UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 or 15(d) of the
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 5, 2023

MOONLAKE IMMUNOTHERAPEUTICS
(Exact Name of Registrant as Specified in Its Charter)

Cayman Islands	**001-39630**	**98-1711963**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Dorfstrasse 29
6300 Zug
Switzerland
(Address of principal executive offices and Zip Code)

41 415108022
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A ordinary share, par value $0.0001 per share	MLTX	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On November 5, 2023, MoonLake Immunotherapeutics (the "Company") issued a press release announcing positive top-line results from its global Phase 2 ARGO trial (M1095-PSA-201) evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis. The Company is hosting a webcast today, Monday, November 6, 2023 at 8:00 am, Eastern Time, to discuss the data results.

A copy of the press release and the webcast presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein. The exhibits furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

Top-line Results from Phase 2 ARGO Trial

On November 5, 2023, the Company announced positive top-line results from its global Phase 2 ARGO trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis ("PsA").

The ARGO trial (M1095-PSA-201), which enrolled 207 patients, met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an American College of Rheumatology ("ACR") 50 response compared to those on placebo at week 12. Specifically, for the 60mg and 120mg doses with induction, respectively, 46% and 47% of patients treated with sonelokimab achieved ACR50 ($p<0.01$ versus placebo); 78% and 72% of patients achieved ACR20; and 29% and 26% achieved ACR70. The primary analyses were based on the most stringent type of analysis for such trials, intention-to-treat with non-responder imputation ("ITT-NRI"). As expected, the 60mg dose without induction did not reach statistical significance, confirming the 60mg and 120mg with induction as the potential dose regimens to carry forward into Phase 3.

All key secondary endpoints were met for the 60mg and 120mg doses with induction. The key secondary endpoint Psoriasis Area and Severity Index ("PASI") 90 was met for all doses with induction; 77% of patients responding at week 12 to the 60mg dose (ITT-NRI, $p<0.001$ versus placebo). For this dose, 58% of patients achieved complete skin clearance (PASI100) at week 12. PASI responses across dose arms were consistent with the previously reported Phase 2b data of sonelokimab in moderate-to-severe plaque-type psoriasis, with the 120mg dose achieving the highest responses for PASI100 (close to 60% of patients at week 12, ITT-NRI) in patients with more severe skin lesions (PASI score ≥ 10 at baseline).

Other clinically relevant secondary endpoints, such as Minimal Disease Activity (MDA), the modified Nail Psoriasis Severity Index (mNAPSI), the Leeds Enthesitis Index (LEI) and the patient self-reported Psoriatic Arthritis Impact of Disease (PsAID-12), each show promising levels of response at week 12.

Adalimumab was used as an active reference to validate responses across arms (not powered for statistical comparisons to active treatment). Sonelokimab 60mg and 120mg (with induction) numerically outperformed adalimumab on the primary endpoint and all key secondary endpoints, with the observed deltas further supporting the potential for sonelokimab as a future leading therapy.

The patient discontinuation rate in the ARGO trial was low at week 12 (less than 4%), similar to what was observed in previous trials of sonelokimab in psoriasis and hidradenitis suppurativa. The safety profile of sonelokimab in ARGO was consistent with previously reported studies with no new safety signals. Specifically, oral candidiasis was observed in less than 2% of patients on sonelokimab, with no case leading to discontinuation. No cases of inflammatory bowel disease (IBD), major adverse cardiovascular events (MACE) or suicidal ideation and behavior ("SI/B") were observed. Overall, sonelokimab continues to show a favorable safety profile. Across the sonelokimab clinical program to date, the Company has not seen any signal of SI/B or liver enzyme elevations related to sonelokimab treatment.

The results suggest that, as early as week 12, the Nanobody® sonelokimab reaches levels of clinical response at or above those seen with other therapies tested in similarly stringent trials. The high performance of sonelokimab and its favorable safety profile continue to support the potential of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated November 5, 2023
99.2	Slide Presentation, dated November 6, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: **November 6, 2023**

MOONLAKE IMMUNOTHERAPEUTICS

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Immunotherapeutics announces landmark Phase 2 results for Nanobody® sonelokimab in active psoriatic arthritis

- First placebo-controlled randomized trial in active psoriatic arthritis (PsA) using a Nanobody® to report positive topline results in support of potential best-in-class profile
- Primary endpoint ACR50 met with up to 47% ($p<0.01$ versus placebo) of patients on sonelokimab achieving ACR50 as early as week 12
- All key secondary endpoints met including up to 77% ($p<0.001$ versus placebo) of patients on sonelokimab achieving PASI90 as early as week 12
- Other secondary endpoints also reached statistical significance at week 12, including endpoints focused on deep tissue inflammation, Minimal Disease Activity (MDA) and patient reported outcomes
- High threshold outcomes, including ACR70 and PASI100, continue to improve beyond week 12, consistent with previous studies of sonelokimab
- Discontinuation rate below 4% and safety results of sonelokimab consistent with previously reported studies with no new safety signals
- The top-line data will be discussed on Monday 6 November, at 2pm CET/8am ET, via webcast (registration link below)

ZUG, Switzerland, November 5, 2023 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive top-line results from its global Phase 2 ARGO trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with active psoriatic arthritis (PsA).

The ARGO trial (M1095-PSA-201), which enrolled 207 patients, met its primary endpoint with a statistically significant greater proportion of patients treated with either sonelokimab 60mg or 120mg (with induction) achieving an American College of Rheumatology (ACR) 50 response compared to those on placebo at week 12. Specifically, for the 60mg and 120mg doses with induction, respectively, 46% and 47% of patients treated with sonelokimab achieved ACR50 ($p<0.01$ versus placebo); 78% and 72% of patients achieved ACR20; and 29% and 26% achieved ACR70. The primary analyses were based on the most stringent type of analysis for such trials, intention-to-treat with non-responder imputation (ITT-NRI). As expected, the 60mg dose without induction did not reach statistical significance, confirming the 60mg and 120mg with induction as the potential dose regimens to carry forward into Phase 3.

All key secondary endpoints were met for the 60mg and 120mg doses with induction. The key secondary endpoint Psoriasis Area and Severity Index (PASI) 90 was met for all doses with induction; 77% of patients responding at week 12 to the 60mg dose (ITT-NRI, $p<0.001$ versus placebo). For this dose, 58% of patients achieved complete skin clearance (PASI100) at week 12. PASI responses across dose arms were consistent with the previously reported Phase 2b data of sonelokimab in moderate-to-severe plaque-type psoriasis, with the 120mg dose achieving the highest responses for PASI100 (close to 60% of patients at week 12, ITT-NRI) in patients with more severe skin lesions (PASI score ≥ 10 at baseline).

Other clinically relevant secondary endpoints, such as Minimal Disease Activity (MDA), the modified Nail Psoriasis Severity Index (mNAPSI), the Leeds Enthesitis Index (LEI) and the patient self-reported Psoriatic Arthritis Impact of Disease (PsAID-12), each show promising levels of response at week 12.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"As part of our efforts to elevate outcomes for patients, we set ambitious goals for our Nanobody® sonelokimab. ARGO is MoonLake's third Phase 2 trial and the first trial in psoriatic arthritis using a Nanobody® to report positive topline results, setting another landmark milestone. Again, we met the objectives we set out for ourselves, in this case for PsA. As with our hidradenitis suppurativa program, the preparation of our Phase 3 program in PsA is rapidly advancing and expected timing of end-of-Phase 2 regulatory meetings will be announced in due course."*

Adalimumab was used as an active reference to validate responses across arms (not powered for statistical comparisons to active treatment). Sonelokimab 60mg and 120mg (with induction) numerically outperformed adalimumab on the primary endpoint and all key secondary endpoints, with the observed deltas further supporting the potential for sonelokimab as a future leading therapy.

The patient discontinuation rate in the ARGO trial was low at week 12 (less than 4%), similar to what was observed in previous trials of sonelokimab in psoriasis and hidradenitis suppurativa. The safety profile of sonelokimab in ARGO was consistent with previously reported studies with no new safety signals. Specifically, oral candidiasis was observed in less than 2% of patients on sonelokimab, with no case leading to discontinuation. No cases of inflammatory bowel disease (IBD), major adverse cardiovascular events (MACE) or suicidal ideation and behavior (SI/B) were observed. Overall, sonelokimab continues to show a favorable safety profile. Across the sonelokimab clinical program to date, the company has not seen any signal of SI/B or liver enzyme elevations related to sonelokimab treatment.

The results suggest that, as early as week 12, the Nanobody® sonelokimab reaches levels of clinical response at or above those seen with other therapies tested in similarly stringent trials. The high performance of sonelokimab and its favorable safety profile continue to support the potential of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases.

