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): **March 10, 2024**

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:

☐ 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 March 10, 2024, MoonLake Immunotherapeutics (the "Company") issued a press release titled "MoonLake announces significant improvements with Nanobody sonelokimab over 24 weeks in active psoriatic arthritis (PsA) and other important updates at its R&D Day."

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit 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 Securities Exchange Act of 1934, as amended (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.

On March 10, 2024, MoonLake Immunotherapeutics (the "Company") made available the presentation used in the Company's March 10, 2024 R&D Day on the Company's website. A copy of the presentation is filed herewith as Exhibit 99.2 and incorporated herein by reference

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibit is being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated March 10, 2024
99.2	Slide Presentation, dated March 10, 2024
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.

MOONLAKE IMMUNOTHERAPEUTICS

Date: **March 11, 2024**

By: /s/ Matthias Bodenstedt
Name: Matthias Bodenstedt
Title: Chief Financial Officer

Exhibit 99.1

MoonLake announces significant improvements with Nanobody® sonelokimab over 24 weeks in active psoriatic arthritis (PsA) and other important updates at its R&D Day

- Positive 24-week data from the ARGO trial of sonelokimab in PsA:
  - Significant improvements observed across all key outcomes, including approximately 60% of patients treated with sonelokimab achieving an ACR50 response at week 24
  - Unprecedented multi-domain responses across joints, skin and other domains, including up to 52% of patients achieving ACR50+PASI100 and up to 61% of patients achieving Minimal Disease Activity (MDA), supporting potential best-in-class profile of sonelokimab
  - Monthly maintenance with 60mg or 120mg doses showed leading responses above TNF reference arm across all key outcomes including in higher treatment goals (ACR70, PASI100, composites) – 120mg added benefit for specific patient subgroups
  - Low discontinuation rate around 5% and safety profile of sonelokimab consistent with previously reported studies with no new safety signals
- Update on sonelokimab in hidradenitis suppurativa (HS):
  - Following interactions with the FDA and EMA, MoonLake intends to commence Phase 3 trials in HS in Q2 2024, under the VELA program; the program is expected to enroll 800 patients and reflect a similar protocol design to that used in the MIRA Phase 2 trial, with top-line primary endpoint data expected as early as mid-2025
  - Real-world data indicates that at least 2 million Americans have been diagnosed with HS as of 2023, highlighting a significant unmet need and impact on healthcare systems, and a market opportunity exceeding $10bn by 2035
- MoonLake further announces that it will imminently commence four additional clinical trials of sonelokimab across dermatology, and rheumatology, including innovative trials in palmo-plantar pustulosis, juvenile HS and seronegative spondyloarthritis
- The Company is hosting an R&D Day on **Sunday, March 10 at 09:00 PDT/12:00 EDT/17:00 CET** via webcast (registration link below), alongside the American Academy of Dermatology (AAD) annual meeting

ZUG, Switzerland, March 10, 2024 – MoonLake Immunotherapeutics ("MoonLake"; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announces that continued treatment with Nanobody® sonelokimab led to significant improvements across all key outcomes at 24-week data from the ARGO trial in psoriatic arthritis (PsA) and other important R&D updates. These updates will be presented and discussed in detail at the Company's R&D Day to be held today, Sunday, March 10 (see access details below).

Positive 24-week data from the ARGO trial in PsA

The ARGO trial, which involved 207 patients with active PsA, demonstrated that the primary endpoint, the American College of Rheumatology (ACR) 50, continued to improve from week 12 and exceeded 60% by week 24. The more rigorous ACR70 outcome was achieved by approximately 40% of patients by week 24. In addition, by week 24, over 80% and 60% of patients treated with sonelokimab achieved Psoriasis Area Severity Index (PASI) 90 and 100, respectively. Both doses of sonelokimab yielded similar results. The responses surpassed those for adalimumab, the active reference arm in the study, and were also higher when indirectly compared to competitors using the same active reference arm as a standard.

Treatment with sonelokimab resulted in unprecedented improvements in composite scores that reflect responses in different domains simultaneously. ACR50+PASI90 up to 59%, ACR 50+PASI 100 up to 52%, ACR 70+PASI 100 up to 48% and MDA up to 61% response. In all composite scores, sonelokimab showed 16-29 percentage point differences to the reference adalimumab arm, comparatively higher to competitors using the same reference arm. While the 60mg dose was found to be sufficient to reach high levels of response in the general trial population, the 120mg dose was found to improve responses further in specific patient sub-groups, which suggests two doses being carried over to Phase 3.

The safety profile of sonelokimab was consistent with previous trials with no new safety signals detected. The discontinuation rate of the second part of ARGO remained low at 5%, in line with other sonelokimab trials. Overall, sonelokimab continues to show a favorable safety profile. Across the sonelokimab clinical program to date, the company has not seen any signal of suicide ideation/behavior (SI/B) or liver enzyme elevations related to sonelokimab treatment.

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: "*These positive results from the ARGO trial at week 24, showing that continued treatment with sonelokimab led to significant improvements across all key outcomes, reinforce the advantages of using a smaller biologic with albumin-binding capability to effectively inhibit IL-17F in addition to IL-17A for the treatment of deep tissue inflammation. We are particularly grateful to the patients and investigators who participated in our Phase 2 program and look forward to initiating our Phase 3 trials in PsA and HS this year.*"

Professor Joseph F. Merola, MD, MMSc, Founding President of the Psoriasis and Psoriatic Arthritis Clinics Multicenter Advancement Network Consortium (PPACMAN), added: *"There is a vital need for new treatment options for psoriatic arthritis - a chronic, inflammatory, recurrent, and debilitating multidomain disease that has profound impact across many aspects of patients' lives. It is highly encouraging to see that the positive high clinical responses across joint and skin endpoints and stringent composite measures, such as minimal disease activity, observed as early as week 12 with sonelokimab were further increased through week 24."*

The 24-week results build upon the 12-week results announced in November 2023. Full results from the ARGO trial will be submitted for publication in a peer-reviewed medical journal. Sonelokimab is not yet approved for use in any indication.

HS positive regulatory status and market opportunity

MoonLake has recently announced the successful outcome of its end-of-Phase 2 interactions with the U.S. Food and Drug Administration (FDA) the E.U. European Medicines Agency (EMA), with both regulatory bodies supporting MoonLake's proposed approach for advancing its Phase 3 program of the Nanobody® sonelokimab in hidradenitis suppurativa (HS). During the R&D Day, the Company will provide further details on trial design, expectations for the single 120mg dose being tested and timelines for this program, named VELA which is set to enroll 800 patients.

Furthermore, the Company will share findings from a recent analysis of US real-world data pertaining to the HS market.[i] It revealed that between 2016 and 2023, two million unique patients were diagnosed and treated for HS, with an average of 240,000 new patients each year as per claims. This corresponds to a ~1% prevalence of diagnosed and treated patients, aligning well with estimates that over 2% of the population, including those undiagnosed and untreated, have HS. These real-world data also substantiate a potential market size exceeding $10bn by 2035. Notably there is a low penetration of current biologics (around 3%) and a high dropout rate from treatment with current biologics within the first year (median of 11 months). Moreover, claims show that HS patients are lost in their treatment journey (e.g., more than 50-60% of patients are on long term on antibiotics and many of them are also on steroids / opioids, and 15% of patients receive surgery in year 1) representing a bleak prognosis for patients, physicians, and healthcare systems. This real-world perspective substantiates the company's market size estimates and highlights the need for more effective therapies.

Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, commented: *"The positive data that is being generated for the Nanobody® sonelokimab across chronic inflammatory indications, including HS, is raising the bar on the level of outcomes that can be achieved for patients. Patients are waiting for new treatment options with a prolonged effect, and the start of the Phase 3 trials is bringing hope that sonelokimab could be a promising potential option to the many patients that live and suffer with HS, a disease that has not received the attention it deserves until recently."*

New indications

MoonLake further announces that it will imminently commence four additional development programs, across dermatology and rheumatology where IL-17A and IL17-F inhibition in deep tissues has the opportunity to lead among all therapies.

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[i]

In dermatology, Phase 2 work is expected to be initiated in palmo-plantar pustulosis (PPP), a debilitating disease affecting a significant number of patients (estimated 0.3% prevalence) and for which there are no currently approved therapies. This new indication will strengthen MoonLake's standing within the dermatology community. Furthermore, MoonLake expects to initiate a Phase 3 trial in juvenile HS a disease that typically begins at this early stage of a patient's life, and also the period in which irreversible damage and inflammatory remission is most critical. It is anticipated that this trial will run concurrently with MoonLake's adult Phase 3 program, marking the first time clinical trial evidence is generated specifically for this demographic.

In rheumatology, MoonLake will also extend its development work in seronegative spondyloarthritis. Phase 2 work in radiographic and non-radiographic axial spondyloarthritis (axSpA) is expected to start this year, with trials featuring an innovative design complementing traditional clinical outcomes with modern imaging techniques, adding two new indications to the pipeline. The Company plans to also run an additional trial in PsA, to link the impact of sonelokimab in traditional clinical outcomes (e.g., ACR50) with objective imaging measurements in different domains. The new axSpA and PsA studies are designed to employ cutting-edge MRI-PET imaging.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"The robust data that we continue to amass with our Nanobody® shows that sonelokimab has the potential to be a best-in-class product in the fast-growing inflammation field, providing us with conviction to help even more patients by expanding into further indications beyond HS and PsA. With the positive feedback received to date from the FDA and EMA, together with our strong financials, we are now rapidly pursuing plans to commence Phase 3 trials in both HS and PsA before the end of this year and are expanding the development pipeline with the aim of elevating care with our next-level therapies via truly innovative clinical trials."*

R&D Day today, Sunday, March 10

MoonLake will hold an R&D Day today, Sunday, March 10 alongside the AAD annual meeting. The event will take place from 09:00 – 11:30 PDT/12:00 – 14:30 EDT/17:00 – 19:30 CET at Hotel Westin Bayview, San Diego and will be webcast for virtual attendees.

The R&D Day will highlight the 24-week ARGO data, discuss regulatory interactions and paths to Phase 3, and other important business updates from MoonLake's executive team including:

- Analysis of the HS and PSA market opportunities and leadership potential for sonelokimab.
- Pipeline updates and details of additional catalysts for 2024 and 2025, including new indications to be pursued.
- Summary and financials.

The event will feature presentations from leading clinicians in dermatology and rheumatology. Professor Joseph Merola, Chair of Dermatology, Professor of Dermatology, Medicine and Rheumatology, UT Southwestern Medical Center and Professor Kenneth B. Gordon, Chair of Dermatology at the Medical College of Wisconsin, will share their perspectives on the potential of MoonLake's investigational Nanobody® sonelokimab in IL-17A and IL-17F driven inflammatory diseases.

A live Q&A session involving all presenters will follow the event. Register to attend either the in-person event or webcast here. A recording and additional details will be available on the Events & Presentations section of the Company's website at www.ir.moonlaketx.com.

Late breaker presentation of the 24-week data from the MIRA trial in HS at the AAD

As announced in March 2024, the 24-week data from the Phase 2 MIRA trial with Nanobody® sonelokimab in moderate to severe HS, will be presented by Professor Brian Kirby MD, FRCPI on March 10 at 14:00 PDT/ 17:00 EDT / 22:00 CET during the late breaking research session 2 (S050) in room 20B at the AAD Annual Meeting, taking place from March 8-12, in San Diego, California.

- 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 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 0.05–4.1% of the global population, with three times more females affected than males. 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 MIRA trial

The MIRA trial (M1095-HS-201) is a global, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of the Nanobody® sonelokimab, administered subcutaneously, in the treatment of adult patients with active moderate-to-severe hidradenitis suppurativa. The trial recruited 234 patients, with the aim to evaluate two different doses of sonelokimab (120mg and 240mg) with placebo control and adalimumab as an active reference arm. The primary endpoint of the trial is the percentage of participants achieving Hidradenitis Suppurativa Clinical Response 75 (HiSCR75), defined as a ≥75% reduction in total abscess and inflammatory nodule (AN) count with no increase in abscess or draining tunnel count relative to baseline. The trial also evaluated a number of secondary endpoints, including the proportion of patients achieving HiSCR50, the change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4), the proportion of patients achieving a Dermatology Life Quality Index (DLQI) total score of ≤5, and the proportion of patients achieving at least 30% reduction from baseline in Numerical Rating Scale (NRS30) in the Patient's Global Assessment of Skin Pain (PGA Skin Pain). Further details are available at: https://www.clinicaltrials.gov/ct2/show/NCT05322473

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 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. In November 2023, MoonLake 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 PsA. 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 American College of Rheumatology (ACR) 50 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.

Sonelokimab has also been assessed in a randomized, placebo-controlled 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 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.

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

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; including the initiation of clinical programs in new indications; anticipated support from regulatory agencies with respect to the Company's development plans, anticipated size and timing of enrollment for the VELA trial, the sufficiency of data from the VELA trial to support regulatory filings in the US and EU, the anticipated trial design for the VELA trial and the timing of expected readouts; our expectations regarding the potential market size for HS; the Company's plans with respect to the commencement of a Phase 3 trial in PsA; 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, 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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MoonLake
MoonLake Immunotherapeutics
R&D Day
San Diego, during AAD
March 10th 2024
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Welcome to our R&D Day

MoonLake

Logistics

Date: March 10th, 2024
Time: 09.00-11:30 PST
Location: Westin San Diego Bayview
(Webcast also available)

Agenda

Topic	Sub-topics	Speaker	Timing
Introduction	- Welcome & session details	Matthias Bodenstedt	5 mins
PsA *Going beyond in Rheumatology*	- PsA, a multi-domain challenge - SLK in a competitive context - ARGO data read-out (24 weeks) - Next steps on Ph 3 program	Prof. Joseph Merola Kristian Reich	40 mins
HS *A franchise building indication in Derm*	- HS, a devastating disease - The MIRA data in context - Regulatory feedback & Ph 3 program - Market size & potential	Prof. Ken Gordon Kristian Reich Jorge Santos da Silva	40 mins
New frontiers for SLK and MLTX	- Unlocking the value of SLK - New Indications - Path forward catalysts 2024/2025	Jorge Santos da Silva	20 mins
Moving Forward	- Financials & next steps - Next steps for MLTX	Matthias Bodenstedt	5 mins
Q&A session			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 preclinical studies, clinical trials and research and development programs; the anticipated timing of the results from those studies and trials; potential market opportunities, estimates of market size, and estimates of market growth; potential indications; the timing of regulatory meetings; the occurrence and timing of market engagement; expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations; the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts; and effects on liquidity and capital resources, including 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", " 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. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management's control including general economic conditions and other risks, uncertainties and factors set forth in the section entitled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in our Annual Report on Form 10-K that was filed with the U.S. Securities and Exchange Commission (the "SEC") on February 29, 2024, as well as factors associated with companies, such as MoonLake Immunotherapeutics, that operate in the biopharma industry. 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

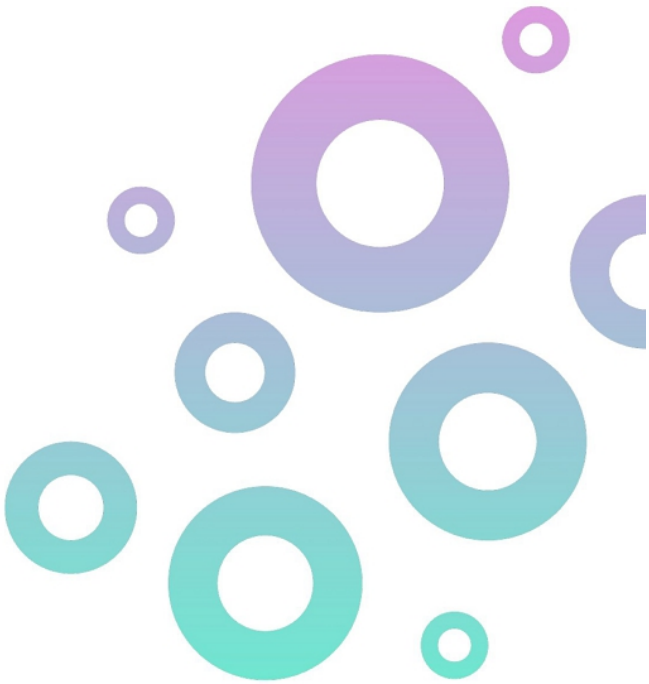
Certain information contained in this presentation relates to or is based on studies, publications, surveys and our own internal estimates and research. In this presentation, we rely on, and refer to, publicly available information and statistics regarding market participants in the sector in which we 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.

MoonLake

Instructions for this session



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

You can **submit your questions** through the Q&A function – questions are only visible to the moderators – 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, 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

MoonLake

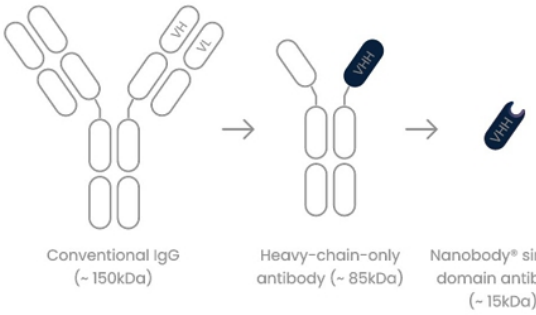
- **Founded in 2021** in Switzerland
- **Nanobody® technology** licensed in initial private round
- **Unique molecule with sonelokimab**, tri-specific IL-17A & IL-17F Nanobody® to elevate treatment in inflammation in a **$40bn+ market**
- **Public on Nasdaq** since April 2022 and **~$750m raised** to date
- **Clinical phase company** successfully concluded phase 2b studies in psoriasis (n=313), HS ("MIRA", n=234), and PsA ("ARGO", n=207)
- **Commencing Phase 3 programs in 2024** with first **commercial launches expected in 2027**
- Driven by a top-tier team, target is to unlock a **pipeline-in-a-product across large indications** from 2023 (>$5bn in HS & PsA alone)

Source: MoonLake Corporate

A differentiated molecule – Do you still Antibody?

