tissue destruction. MoonLake's MIRA trial represents a landmark milestone in HS clinical development as it is the first known trial to use Hidradenitis Suppurativa Clinical Response (HiSCR) 75 as its primary endpoint. Using a ≥75% improvement of HiSCR as the primary endpoint reflects MoonLake's goal to revolutionize patient outcomes by seeking a greater reduction in disease markers than is typically tested in clinical trials.

MoonLake also remains on schedule with its global Phase 2 trial of sonelokimab in PsA (M1095-PSA-201) ("ARGO"). MoonLake previously announced FDA clearance for this trial, and has since received US central IRB approval. This global trial is designed to evaluate the efficacy and safety of different doses of SLK compared to placebo, with adalimumab as an active reference arm. The trial is expected to recruit approximately 200 patients with active PsA, and is the first known trial in PsA to use a Nanobody®.

Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said: *"We are on schedule with our plan, and our next readouts are expected from mid-2023. As we look at the competitive landscape, we are increasingly confident we will add to the high efficacy observed in our Phase 2b psoriasis trial with differentiating data in HS and PsA. IL-17 inhibition was shown to work in both indications by secukinumab, an IL-17A-only inhibitor. In our view and based on competitive data shown for bimekizumab, sonelokimab's ability to efficiently inhibit IL-17F in addition to IL-17A could represent a step-up in treating inflammation in these devastating diseases. On top of that, the fact that we have a much smaller molecule with an albumin-binding domain, provides an opportunity for further efficacy. For example, we have seen izokibep (a small sized non-biologic molecule also with an albumin-binding domain) show early Phase 2 efficacy in PsA, despite being an IL-17AA-only inhibitor. We continue to see competitive data from orals emerging in our space, but these molecules generally provide modest levels of efficacy (e.g., in psoriasis) or no efficacy (e.g., HS) versus biologics. We believe they will remain a niche group in a much larger market across different inflammatory diseases."*

As of September 30, 2022, MoonLake held cash, cash equivalents and short-term marketable debt securities of $83.5 million, compared to $92.7 million as of June 30, 2022.

Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said: *"Our unwavering focus on the clinical development of sonelokimab and our lean setup allow us to operate very efficiently without compromising on quality. We have cash runway into the second half of 2024, which brings us 12 months or more beyond our expected data read-outs*."

Research and development expenses for the quarter ended September 30, 2022, were $9.0 million, as compared to $11.4 million in the previous quarter. This decrease was primarily due to a one-off milestone expense in the previous quarter. Expenses for contracted clinical development increased by $3.7 million, reflecting the ongoing clinical trial in HS and trial set-up activities for the upcoming clinical trial in PsA.

General and administrative expenses for the quarter ended September 30, 2022, were $5.7 million, as compared to $6.3 million in the previous quarter. This decrease was primarily due to business combination closing transaction costs in the previous quarter.

Other income and other comprehensive income for the quarter ended September 30, 2022 were $38,000 and $167,000 respectively, attributable to foreign currency exchange gains, actuarial income on pension obligations and an unrealized net gain on short-term investments in marketable securities.

Net loss for the quarter ended September 30, 2022, was $14.7 million, compared to $17.4 million in the previous quarter. As of September 30, 2022, there were 53.3 million fully diluted ordinary shares outstanding.

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 HS and PsA – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake Immunotherapeutics AG, subsidiary of MoonLake Immunotherapeutics, 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 the ability to design 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 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 trial 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 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). On May 5, 2022, MoonLake announced it initiated its Phase 2 MIRA trial in HS (NCT05322473, M1095-PSA-201), which includes multiple arms and is expected to have over 200 patients.

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 SLK, administered subcutaneously, in the treatment of adult patients with active moderate to severe HS. The trial is expected to comprise of over 200 patients, and is designed to 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 HiSCR75, defined as a ≥75% reduction in total abscess and inflammatory nodule count with no increase in abscess or draining tunnel count relative to baseline. The trial is also designed to evaluate a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System, the proportion of patients achieving a Dermatology Life Quality Index total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale in the Patient's Global Assessment of 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 SLK, 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.

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 preclinical studies, continued 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. 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.