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: "*The positive topline results from the pivotal-like ARGO trial establish the Nanobody® sonelokimab as an innovative potential treatment in another chronic inflammatory disease, psoriatic arthritis. Importantly, the results confirm our expectations in terms of dosing, clinical responses and safety findings. We believe that we have elevated the therapeutic bar by reaching important clinical outcomes at week 12. The data also support sonelokimab's unique molecule characteristics and mode of action to effectively inhibit IL-17F in addition to IL-17A in deep tissue inflammation. The positive outcome of the ARGO trial would not have been possible without the support and participation of the patients and investigators to whom we are grateful.*"

Joseph F. Merola, MD, MMSc, Professor of Dermatology, Medicine and Rheumatology, Distinguished Chair of Dermatology at UT Southwestern Medical Center added: *"Psoriatic arthritis is a chronic, inflammatory, recurrent, and debilitating multidomain disease that has profound and wide-ranging impacts across many aspects of patients' lives. As a physician, I see tremendous need for new treatment options for people living with PsA, particularly for therapies that reach high thresholds of response (e.g., ACR70, PASI100) and that simultaneously improve the disease domains that matter most for patients. The positive high clinical responses across joint and skin endpoints and stringent composite measures such as minimal disease activity observed with sonelokimab as early as week 12 in the Phase 2 ARGO trial are encouraging, demonstrating its promise as a potential future treatment option.*"

These topline data will be discussed on Monday November 6, 2023 at 2pm CEST/8am ET before the Nasdaq market opens, via webcast at:

https://edge.media-server.com/mmc/p/bp43a4xr

A replay of the webcast and the presentation document will be made available at https://ir.moonlaketx.com.

The ARGO trial proceeds to week 24, with a 4-week safety follow-up. Important data is being collected regarding longer-term efficacy and safety of sonelokimab, as well as results from the cross-over of patients treated with placebo or adalimumab to sonelokimab and the continued monthly dosing of sonelokimab.

Today's top-line data announcement follows the announcement in July 2023 that the ARGO trial successfully completed randomization of its target 200 patients, several weeks ahead of schedule (read more here). Full results from the ARGO trial will be submitted for publication in a peer-reviewed medical journal and for presentation at an upcoming scientific meeting.

The positive top-line12-week results from the Phase 2 ARGO trial in PsA follows the positive top-line 12-week and 24-week results from the Phase 2 MIRA trial in hidradenitis suppurativa (HS) as announced in June 2023 (read more here) and October 2023 (read more here). The MIRA trial set a landmark milestone as the first placebo-controlled randomized trial in HS to report positive top-line results using HiSCR75 as the primary endpoint.

Sonelokimab is not yet approved for use in any indication.

- Ends -

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic and progressive inflammatory arthritis associated with psoriasis primarily affecting the peripheral joints. The clinical features of PsA are diverse, involving pain, swelling, and stiffness of the joints, which can result in restricted mobility and fatigue. PsA occurs in up to 30% of patients with psoriasis, most commonly those aged between 30 and 60 years. The symptom burden of PsA can have a substantial negative impact on patient quality of life. Although the exact mechanism of disease is not fully understood, evidence suggests that activation of the IL-17 pathway plays an important role in the disease pathophysiology.

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 Nanobody® sonelokimab, administered subcutaneously, in the treatment of adult patients with active PsA. The trial 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 also evaluates a number of secondary endpoints, including improvement compared to placebo in ACR20, complete skin clearance as measured by at least a 100% improvement in the Psoriasis Area and Severity Index (PASI), 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

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 is being assessed in two trials, the Phase 2 ARGO trial in PsA (trial ongoing) and the Phase 2 MIRA trial in HS. 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 clinically relevant outcomes.

Sonelokimab has also been assessed in a randomized, placebo-controlled Phase 2b trial (NCT03384745) in 313 patients with moderate-to-severe plaque-type psoriasis. Clinical response (considering the Investigator's Global Assessment Score 0 or 1, and the Psoriasis Area and Severity Index 90/100) was 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 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 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 their ability to be designed into multivalent therapeutic molecules with bespoke target combinations.

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. The terms Nanobody® and Nanobodies® are trademarks of Ablynx, a Sanofi company.

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 clinical trials and research and development programs; and the anticipated timing of the results from those trials, including completing the MIRA trial and top-line data from the ARGO trial; and the efficacy of our products, if approved, including in relation to other products. 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, and reliance on third parties to conduct and support its 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, 2022 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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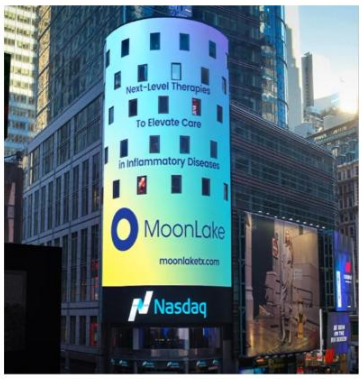
Exhibit 99.2


MoonLake
MoonLake Immunotherapeutics
R&D Day Webcast
Presentation Document – Results ARGO trial
November 6th 2023
© 2023 | Proprietary | MoonLake TX
W: moonlaketx.com | E: info@moonlaketx.com

Welcome to our R&D Day

MoonLake

Date: November 6th, 2023
Time: 8am EDT
Location: Nasdaq (Webcast)



Topic	Sub-topics	Lead	Timing
Intro	- Key messages	Jorge Santos da Silva	5 mins
PsA – ARGO trial Primary Endpoint Readout	- ARGO's profile, incl. baseline - Efficacy data at primary & secondary endpoints - Safety data & other secondaries - Discussing impact of ARGO in PsA	Kristian Reich	30 mins
Moving Forward	- Conclusions - Overall value of MLTX - Path forward	Jorge Santos da Silva	10 mins
Q&A		Matthias Bodenstedt	To end

Source: MoonLake Corporate

Disclaimer

MoonLake

Forward Looking Statements

Certain statements in this presentation may constitute "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 our expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for clinical trials and research and development programs, including our MIRA trial in HS; the anticipated timing of the results from those trials expected near-term catalysts with respect to our clinical trials; and expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations. 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", " strive", "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that such statement is not forward looking. Forward-looking statements are based on current expectations and assumptions that, while we and our management consider reasonable, 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 our business in general and limited operating history, the risk that past results may not be predictive of future results, difficulty enrolling patients in clinical trials, and reliance on third parties to conduct and support our clinical trials, and the other risks described in or incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the Securities and Exchange Commission. Nothing in this presentation 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 presentation, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. We neither undertake nor accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in our expectations or in the events, conditions or circumstances on which any such statement is based. This presentation does not purport to summarize all of the conditions, risks and other attributes of MoonLake Immunotherapeutics.

Industry and Market Data

Certain information contained in this presentation relates to or is based on studies, publications, surveys and our own internal estimates and research. In this presentation, we rely on, and refer to, publicly available information and statistics regarding market participants in the sector in which we compete and other industry data. Any comparison of us to any other entity assumes the reliability of the information available to us. We obtained this information and statistics from third-party sources, including reports by market research firms and company filings. In addition, all of the market data included in this presentation involve a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our internal research is reliable, such research has not been verified by any independent source and we have not independently verified the information.

Trademarks

This presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, trade names and copyrights referred to in this presentation may be listed without the TM, SM © or ® symbols, but we will assert, to the fullest extent under applicable law, the rights of the applicable owners, if any, to these trademarks, service marks, trade names and copyrights.

Source: MoonLake Corporate

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Instructions for this session

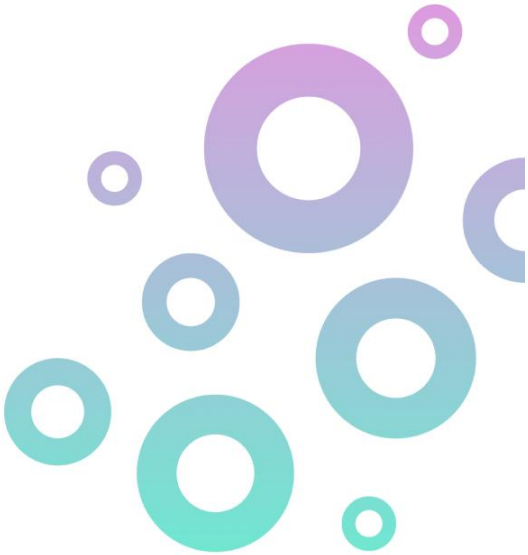
Please **take note of the disclaimer** on the prior page

You can **submit your questions through the Q&A function** – we will address as many questions as possible at the end of this session

The presentation and a **replay** will be made available on our IR website

For any **technical issues** during the webcast, please also use the Q&A function to request support

Other requests should be directed to ir@moonlaketx.com or media@moonlaketx.com



Source: MoonLake Corporate

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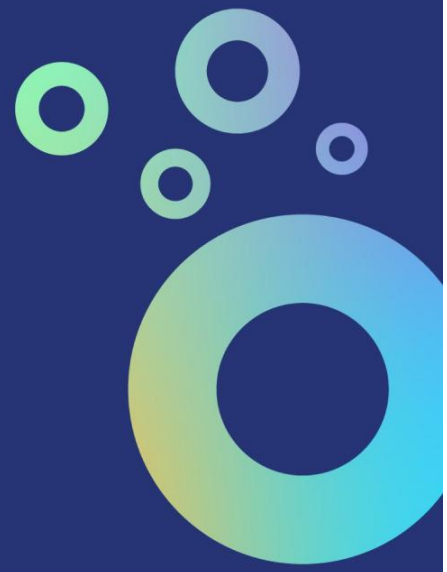
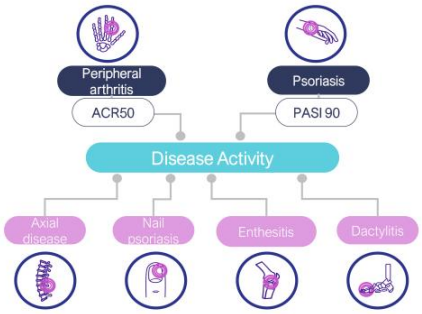
Introduction