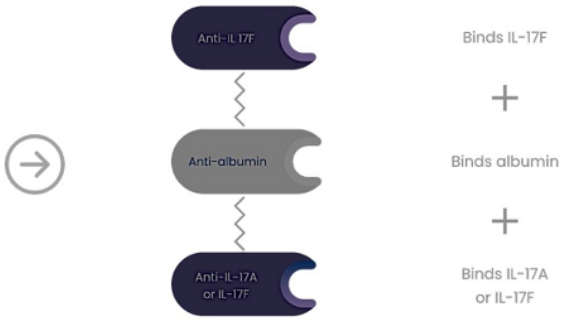
MoonLake

Nanobodies® are much smaller than traditional antibodies



Conventional IgG (~ 150kDa) | Heavy-chain-only antibody (~ 85kDa) | Nanobody® single-domain antibody (~ 15kDa)

They can be designed to have multiple and different binding domains



IL-17A & IL-17F

Sonelokimab is a ~40kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible spacers - around a quarter of the size of traditional antibodies

With 2 domains, it binds with high affinity to IL-17A and IL-17F – a third domain binds human albumin

Subcutaneous administration, Q4W

Source: MoonLake Research

It's all about the dimers

MoonLake

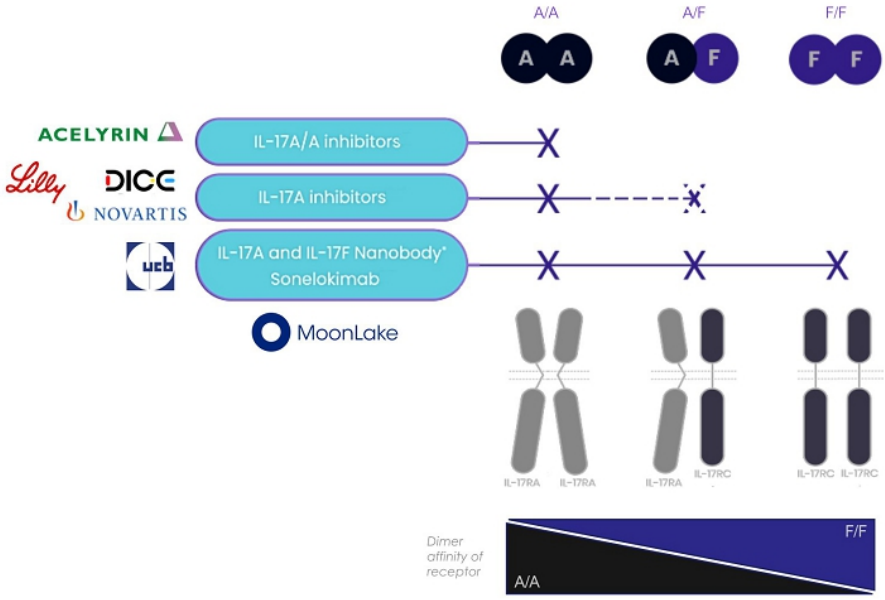
Illustrative

IL-17A and IL-17F function as dimers to drive inflammation, through activation of IL-17RA & RC receptor complexes

Different IL-17RA & RC chains combine to form complexes, and those have different affinity for different dimers[1,2]

Not all IL-17-targeting therapeutics can inhibit IL-17A/A, IL-17A/F and IL-17F/F dimers

SLK is the only asset that binds all dimers and with similar affinity



1 Liu S, et al. Nat Commun. 2013;4:1888; 2 Goepfert A, et al. Immunity. 2020 Mar 17;52(3):499-512

Source: MoonLake Research

SLK rapidly becoming a leader in large inflammatory diseases

MoonLake

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

PsA ARGO 24 -eek data presented today, also information on other indications

Source: MoonLake Corporate

MoonLake

PsA

Going beyond in Rheumatology

MoonLake

PsA – A multidomain challenge

Prof. Joseph F. Merola

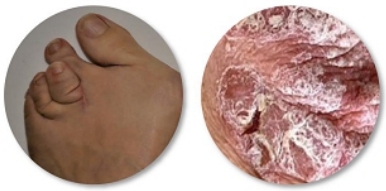
Prof. Merola is a consultant and/or investigator for Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, AbbVie, Eli Lilly, Novartis, Janssen, UCB, Sanofi, Regeneron, Sun Pharma, Biogen, Pfizer, MoonLake Immunotherapeutics

PsA is a multidomain disease, involving joints and skin

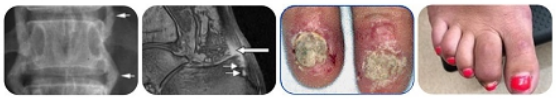
PsA is a multidomain disease

Treatments are assessed using clinical and patient-reported outcomes across domains

Key clinical endpoints
Joints and skin[4]



Other clinical domains[4]



Axial | Enthesitis | Nail | Dactylitis

Patient-reported outcomes[5]

Function e.g. HAQ

Pain e.g. VAS

Disease severity e.g. PGA

Multidomain composite outcomes[5]

Multidomain composite outcomes are used with increasing prominence in clinical trials to assess treatment impact simultaneously across domains

MDA **Minimal Disease Activity**

= ≥5 out of 7 stringent multidomain outcomes

Tender joints | Swollen joints | Skin lesions | Tender entheses | HAQ | Pain | PGA

ACR + PASI **Response in joints + skin**

ACR50 + PASI100

Can we elevate to ACR70 + PASI 100?

1 https://www.psoriasis.org/psoriasis-statistics/ Accessed Mar 2024 2 Merola et al Dermatol Ther 2023;13:2635–2648 3 Luce et al AAD 2024:Poster 50361 4 Coates et al Nat Rev Rheumatol 2022;18:465–479 | Dactylitis and nail/skin images courtesy of Prof. Joseph F. Merola and Prof. Kristian Reich, respectively [please do not reproduce] | Other images reproduced (CC-BY licenses) from Mochizuki et al Case Rep Rheumatol 2018;2018:4216938, Jurik Insights Imaging 2011;2:177–191, McQueen et al Arthritis Res Ther 2006;8:207 5 Gossec et al J Rheumatol 2018;45:6–13

PsA is common and often underdiagnosed — and undertreated

PsA is common

- **1.5 million Americans are thought to be living with PsA**[1]
  30% of patients with PSO progress to a PsA diagnosis[2]
- **47% of patients already have musculoskeletal symptoms** at PSO diagnosis[3]

However, PsA is **often underdiagnosed** or **undertreated**

~2 in 5 patients with PsA were underdiagnosed
in the PREPARE non-interventional study[4]

~2 in 5 patients diagnosed with PsA are not on biologics
in a recent international survey[5]

New research at AAD 2024

Among surveyed US patients with PSO:

41% already had joint symptoms, but in most cases had not discussed treating these symptoms with their doctor[6]

1 Johns Hopkins Medicine [https://www.hopkinsarthritis.org/arthritis-info/psoriatic-arthritis] Accessed Mar 2024 2 National Psoriasis Foundation [https://www.psoriasis.org/psoriasis-statistics] Accessed Mar 2024 3 Merola et al Dermatol Ther 2023;13:2635–2648 4 Mease et al. J Am Acad Dermatol. 2013;69:729–35 5 Tillett et al. Rheumatol Ther. 2020;7:617–37 6 Luce et al AAD 2024;Poster 50361

The symptom burden of PsA leads to substantial work impairment

Functional impairment

44%

Work impairment

among patients with PsA in the COPPAR registry (N=113)[1]

A **>30%** and **>25%** prevalence in PsA of anxiety and depression[2]

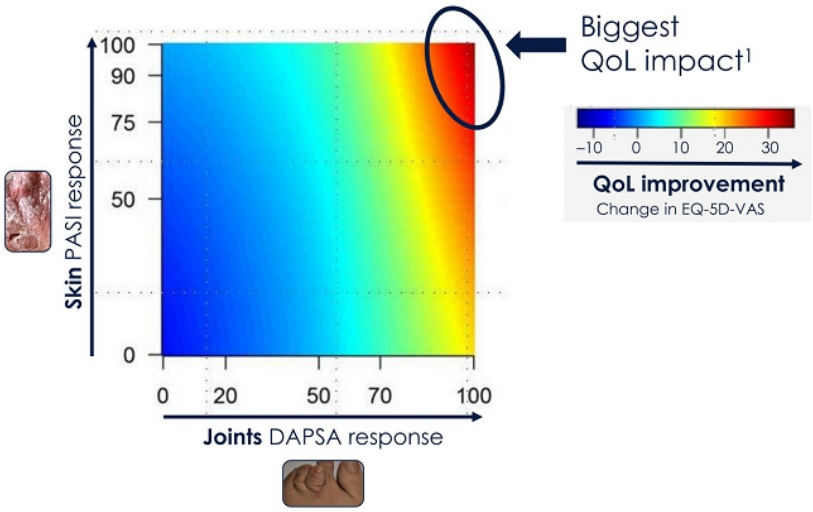
4 in 5 patients report fatigue,[3] with a major impact on physical activity

- **Fatigue**, **pain**, **anxiety**, **depression** and **disturbed sleep**[1,5,6] are interconnected symptoms[4] linked to work impairment
- **Multidomain** disease[7] is also associated with work impairment, including **skin**, **polyarticular**, and **entheseal** involvement

Using treatments that better resolve symptoms will have wide-ranging benefits for patients and society

1 Shadick et al ACR 2023:Poster 0488 Rheum Dis 2020;79 (suppl 1):AB0821
2 Vestergaard et al RMD Open 2024;10:e003412
3 Gossec et al J Rheumatol 2022;49:1221–8
4 Haugeberg et al Arthritis Res Ther 2020;22:198
5 Gossec et al Ann
6 Spindler et al J Am Acad Dermatol 2021;85:910–922
7 Walsh et al Joint Bone Spine 2023;90:105534

High clinical response in skin, in addition to joints, is critical for patients



Multidomain PsA leads to more pronounced QoL impairment[2]

- A greater risk of **flare**
- More substantial **work impairment**
- Higher rates of **anxiety** and **depression**
- Worse overall **quality of life** scores

→ **Assess response in both joints + skin**

ACR + PASI

It is critical to assess treatment response in both joints and skin to make the biggest difference to patients

Image credits: skin—courtesy of Prof. Kristian Reich. joints—Mochizuki et al Case Rep Rheumatol 2018:2018:4216938 1 Quality of life data from 402 patients with PsA and moderate-to-severe skin involvement (≥3% BSA) after 24 weeks on therapy/placebo in the SPIRIT Phase 3 clinical study program (heat map image reproduced with permission from Prof. Merola) | Kavanaugh et al Arthritis Rheumatol 2017:69(suppl 10):AB2539 2 Tillett et al Rheumatol Ther 2020:7:617–37

Most patients currently do not achieve MDA, even with biologics

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

77% did not achieve MDA

% of patients who achieved MDA in a US real-world study

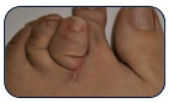
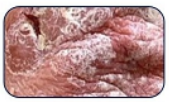
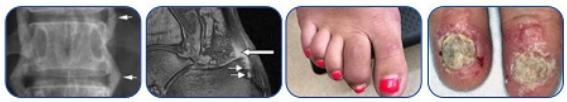
Patients who do not achieve MDA may also have a higher overall disease burden, e.g.:[2]

- More fatigue
- Worse physical function
- Worse mental function
- Greater quality of life impact

Treatment ceiling in PsA: advances in PsA treatment have led to success in some domains, but achievement of MDA with biologics remains challenging, even for newer therapies

1 Data from the CorEvitas registry (N=1,251); Ogdie et al ACR 2021;abstract 1344 2 Coates et al RMD Open 2019;5:e001002.

IL-17i is the only biologic class preferred in all clinical domains of PsA

	Joints	Skin	Other domains				
							
Preferred biologic(s)[1]	**Peripheral arthritis**	**Psoriasis**	**Axial**	**Enthesitis**	**Dactylitis**	**Nails**	**Radiographic progression**
IL-17i	✓	✓	✓	✓	✓	✓	✓
TNFi	✓	✓	✓	✓	✓	✓	✓
IL-12/23i	✓	✓	✗	✓	✓	✓	✗
IL-23i	✓	✓	✗	✓	✓	✓	✗

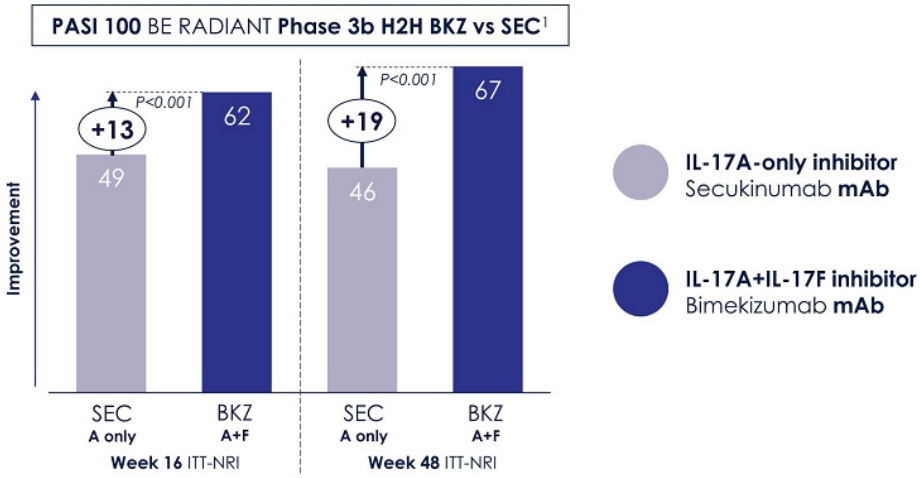
1 Preferred biologic classes are based on the expert interpretation of clinical study results by Prof. Merola. Dactylitis and nail/skin images courtesy of Prof. Joseph F. Merola and Prof. Kristian Reich, respectively (please do not reproduce) | Other images reproduced (CC-BY licenses) from Mochizuki et al Case Rep Rheumatol 2018:2018:4216938, Jurik Insights Imaging 2011:2:177–191, McQueen et al Arthritis Res Ther 2006;8:207

Can we optimize IL-17 inhibition?

As the class of choice for addressing all domains in PsA, **innovation on MOA is centered on optimizing IL-17i**, based on increasing evidence that IL-17F drives psoriatic inflammation alongside IL-17A…

Skin: Plaque psoriasis
(Moderate-to-severe)

Primary endpoint:
PASI 100 at Week 16



Inhibition of **both IL-17A+IL-17F** provides **greater benefits** in skin vs. inhibition of IL-17A only

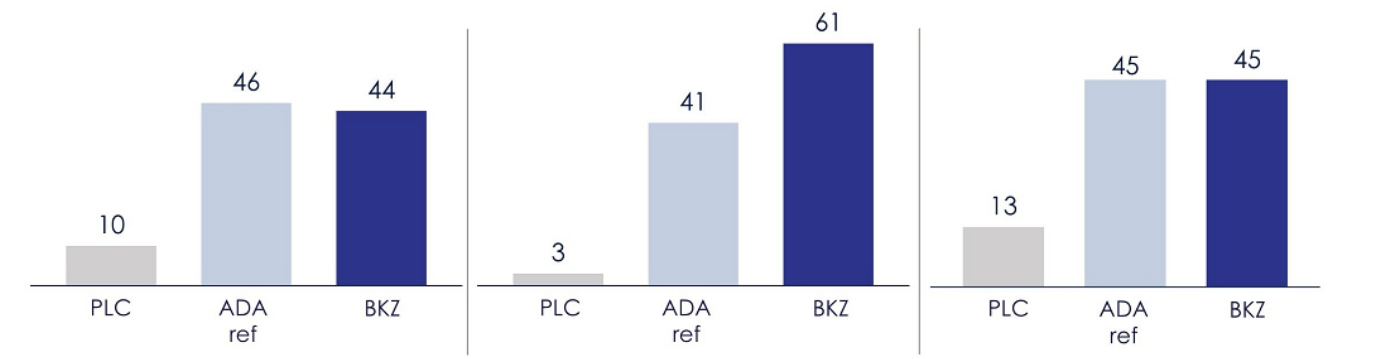
A study in patients with moderate-to-severe psoriasis; only a subset of participants had PsA and the clinical significance of the findings is unclear (there are no head-to-head studies of these two MOAs in PsA): Reich et al N Engl J Med. 2021;385:142–52
Image of skin courtesy of Prof. Kristian Reich

IL-17A and IL-17F dual inhibition is a newly validated MOA in PsA

Bimekizumab IL-17A and IL-17F inhibitor (160 mg Q4W) | BE OPTIMAL (Phase 3 **PsA**)[1]

Week 16 NRI-ITT

- Patients enrolled in the study were biologic-naïve — similar results were seen a TNF-IR study[2]



Inhibition of **both IL-17A and IL-17F** provided **high levels** of **skin + joints** responses at Week 16

1 NRI, non-responder imputation; McInnes et al Lancet 2023;401:25–37; 2 Merola et al Lancet 2023;401:38–48

Sonelokimab is a novel humanized Nanobody® targeting IL-17A+IL-17F

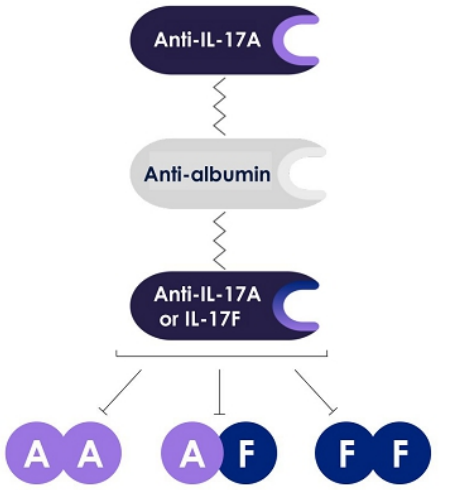
As a **Nanobody®**, **sonelokimab (SLK)** is designed to penetrate difficult-to-reach tissues and directly target sites of inflammation:[1,2]

- **Small size** (~40 kDa vs. ~150 kDa for a conventional mAb)
- **Albumin-binding domain** to extend half-life and target sites of inflammation

Sonelokimab Phase 2b in psoriasis[1]

- Rapid and durable skin clearance (PASI 100) with no unexpected safety findings

Sonelokimab Nanobody® ~40 kDa[1,2]



Inhibits IL-17A/A, IL-17A/F, and IL-17F/F dimers

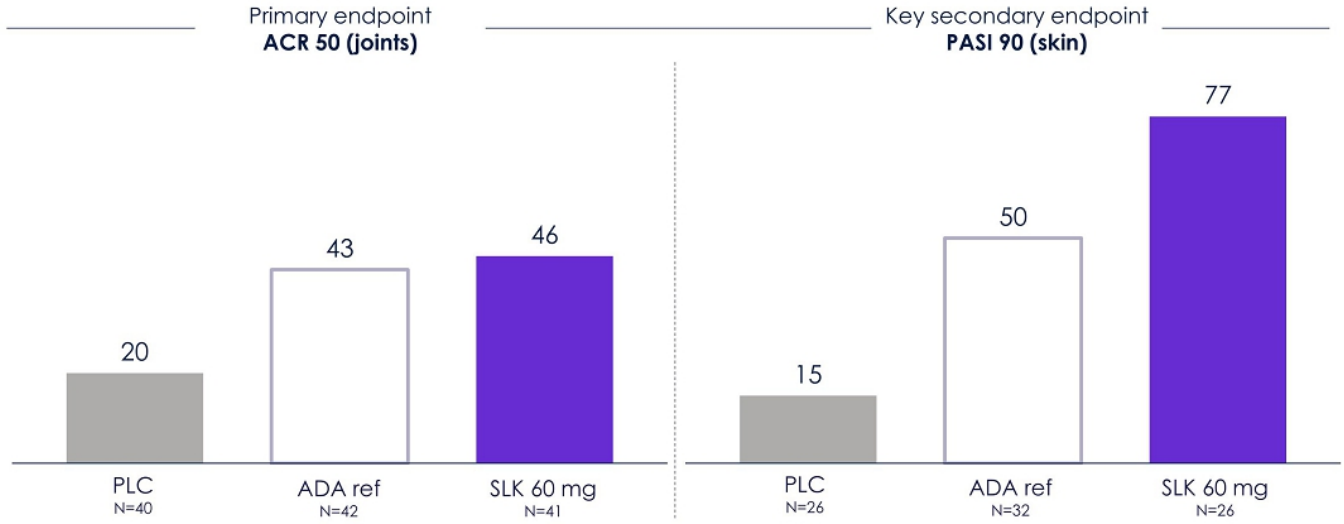
IL, interleukin; mAb, monoclonal antibody; PASI, Psoriasis Area and Severity Index.
1. Papp KA, et al *Lancet*. 2021; 397:1564–1575; 2. Svecova D, et al *J Am Acad Dermatol*. 2019; 81:196–203.

