



## MoonLake Secures up to \$500 Million in Non-Dilutive Financing from Hercules Capital and Announces a Capital Markets Update on April 29 to Provide Important Clinical Updates

April 3, 2025

- Agreement with Hercules Capital significantly increases financial and operational strength, provides up to \$500 million in capital with no dilution to shareholders, an attractive cost of capital and low operational and strategic incumbrances, and sets a new standard for the quantum of a nondilutive facility for a development-stage therapeutics company.
- Facility adds to the \$448 million cash position disclosed in previously filed 10-K and provides funding for the next steps of the Company's growth, including the expected launch of sonelokimab in 2027, additional clinical trials and further investments for growth.
- The Company will hold an in-person and virtual Capital Markets Update on Tuesday, April 29, 2025, in New York, to discuss the Hercules partnership and provide important clinical updates, including the presentation of the baseline characteristics and expected primary endpoint readout date for the Phase 3 VELA program in hidradenitis suppurativa ("HS"), and an earlier-than-expected interim read out of the Phase 2 LEDA study in palmoplantar pustulosis ("PPP").

**Zug, Switzerland**, April 3, 2025 – MoonLake Immunotherapeutics (MoonLake; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced that it has entered into an agreement with Hercules Capital, Inc. (NYSE:HTGC), a leader in customized debt financing for companies in the life sciences and technology-related markets, for up to \$500 million in non-dilutive capital, of which \$75 million drawn down at close and additional tranches will become available upon achievement of certain pre-specified milestones that are aligned with MoonLake's strategy and funding needs.

The additional capital strengthens MoonLake's balance sheet and provides financial support to rapidly advance sonelokimab and bring to market an investigational ~40 kDa humanized Nanobody® designed to directly target sites of inflammation by inhibiting all relevant IL-17 dimers (namely the IL-17A/A, IL-17A/F, and IL-17F/F dimers) and penetrating difficult-to-reach inflamed tissues.

**Matthias Bodenstedt, Chief Financial Officer at MoonLake Immunotherapeutics, said:** "We are extremely excited to partner with Hercules Capital that recognizes the value and potential of sonelokimab. We were able to secure deal terms, including a very sizable commitment and a highly competitive cost of capital. This financing facility further bolsters our already robust cash position without diluting our shareholders' stakes and effectively removes any perceived financing overhang as we approach our pivotal data readout for the HS VELA program this summer."

**Bryan Jadot, Group Head and Senior Managing Director at Hercules Capital and John Miotti, Principal at Hercules Capital, added:** "We are thrilled to partner with MoonLake Immunotherapeutics and support their mission of improving treatment outcomes for patients living with inflammatory diseases. This transaction highlights our commitment to empowering biotech companies as they navigate the critical path from clinical trials to market success"

### Capital Markets Update

The Company plans to further discuss how the new facility provides financial and operational strength over the coming years and how it impacts its broader financing strategy, and plans to discuss important clinical updates, at an in-person and virtual Capital Markets Update on Tuesday, April 29, 2025 in New York. Further details will be announced closer to the date.

### Current Trials and Upcoming Data Readouts

MoonLake is rapidly progressing a total of eight Phase 2 and Phase 3 clinical trials, plus other ancillary trials and expects to read out pivotal Phase 3 data for HS as of mid-2025. In the upcoming Capital Markets Update, the Company expects to share details on patient baseline characteristics for the VELA program and narrowed guidance with respect to the timing of the primary endpoint read-out, following screening of the last patients. MoonLake also anticipates sharing an interim read out from the Phase 2 LEDA trial of sonelokimab in palmoplantar pustulosis (PPP), the first clinical trial in PPP for an IL-17A and IL-17F inhibitor.

**Dr. Jorge Santos da Silva, Chief Executive Officer of MoonLake Immunotherapeutics, said:** "The new \$500 million facility further strengthens our financial position. With this facility and existing cash balance, we are in control of our financing strategy, and we can drive the advancement of sonelokimab in multiple indications, while building our commercial readiness activities including in the United States. I am confident that narrowed guidance on the VELA primary endpoint readout and the presentation of baseline characteristics will continue to demonstrate our ability to execute and further validate the expectations on sonelokimab. I am very glad that the PPP Phase 2 LEDA trial recruited much faster than anticipated and that we will be able to share data with the market sooner than expected. This will further contribute to building the position of sonelokimab as a high-potential, multi-indication asset that can truly change the lives of patients."

Leerink Partners served as exclusive financial advisor to MoonLake on the term loan financing. Gibson, Dunn & Crutcher LLP and Kellerhals Carrard, served as legal counsel to the Company. DLA Piper LLP and Schellenberg Wittmer served as legal counsel to Hercules Capital.

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### About MoonLake Immunotherapeutics

MoonLake Immunotherapeutics is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational

Nanobody<sup>®</sup> 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](http://www.moonlaketx.com).

### **About Nanobodies<sup>®</sup>**

Nanobodies<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Nanobodies<sup>®</sup> are trademarks of Ablynx, a Sanofi company.