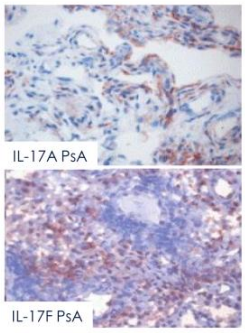
PsA: IL-17F dependent multi-domain disease in difficult-to-reach tissues

MoonLake

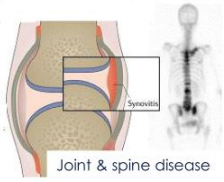
PsA is a multi-domain deep-tissue disease…



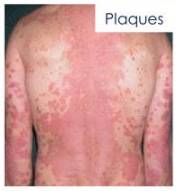
…with 3x IL-17F vs IL-17A[1]…



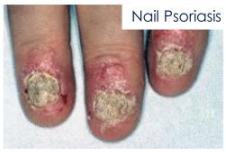
…and causing devastating damage



Joint & spine disease



(PsA starts as enthesitis[2], with IL-17F producing cells in associated plaques[3] and axial disease[4-6], and with 80% of patients suffering from nail psoriasis[7])



Market size

0.5% Global prevalence

10+ USD bn sales beyond 2030

Unmet Needs

80% or more patients with multiple disease domains

10% skin involvement in PsA patients – severe skin disease

20% is still standard ACR level of improvement

1 van Baarsen LG, et al. Arthritis Res Ther. 2014; 16:426-436; 2 Schett G, et al. Nature Reviews Rheumatology. 2017; 13:731-741; 3 Prinz JC, et al. J Exp Med. 2020 Jan 6;217(1):e20191397; 4 Sweet K, et al. RMD Open 2021;7:e001679; 5 Shao M, et al. Clin Immunol 2020;213:108374; 6 Lories RJ and McInnes IB. Nature Medicine. 2012; 18:1018-1019; 7 Reich K. J Eur Acad Dermatol Venereol. 2009; 23 Suppl 1:15-21; Clinical pictures K. Reich

Source: MoonLake Medical, Clinical pictures K. Reich

The key messages

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MLTX's ARGO trial is a SUCCESS

- Joints: **ACR50 primary endpoint met at wk 12** for 60mg and 120mg induction doses – up to 47% ACR50 ($p<0.01$ vs placebo)
- Skin: **PASI90 secondary endpoint met at wk 12** also for 60mg and 120mg induction doses – up to 77% PASI90 ($p<0.001$ vs placebo)
- Other **secondary end points met at wk 12, wk16 data indicated continued improvement**– *impact of SLK for PsA patients is clear (e.g., PASI100, ACR70, MDA)*
- **No new safety signals** – *continues to indicate favorable safety profile*

MLTX's SLK Nanobody® continues to open a new era in therapy

- Differentiating on **multi-domain responses – consistency across skin & joint scores**
- Potential to use both doses (60mg and 120mg), advantageous for label
- Highest numbers **on higher level outcomes** (e.g., ACR70, PASI100) at week 12
- Impact in **important disease activity scores** as early as week 12
- Differentiating with **favorable safety profile**

MLTX positioned to become a leader in I&I

- Our view: SLK now a **leading potential asset in HS, PsA & PsO** (all multi-bn markets)
- A **wealth of potential indications** to further pursue ($30bn+)
- Soon **Ph3-ready in 3+ TAs** – expected to start Ph3s in 2024

Source: MoonLake Corporate

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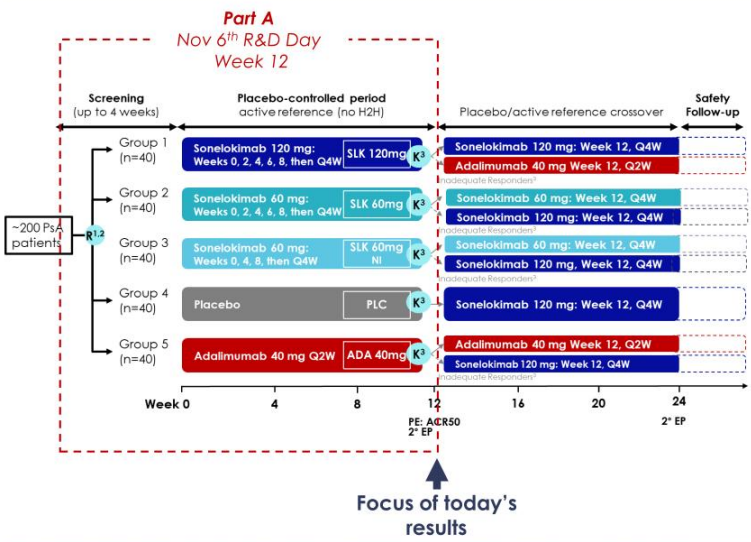
ARGO Trial
Results

ARGO: Phase 2 trial design



Key design elements of ARGO

- Global study with approx. **50 sites**, with **207 patients** randomized
- **Double-blind, placebo-controlled, active reference arm**
- **Active PsA** (TJC68 ≥3, SJC≥3, current active PsO and/or confirmed PsO)
- **ACR50** as primary endpoint, PASI90 as key secondary endpoint
- **ITT-NRI** primary analysis; Stratification by sex, previous bio use
- Groups 1 ("**SLK 120mg**" with induction) and 2 ("**SLK 60mg**" with induction) are doses previously used in SLK trials
- Group 3 ("**SLK 60mg NI**", no induction) was used to support requirement for induction dosing

Notes: 1 Randomization stratified by sex and prior exposure to biologics; 2 At Week 0/Day 1, all eligible participants were randomized 1:1:1:1:1:3 in the cross-over period, starting at Week 12, participants on sonelokimab 120 mg who did not achieve an adequate response switched to adalimumab 40 mg Q2W until Week 24; participants on sonelokimab 60 mg (started at baseline Q2W or Q4W) who did not achieve an adequate response switched to sonelokimab 120 mg Q4W until week 24; participants on adalimumab who did not achieve an adequate response switched to sonelokimab 120 mg Q4W until Week 24; an adequate response is defined as a reduction of the tender and swollen joint count of ≥20%. Participants on placebo at Week 12 were switched to sonelokimab Q4W until Week 24

Source: MoonLake Clinical

Baseline: All arms of the ARGO trial are **well balanced**

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Patient characteristics	Overall ARGO (n=207)	Main arms: Placebo (n=40)	Sonelokimab 60mg NI (n=41)	Sonelokimab 60mg (n=41)	Sonelokimab 120mg (n=43)	Active reference: Adalimumab (n=42)
Age, yrs, mean	**49**	47	50	48	50	48
Female, %	**49**	48	51	49	49	50
BMI, kg/m^2, mean	**29.0**	27.9	29.6	27.7	30.3	29.3
Duration of PsA, yrs, mean	**5.4**	5.7	6.0	6.2	4.9	4.1
Prior biologic use, %	**17**	15	20	17	19	17
Concomitant non-biologic DMARD, %	**70**	68	81	63	67	69
Concomitant MTX, %	*67*	*65*	*78*	*56*	*67*	*67*
Tender Joint Count (TJC68), mean	**17**	17	18	17	17	16
Swollen Joint Count (SJC66), mean	**9**	9	11	9	9	10
Affected BSA ≥ 3%, %	**69**	67	78	63	63	76
PASI (BSA ≥ 3%), mean	**7.2**	7.1	6.7	8.0	7.2	7.3
Nail psoriasis (mNAPSI > 0), %	**55**	55	59	54	40	67
mNAPSI, mean	*13.4*	*15.2*	*16.0*	*11.5*	*14.4*	*10.5*
Presence of enthesitis (LEI > 0), %	**32**	36	34	39	26	24
LEI score, mean	*2.4*	*1.9*	*2.9*	*2.9*	*2.7*	*1.6*
Presence of dactylitis, %	**12**	13	10	12	12	12
Patient Pain (PtAAP), mean	**58**	56	60	60	55	58
PsA Impact of Disease (PsAID) 12, mean	**4.2**	3.9	4.3	4.6	3.9	4.5

Source: MoonLake Clinical

Disposition: The ARGO trial has a drop-out of rate of < 4%

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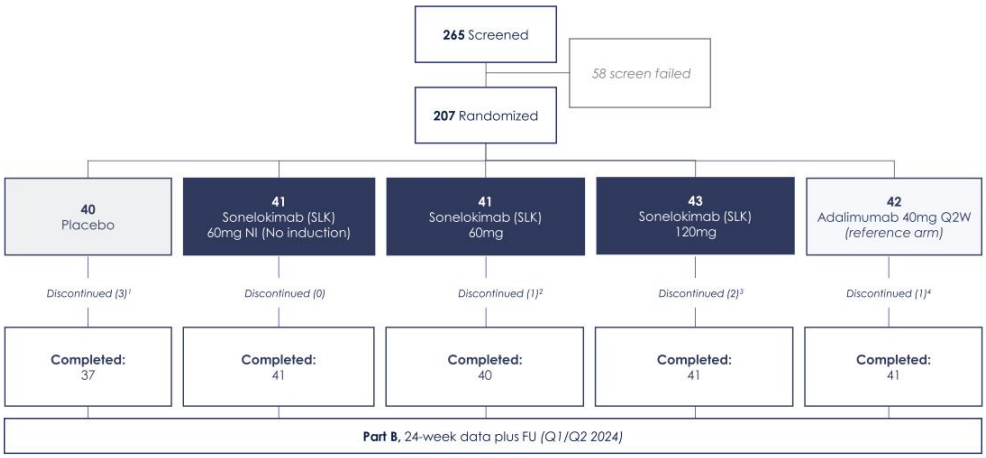
Disposition (Part A)