SLK achieved high levels of response in joints and skin by Week 12

Sonelokimab IL-17A and IL-17F inhibitor (Nanobody) | ARGO (Phase 2 **PsA**)

Week 12 NRI-ITT

- Both bio-naïve and -experienced patients were enrolled in the study

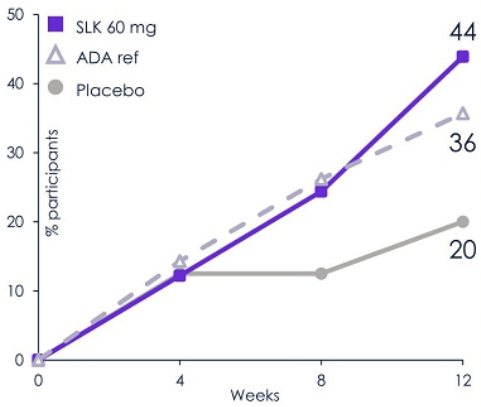


Inhibition of **IL-17A and IL-17F** with a Nanobody **showed promising efficacy in both skin + joints**

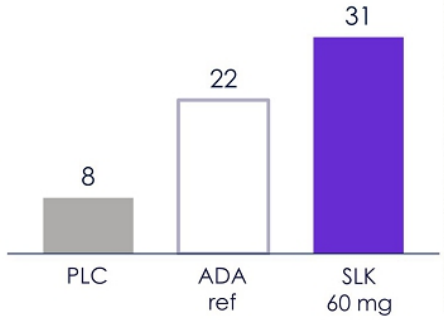
The SLK Nanobody® also showed promising responses in composite scores

Sonelokimab ARGO | **Week 12** ITT-NRI

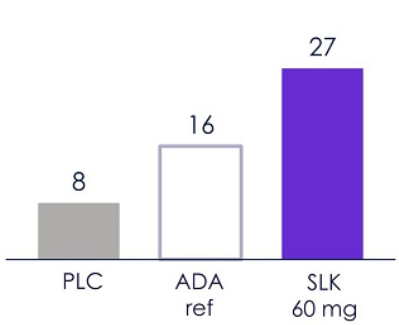
Multidomain endpoint
MDA



Joints + skin composite
ACR 50 + PASI 100



Higher threshold
ACR 70 + PASI 100



SLK treatment provided a **multidomain** response in the ARGO trial
that met stringent, high-threshold endpoints such as **MDA** and **ACR 70 + PASI 100**

Summary

- **Unmet need across multiple domains** demands novel PsA therapies
- **MDA** is a **PsA-specific**, stringent endpoint that sets **a high bar across domains**, while **ACR + PASI composites** allow simultaneous assessment of key domains
- **IL-17A + IL-17F inhibition** has the potential to optimize outcomes across PsA domains, including **MDA** and **joint + skin** composites
- **Sonelokimab** is designed to combine the '**best of both worlds**': IL-17A + IL-17F inhibition, mediated by a small, albumin-binding Nanobody®
- In the Phase 2 ARGO trial, inhibition of IL-17A + IL-17F with the Nanobody® **sonelokimab led to high levels of multidomain response** by Week 12, with no sign of plateauing

Week 12 data in the ARGO trial **set high expectations of continuing increases in key endpoints, as well as multidomain composites**, to Week 24 with SLK treatment

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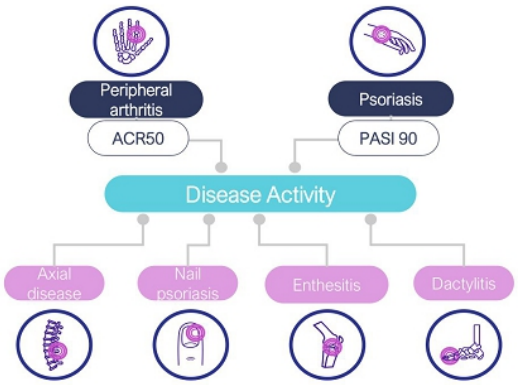
ARGO trial 24 wk data

Kristian Reich

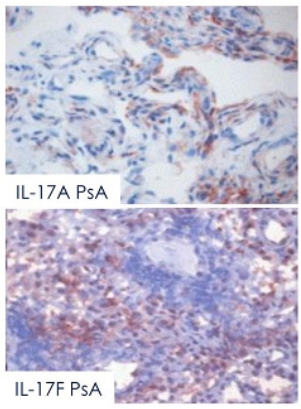
PsA: IL-17F dependent multi-domain disease in difficult-to-reach tissues

MoonLake

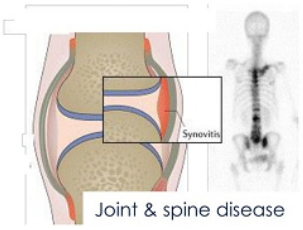
PsA is a multi-domain deep-tissue disease…

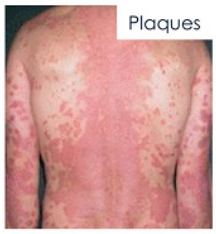


…with 3x IL-17F vs IL-17A[1]…

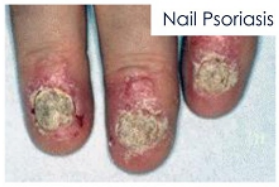


…and causing devastating damage





(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

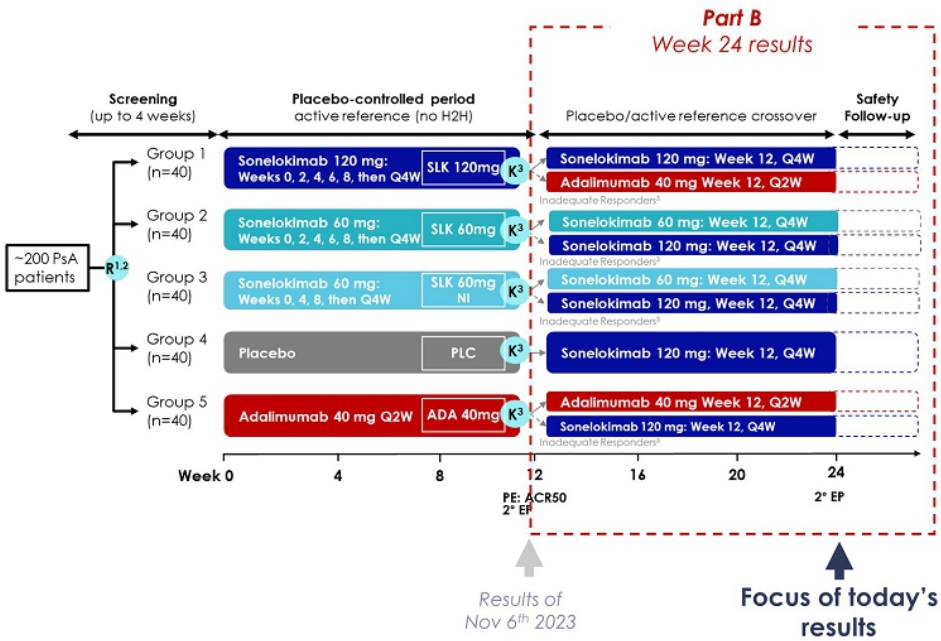
10% skin involvement in PsA patients – severe skin disease

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;7e001679; 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

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
- **SLK 120mg** and **SLK 60mg reached stat sig at wk 12**
- Group 3 ("**SLK 60mg NI**", no induction) had not reached stat sig at wk 12
- **Some crossover arms** not analyzed separately (small samples, 5-7 pts/arm)

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

Disposition: The ARGO trial had a drop-out of rate of 5% in Part B

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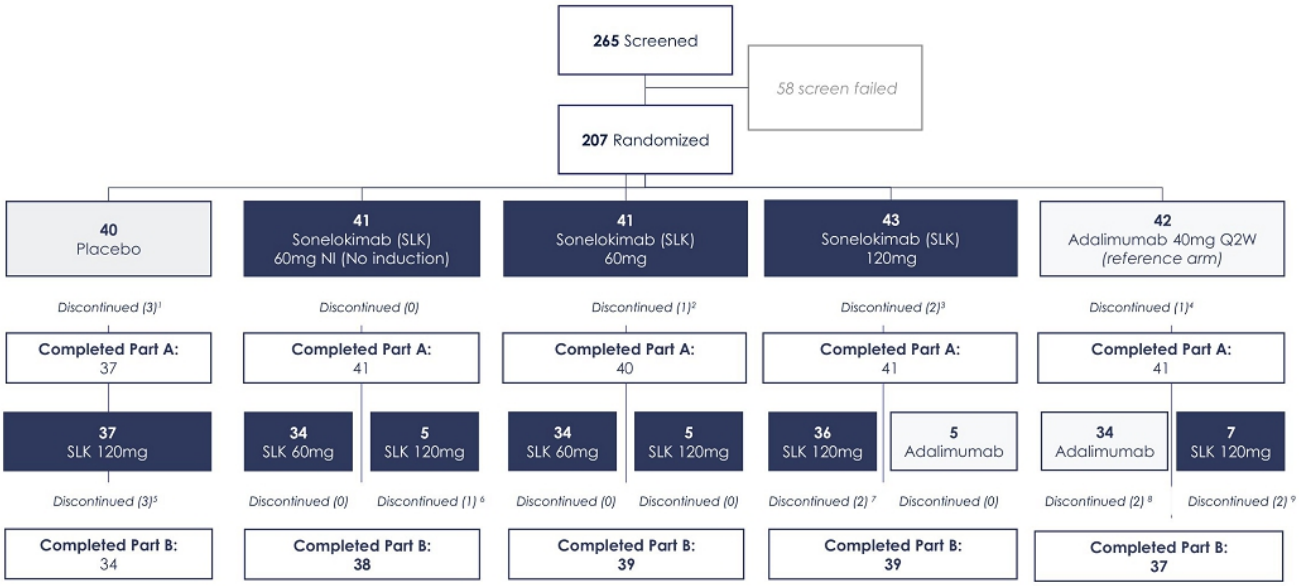
Disposition (Part A+B)



Part B Database lock 7th February 2024. AE =Adverse Event, Wdw by S = Withdrawal by Subject; Completed Part A = completed treatment up to Week 10 and completed assessments to Week 12; 3 patients did not subsequently enter part B; 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; 5: 3 x AE; 6: 1 1x Wdw by S; 7: 1 x AE 1x Wdw by S; 8: 1 x PD 1 x Wdw by S; 9 1 x AE 1 x PD

Source: MoonLake Clinical

SLK efficacy **in joints continues to improve** to wk 24, with **high responses**

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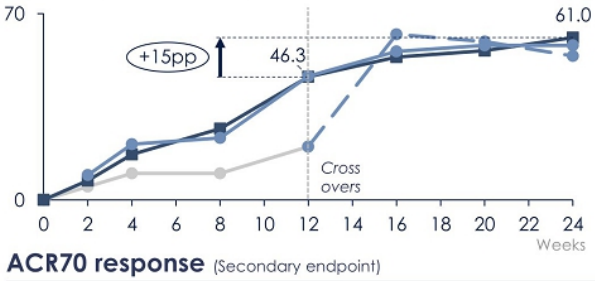
PLC — SLK 60mg — SLK 120mg — PLC->SLK 120mg

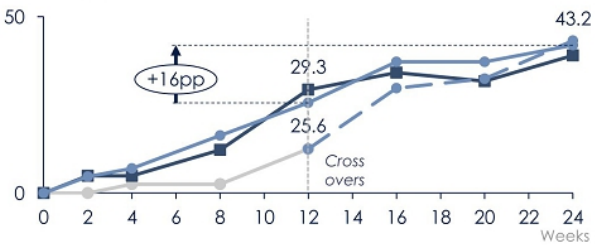
ACR50 response (Primary endpoint)

Percent (%) pts reaching score, NRI[1]



ACR70 response (Secondary endpoint)

Percent (%) pts reaching score, NRI[1]



Cross-trial comparison to BKZ

Note: Comparison across trials have inherent limitations. No head-to-head trials 1 ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 2 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL;

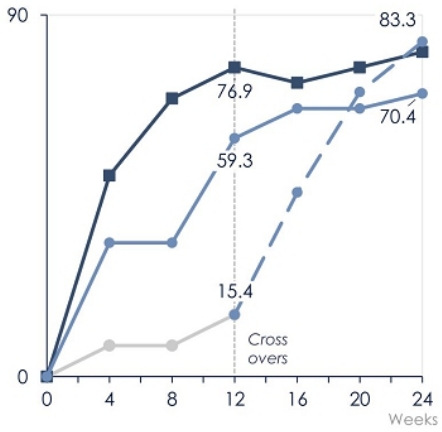
Source: MoonLake Clinical

Skin outcomes continue to improve to wk 24, beyond competitors

PLC — SLK 60 — SLK 120 — PLC->SLK 120

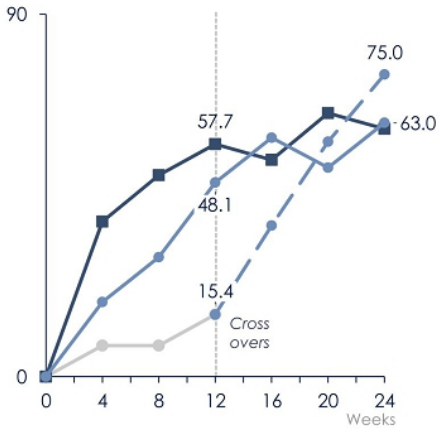
PASI90 response

Percent (%) pts reaching score, NRI[1]



PASI100 response

Percent (%) pts reaching score, NRI[1]



PASI response rates with **SLK continue to increase to week 24** - clinical response has not plateaued

Placebo crossover arms achieve **83% PASI90** and **75% PASI100** rates after just 12 weeks of SLK treatment

Deltas between SLK dose and adalimumab at wk 24 up to **27% for PASI90 and 25% for PASI100**

SLK 60mg & 120mg numerically outperform adalimumab on **every PASI score** tested at wk 24 (as well as ACR)

SLK responses are numerically higher than observed with BKZ, (73% PASI90 and 56% PASI100 in BE OPTIMAL at wk 24)[2]

Note: Comparison across trials have inherent limitations. No head-to-head trials 1 Subset of participants with BSA >=3% at baseline, ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards 2 2 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL

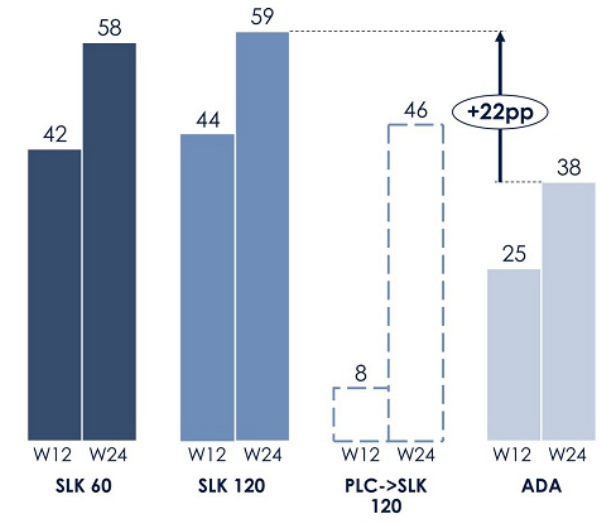
Source: MoonLake Clinical

Most patients meet **both joint & skin** outcomes – **a differentiated profile**

MoonLake

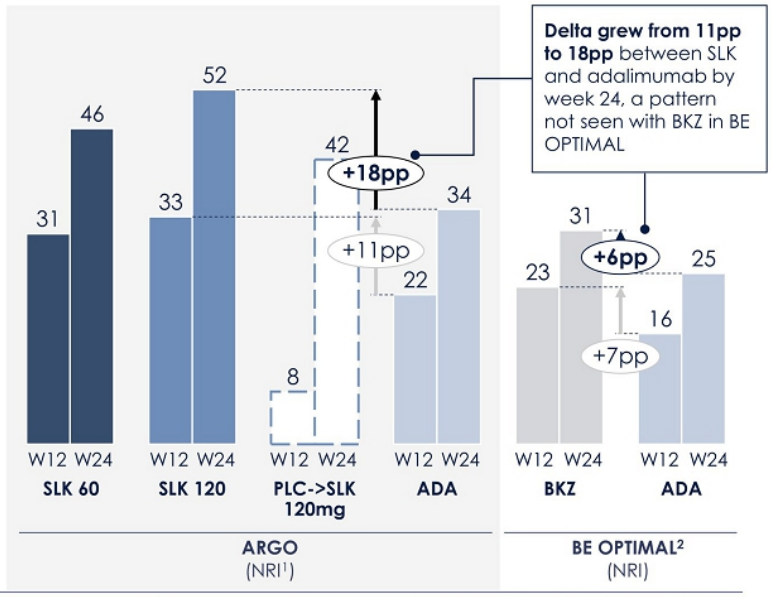
Patients reaching both ACR50 and PASI90

Percent (%) pts reaching score, NRI[1]



Patients achieving both ACR50 and PASI100

Percent (%) pts reaching score



Note: Comparison across trials have inherent limitations. No head-to-head trials 1 Subset of participants with BSA >=3% at baseline. ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 2 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL

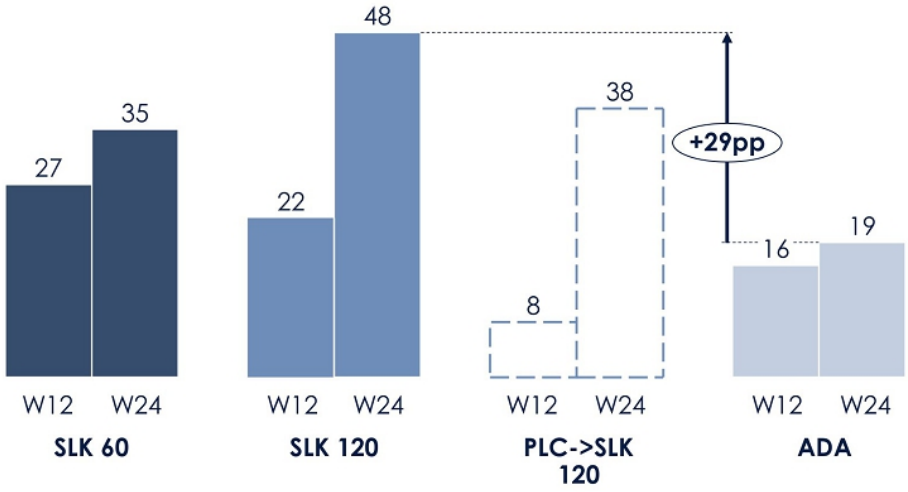
Source: MoonLake Clinical

SLK efficacy is **further shown with a higher the treatment goal**

MoonLake

Patients reaching both ACR70 and PASI100

Percent (%) pts reaching score, NRI[1]



Almost **50% of patients** reach both ACR70 & PASI100 with SLK

At week 24 delta to adalimumab in this **high bar composite score is close to 30pp**

Strong signal of **elevated efficacy vs adalimumab**[2] on this higher hurdle endpoint

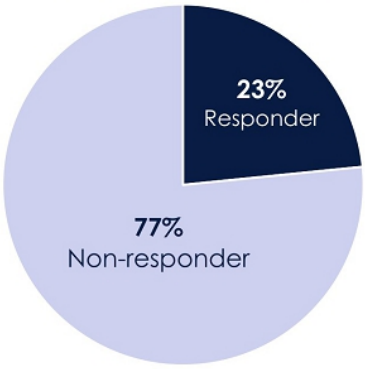
1 Subset of participants with BSA >=3% at baseline, ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards;
2 Nominal p value, post-hoc analysis (p<0.05), study not powered for statistical comparison between SLK and ADA arms