### **About Sonelokimab**

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody<sup>®</sup> consisting of three variable regions of heavy-chain-only antibodies domains (VHHs) 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, hidradenitis suppurative (HS) and psoriatic arthritis (PsA), and the Company is pursuing other indications in dermatology and rheumatology, including adolescent HS, palmo-plantar pustulosis (PPP) and axial spondyloarthritis (axSpA).

For adults with 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.

Sonelokimab is currently undergoing evaluation in the VELA-TEEN Phase 3 trial, which is the first clinical study specifically focused on adolescent patients with moderate-to-severe HS.

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<sup>®</sup> sonelokimab over 24 weeks in patients with active PsA. Significant improvements were observed across all key outcomes, including approximately 60% 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 an 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.

Sonelokimab is also being assessed in the Phase 2 LEDA trial, which is ongoing for PPP, a debilitating inflammatory skin condition affecting a significant number of patients.

Additionally, sonelokimab is being assessed in the ongoing Phase 2 S-OLARIS trial for active axSpA. The trial features an innovative design complementing traditional clinical outcomes with cellular 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 the VELA program**

The Phase 3 VELA program is expected to enroll 800 patients across VELA-1 and VELA-2. Both global, randomized, double-blind, placebo-controlled trials are identical in design evaluating the efficacy and safety of the Nanobody<sup>®</sup> 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 is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response (HiSCR) 75, 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 trials 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 reduction of ≥4, the proportion of patients achieving at least 50% reduction from baseline in Numerical Rating Scale (NRS50) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain) and complete resolution of Draining Tunnels (DT100). Further details are available under NCT06411379 and NCT06411899 at [ClinicalTrials.gov](http://ClinicalTrials.gov).

### **About the VELA-TEEN trial**

The Phase 3 VELA-TEEN trial is an open-label, single-arm trial designed to evaluate sonelokimab 120mg administered subcutaneously once every two weeks (Q2W) until week six and once every four weeks (Q4W) from week eight onwards. The trial aims to enroll 30-40 adolescents, aged 12-17,

with moderate-to-severe hidradenitis suppurativa, from U.S. sites experienced in clinical trials and pediatric dermatology. The primary trial phase will be 24 weeks with a primary endpoint evaluating the pharmacokinetics, safety, and tolerability of sonelokimab. VELA-TEEN will also evaluate several secondary endpoints, including the proportion of patients achieving the higher clinical response measure of the Hidradenitis Suppurativa Clinical Response Score (HiSCR) 75, in addition to HiSCR50. Other outcomes are the change from baseline in the International Hidradenitis Suppurativa Severity Score System (IHSS4), which includes the quantitative measure of draining tunnels, and the proportion of patients achieving a meaningful reduction of the Children's Dermatology Life Quality Index (CDLQI) and the Patients Global Assessment of Skin Pain (PGA Skin Pain). Further details are available under NCT06768671 at ClinicalTrials.gov.

### **About Hidradenitis Suppurativa**

Hidradenitis suppurativa (HS) 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 an estimated 2% of the 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 projected to reach \$15bn 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-17F-mediated inflammation as a key driver of the pathogenesis of HS, with other identified risk factors including genetics, cigarette smoking, and obesity.

### **About the LEDA Trial**

The LEDA trial is a Phase 2 trial designed to evaluate the efficacy and safety of sonelokimab 120mg administered subcutaneously in adult patients with palmoplantar pustulosis (PPP). The primary endpoint of the trial is percent change from baseline in Palmoplantar Psoriasis Area and Severity Index (ppPASI) with important secondary endpoints including ppPASI75 (at least 75% improvement in the ppPASI). The LEDA trial features an innovative translational research program using peripheral blood and tissue biomarkers as trial controls.

The trial design has been informed by previous successful studies of sonelokimab, including the landmark Phase 2 MIRA trial in hidradenitis suppurativa, which identified the optimal dosing and demonstrated the potential of sonelokimab to target deep tissue inflammation effectively.

### **About Palmoplantar Pustulosis**

Palmoplantar Pustulosis (PPP) is characterized by the development of blister-like pustules within erythematous, scaly plaques on the palms and the soles of the feet. PPP typically develops in adulthood, more frequently impacts females. Patients frequently experience significant pain, burning, and itching sensations on the palms and soles of the feet which can be debilitating and impair their ability to work, sleep, or perform other activities of daily living. Currently, the treatment of PPP is challenging with a significant unmet need for novel therapies to reduce the symptom burden for patients. Evidence suggests that activation of the IL-17 pathway has an important role in 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: enrollment for clinical trials, including the Phase 3 VELA program, the VELA-TEEN trial and the LEDA trial; expectations regarding the MoonLake's cash position; the efficacy and safety of sonelokimab for the treatment of adult HS, adolescent HS, and PPP, including in comparison to existing standards or care or other competing therapies, clinical trials and research and development programs; the anticipated timing of the results from those studies and trials, including timing of topline results from the Phase 3 VELA trials in adult HS, and potential market opportunities for sonelokimab; and MoonLake's anticipated cash position. 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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**Attachment**

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