Note: Part A (week 12)database lock 12th October 2023. AE =Adverse Event, Wdw by S = Withdrawal by Subject; Completed Part A = completed treatment up to Week 10 and completed assessments to Week 12; 1 1x Not Treated, 1x Wdw by S & 1 x Lack of Effect; 2: 1x Protocol withdrawal criteria; 3: 1x AE (not related to treatment) & 1x Wdw by S; 4: 1x Wdw by S

Source: MoonLake Clinical

ACR50: SLK reaches the **highest scores seen** at week 12

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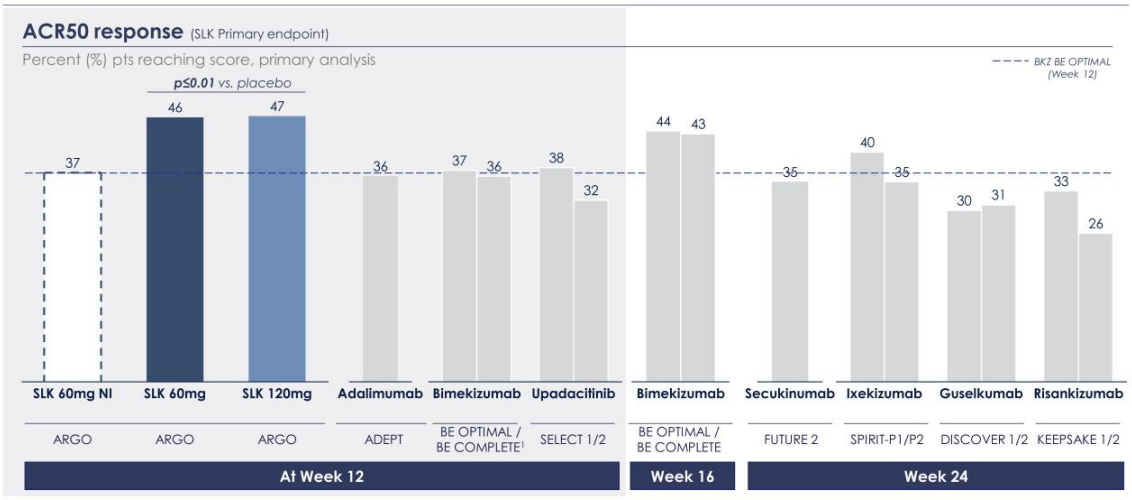

For reference: ADA 43% ACR50 (ARGO); ADA 46% ACR50 (BE OPTIMAL)

Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. Multiplicity-controlled p-values from a logistic regression with covariates for sex and prior biologic use 1 Not the primary analysis, estimated from trial published data

Source: MoonLake Clinical

ACR50 primary endpoint responses increase over time

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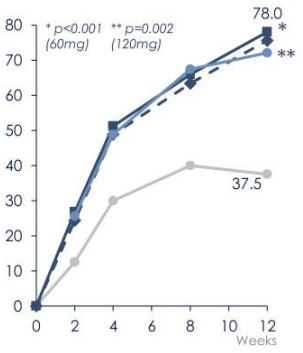
PLC — SLK 60mg NI — SLK 60mg — SLK 120mg

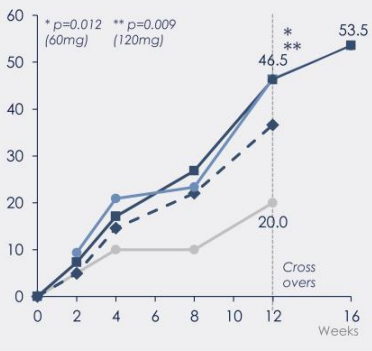
ACR20 response

Percent (%) pts reaching score, ITT-NRI



ACR50 response (Primary endpoint)

Percent (%) pts reaching score, ITT-NRI



Primary endpoint met for 60mg and 120mg – SLK 60mg NI not significantly different from PLC

High response levels across all ACR levels measured

As expected, **60mg dose of SLK is sufficient** to drive promising ACR50 responses

Scores **increase over time** esp. for the higher scores

PLC higher vs. **4-13% in similar trials**[1], and **before control with the ADA active reference** arm

*, ** multiplicity-controlled p-values from a logistic regression with covariates for sex and prior biologic use. All patients have reached week 16, week 24 database to be locked in Q1 2024 1 Including comparable trials: ADEPT, DISCOVER 1 and 2, SPIRIT-P1, BE OPTIMAL (BKZ, 7%), FUTURE 2, KEEPSAKE 2, SELECT 1 (highest PLC, 13%)

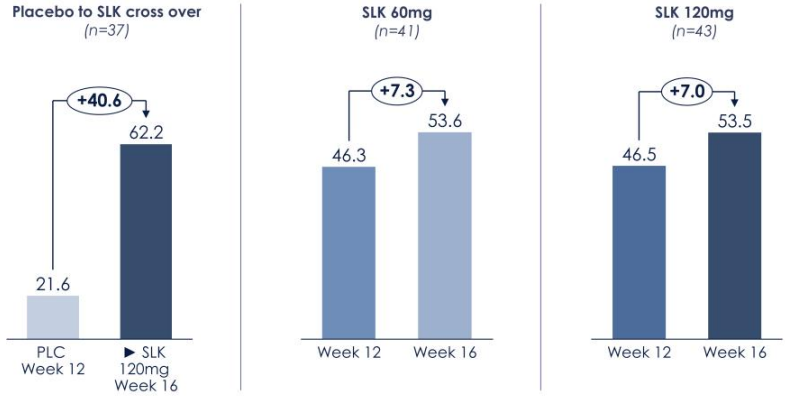
Source: MoonLake Clinical

Beyond week 12: continued ACR50 improvement for main doses

MoonLake

ACR50 responses at week 16

Percent (%) of patients in each arm, ITT[1]



SLK **ACR50 response increases with monthly maintenance dosing**, reaching to 50%+ (60mg NI plateaus at week 16)

1 Subjects who switched treatment at Wk 12 were counted as non-responders at Wk 16. Subjects who ended the study per protocol had their Wk 12 ACR50 response carried forward. All patients have reached week 16, week 24 database to be locked in Q1 2024

Source: MoonLake Clinical

Beyond week 12: the same is observed for ACR70

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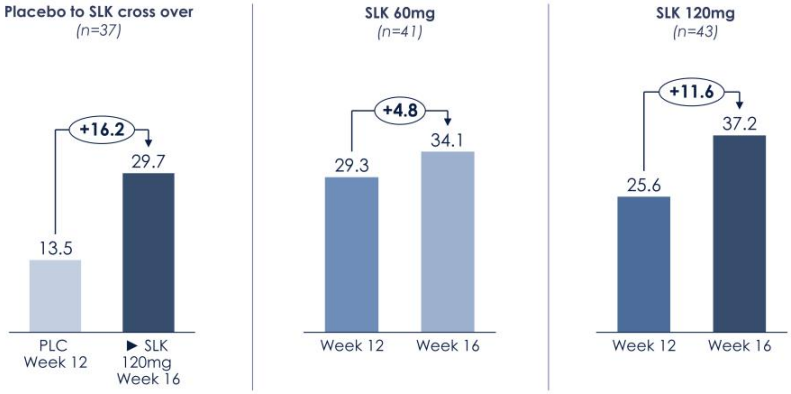
ACR70 responses at week 16

Percent (%) of patients in each arm, ITT[1]



ACR70 response also continues to increase **with monthly maintenance dosing** to levels **over 35%** - above competitors

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. 1 Subjects who switched treatment at Wk 12 were counted as non-responders at Wk 16. Subjects who ended the study per protocol had their Wk 12 ACR70 response carried forward. All patients have reached week 16, week 24 database to be locked in Q1 2024

Source: MoonLake Clinical

SLK reaches the **highest PASI90** scores already at week 12

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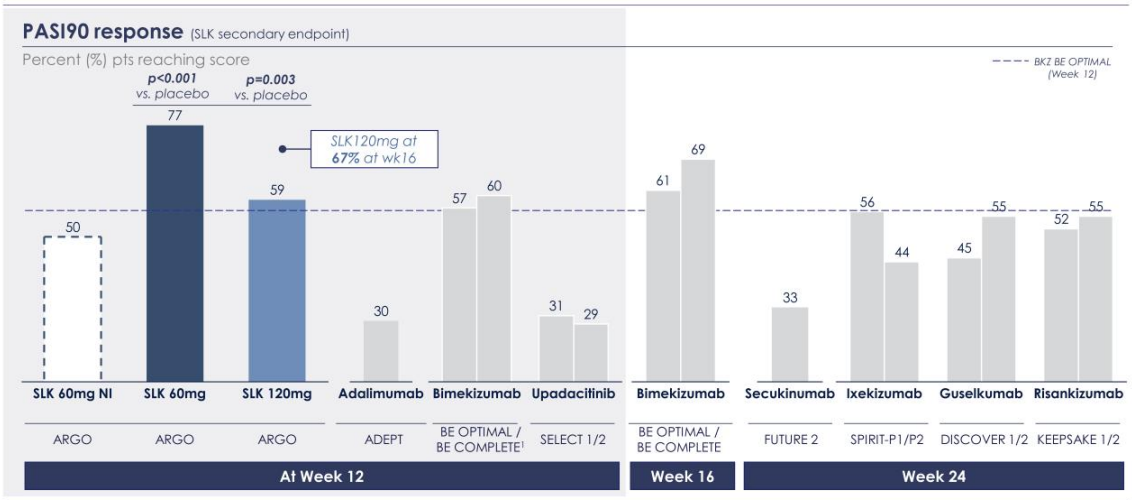

