MoonLake Immunotherapeutics and SHL Medical collaborate to jointly develop an autoinjector for sonelokimab supply

May 3, 2023

ZUG, Switzerland, May 3, 2023 – MoonLake Immunotherapeutics (NASDAQ: MLTX) ("MoonLake"), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that it has signed a collaboration agreement 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.

SHL Medical will use its market-proven Molly® modular platform technology to develop the autoinjector and provide its device development expertise, assembly guidance, and production competencies to support the drug-device project. A total of 17 combination products that leverage the Molly® autoinjector technology have been approved in at least 69 countries, enabling home treatment in a wide range of therapeutic areas that require injectable medicines.

Oliver Daltrop, Chief Technical Officer of MoonLake Immunotherapeutics, said: *"MoonLake is proud to be partnering with a world leader in advanced autoinjector development to provide sonelokimab for clinical and potentially commercial supply. As we actively plan for a Phase 3 program and commercial readiness, SHL's expertise will greatly enhance our ability to introduce sonelokimab in an autoinjector format that could provide a benefit for patients, if approved."*

Ulrich Faessler, Chief Executive Officer at SHL Medical, added: *"SHL Medical and MoonLake are united by our shared passion for pursuing innovation and going beyond to deliver novel therapies that help unlock value and improve patients' lives. Working with MoonLake while sonelokimab is in development allows us to carry out strategies that best complement MoonLake's clinical and commercial needs. We are excited about the collaboration and look forward to potentially bringing the innovative Nanobody® technology for dermatologic and rheumatic inflammatory indications to patients worldwide."*

Sonelokimab is an investigational Nanobody®, currently in clinical development for a number of indications. Its ability to efficiently inhibit IL-17F in addition to IL-17A could represent a major improvement in treating inflammation for hidradenitis suppurativa, a severely debilitating chronic skin condition resulting in irreversible tissue destruction. This hypothesis has been further supported by recent clinical data presented at the American Academy of Dermatology Annual meeting. Sonelokimab's smaller size versus traditional antibodies and albumin-binding domain provide an opportunity for further efficacy.

Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis in which it demonstrated a rapid and durable skin clearance (PASI100) with no unexpected safety findings.

Top-line results for a Phase 2 trial of sonelokimab in moderate-to-severe hidradenitis suppurativa (NCT05322473), 'MIRA', are expected around the end of June 2023 with final read-out by Q4 2023. Patient enrollment in a global Phase 2 trial (NCT05640245), 'ARGO', in psoriatic arthritis is on schedule with primary end-point readout expected at the end of 2023.

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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 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.

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).

Two global Phase 2 trials are currently underway to evaluate sonelokimab in moderate-to-severe hidradenitis suppurativa (NCT05322473), 'MIRA' and in psoriatic arthritis (NCT05640245) "ARGO").

Sonelokimab is not yet approved for use in any indication.

About SHL Medical
SHL Medical is a world-leading solutions provider in the design, development, and manufacturing of advanced delivery devices such as autoinjectors, pen injectors, and innovative specialty delivery systems for large-volume and high-viscosity formulations. It offers final assembly, labeling, and packaging solutions for its drug delivery devices, and also provides contract manufacturing and engineering services for the production of complex medtech and industrial products.

With locations in Switzerland, Taiwan, Sweden, and the US, SHL Medical's experienced designers and engineers develop product enhancements and breakthrough drug delivery solutions for pharma and biotech clients globally. Significant investments in R&D have enhanced its broad pipeline of next-generation drug delivery systems that support ongoing innovations in drug development and digital healthcare. This includes advanced reusable and disposable injectors that can accommodate large-volume and high-viscosity formulations and can be enhanced through digital implementations.

For additional information, visit www.shl-medical.com.

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: developing an autoinjector for sonelokimab. 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 and other risk described in MoonLake's filing with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K and subsequent quarterly reports, .

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
info@moonlaketx.com

MoonLake Immunotherapeutics Media
Patricia Sousa
media@moonlaketx.com

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

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