Source: MoonLake Clinical

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

MoonLake

>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

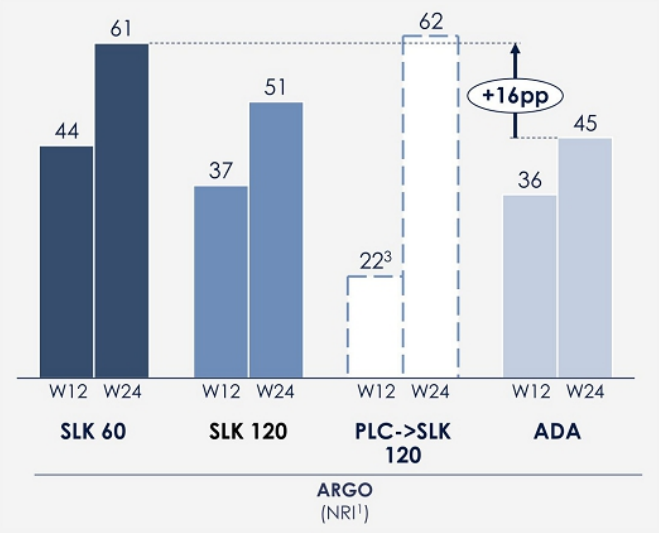
Source: Prof Joseph Merola

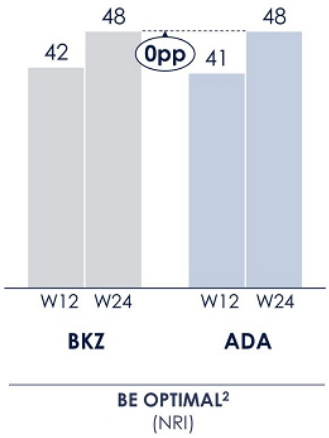
Impact of SLK on MDA is clear: 60%+ of patients reach this high goal

MoonLake

Patients reaching Minimal Disease Activity (MDA)

Percent (%) pts reaching score





SLK brought over 50% of patients to MDA response across arms, higher than has been seen in previous PsA trials

Delta to adalimumab was observed (up to 16pp) within the trial, which **has not been the case with BKZ** in the trial that incl. the same reference arm

Note: Comparison across trials have inherent limitations. No head-to-head trials 1 ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 2 Ritchlin et al. Ann Rheum Dis 2023;82:1404–1414 BE OPTIMAL; 3 Differs from the overall PLC rate at Week 12 (20%) because this includes only those participants who were crossed over to SLK 120mg at W12

Source: MoonLake Clinical

SLK also shows **higher responses in deep-tissue** at wk 24

MoonLake

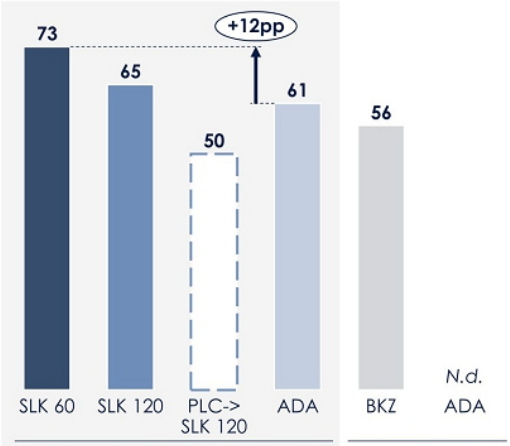
Nail PsO Severity (mNAPSI)

Mean change from baseline

ARGO
(Wk 24, LOCF[1])

Nail PsO Resolution (mNAPSI=0)

Percent (%) of pts with mNAPSI>0 at baseline that achieve mNAPSI=0

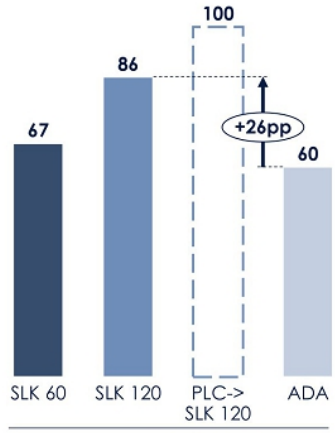


ARGO
(Wk 24, NRI[2])

BE OPTIMAL[3]
(Wk 24, NRI)

Leeds Enthesitis Index (LEI)

Percent (%) of pts with LEI 2+ at baseline that improved 2+ pt



ARGO
(Wk 24, NRI[2])

Deltas to adalimumab continue to improve from week 12 to week 24

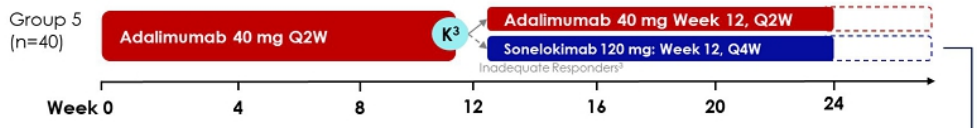
Note: Comparison across trials have inherent limitations. No head-to-head trials. 1 Last observation carried forward for all missing values; 2 ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 3 Merola et al., ACR Convergence 2023 poster 1433, estimate from graph

Source: MoonLake Clinical

Part B crossover signals **potential of SLK in TNF non-responders**

MoonLake

ARGO trial design – Adalimumab group re-allocation at Week 12



Patients reaching Minimal Disease Activity (MDA)

Percent (%) pts reaching score, NRI[1]

- In the 7 participants crossed from ADA to SLK 120mg, **MDA response rates at week 24 were similar to the other SLK arms** after 12 weeks of SLK exposure
- **Similar trends were seen on other endpoints** (e.g. PASI, mNAPSI, PhGADA, PROs, etc.)
- *Due to small n numbers, the crossover arms are not sufficiently powered for definitive comparisons with the other arms*
- We will **explore SLK potential in TNF-IR patients** in Phase 3

Note: Comparison across trials have inherent limitations. No head-to-head trials 1 Subset of participants with BSA >=3% at baseline, ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 2 Total of 7 inadequate ADA responders crossed over to SLK 120mg Inadequate response was defined as <20% improvement in either SJC or TJC by Week 12

Source: MoonLake Clinical

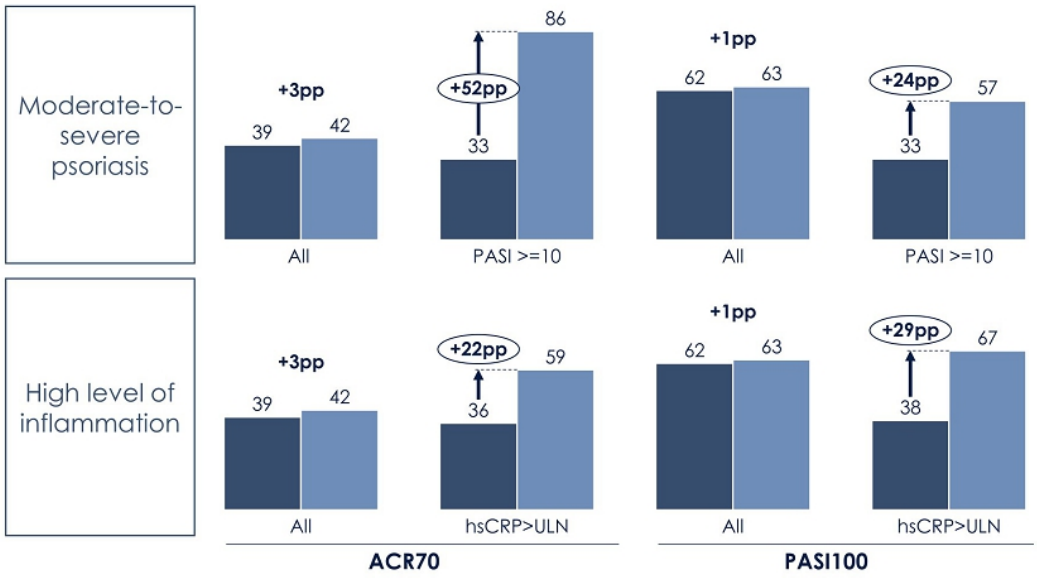
Higher 120mg efficacy in key subgroups

MoonLake

Response rates at week 24 (subgroups)

SLK 60mg SLK 120mg

Percent (%) of pts, NRI[1]



- Key subgroups may further **benefit with 120mg** vs 60 mg
- Incl. those with **high level of skin involvement** (moderate-to-severe PsO) and **high level of inflammation** (high CRP)
- Or patients with **high PsA disease activity** (DAPSA≥28) and presence of **nail disease** (mNAPSI>0)
- Other subgroups benefit at wk12 but the 60mg "catches-up" in many patients at wk 24 – **up-titration likely a case-by-case decision for these patients** (e.g., high MTX use, high weight, prio Bx use)
- Patients benefiting from higher dosing (from start or up-titration) **estimated to be 20-30%** of the trial population

1 ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards;

Source: MoonLake Clinical

Safety: **no notable signals,** a favorable benefit-risk profile in PsA

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	Part A				Part A + B		
	Placebo	**Sonelokimab** 60mg w/induction	**Sonelokimab** 120mg w/induction	**Adalimumab** *(active reference)*	**Sonelokimab** 60mg	**Sonelokimab** 120mg	**Adalimumab** *(active reference)*
Patients with events, n	39	41	43	42	82	97	47
Any TEAE	15 (38.5%)	14 (34.1%)	17 (39.5%)	14 (33.3%)	37 (45.1%)	57 (58.8%)	22 (46.8%)
Any SAE	0	1 (2.4%)	0	0	1 (2.4%)[2]	4 (4.1%)[2]	0
Any TEAE leading to discontinuation	0	0	1 (2.3%)	0	0	6 (6.2%)[4]	0
Fatal TEAE	0	0	0	0	0	0	0
Most frequent TEAEs[1]							
Nasopharyngitis	1 (2.6%)	1 (2.4%)	0	3 (7.1%)	5 (5.6%)	5 (5.2%)	4 (8.5%)
Upper respiratory tract infection	1 (2.6%)	2 (4.9%)	1 (2.3%)	1 (2.4%)	5 (5.6%)	4 (4.1%)	2 (4.3%)
Injection site erythema (reaction)	0	2 (4.9%)	3 (7.0%)	1 (2.4%)	3 (3.7%)	3 (3.1%)	1 (2.1%)
Adverse events of special interest							
IBD	0	0	0	0	0	0	0
Diarrhea	0	1 (2.4%)	0	1 (2.4%)	1 (1.2%)	2 (2.1%)	1 (2.1%)
Candidiasis							
Oral Candidiasis	0	1 (2.4%)	0	0	2 (2.4%)	2 (2.1%)	0
Oropharyngeal Candidiasis	0	0	0	0	0	0	0
Esophageal Candidiasis	0	0	0	0	0	0	0
Vulvovaginal Candidiasis	0	0	0	0	0	0	0
Skin Candidiasis	0	0	0	0	0	0	0
Genital Candidiasis	0	0	0	0	0	0	0
Other adverse events of interest							
Serious hypersensitivity	0	0	0	0	0	0	0
Serious infection	0	1 (2.4%)	0	0	1 (2.4%)[2]	1 (1.0%)[2]	0
MACE	0	0	0	0	0	0	0
Liver AST/ALT > 5x ULN[3]	0	0	0	0	0	0	0

ALT, Alanine aminotransferase and AST, Aspartate transaminase; IBD, inflammatory bowel disease; MACE, major adverse cardiovascular event; SAE, serious adverse event; TEAE, treatment-emergent adverse event; ULN, upper limit of normal; 1 Top three most frequent AEs in the SLK groups. Note: The adalimumab therapy used in the MIRA trial was the originator drug (citrate-free formulation); 2 No SAEs judged to be treatment related; 3 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; 4 TEAEs leading to discontinuation included 1 x tonic-clonic seizure, 1x Furuncle, 1x Pharyngeal abscess & Subcutaneous emphysema,1 x Tonsillar inflammation, 1 x Epididymitis, 1 x Arthritis

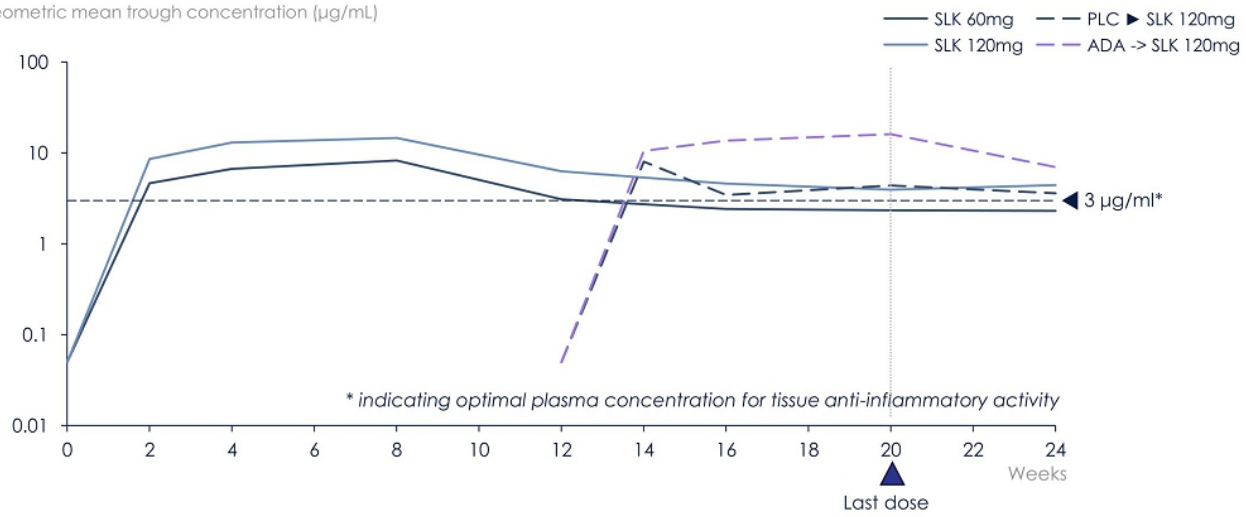
Source: MoonLake Clinical

PK data shows ARGO PsA **doses behave as expected**

MoonLake

SLK trough concentrations

Sonelokimab geometric mean trough concentration (µg/mL)



Trough concentrations of crossed over arms **replicate data** from first 12 weeks, **rapidly bringing SLK above** optimal plasma concentration (to reduce large amounts of target) and **remaining above level** as patients move to maintenance dose

Source: MoonLake Clinical

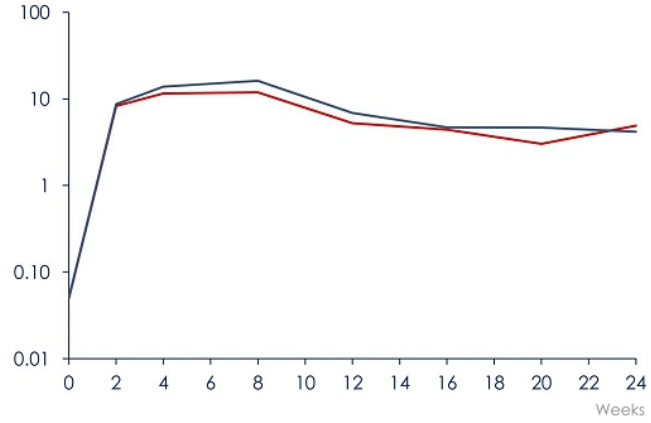
No signs of clinically relevant immunogenicity

MoonLake

Treatment emergent ADA — Yes (Y) — No (N)

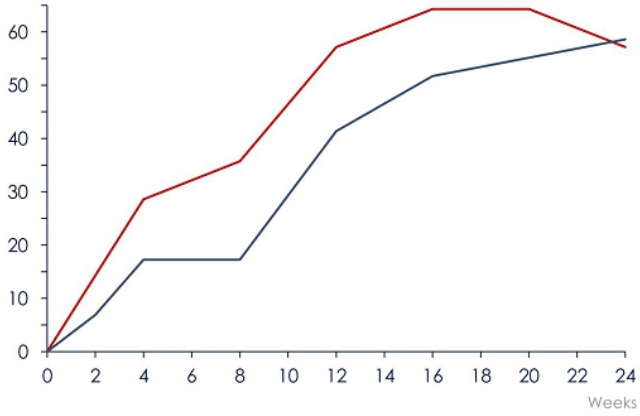
SLK trough concentrations were unaffected by treatment-emergent ADA status

SLK 120mg geometric mean trough concentration (µg/mL) by ADA status



Furthermore, clinical response was unaffected by anti-drug antibodies[1]

SLK 120mg ACR50 response rate (%) by ADA status



Similar for 60mg dose

Source: MoonLake Clinical

PsA: A clear path towards Phase 3 (current plan)

MoonLake

What know now from ARGO

- **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 program size** (potentially ~1,100-1400) expected to **reduce variations** driven by small groups
- **Sub-groups** with up-titration potential identified
- **Endpoints confirmed** for Phase3 – ACR50 & PASI90 – but with expected **primary endpoint at week 16 and emphasis on composite secondaries**
- Currently planning **two trials**
  - **TNF-IR** trial
  - **Bio-naïve** trial

Planned FDA EoP2 timeline
(parallel with EMA):

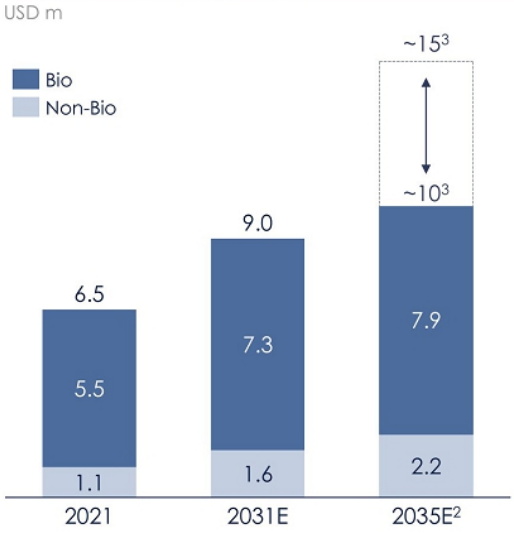
- Submission of FDA meeting request: Q1 2024
- Submission of FDA briefing book: Q1 2024
- FDA Meeting: Expected Q2 2024
- Full TFLs from the Ph 2 PsA trial (ARGO) due by Q2 2024

Source: MoonLake Clinical

IL-17 expected to become largest MoA in PsA in the next years

MoonLake

PsA market size estimates[1]



Key notes

- IL-17 becomes **largest drug class** in the next years in PsA (already estimated as 35-40% of market in 2031)
- Most data sources, incl. DRG/Carivate have BKZ latest estimates performed **before BE COMPLETE** (Ph 3) results
- **SLK is not yet part** of general, publicly available estimates – although an all-analysts-average places **sales for PsA above blockbuster level**
- BKZ is **~18% of IL-17** class by 2031 according to DRG/Clarivate, which is **likely an underestimation** versus SEC or IXE
- Most analysts suggest a small percentage market share for SLK only (~1-15%) – likely **an underestimation** versus any biologic leading any immunology market[4]