For reference: ADA 50% PASI90 (ARGO); ADA 41% PASI90 (BE OPTIMAL)

Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. Multiplicity-controlled p-values for SLK from a logistic regression with covariates for baseline PASI, sex and prior biologic use 1 Estimated from trial published data

Source: MoonLake Clinical

ARGO **met PASI90 key secondary endpoint** in PsA

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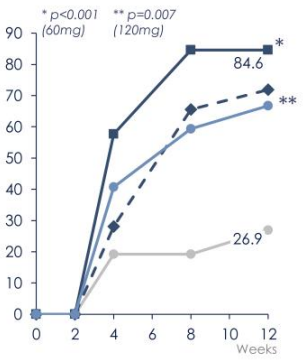
PLC — SLK 60mg NI — SLK 60mg — SLK 120mg

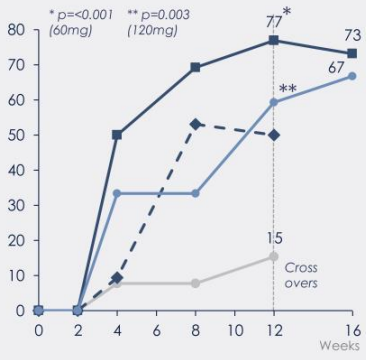
PASI75 response

Percent (%) pts reaching score, ITT-NRI



PASI90 response (Key secondary endpoint)

Percent (%) pts reaching score, ITT-NRI



- All **doses significantly respond** across PASI scores
- **Above all comparable** data for other products at week 12 incl. BKZ
- Versus ACR, 60 and 120 mg **doses separate for PsA skin lesions**
- **60mg performs well** in terms responses for **overall PsA skin lesions** at week 12
- A higher dose likely required for **PsA subgroups with moderate-to-severe skin involvement** and deeper responses

PASI90 multiplicity-controlled and PASI75 nominal p-values from a logistic regression with covariates for sex and prior biologic use. All patients have reached week 16, week 24 database to be locked in Q1 2024

Source: MoonLake Clinical

The 120mg is the **most effective dose for moderate-to-severe skin PsO**

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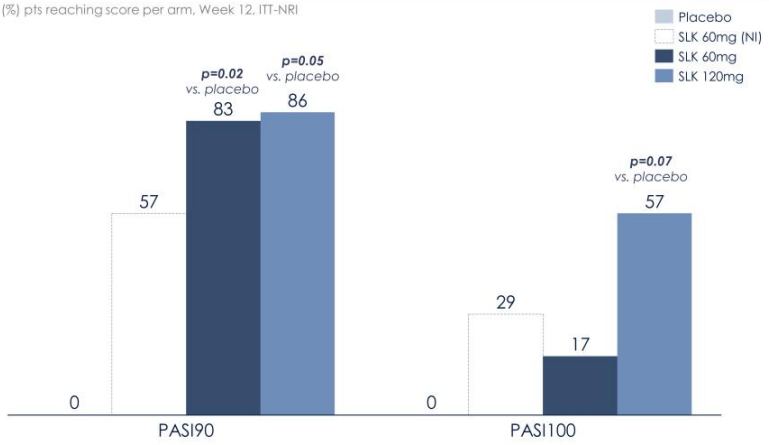
PASI responses in ARGO patients with **PASI ≥ 10**

Similar skin to our PsO trial[1]

Percent (%) pts reaching score per arm, Week 12, ITT-NRI



Whereas 60mg is sufficient for overall PsA population, **120mg is still most effective for PsO** (as per our 313 patient Phase 2b[1])

Nominal P values from a logistic regression with covariates for baseline PASI, sex, prior biologic use, treatment and treatment by baseline PASI interaction 1 Papp et al. Lancet. 2021;397:1564–75

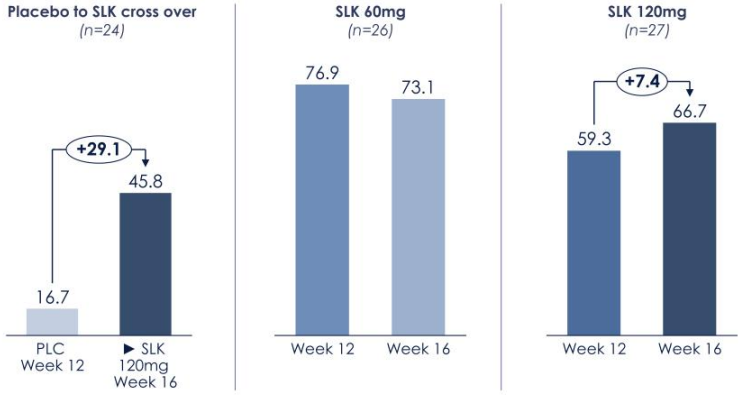
Source: MoonLake Clinical

Beyond week 12: Cross overs show continued PASI90 improvement

MoonLake

PASI90 responses at week 16

Percent (%) of patients in each arm, ITT



Placebo **switch to SLK** rapidly elevates PASI90 responses
All monthly doses of **SLK drive PASI90 to close or above 70%** to week 16 (above other PsA leading assets)

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. For placebo cross overs to SLK the responses only include patients that received SLK in Part B. Subjects who ended the study per protocol or switched treatment at Wk 12 had their Wk 12 PASI 90 response carried forward. All patients have reached week 16, week 24 database to be locked in Q1 2024

Source: MoonLake Clinical

Beyond week 12: Cross overs show continued PASI100 improvement

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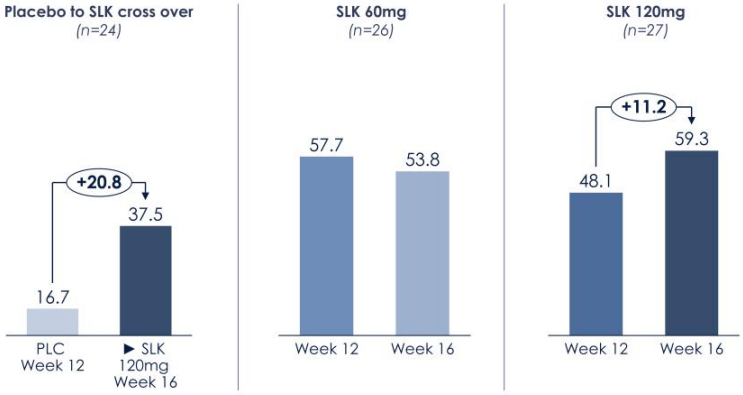
PASI100 responses at week 16

Percent (%) of patients in each arm, ITT



Placebo **switch to SLK** rapidly elevates PASI100 responses
All monthly doses of **SLK drive PASI100 above 50%** to week 16 (and above other PsA leading assets)

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. For placebo cross overs to SLK the responses only include patients that received SLK in Part B. Subjects who ended the study per protocol or switched treatment at Wk 12 had their Wk 12 PASI 100 response carried forward. All patients have reached week 16, week 24 database to be locked in Q1 2024

Source: MoonLake Clinical

How does SLK compare to BKZ in ACR50 and PASI90?

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Comparison of ARGO and BE OPTIMAL using active reference arm

At primary endpoint, **SLK performs better than BKZ in ACR50 or PASI90** using the ADA active reference arm to compare (most reliable comparison)

Also, using the active ADA reference arms in each trial, we can **reliably determine delta to placebo – 39ppt** for ACR50

SLK delta to placebo for PASI90 is **62ppt**

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. 1 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL

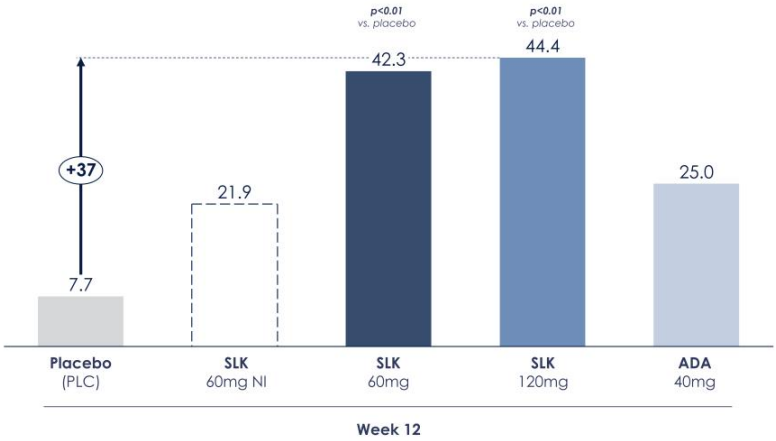
Source: MoonLake Clinical

SLK brings over 40% of patients to **both ACR50 and PASI90** at week 12

MoonLake

Patients reaching both ACR50 and PASI90

Percent (%) pts reaching score, ITT-NRI



- Over **40% of patients** reach both ACR50 and PASI90
- Both **60 mg and 120mg** with induction behave similarly
- As would be expected in PsA, for **some subgroups and some timepoints** one dose performs better than the other, e.g.,
  - 120mg better in patients with moderate-to-severe or nail PsO
  - 60mg is sufficient to control joint inflammation
- The **non-induction dose is not sufficient** to optimally control inflammation in PsA

Note: Nominal p-values from a logistic regression with covariates for sex and prior biologic use; all patients with BSA>=3% at baseline, and distribution of such patients is balanced between arms (see baseline details). Comparison across trials, with inherent limitations. No head-to-head trials.