CONTACT

MoonLake Immunotherapeutics Investors
Matthias Bodenstedt, CFO
ir@moonlaketx.com

MoonLake Immunotherapeutics Media
Patricia Sousa, Director Corporate Affairs
media@moonlaketx.com

Matthew Cole, Mary-Jane Elliott
Consilium Strategic Communications
Tel: +44 (0) 20 3709 5700
media@moonlaketx.com
MoonLake@consilium-comms.com

MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in USD, except share data)

	September 30, 2022 (Unaudited)	December 31, 2021
Current assets		
Cash and cash equivalents	$ 41,204,667	$ 8,038,845
Short-term marketable debt securities	42,254,788	—
Other receivables	600,536	148,774
Prepaid expenses	4,479,194	1,449,096
Total current assets	**88,539,185**	**9,636,715**
Non-current assets		
Property and equipment, net	52,679	45,739
Total non-current assets	**52,679**	**45,739**
Total assets	**$ 88,591,864**	**$ 9,682,454**
Current liabilities		
Trade and other payables	$ 1,056,253	$ 1,569,290
Short-term loans	—	15,000,000
Accrued expenses and other current liabilities	4,962,470	4,518,311
Total current liabilities	**6,018,723**	**21,087,601**
Non-current liabilities		
Pension liability	4,985	239,860
Total non-current liabilities	**4,985**	**239,860**
Total liabilities	**6,023,708**	**21,327,461**
Commitments and contingencies (Note 15)		
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);	—	72,466
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	—	38,537
Treasury Shares, 1,942,837 as of December 31, 2021	—	(6,202)
Class A Ordinary Shares: $0.0001 par value; 500,000,000 shares authorized; 36,925,639 shares issued and outstanding as of September 30, 2022	3,693	—
Class C Ordinary Shares: $0.0001 par value; 100,000,000 shares authorized; 15,775,472 shares issued and outstanding as of September 30, 2022	1,578	—
Additional paid-in capital	123,825,896	42,061,984
Accumulated deficit	(68,788,276)	(53,643,615)
Accumulated other comprehensive income (loss)	245,283	(168,177)
Total shareholders' equity (deficit)	**55,288,174**	**(11,645,007)**
Noncontrolling interests	27,279,982	—

Total equity (deficit)	**82,568,156**	**(11,645,007)**
Total liabilities and equity (deficit)	**$ 88,591,864**	**$ 9,682,454**

MOONLAKE IMMUNOTHERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(Amounts in USD, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021 (As restated)**	**2022**	**2021 (As restated)**
Operating expenses				
Research and development	(9,024,437)	(669,528)	(30,679,842)	(30,536,746)
General and administrative	(5,746,064)	(5,597,688)	(17,685,152)	(8,762,925)
Total operating expenses	**(14,770,501)**	**(6,267,216)**	**(48,364,994)**	**(39,299,671)**
Operating loss	**(14,770,501)**	**(6,267,216)**	**(48,364,994)**	**(39,299,671)**
Other income (expense), net	37,593	(20,840)	352,227	
Loss before income tax	**(14,732,908)**	**(6,288,056)**	**(48,012,767)**	**(39,325,510)**
Income tax expense	(8,740)	–	(25,354)	–
Net loss	**(14,741,648)**	**(6,288,056)**	**(48,038,121)**	**(39,325,510)**
Of which: net loss attributable to controlling interests shareholders	*(10,110,452)*	*(6,288,056)*	*(32,865,429)*	*(39,325,510)*
Of which: net loss attributable to noncontrolling interests shareholders	*(4,631,196)*	–	*(15,172,692)*	–
Net unrealized gain on marketable securities and short term investments	77,006	–	77,006	–
Foreign currency Translation	–	–	567	–
Actuarial income (loss) on employee benefit plans	89,586	1,000	456,883	–
Other comprehensive income (loss)	166,592	1,000	534,456	–
Comprehensive loss	**(14,575,056)**	**(6,287,056)**	**(47,503,665)**	**(39,325,510)**
Comprehensive loss attributable to controlling interests shareholders	*(9,998,892)*	*(6,287,056)*	*(32,507,526)*	*(39,325,510)*
Comprehensive loss attributable to noncontrolling interests	*(4,576,164)*	–	*(14,996,139)*	–
Weighted-average number of Class A Ordinary Shares, basic and diluted	36,925,639	–	25,830,560	–
Basic and diluted net loss per share attributable to controlling interests shareholders	**$ (0.27)**	**–**	**$ (1.27)**	**–**
Weighted-average number of Common Shares	–	2,390,587	–	9,689,627
Basic and diluted net loss per Common Share	**–**	**$ (2.63)**	**–**	**$ (4.06)**

1 For additional details, refer to *Note 3 – Basis of Presentation and Significant Accounting Policies - Restatement of Consolidated Financial Statements as of and for the Three and Nine-months Ended September 30, 2021* in the unaudited condensed consolidated financial statements filed on Form 10-Q for the quarter ended September 30, 2022.
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 September 30, 2022.

MoonLake

Source: MoonLake Immunotherapeutics AG