1 Based on DRG/Clarivate data ("Bio" included TNFs, IL-12/23, IL-17 and IL-23 related assets; "Non-Bio" includes all DMARDs, JAK inhibitors and selection co-stimulation modulators); 2 Based on extending sales to 2035 using a 5-year historical CAGR (2027-2031); 3 Upper bound of range indicated in Analyst Reports that cover MLTX (where available); 4 Considering DRG data from 16 Immunology indications: PsA, RA, Asthma, Moderate adult AD, Severe adult AD, nr-axSpA, AS, CU, LN, SLE, PsO, COPD, Acute CD, Maintenance CD, Acute UC, Maintenance UC (where avg. biologic share per indication is ~13%, share of second leading biologic is ~23% and share of leading Biologic is 36%
Source: MoonLake, DRG/Clarivate, Analyst Reports

PsA: ARGO results confirm SLK as the potential leader in PsA

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Unprecedented multi-domain response	**60%** of patients reach **MDA** and **~60%** reach **ACR50+PASI90**, at wk 24 - *confirming consistent multi-domain impact of SLK*
Greater depth of response	**40%+** reach **ACR70 and 60%+ reach PASI100 by** wk 24, with **~50%** patients reaching the **ACR70+PASI100 composite** – *long lasting effect and not yet maxed out*
More disease control	**Fast onset** (ACR50, 27% wk 8) coupled with **increasing efficacy** at wk 24 (ACR50, **61%** wk 24) – *also reflected in deep tissue (70% nail clearance) and patient reported outcomes*
Flexible dosing	**60mg confirmed as sufficient** to achieve leading results in most domains, **120mg adds benefit in specific subgroups** – *highly convenient regimens (monthly maintenance)*
Beyond current biologics	At wk 24, **patients respond better with SLK** vs. ADA in all critical scores and higher than other Bx – *a differentiated step-up*
Favorable safety profile	**No new** signals, **mAb-like ISR** rate, *Candida* (if present) **transient** and with **no discontinuations**

Source: MoonLake Corporate

MoonLake

HS

Franchise building indication

MoonLake

HS – A devastating disease

Prof Kenneth B. Gordon

Prof Gordon has received honoraria and/or research support from the following pharmaceutical companies: AbbVie, Amgen, Arcutis, Bristol-Myers Squibb, Boehringer Ingelheim, Dermavant, DICE, Incyte, Eli Lilly, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Protagonist, UCB, Union

Hidradenitis suppurativa: a challenge and an opportunity

HS is **progressive** and results in **irreversible tissue destruction** over time…[1]

…we need HS therapies that treat **all types of lesions**, with the **opportunity for inflammatory remission**

Delayed and insufficient treatment are **critical gaps** in disease management…[2]

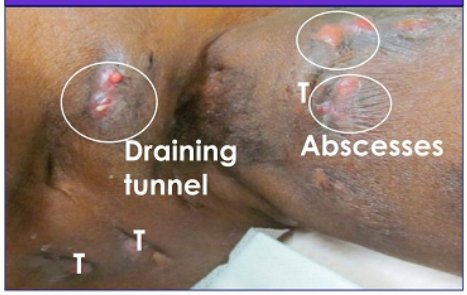
…we need HS therapies that provide **sustained and significant improvements** to patients' lives

2% Est. global prevalence

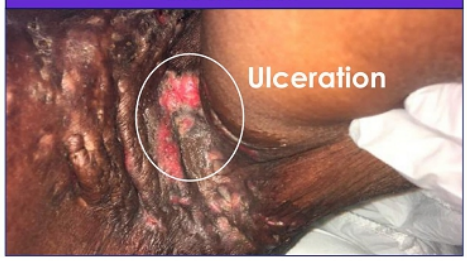
Delayed (and **under-**) **diagnosis** drive conservative prevalence estimates…[2,3]

…we need HS therapies that are **developed with all patients in mind** — reflecting many millions of people

Advanced disease with deep abscesses and tunnels[4]



Late-stage disease with extensive scarring and ulceration[4]



1 Sabat et al Nat Rev Dis Primers 2020;6:18 2 Krueger et al Br J Dermatol 2024;190:149–162 3 Ingram et al EADV 2023;Poster P0046 4 T, tunnel | Pictures courtesy of Prof. Kenneth B. Gordon and Dr Gretchen M. Roth

HS is characterized by a profound burden for patients and society

Symptoms[1]

Key symptoms include...

- **Pain**
- **Malodorous drainage**
- **Low mood/depression**

...and may be more burdensome in patients with draining tunnels

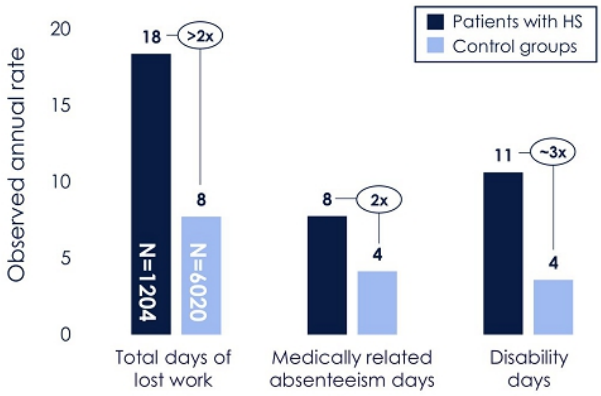
Hospitalizations

Hospitalization and ER visits are common for patients with HS[2]

- **30% of patients with HS were hospitalized** as an inpatient on ≥1 occasion, in a US claims database covering 2016–2019[2]
- **6 days in hospital** and **$33k costs** represent a typical hospitalization of a patient with HS, according to NIS data[3]

Work and employment burden

In the US, HS leads to **>2x days of lost work** and nearly **3x** disability days vs controls[4]

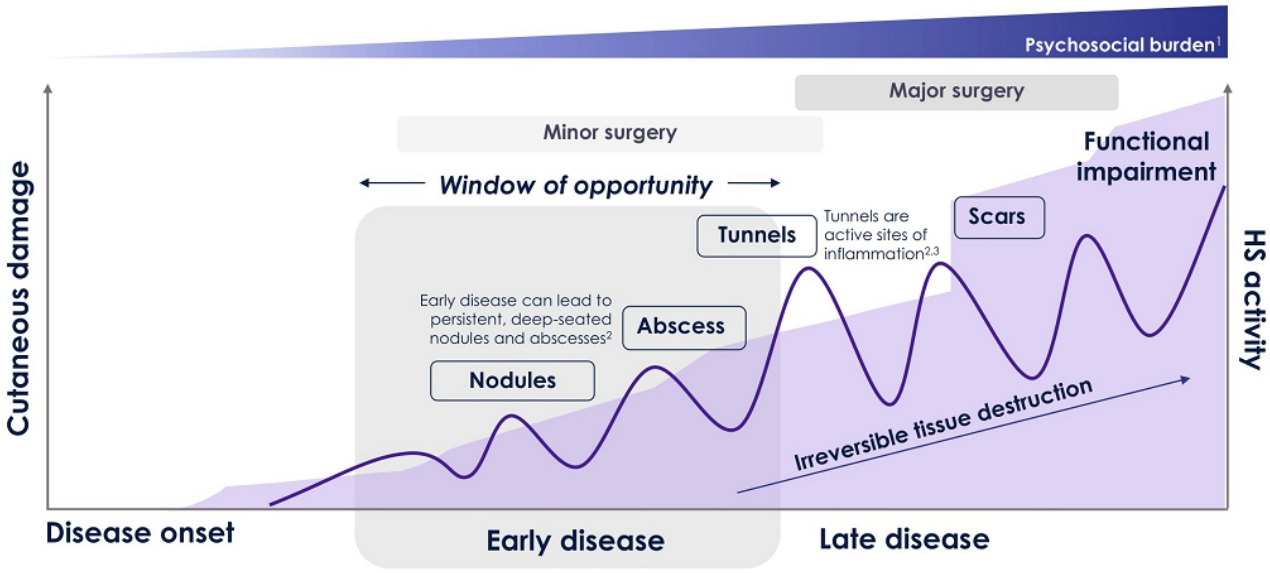


A similarly severe impact on work and employment is seen in Europe[5]

NIS, National Inpatient Sample

1 Ingram et al EHSF 2023:Poster P139 2 Chopra et al SID 2022:Poster 343 3 Bhattaru et al AAD 2023:Poster 43666 4 Tzellos et al Br J Dermatol 2019;181:147–154 5 Schneider-Burrus et al Br J Dermatol 2023;188:122–130

Chronic inflammation in HS progresses to irreversible tissue destruction



Resolution of **nodules, abscesses and tunnels** in a **'Window of Opportunity'** may offer the possibility of remission

Figure adapted from Martorell et al Actas Dermosifiliogr 2016;107(Suppl 2):32–42

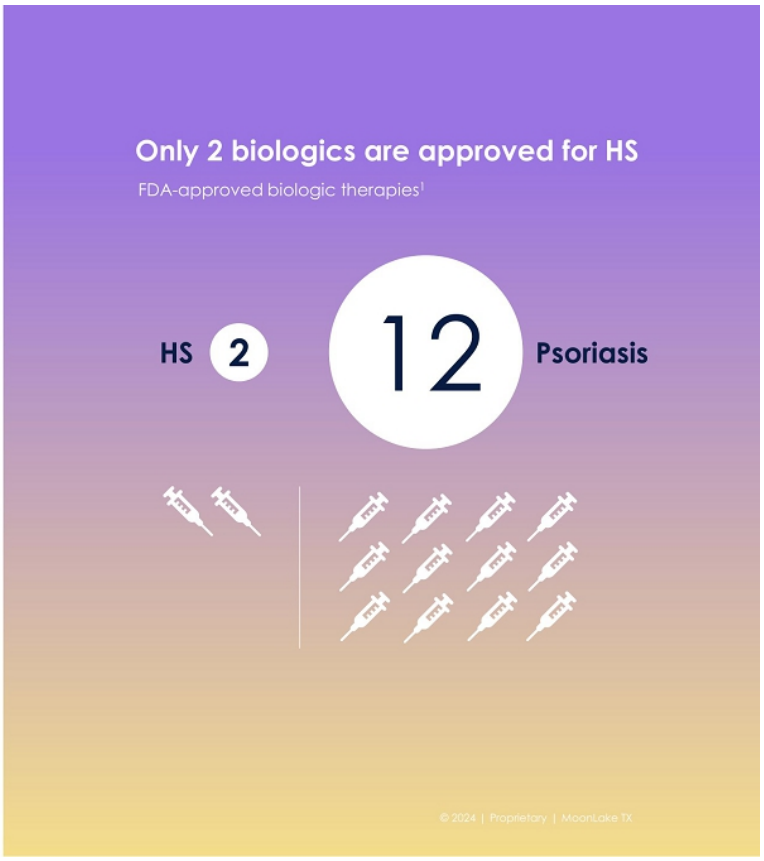
1 Ooi et al JAAD Int 2023;10:89–94 2 Sabat et al. Nat Rev Dis Primers 2020;6:18 3 Navrazhina et al J Allergy Clin Immunol 2021;147:2213–2224

Can we treat HS more effectively in the 'Window of Opportunity'?

We need

- **More treatment options**
- **Better therapies**
- **Shorter time to treatment**

to allow health systems to move patients onto treatment more quickly, and to keep them there



1 Drugs @ FDA: HS — adalimumab, secukinumab. Psoriasis — etanercept, infliximab, adalimumab, ustekinumab, certolizumab pegol, secukinumab, ixekizumab, brodalumab, bimekizumab, guselkumab, tildakizumab, risankizumab

Current therapy with adalimumab has high discontinuation rates

Median drug survival
Adalimumab in US patients with HS[1]

<1 year

1 in 3 US patients with HS **discontinue** adalimumab within **6 months**[1]

Patient groups with the highest burden of drug discontinuation…[1]

Women

Medicaid coverage

Younger adults

Recent surgery

→ Similar rates observed in Europe: median drug survival reported from 8–9 months (Denmark) to 18 months (Netherlands)[2]

1 Kimball et al EHSF 2024;T6-P-08 2 Data also available for Austria | Ring et al JAMA Dermatol 2022;158:184–188, Prens et al Br J Dermatol 2021;185:177–184, Wiala et al EADV 2023;P0134, Ring et al Br J Dermatol 2024;doi:10.1093/bjd/ljae042

What do we need from an effective therapy in HS?

Sustained efficacy is key for both derms and patients[1,2] and is central to other aims of treatment

Hospitalizations[3,4]

- Reduce the burden of inpatient and ER visits
- Reduce surgical interventions

Symptoms[6]

Alleviate symptom burden by resolution of all inflammatory lesion types, including tunnels

Work and employment burden[5]

- Enable employment
- Increase personal happiness and social integration

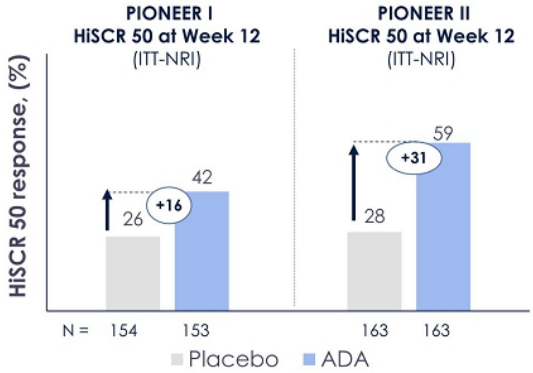
Established safety profile[1,6] — Risk of serious adverse events is another important consideration for both derms and patients

The consequences of uncontrolled HS are substantial for all aspects of patients' lives and society

1 Ingram et al EHSF 2023;16-O-15 2 Ring et al Br J Dermatol 2024;doi:10.1093/bjd/ljae042 3 Garg et al J Am Acad Dermatol 2020;82:366–376 4 Krueger et al Br J Dermatol 2024;190:149–162
5 Schneider-Burrus et al Br J Dermatol 2023;188:122–130 6 Willems et al Patient 2023;16:153–164

Treatment goals have not been advanced in eight years

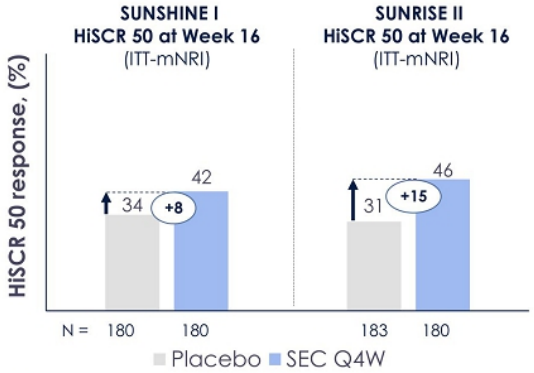
Adalimumab (Humira®[1]) **FDA HS approval 2015**[1]
- **TNF inhibitor** Traditional mAb (~148kDa)



50% improvement (HiSCR50) in approx. 50% of patients

8 years

Secukinumab (Cosentyx®[3]) **FDA HS approval 2023**[2]
- **IL-17A inhibitor** Traditional mAb (~150 kDa)



50% improvement (HiSCR 50) in approx. 45% of patients

Additional therapeutics with alternative mechanisms of action and higher levels of response urgently needed

1 ITT-NRI, non-responder imputation in an intention-to-treat population | Humira® Prescribing Information, Kimball et al N Engl J Med 2016;375:422–434
2 ITT-mNRI, modified non-responder imputation in an intention-to-treat population | Cosentyx® Prescribing Information, Kimball et al. Lancet 2023;40:747–761

Can targeting IL-17A + IL-17F advance treatment goals in HS?

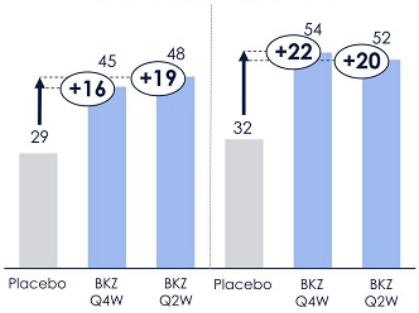
Bimekizumab (Bimzelx®)
- **IL-17A and IL-F inhibitor** Traditional mAb (~150kDa)

Primary endpoint

HiSCR 50 at Week 16 (ITT-mNRI)

BE HEARD I — **BE HEARD II**

PBO N=~73, BKZ N=~290 per arm

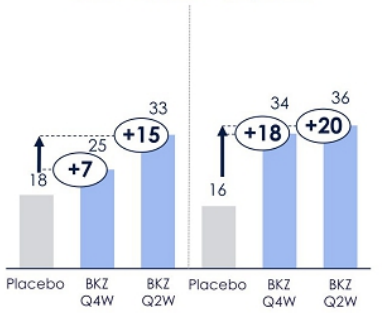


Secondary endpoint

HiSCR 75 at Week 16 (ITT-mNRI)

BE HEARD I — **BE HEARD II**

PBO N=~73, BKZ N=~290 per arm



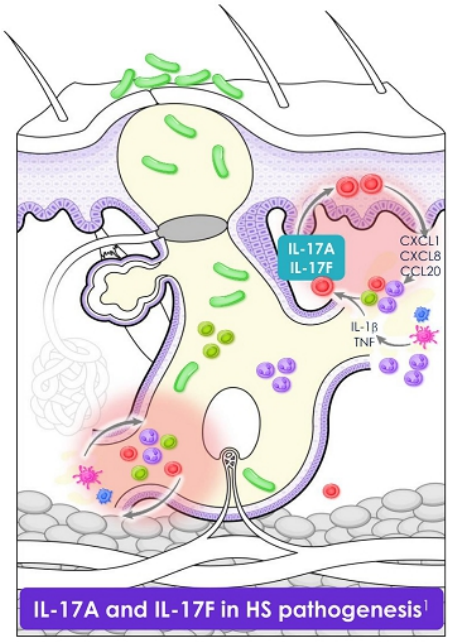
- Safety profile: No unexpected findings (oral candidiasis as expected from MOA)
- Maintenance of response: Phase 3 data showed continued efficacy to Week 48

Elevating trial endpoints

- Primary endpoint response was within the range of reports from earlier HS trials
- HiSCR 75 data suggested possibility of achieving higher threshold responses in HS than HiSCR 50

mNRI: modified non-responder imputation, with missing data due to adverse events or lack of efficacy, and systemic antibiotic initiation or intensification, imputed as non-response
Kimball et al AAD 2023:late-breaking presentation

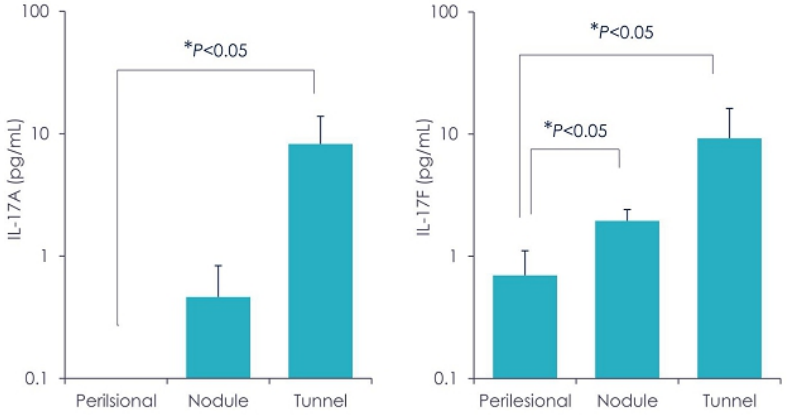
Elevated IL-17A + IL-17F in HS: rationale for targeting both cytokines



IL-17A and IL-17F in HS pathogenesis[1]

Both IL-17A and IL-17F are elevated in HS lesions, including inflammatory nodules and draining tunnels

MoonLake research[2]



IL-17A and IL-17F protein levels measured by cytokine array

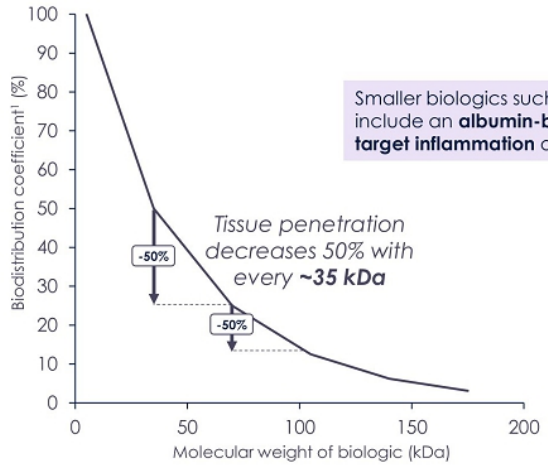
Data represent mean ± SEM. N=6 biopsy lysate samples for each tissue

1 Figure reproduced under the terms of the CC-BY license | Krueger et al Br J Dermtol 2024 23:190:149–162

2 SEM, standard error of the mean | Reich et al EHSF 2024;T1-P-03

Can Nanobodies® improve outcomes in HS?