Source: MoonLake Clinical

Let's look further: In ACR70 SLK further differentiates

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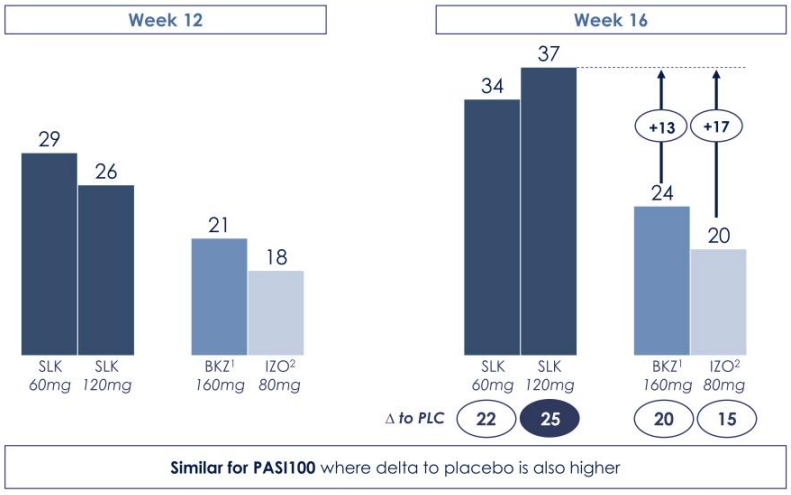
ACR70 response (% of patients)



Similar for PASI100 where delta to placebo is also higher

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Placebo for SLK is 12.5%, for BKZ is 3% and for IZO is 5%. All patients have reached week 16, week 24 database to be locked in Q1 2024 1 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL 2 Behrens et al. 2022 EULAR OP

Source: MoonLake Clinical

Let's look further: SLK brings 1 in 3 patients to **both ACR50 and PASI100**

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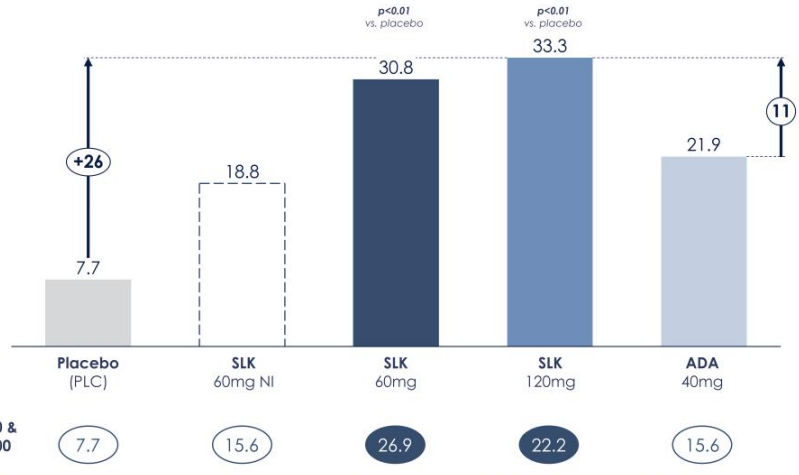
Patients reaching both ACR50 and PASI100 at week 12

Percent (%) pts reaching score, ITT-NRI



ACR70 & PASI100 (%)	7.7	15.6	26.9	22.2	15.6

- **One third of patients** reach ACR50 and PASI100
- That is **higher than other competitors** have shown, including BKZ, IXE, or SEC
- ACR50+PASI100 **SLK above BKZ** (16.1%, wk 12[1])
- While data from other products has not been disclosed for **ACR70 and PASI100, SLK numbers already show close to 1 in 4 patients** could aspire to this level of response

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Nominal p-values from a logistic regression with covariates for sex and prior biologic use; all patients with BSA>=3% at baseline, and distribution of such patients is balanced between arms (see baseline details) | Warren et al., EADV 2021, P0353

Source: MoonLake Clinical

MDA: A composite of ambitious clinical response targets in joints & skin

>3 in 4 patients do not achieve MDA
within 6 months of biologic initiation[1]

% of patients who were MDA responders

MDA breakdown[2]

MDA (Minimal Disease Activity) denotes a patient who has achieved **≥5 of the following 7 criteria**:

1. **Joints:** TJC ≤1
2. **Joints:** SJC ≤1
3. **Skin:** PASI ≤1 *(or BSA ≤3%)*
4. **Entheses:** Tender entheseal points ≤1
5. **PRO:** Patient pain VAS ≤15
6. **PRO:** Patient global activity VAS ≤20
7. **PRO:** HAQ-DI VAS ≤0.5

Achievement of MDA clinical responses with any biologic remains low

1 Data from the CorEvitas registry (N=1,251); Ogdie et al. ACR 2021;abstract 1344; 2 BSA, body surface area; HAQ-DI, Health Assessment Questionnaire Disability Index; PASI, Psoriasis Area and Severity Index; PRO, patient-reported outcome; S/TJC, swollen/tender joint count; VAS, visual analog scale; Gossec et al. J Rheumatol. 2018;45:6–13

Source: Prof Joseph Merola

Achievement of leading MDA responses **already at week 12** for SLK

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Minimal Disease Activity (MDA) response in ARGO

Percent (%) of patients in each arm, ITT-NRI

At week 12, MDA responses of SLK **already above what would was observed** in data from other products

At week 16, the ADA arm was similar to week 12 whereas **SLK responses keep increasing – 120 mg close to 50%**

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Nominal p-value from a logistic regression with covariates for sex and prior biologic use. All patients have reached week 16, week 24 database to be locked in Q1 2024 1 Estimated from data published for the respective study (Merola et al. Lancet. 2023;401:38–48 BE COMPLETE. McInnes et al. Lancet. 2023;401:25–37 BE OPTIMAL)

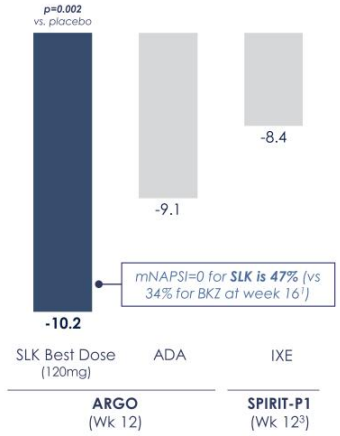
Source: MoonLake Clinical

SLK has highest responses **in deep tissue inflammation**

MoonLake

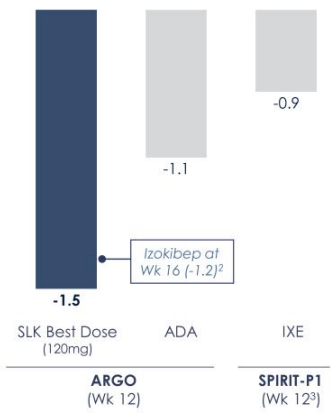
Nail PsO Severity Index ((m)NAPSI)

Mean change from baseline



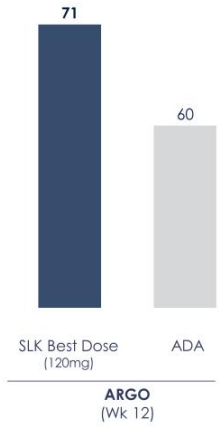
Leeds Enthesitis Index (LEI)

Mean change from baseline



Leeds Enthesitis Index (LEI)

Percent (%) of pts with LEI 2+ at baseline that improved 2+ pt, ITT-NRI



Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Nominal p-values, from MMRM including co-variates: baseline mNAPSI , sex, prior biologic use, visit, treatment and visit-by-treatment interaction 1 Merola et al. ACR 2023 Abstract #1433 2 Kurt de Vlam et al. ACR 2022 Poster #2151 (estimated from graph) 3 Mease et al. Ann Rheum Dis 2017;76:79-87 (NAPSI and LEI)

Source: MoonLake Clinical

SLK impacts **outcomes** reported by patients and physicians

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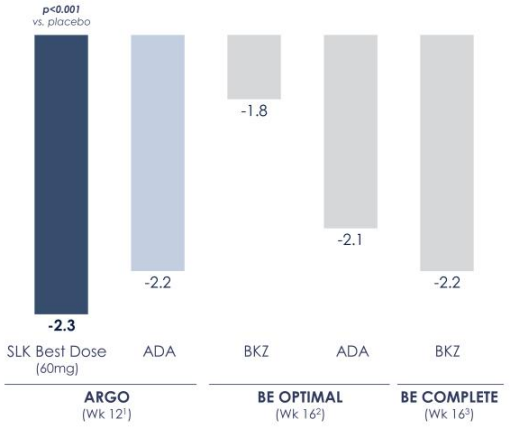
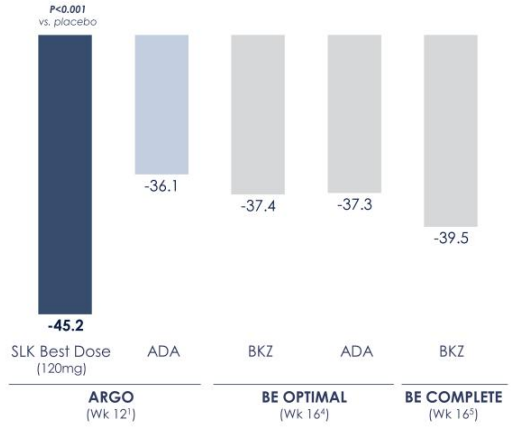
PsA Impact of Disease (PsAID-12)

Mean change from baseline, MMRM[1]



Physician global assessment of disease (PhGADA)

Percent (%) of patients, MMRM



SLK continues to impact **outcomes that matter for patients**, with **higher performance versus competitors** already at week 12

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Nominal p-values vs. placebo. 1 SLK analysis MMRM including co-variates: baseline, sex, prior biologic use, visit, treatment and visit-by-treatment 2 McInnes et al. Lancet. 2023;401:25–37 3 Merola et al. Lancet. 2023;401:38–48 4 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 5 Coates et al. ACR 2023 Abstract #2230

Source: MoonLake Clinical

Safety: **no notable signals** indicating a strong profile in PsA

MoonLake

	Placebo	Sonelokimab 60 mg NI	Sonelokimab 60 mg	Sonelokimab 120 mg	Adalimumab *(active reference)*
Patients with events, n (%)	39	41	41	43	42
Any TEAE	15 (38.5%)	12 (29.3%)	14 (34.1%)	17 (39.5%)	14 (33.3%)
Any SAE	0	0	1 (2.4%)[2]	0	0
Any TEAE leading to discontinuation	0	0	0	1 (2.3%)[3]	0
Fatal TEAE	0	0	0	0	0
Most frequent TEAEs[1]					
Upper respiratory tract infection	1 (2.6%)	3 (7.3%)	2 (4.9%)	1 (2.3%)	1 (2.4%)
Injection site erythema (reaction)	0	0	2 (4.9%)	3 (7.0%)	1 (2.4%)
Headache	0	0	1 (2.4%)	2 (4.7%)	0
Adverse events of special interest					
IBD	0	0	0	0	0
Diarrhea	0	0	1 (2.4%)	0	1 (2.4%)
Candidiasis					
Oral Candidiasis	0	1 (2.4%)	1 (2.4%)	0	0
Oropharyngeal Candidiasis	0	0	0	0	0
Esophageal Candidiasis	0	0	0	0	0
Vulvovaginal Candidiasis	0	0	0	0	0
Skin Candidiasis	0	0	0	0	0
Genital Candidiasis	0	0	0	0	0
Other adverse events of interest					
Serious hypersensitivity	0	0	0	0	0
Serious infection	0	0	1 (2.4%)[2]	0	0
MACE	0	0	0	0	0
Liver AST/ALT > 5x ULN	0	0	0	0	0

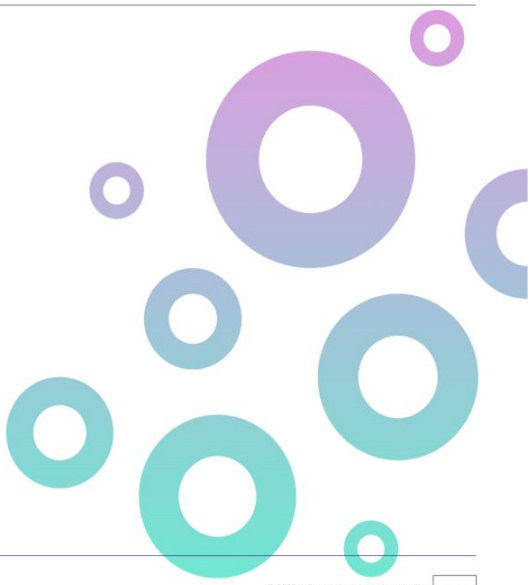
TEAE, treatment emergent adverse event; SAE, serious adverse event 1 Preferred terms (PTs) as per MEDRA (v26); 2 acute appendicitis leading to appendectomy, SAE due to hospitalization, not-related. 3 Patient discontinued at Week 10 due to AE of tonic clonic seizure, not related to treatment. One case with elevated transaminases >3x ULN in adalimumab arm reported as an AE: one case of transient elevated transaminases and CK concurrent with a reported event of exercise-related muscle inflammation in SLK 60 mg

Source: MoonLake Clinical

SLK continues to show a **favorable benefit-risk profile**

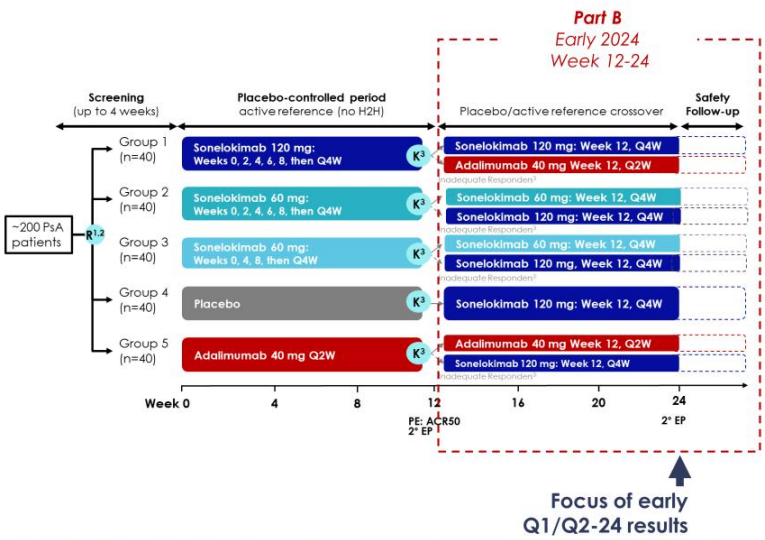
MoonLake

- **From the ARGO trial**
  - — No notable signals and no new signals
  - — No MACE, no IBD, no malignancies, no SI/B
  - — mAb-like ISR levels, no liver signals
  - — Less than 3% oral candidiasis on 60mg, none in 120mg - No discontinuations due to candidiasis
- **Beyond the ARGO trial**
  - — SLK has a favorable safety profile based on multiple trials (PsO, HS, PsA) involving ~700 pts
  - — We see no signal of SI/B related to SLK treatment
  - — We have not observed any signal related to liver enzyme elevations in patients exposed to SLK



Source: MoonLake Clinical

Guidance: What to expect from the second part of the ARGO trial



What we are looking for at Week 24

- Early data from wk 16 confirming **cross-over of patients from placebo elevates responses** – this will be analyzed in Part B
- It appears responses on the SLK **arms with induction (60 and 120mg) are either maintained or improved** at week 16 – this will be determined further in Part B
- Specific improvements on **switches to monthly dosing** also planned to be shared
- Results will be shared either through a presentation like today – as of **early 2024** – or through a conference
- A **peer-reviewed publication** is expected in due course

Notes: 1 Randomization stratified by sex and prior exposure to biologics; 2 At Week 0/Day 1, all eligible participants were randomized 1:1:1:1:1; 3 In the cross-over period, starting at Week 12, participants on sonelokimab 120 mg who have not achieved an adequate response will receive adalimumab 40 mg Q2W until Week 24; participants on sonelokimab 60 mg (started at baseline Q2W or Q4W) who have not achieved an adequate response will receive sonelokimab 120 mg Q4W until week 24; participants on adalimumab who have not achieved an adequate response will receive sonelokimab 120 mg Q4W until Week 24; an adequate response is defined as a reduction of the tender and swollen joint count of ≥20%. Participants on placebo will receive sonelokimab Q4W until Week 24

Source: MoonLake Clinical

A clear path towards Phase 3

MoonLake

What we already know at week 12

- **Dose-response pattern in line with findings** in plaque-type Psoriasis (PsO, 313 patients) and Hidradenitis Suppurativa (HS, 234 patients)
- Doses with **optimal benefit-risk profile** identified for PsA – **60 mg & 120mg** (with induction)
- Support of **favorable safety profile**
- Main ARGO study design **elements will be replicated in Phase 3** design
- **Larger trial size** (potentially ~800 per trial) expected to **reduce variations** driven by small groups (e.g., prior biologics in ACR50 PLC)
- **Endpoints confirmed** for Phase3 – ACR50 & PASI90 – but with expected **primary endpoint at week 16**
- Currently planning **two trials**
  - **TNF-IR** PLC-controlled trial
  - **Bio-naïve** PLC- and adalimumab-controlled trial

Open points to week 24

- Additional ARGO data to be considered in terms of e.g., expected responses, powering requirements, secondary endpoints
- 24-week results also need to be considered, for example impact of weight etc. to determine key sub-groups
- Considerations for two doses or dose escalation to address different sub-groups (e.g., with PASI≥10)
- ARGO full safety profile to confirm benefit-risk and any adjustments required to inclusion/exclusion

Source: MoonLake Clinical

MoonLake

Research & Clinical Summary

The scientific rationale for a unique molecule

- SLK has unique IL-17F and A binding properties, a key inflammation MoA
- SLK has enhanced tissue penetration, reaching where mAbs cannot
- Direct evidence in animal models of differential penetration into joints

What ARGO shows – impact of SLK Nanobody® in PsA

- ACR50 primary endpoint met with highest scores observed so far
- PASI90 secondary endpoint also met with highest scores observed so far
- Higher outcomes (ACR70, PASI100) vs current standards
- Impact on what matters for patients & physicians: MDA, mNAPSI, LEI, etc.
- Favorable safety tolerability profile, as observed previously in other trials

Optimal outcome for fast clinical development

- Winning dose regimen and endpoints now known for Phase 3
- Builds on HS and PsO data and de-risks next MLTX trials

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. SLK binding properties and tissue penetration data have been presented previously