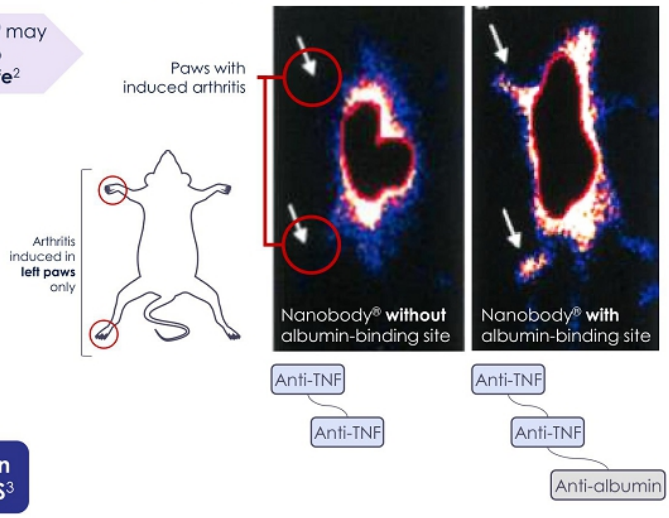
Smaller biologics → higher tissue uptake[1]



Smaller biologics such as Nanobodies® may include an **albumin-binding domain** to **target inflammation** and **extend half-life**[2]

Albumin-binding domains target inflammation

Accumulation of Nanobodies® 24 h after treatment[2]
Distribution of anti-TNF Nanobodies® +/- albumin-binding site 24h after a single injection in mice with collagen-induced arthritis



Nanobodies® are designed to directly target sites of inflammation in difficult-to-reach tissues, such as the deep dermal tunnels in HS[3]

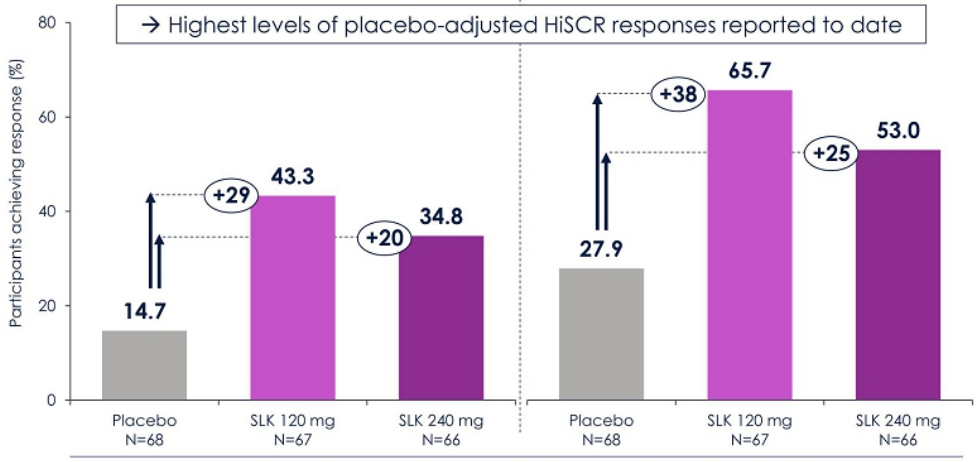
1 Biodistribution coefficient, calculated as tissue concentration/plasma concentration in muscle (other tissues ranged from 14 to 41 kDa molecular weight change required for a 50% difference in tissue penetration); Li et al. mAbs 2016;8:113–9
2 Coppieters et al. Arthritis Rheum 2006;54:1856–66 3 Krueger et al Br J Dermatol 2024;190:149–162

High levels of response were seen with sonelokimab in the MIRA trial

MIRA efficacy at Week 12

Primary endpoint 1st time in an HS trial

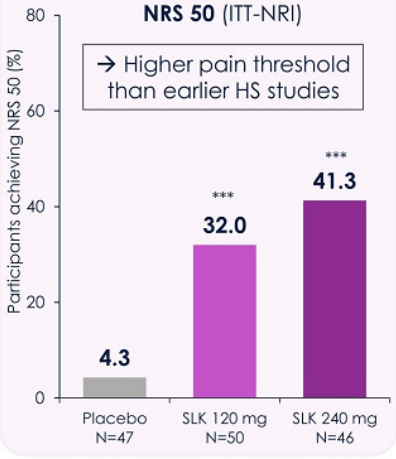
Key secondary endpoint



Sonelokimab was well tolerated with no unexpected safety findings

Pain at Week 12

SLK achieved pain responses at the high threshold of NRS 50

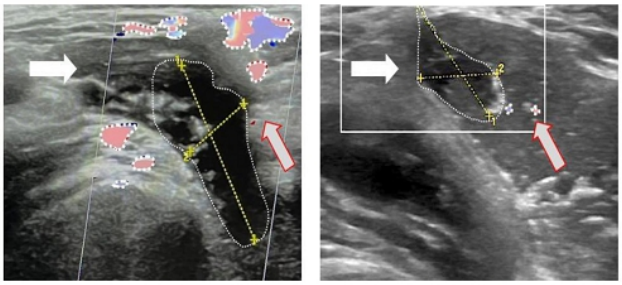


Peer-reviewed Week 24 data will be presented today at AAD Late-breaking research session, 14:00 PST

Kimball et al EADV 2023;late-breaking presentation D1T01.1H

Imaging lesions beneath the skin shows a direct effect on tunnels

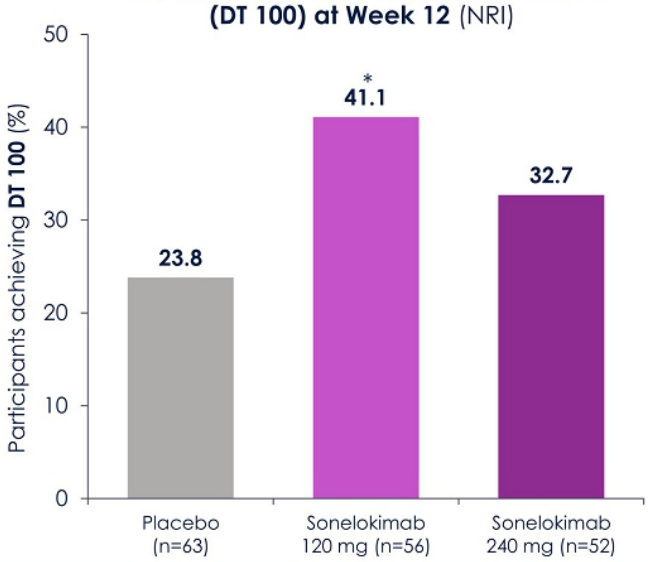
An exploratory ultrasound sub-study measured direct evidence of draining tunnel changes with SLK



Baseline Week 12

- Case study of a participant randomized to the sonelokimab 240 mg treatment arm
- Reduction in tunnel diameter and inflammatory activity observed at Week 12

Complete resolution of draining tunnels (DT 100) at Week 12 (NRI)



Phase 3 will be critical to better understand the potential of SLK as a Nanobody to improve clinical outcomes

Ultrasound images show the same draining tunnel (white arrow) at baseline and week 12; color-shaded areas indicate active inflammation (duplex signal of increased blood flow in the peri-tunnel area; grey arrow) | Kirby et al ISDS 2023:P260

After MIRA: what I would like to see in a Phase 3 program

A key goal of Phase 3 will be to show consistency with Phase 2, while always maintaining a patient-centered focus

ENDPOINT SELECTION

High level endpoints, such as **HiSCR 75**, **DT 100**, **IHS4-100**

MAINTENANCE OF RESPONSE

Assessing the **longevity** of treatment effect is critical

PATIENT POPULATION

Baseline disease severity is key for interpreting results

Phase 3

OPTIMAL DOSE

Dose based on **risk–benefit** evidence per **regulators**

SIMPLE PROTOCOL

A protocol **consistent with MIRA**, attractive to derms

COHORT SIZE

Enroll **sufficient number of patients** to satisfy regulators

Looking at high level endpoints and including patients with severe disease reflects patients in clinical practice

Expert opinion of Prof. Kenneth B. Gordon

MoonLake

SLK differentiation & Phase 3 program

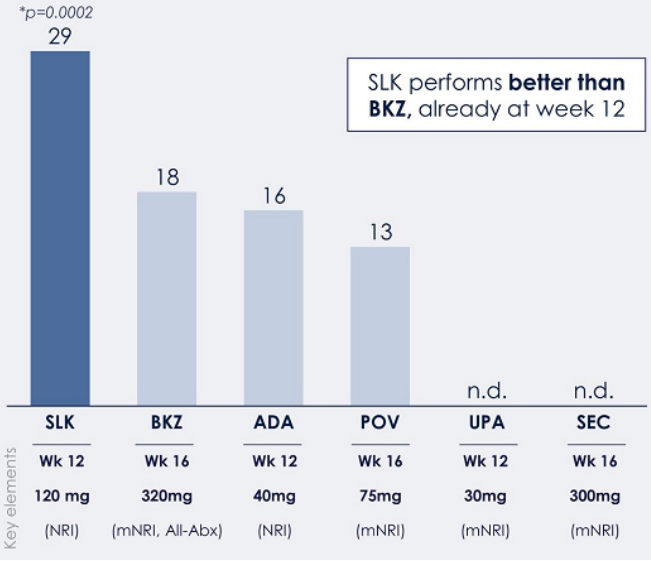
Kristian Reich

Recap: Setting a new bar in HS for primary endpoints

MoonLake

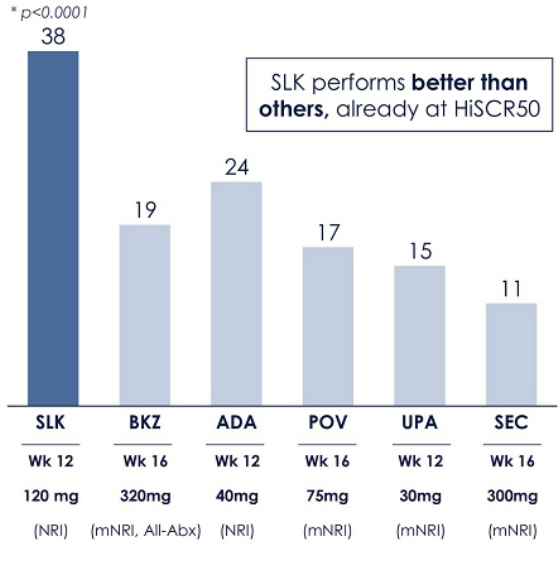
HiSCR75 delta to PLC (Primary endpoint only for SLK)

Percent delta for best doses, primary analysis



HiSCR50 delta to PLC (Primary endpoint for others[1])

Percent delta for best doses, primary analysis



Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. 1 POV used mean AN count reduction as primary endpoint 2 Estimation of HiSCR75 delta to PLC at wk 16 using the avg. response of the 2 crossed-over groups from PLC to SLK doses at wk 12 (PLC plateaus already from week 8) and the wk 16 response for the 120mg arm; PLC, Placebo; SLK, Sonelokimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD I/II); ADA, Adalimumab (pooled PIONEER I/II); POV, Povorcitinhib (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE)

Source: MoonLake Clinical (R&D Day June 27th 2023)

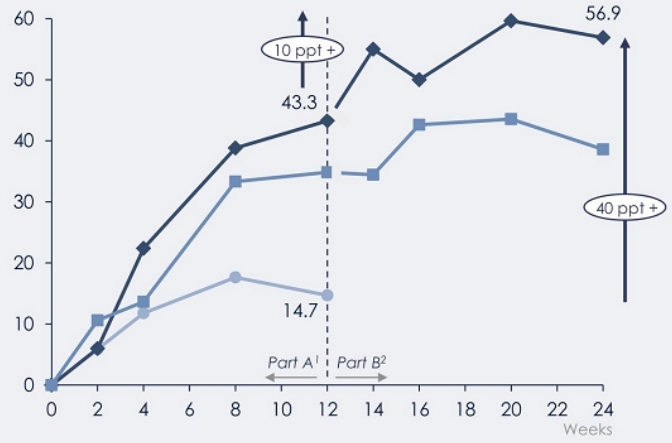
HS: Response with SLK increases through week 24, with monthly dose

MoonLake

PLC SLK 120mg SLK 240mg

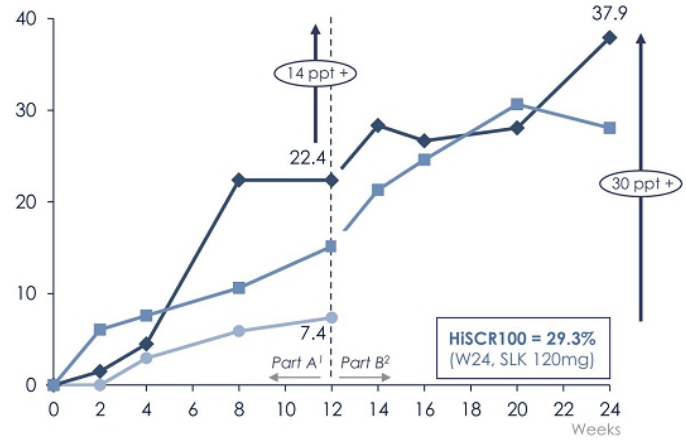
HiSCR75 response (Primary endpoint)

Percent (%) pts reaching score



HiSCR90 response

Percent (%) pts reaching score



Significant increase in number of patients **reaching HiSCR75** with convenient **monthly injection**
Deepening of responses with monthly maintenance dosing, as close to **40% of patients reach HiSCR90** by week 24

1 ITT-NRI data up to Wk 12 (Part A) 2 As observed data from Wk 14-24 (Part B)

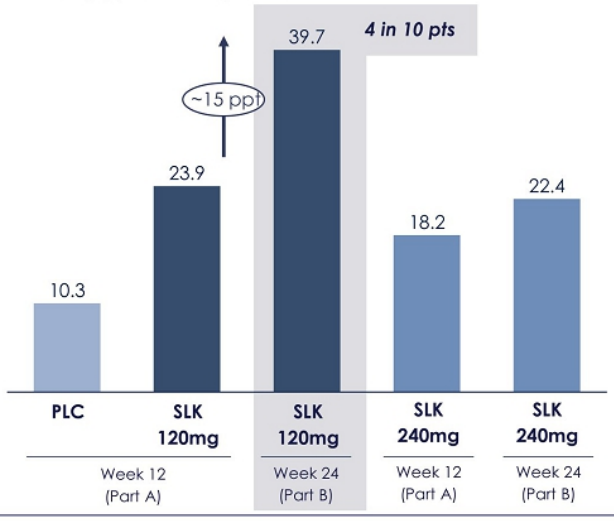
Source: MoonLake Clinical

HS: SLK allows patients & physicians to aim for inflammatory remission

MoonLake

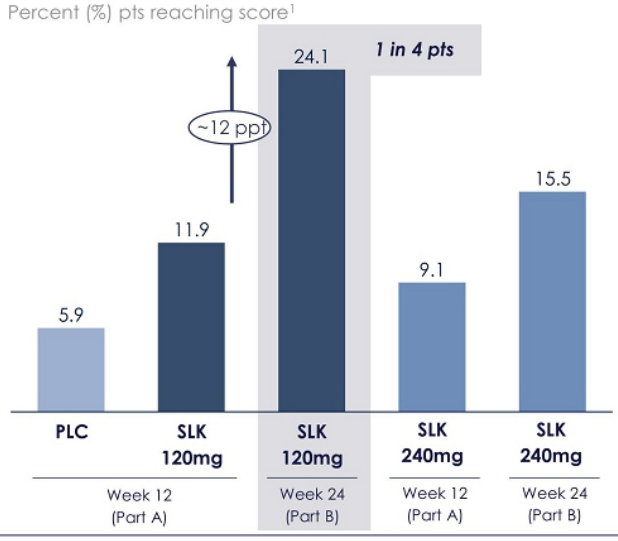
IHS4-90 response

Percent (%) pts reaching score[1]



IHS4-100 response

Percent (%) pts reaching score[1]



Monthly SLK deepens **IHS4 response** (e.g., IHS4-90 and IHS4-100)
About 1 in 4 four HS patients on monthly SLK 120mg achieve **inflammatory remission** (IHS4-100)

1 ITT-NRI data up to Wk 12; as observed data after week 12

Source: MoonLake Clinical

HS: The results are staggering and confirm SLK as the potential leader

MoonLake

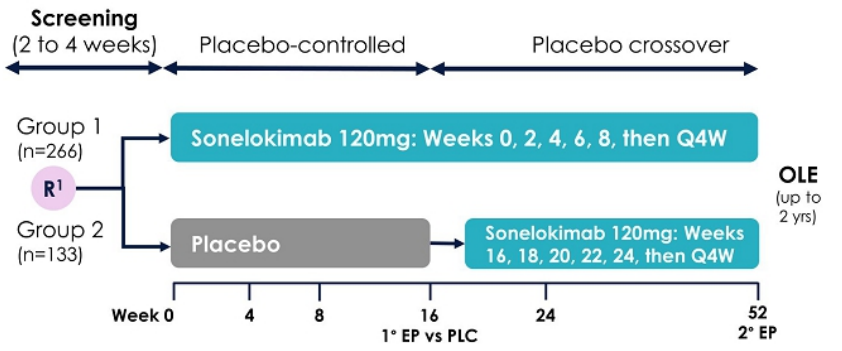
Higher HiSCR75 with Q4W dosing	**57%** of patients reach **HiSCR75** at week 24 with 120mg (**10ppt**+)
Greater depth of responses	**40%** patients reach **HiSCR90 and IHS4-90** by week 24 (**14ppt** +)
More disease control	**1 in every 4** patients in **inflammatory remission (IHS4-100)** & **40%+ report absent or minimal** disease activity (PGI-S)
Best dose confirmed	**120mg is best performing dose** across the board and dose **behavior replicated** from wk 12
Effect on TNF patients	At wk 24 **patients respond better with SLK** vs. ADA; **non-responders reach SLK-like responses** within 12 weeks
Favorable safety profile	**No new** signals, **no IBD**, or **malignancy**, **mAb-like ISR** rate, *Candida* (if present) **transient** and with **no discontinuations**

Source: MoonLake Corporate

HS: Very positive FDA & EMA EoP2 meeting, **HS highly de-risked**

MoonLake

Phase 3 protocol post FDA EoP2 meeting



Protocol repeated 2x (n=800 pts) – VELA I and II (both follow the same protocol)

Detailed interaction correspondence with FDA and EMA available
Comparable Phase 2 and 3 protocols available

- One dose phase 3 – FDA agrees HS **dosing is very clear** (120mg)
- 800 patients only (compared with Novartis, UCB, others) – FDA sees **Ph 2 as registrational** and considers patient data from other indications
- All other areas including stats, analytics etc. all **clear and low risk**
- Allows being **forward with primary endpoint** already in mid 2025, launch in 2027 (within 18-24 months of BKZ launch)
- **Cash in hand** for HS trial with no risk to other trials
- **Simpler protocol** compared to Phase 2 with stats that will likely **favor delta to PLC** (e.g., mNRI vs. NRI)

1 Randomization stratified by Hurley stage status (II vs. III) and prior biologic use (Y/N). Patients in Hurley stage III limited to ~40%; 2responder: HiSCR75 on two consecutive visits 4 weeks apart

Source: MoonLake Clinical Development

2. HS: VELA builds on the success of MIRA

MoonLake

Announcing Phase 3 HS program:

VELA I

VELA II

The MoonLake HS clinical trials continue to be the **only ones with HiSCR75 as the primary endpoint**

Source: MoonLake ClinDev

HS: Pivotal-like MIRA design is replicated in Ph3, in contrast to other trials

MoonLake

BKZ Ph2[1,2] n=90	**BKZ Ph3 (BH II)**[3,4] n=509	**MLTX Ph2 (MIRA)** n=234	**MLTX Ph3 (VELA)** n=800
Trial structure			
Only one dose tested	Two doses tested	Two doses tested	One dose tested
Loading dose	No loading dose	No loading dose	No loading dose
21 patients received placebo	74 patients received placebo	68 patients received placebo	266 patients receive placebo
Double Blinded/Placebo-controlled	Double Blinded/Placebo-controlled	Double Blinded/Placebo-controlled	Double Blinded/Placebo-controlled
Stats analyses			
PPS with no clear Abx Tx rules	ITT with Abx Tx rules	ITT with Abx Tx rules	ITT with Abx Tx rules
NRI, as observed[5]	mNRI	NRI	mNRI
Bayesian augmentation +40 PBO, ADA	No Bayesian augmentation	No Bayesian augmentation	No Bayesian augmentation
9% placebo HiSCR 75	16% placebo HiSCR 75	15% placebo HiSCR 75	Replication of PhII expected
12% discontinuations primary period	~8% discontinuations primary period	~5% discontinuations primary period	Low discontinuations expected
Cohort characteristics			
0% prior biologic use[6]	13% prior biologic use	18% prior biologic use[7] with 30% cap	30% prior biologic cap[9]
Mandatory topical antiseptic	No mandatory antiseptic	No mandatory antiseptic	No mandatory antiseptic
≥3 AN lesions	≥5 AN lesions	≥5 AN lesions	≥5 AN lesions
Mean AN # 14.5 BKZ vs 22.1 PBO	Mean AN # 17.7 BKZ Q4W[8] vs 14.4 PBO	Mean AN # balanced 14.6 SLK 120 vs 14.5 PBO	Balanced mean AN expected
49% Hurley II	61% Hurley II	64% Hurley II	40% Hurley III cap
No limit on concomitant Abx (% not reported)	Concomitant Abx limit not reported (9% at baseline in overall population)	30% limit on concomitant Abx (11% at baseline in overall population)	30% limit on concomitant Abx
1 stratification factor (Hurley)	2 stratification factors (Hurley, ABX)	2 stratification factors (Hurley, prior Bx)	3 stratification factors (Hurley, prior Bx, region)

1 Glatt et al. JAMA Dermatol 2021;157:1279–88; 2 NCT03248531; 3 Kimball et al. AAD 2023;oral presentation; 4 NCT04242498; 5 Sensitivity analysis presented as key data in primary publication; 6 No prior TNFi or IL-17i as per protocol — other prior biologic experience is not clarified in study publications 7 No primary failures or patients unsuitable for therapy 8 Mean AN # 17.2 for Q2W→Q4W arm and 14.7 for Q2W→Q2W arm 9 previous IL-17A/F excluded, no primary failure to IL-17i
Note: comparisons across trials, with inherent limitations. Not head-to-head trials. Not all trial details might be captured in full. VELA designs subject to final regulatory approval
Source: MoonLake Clinical

MoonLake

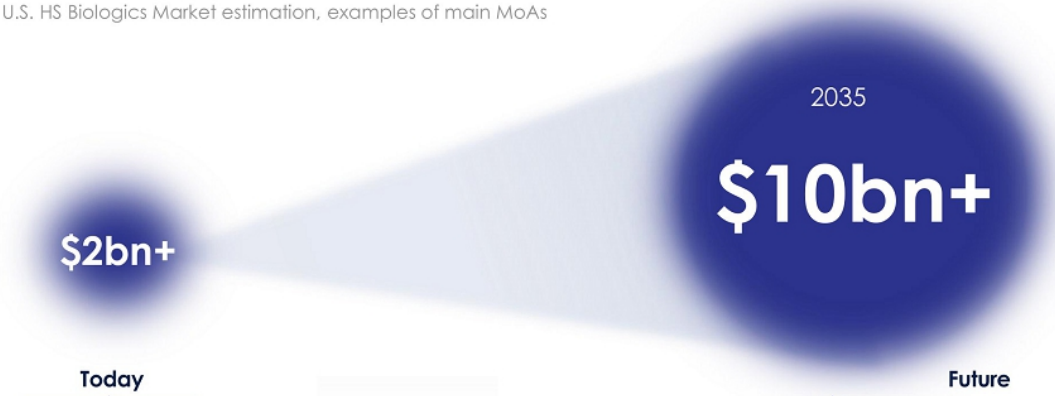
HS is the next large indication in Derm

Jorge Santos da Silva

Recap: The HS market is expected to growth to >10bn USD by 2035

MoonLake

U.S. HS Biologics Market estimation, examples of main MoAs



SLK as "Best of both worlds" ***MoA & molecule characteristics***

- ✓ Leading HiSCR75 response
- ✓ Effect on tunnels (penetration)
- ✓ Speed and depth of response
- ✓ Inflammatory Remission
- ✓ Patient Reported outcomes
- ✓ TNF-IR switching advantageous
- ✓ Safety profile

Today

HUMIRA adalimumab
TNF a (mAb)
AbbVie

Only ~50% of patients achieve HiSCR50 at wk 12

Limited durability of response (<11 m)

Future

Cosentyx (secukinumab)
IL-17 A (mAb)
Novartis

Marginally lower efficacy vs. Humira but **durable response** and good safety

Key strategic focus for Novartis

Bimzelx (bimekizumab)
IL-17 A+F (mAb)
UCB

Data supporting **IL 17A&F inhib. as best MoA** in HS

US launch expected in 2025, as key driver for UCB

SLK
IL-17A & F (small bio)
MoonLake

SLK uses **best MoA and is highly differentiated** (efficacy and likely safety)

Unique features (tunnels, convenience etc.)

JAK-inhibitors
JAKs (chem)
AbbVie / Incyte

No improvements in efficacy vs approved drugs

Focus on **later line treatments**

Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. 1 POV used mean AN count reduction as primary endpoint; PLC, Placebo; SLK, Sonelokimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD I/II); ADA, Adalimumab (pooled PIONEER I/II); POV, Povorcitinhib (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE). Launch dates based on MoonLake estimate

Source: MoonLake Commercial, DRG/Clarivate, academic journals, CBO; Komodo Health

Market: Large market size is substantiated by real-world data

MoonLake

U.S. adult HS patients

Claims methodology

- **Source are unique U.S. patients** from prescription claims data
- **~250m** U.S. patient lives (~75% coverage)
- **Diagnosed & treated** patients with HS diagnosis (ICD-10 L73.2)

Key insights (extrapolated to 100% of U.S. population)

~2.0m	**Unique patients diagnosed and treated** in 2016-2023[1]	**Confirms** large existing HS population	1
~240k	**New diagnosed and treated patients every year** (previously undiagnosed)[2]	**Confirms** underdiagnosis & future growth potential	
~40k/56k	**Adalimumab / Biologics** treated patients in 2023[3]	**Confirms** current Bx market size estimates	2
~30%	**Bx prescriptions are non-Adalimumab** in 2023[3]	**Confirms** high unmet need & need for new treatments	
~25%	**Growth p.a. in Biologics-treated** pts in 2016-2023[4]	**Confirms** high unmet need & Bx market growth potential	

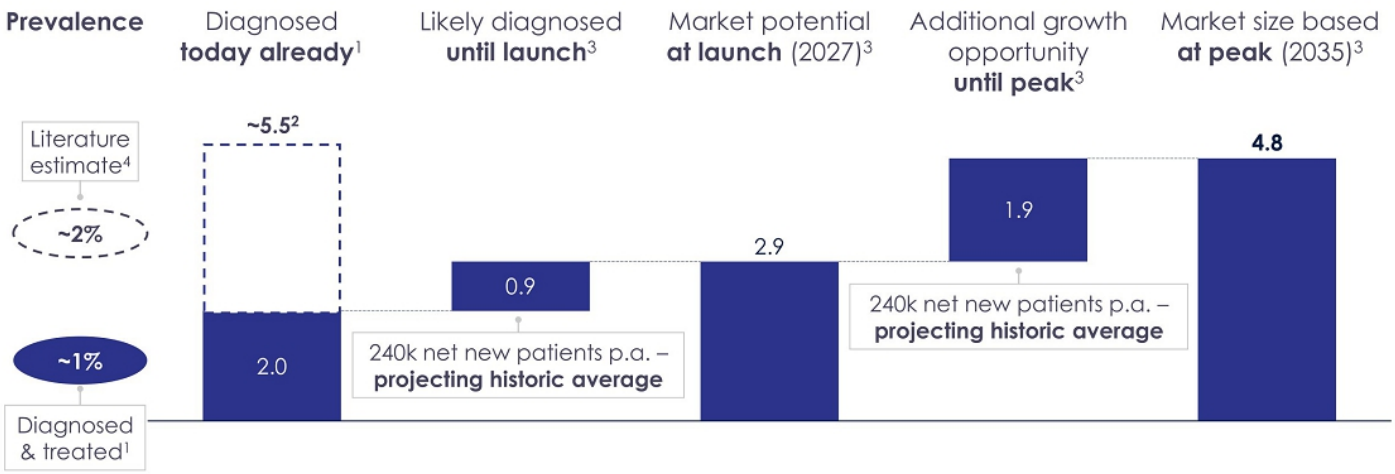
Note: Biologics (Bx) includes other targeted therapies (e.g., JAKs, PDE4i); 1. Patients ≥18 years with a HS diagnosis in 2016-2023; Extrapolated based on ~75% claims coverage rate (U.S. claims data); 2. historic average of annually net new diagnosed HS patients in 2016-2023, based on~75% coverage rate; 3. Patients with a HS-related Bx prescription in 2023 AND a HS diagnosis in 2016-2023; 4. Based on historic growth of patients with a HS-related Bx prescription in the given year and a preceding HS diagnosis

Source: MoonLake Commercial,

1 **Market:** Claims alone show ~2M HS patients – not incl. undiagnosed

MoonLake

U.S. adult HS patients



Claims confirm significant HS market already today we see ~1% of the population being diagnosed & treated

1. Includes patients ≥18 years with a HS diagnosis in 2016-2023; Extrapolated based on ~75% claims coverage – showing a 0.8% of U.S. Population HS diagnosed and treated; 2. Scaling the 2M patients (0.8%) to 2.1% prevalence (as per literature – see footnote 4); 3. Based on extrapolating historic average of annually net new diagnosed HS patients from 2024-2027; based on ~75% U.S. claims coverage; 4. Piens L. et al. Br J Dermatol. 2022

Source: MoonLake Commercial,

1 **Market:** HS patients face challenging journey – even years after Dx

MoonLake

U.S. adult HS patients

	Therapy post HS diagnosis	
	Year 1[1]	Year 2-3, of year 1[2]
Patients on antibiotics or steroids – most continue longer-term	**55%+**	65%+
Patients visiting an emergency room – most continue to have visits	**30%+**	55%+
Patients that undergo HS related surgery – continue to have surgeries	**15%**	20%
Patients on biologics – few remain on drug uninterruptedly[3]	**3%**	0.6%

Patients are cycling through various supportive care treatments – pre and post biologics

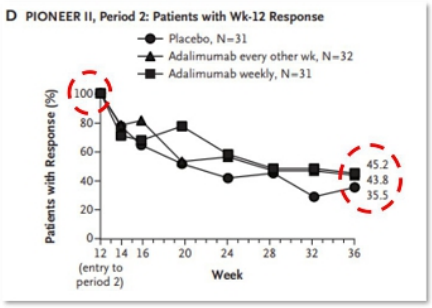
1. HS patients receiving respective care in the first year after diagnosis; 2. HS patients receiving respective care in years 2 and 3 post diagnosis, as a % of year 1 patients, 3. Consecutively on drug for >24m

Source: Market research, © 2023 Komodo Health, Inc. All rights reserved.

1 **Market:** Adalimumab with limited duration of response in real world

MoonLake

Trial results: Maintenance of response

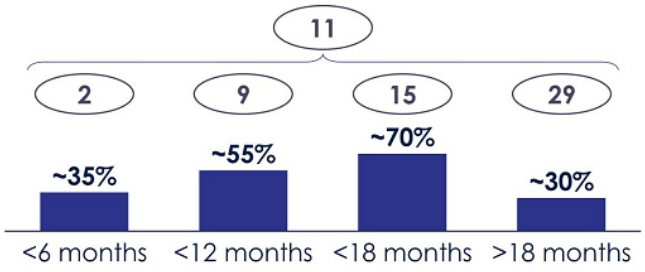


~55% did not maintain response after 9m

Claims: Duration of therapy (N=53k)[1]

% of patients by months on therapy (prescription fill breaks >3 months treated as new treatment)

xx Median duration (m) on therapy



~11m median duration of treatment

Not linked to U.S. access & affordability hurdles, given European studies show similar results[2]

Claims data confirms limited duration of therapy (~11m median) for Adalimumab in real-world patients, leaving them without efficacious HS treatment option

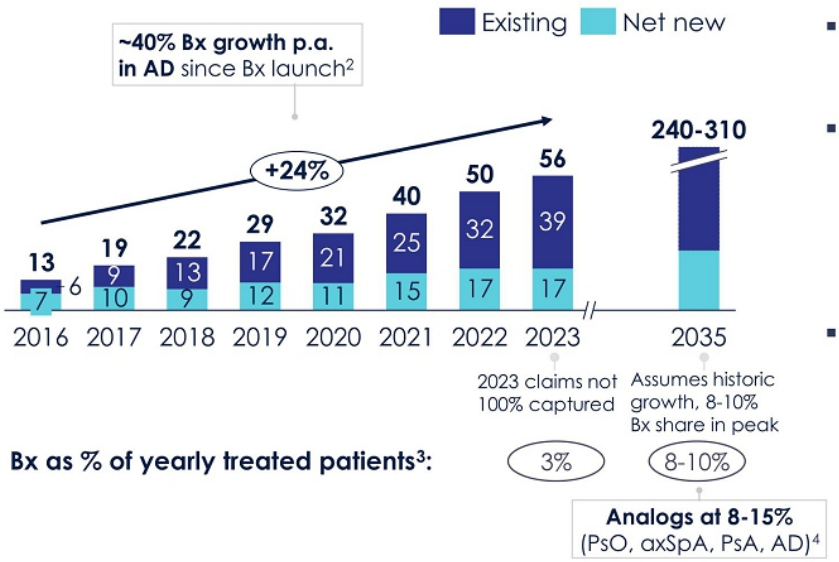
1. Average duration of treatment for the period of 2016-2023 for HS-relevant Adalimumab patients with a prescription start in until 2022; 2. E.g., Prens L.M. et al. *Br J Dermatol. 2021 Jul;185(1):177-184.* doi: 10.1111/bjd.19863, Ring H.C. et al. *JAMA Dermatol. 2022 Feb 1;158(2):184-188.* doi: 10.1001/jamadermatol.2021.4805.

Source: MoonLake Commercial, . N Engl J Med 2016; 375:422-434; JAMA Dermatol. 2022 Feb; 158(2): 1–5.

2 **Market:** Growth and unmet need expected to remain high

MoonLake

HS Biologics and targeted treatment patients in U.S. (k)[1]



- **Bx treatments with strong grows at ~25% p.a.** from 2016 to 2023
- Today's Bx share is starting from a small base due to limited **effective Bx treatments and low durability of Adalimumab** (~3% of yearly treated patients)
- **~30% of Bx treatments other than Humira** (e.g., ixekizumab), further highlighting the **need for a novel and effective treatment options in HS**

1. Patients with a HS-relevant biologics prescription in the respective year and a preceding HS diagnosis; includes JAKs and PDE4i; 2. Annual growth in Bx for patients with a preceding AD diagnosis in 2017-2023; 3. Share of patients with a HS-relevant biologics prescription in the respective year as % of the annually treated HS population (~65%); 4. Share of patients with a relevant Biologics prescription for PsO / axSpA / PsA in 2023 as % of the total patients with a PsO / axSpA / PsA diagnosis in 2016-2023

Source: MoonLake Commercial, Market research, © 2023 Komodo Health, Inc. All rights reserved.