Source: MoonLake Clinical

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Moving Forward

SLK is a potential leader in large inflammatory diseases

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	Trial	Patients (n)	Leading MoA	SLK leading asset
 **HS**	Phase 2b (MIRA) *Placebo-controlled with Cosentyx™*	234	IL-17A & F TNF & IL-17A	**Highest** ever primary endpoint (HiSCR75), **largest** deltas to placebo, depth of responses
 **PsO**	Phase 2b *Placebo-controlled with Humira™*	313	IL-17A & F IL-23 & IL-17A	**Largest** delta vs market leader Cosentyx™ at PASI100, compared to BKZ, IL-23, etc.
 **PsA**	Phase 2b (ARGO) *Placebo-controlled with Humira™*	207	IL-17A & F TNF & IL-17A	**Highest responses** in skin/joints, MoA shows **best** data
 *Other Rheum & Derm*	TBA	TBA	IL-17A & F Other	IL-17A & F inhibition **best** data in AS, nr-AxSpA, enthesitis…

PsA ARGO 24 week data in early 2024, also decisions on other indications

Source: MoonLake Corporate

A promising MoA…

- **Highest responses**

  IL-17A & F inhibition showed highest & most durable responses (BKZ & SLK)

- **Favorable safety profile**

  Long history of consistent safety for IL-17, where Candida ("thrush") is main adverse event – vs. TB, ISRs, cancer, infections, CV events, death… (with TNFa or JAK1)

- **Leading potential**

  Top 2 typically get 2/3 of indication bio sales (avg. $4bn+)[1]

… and a differentiated molecule

- **Elevated Performance**

  SLK shows highest responses at high treatment goals, HiSCR75, IHS4-100, PsO PASI100, PsA ACR50/70+PASI90/100 and key patient outcomes

- **Higher goals**

  Combines higher primary clinical endpoints in comparisons to gold-standards like Humira® (or Cosentyx®)

- **Improved convenience**

  Monthly 1ml maintenance injections and leading benefit-risk profile

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. 1 Based on analysis of 2023 sales of 11 indications (PsO, RA, Asthma, AD, AxSpA, CU, SLE, PsA, COPD, CD, UC) – 2030 ranges are even higher

Source: DRG, MoonLake Corporate

SLK is a potential leader in Type 3 diseases

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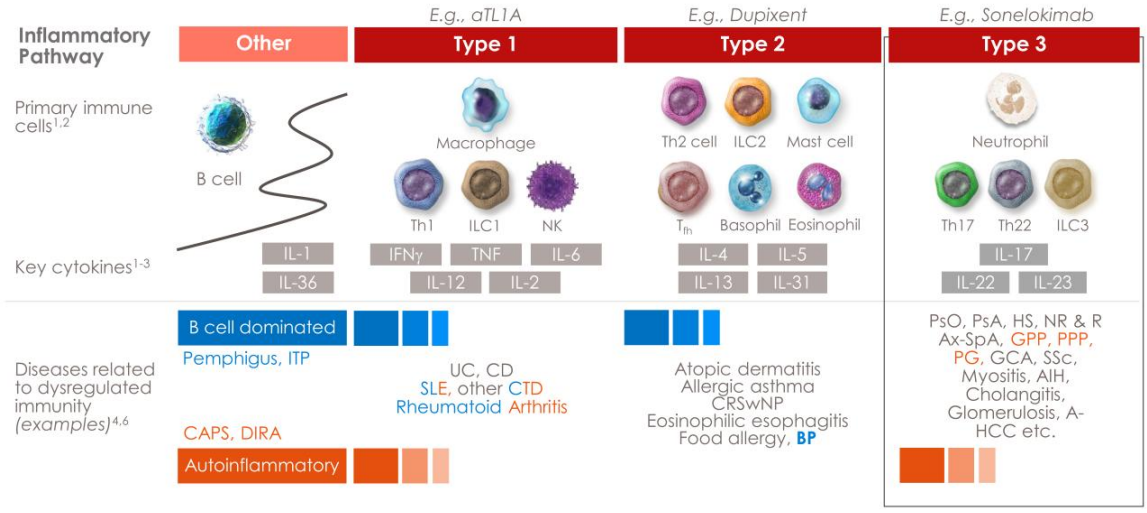


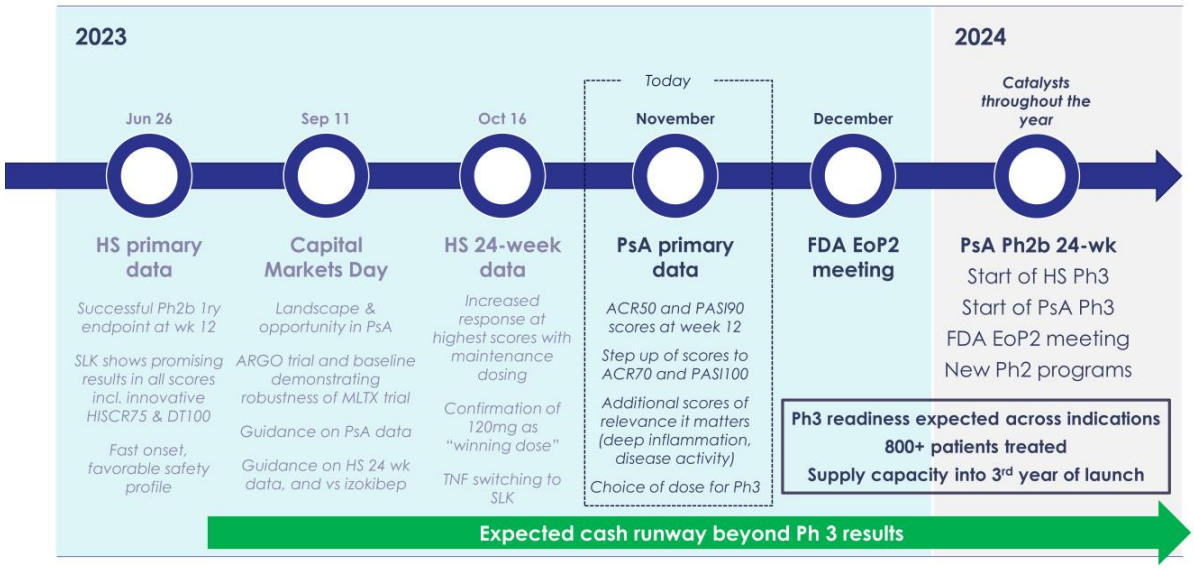
Note: Simplified depiction based on key published information, not meant to be exhaustive in nature. AD, atopic dermatitis; IFNγ, interferon gamma; IL, interleukin; ILC, innate lymphoid cell; NK, natural killer; Tfh, follicular helper; Th, T helper.

1 Kaiko GE, et al. *Immunology*. 2008;123:326-338. 2 Eyerich K, Eyerich S. *J Eur Acad Dermatol Venereol*. 2018;32:692-703. 3 Raphael I, et al. *Cytokine*. 2015;74:5-17. 4 Nakayama T, et al. *Annu Rev Immunol*. 2017;35:53-84. 5 Coates LC, et al. *Semin Arthritis Rheum*. 2016;46:291-304. 6 Gandhi NA, et al. *Expert Rev Clin Immunol*. 2017;13(5):425-437.

Source: MoonLake Corporate

MLTX has a full set of expected catalysts to year end, more in 2024

MoonLake



Source: MoonLake Corporate

MLTX operates from a position of strength

Cash, cash equivalents & short-term marketable securities in USD M

- **Strong balance sheet with USD 496M** in cash, cash equivalents and short-term marketable debt securities as per September 30, 2023
- **Low cash burn of USD 5.8M in Q3-2023** demonstrating cost-efficient set up and focus of MLTX
- **Expected cash runway until the end of 2026**, covering
  - Completion of ongoing Ph2 programs in HS & PsA
  - Ph3 program in HS
  - Ph3 program in PsA
  - Additional Ph2 program
  - Submission of BLA
  - All other base spend

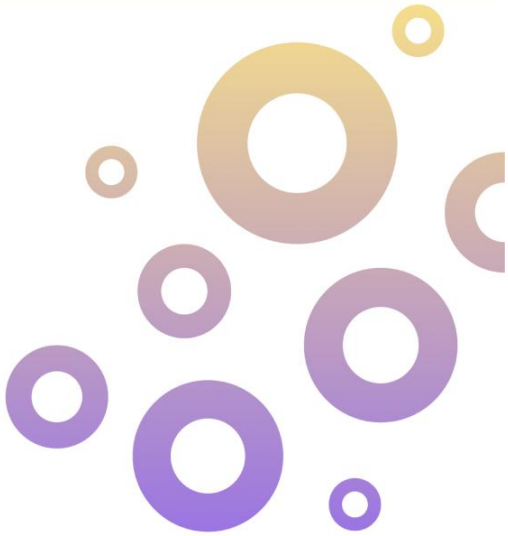
1 Differences may not add up due to rounding

Source: MoonLake Finance

MLTX has the potential to become a leader in I&I

MoonLake

- **Best in class potential** – SLK is a promising molecule as shown by Ph 2b data in HS and PsO, and now the primary endpoint data in PsA
- **Rarefied air** – only 2 molecules can inhibit all IL-17 pro-inflammatory dimers, only SLK combines that MoA with unique molecular characteristics that differentiate it
- **MLTX = Robust trials** – pivotal-like designs provide differentiating insight, esp. in diseases like HS, PsA, PsO & related inflammatory conditions
- **Potential multi Bn drug** – SLK may impact very large markets that are growing fast now, with potential over $70bn, as a leading asset in Type 3 inflammation
- **Our time** – MLTX has key near-term catalysts and is in a position of financial stability and strength



Source: MoonLake Corporate

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Q&A


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