2 **Market:** Humira accounts for most of current $2bn+ biologics market

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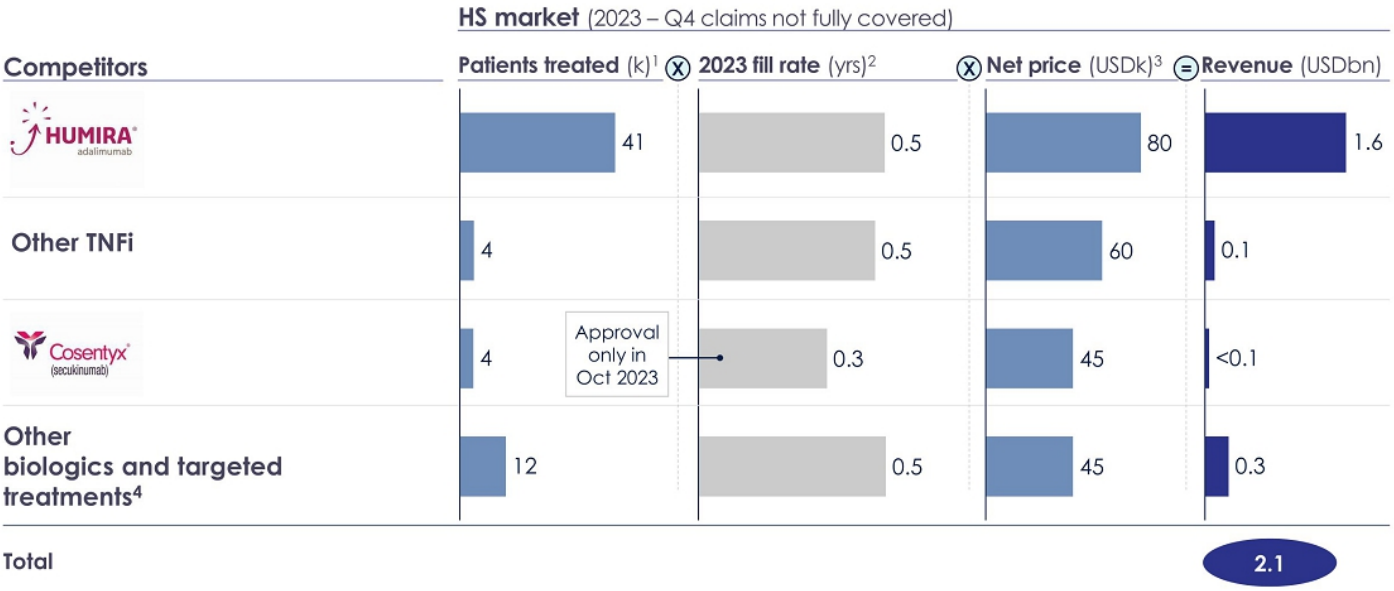
2023 claims not 100% captured yet (time lag)



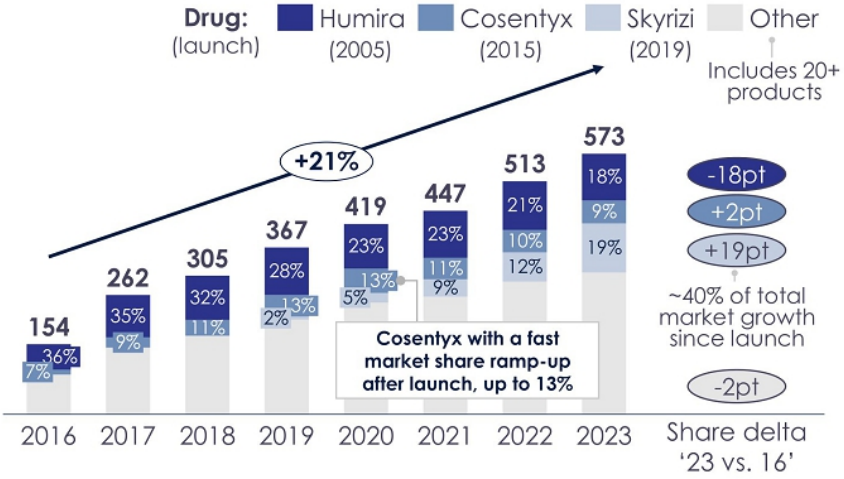
1. Includes patients with a prescription of the respective drug in 2023 AND a corresponding HS diagnosis (U.S. claims data); 2. Based on average days supplied across all patients on the respective drug in 2023 (Avg. fill rate for all patients with a prescription in 2023); 3. Calculated as annualized WAC (for maintenance therapy) net of total GTN incl. service fees, statutory & confidential discretionary rebates, etc. (based on market research); *4. Includes JAKs and PDE4i*

Source: MoonLake Commercial, Market research, © 2023 Komodo Health, Inc. All rights reserved.

2 **Market:** PsO shows clinical differentiation wins over time-to-market

MoonLake

PsO biologics patients in U.S. (k)[1]



- **Better clinical profile matters most**: After their respective launches Cosentyx and Skyrizi are capturing a big share of the market
- **New entrants are growing the market**: Upon their launches the biologics market has grown substantially (Skyrizi accounted for 40% of market growth)
- **Disease area leadership can be built despite launching later**: Skyrizi is market leader in PsO (~19% share in 2023) among 20+ biologics competitors

New entrants capture substantial share in PsO and increase market growth rate by improving efficacy and setting a new bar for treatment outcomes (e.g., PASI100), despite not being first-to-market

1. Patients with a biologics prescription in the respective year and a preceding PsO diagnosis;

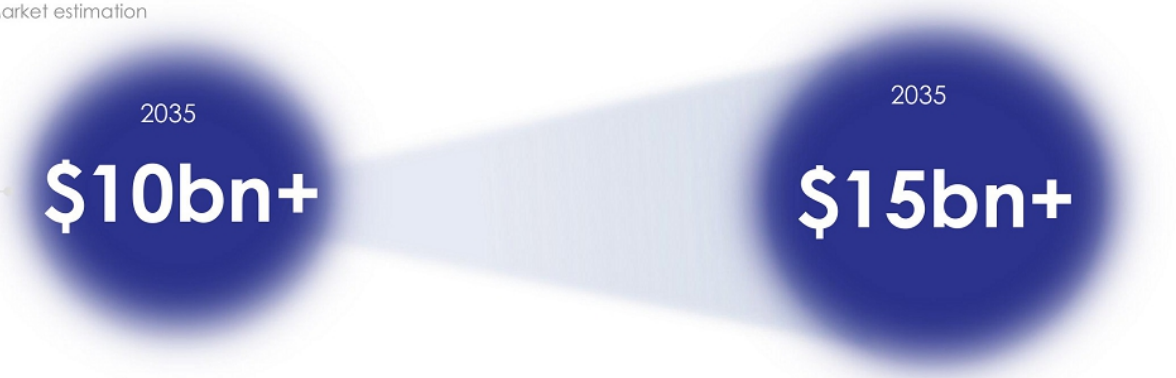
Source: Market research, © 2023 Komodo Health, Inc. All rights reserved.

Market: The HS market might be even larger than $10bn in 2035

MoonLake

U.S. adults HS Biologics Market estimation

~$10bn+ U.S. market size projection based on very conversative extrapolations of historic growth



Diagnosed prevalence	**4.8m** based on claims extrapolation[1]	Higher HS awareness increases diagnosis and treatment rate	**5m+** likely given claims only capture diagnosed & treated[2]
Biologics adoption	**~8%**	More efficacious treatment options increase Bx adoption to levels of analogs	**~10%** analogs ~15% (PsA, axSpA[3])

Through recent claims analyses we cannot only substantiate the projected 2035 $10bn HS market in the U.S. but we believe the true HS market in the U.S. has potential to become $15bn+

1. Patients ≥18 years with a HS diagnosis in 2016-2023; Extrapolated based on ~75% claims coverage rate, further conservatively extrapolating historic average of annually net new diagnosed HS patients from 2024-2027 and ~70% of historic average of annually net new diagnosed HS patients from 2028-2035; Assumes based on ~75% claims coverage rate, 2. Share of patients with a relevant Bx prescription for PsO / axSpA / PsA in 2023 as % of the total patients with a PsO / axSpA / PsA diagnosis in 2016-2023; 3. extrapolated based on SLK opportunity and Humira-like prices

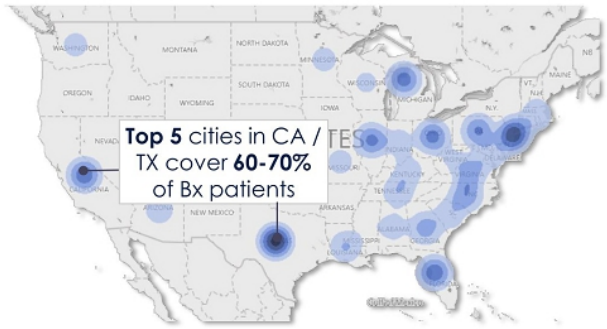
Source: MoonLake Commercial,

Targeting: Achieving SLK blockbuster status in concentrated landscape

MoonLake

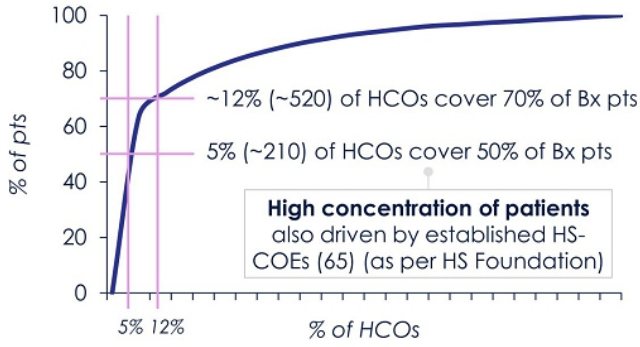
U.S. adult HS patients on biologics

Distribution by state



15 states in the U.S. cover **~70% of Biologics** treated patients[1]

Distribution by HCO in top 15 states



12% of HCOs cover **~70% of Biologics** patients[1] (within top 15 states)

Targeted Go-To-Market approach enables to unlock SLK blockbuster status in concentrated HS landscape

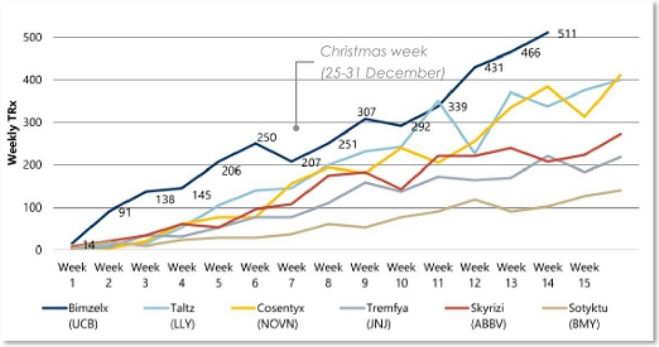
1. Based on Komodo Health claims data: Includes patients with a Bx prescription in 2022 and a HS diagnosis in 2015-2022

Source: Market research, © 2023 Komodo Health, Inc. All rights reserved., MoonLake Commercial

Competition: Bimzelx above expectations – SLK is **further differentiated**

MoonLake

Bimzelx confirms A&F as winning MoA with fast market uptake and good clinical data (in Plaque Psoriasis)



SLK shows a differentiated profile across multiple trials and clinical outcomes

- SLK has shown **leading responses** at wk 12 and week 24 in across **all relevant outcomes in HS (**MIRA trial), incl. being the **first to use HiSCR75** as primary endpoint, showing largest **deltas to placebo in different HiSCRs**, bringing **one quarter of patients to inflammatory remission**, demonstrating **impact on tunnels** etc.
- SLK shows **leading responses across all relevant outcomes in PsA** (ARGO trial) at wk 12 and wk 24, **especially in multi-domain scores** where other drugs appear to struggle
- Original data in Psoriasis (PsO) indicates that **SLK also has leading responses in skin inflammation and can sustain longer-term responses**

Bimzelx has achieved leadership in the dynamic market share of the IL-17 class, withnshare reaching ~40%

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. 1 Warren et al., EADV 2021, P0353

Source: MoonLake Commercial, IQVIA, Barclays Research, RAPID Weekly Audit, November 2023-December 2023 (Copyright IQVIA), Company statements

HS: SLK is most convenient

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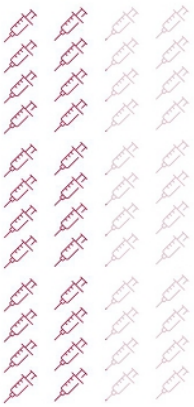
Maintenance injection schedule

15s injection time
per 1ml syringe[1]



15s injection time
per 1ml syringe[2]

SLK

3s injection time
per 1ml syringe

Substantially fewer and quicker injections
(5x faster injection)

Note: 320 mg for Bimzelx and 300mg for Cosentyx require 2 syringes per application – then every two weeks [Q2W] applied 1. Trial includes Q2W and Q4W dosing regimens (both requiring 2 injections) – TBD on actual label 2. Available as 2x 150mg (4 injections) and 300mg/2ml pens; Standard dose as Q4W, but possibility to move to 300mg Q2W

Source: Product leaflets, Company information, MoonLake Commercial

Recap: HS provides a sizable market with high unmet need

MoonLake

- **Sizeable, underdiagnosed market:** 2m patients today, >240k newly diagnosed patients every year
- **Albeit starting from a small base** (~13k in 2016) **biologics market is growing rapidly** (25% p.a.): similar trajectory to other markets such as PsO, AD etc.
- **Severe unmet need** with current options: patients cycled through with no disease control
- **HS causes a significant burden to patients and health systems** (ER visits, surgeries, medications)
- **SLK has potential to be the most differentiated:** Patients ~11m in ADA, ~4x SEC patients needed to get to SLK outcome (HiSCR50), 10-20ppt higher in key scores versus BKZ

*Market likely **among the largest across Inflammation (15bn+)** and able to accommodate different players: **SLK positioned as potential leader***

Source: MoonLake Commercial

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New indications

New frontiers for SLK and MLTX

SLK is a unique molecule: Nanobody® that targets IL-17 A & F

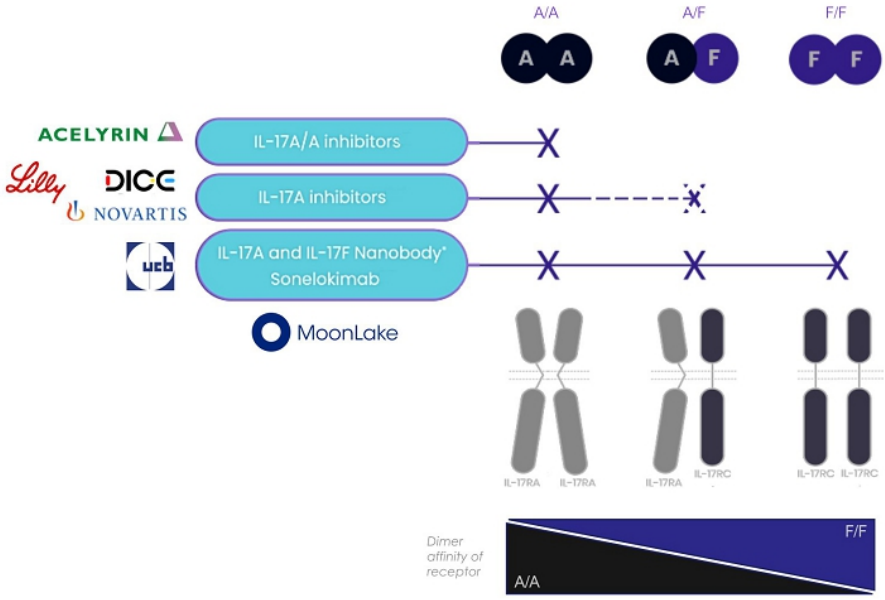
Illustrative

IL-17A and IL-17F function as dimers to drive inflammation, through activation of IL-17RA & RC receptor complexes

Different IL-17RA & RC chains combine to form complexes, and those have different affinity for different dimers[1,2]

Not all IL-17-targeting therapeutics can inhibit IL-17A/A, IL-17A/F and IL-17F/F dimers

SLK is the only asset that binds all dimers and with similar affinity



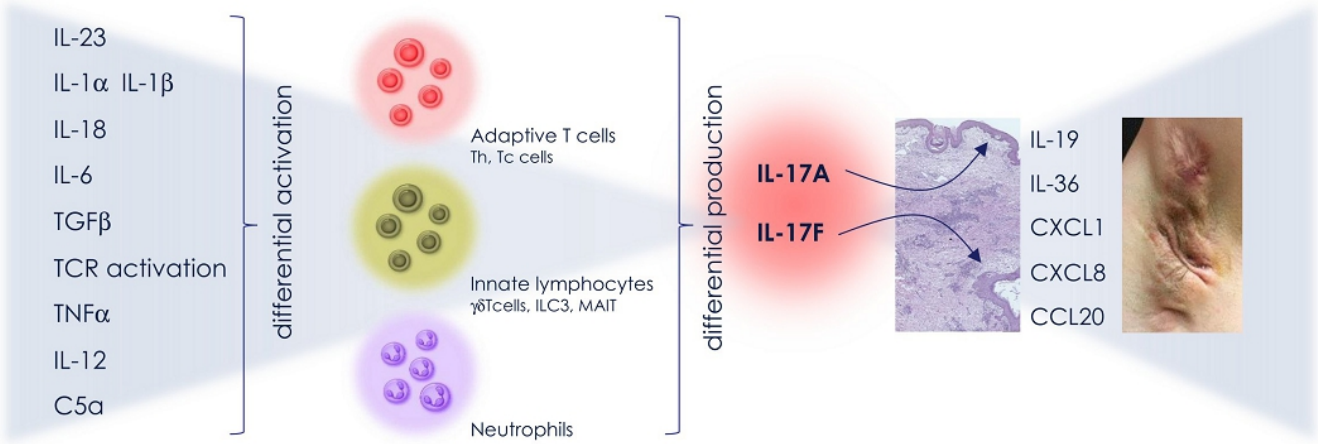
1 Liu S, et al. Nat Commun. 2013;4:1888; 2 Goepfert A, et al. Immunity. 2020 Mar 17;52(3):499-512

Source: MoonLake Research

Key MoA: IL-17A & F is at the crux of **many** inflammation pathways

MoonLake

Multiple stimuli induce subsets of immune cells to produce IL-17A and F	Different cell types preferentially produce IL-17 A and/or F	**IL-17A and F as "bottleneck" in many pathologies**	IL-17A and F induce multiple pro-inflammatory effectors, e.g. activation of keratinocytes

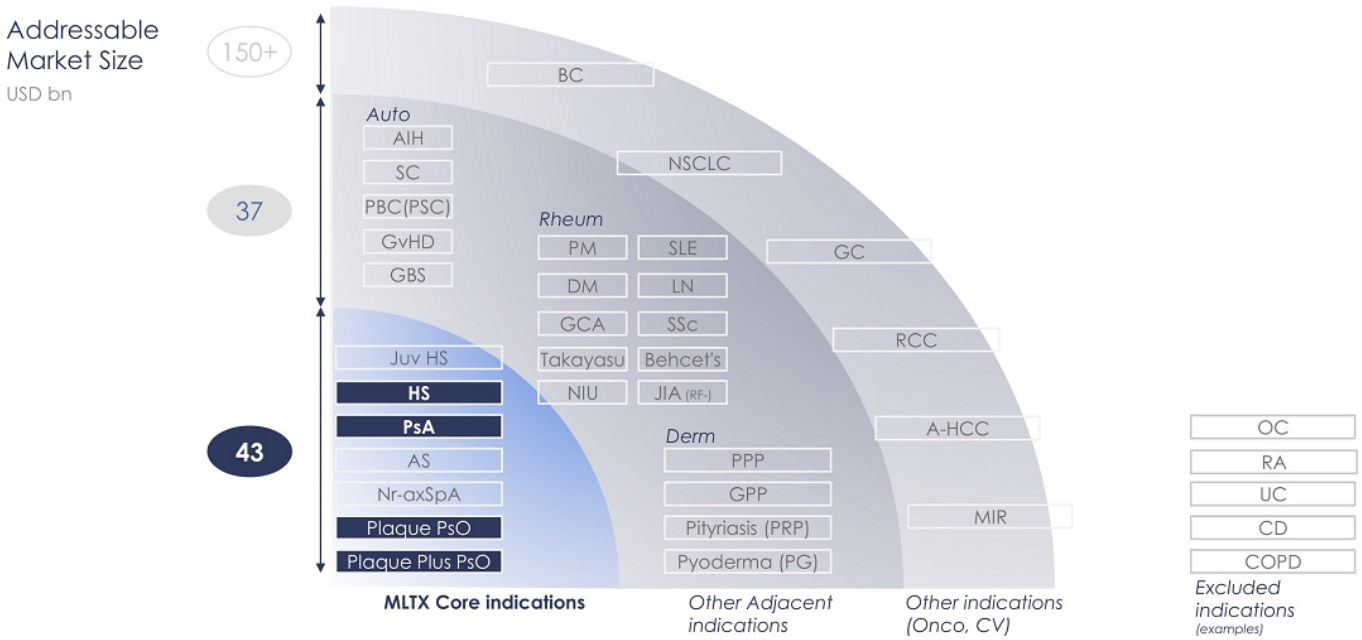


Targeting upstream or downstream pathways to IL-17A and F has led to several failures as **pathways are redundant**

Source: MoonLake Clinical

Many diseases involve IL-17A&F as a key pathway, beyond **HS and PsA**

MoonLake



Abbreviations: HS (Hidradenitis suppurativa), PsA (psoriatic arthritis), AS (Ankylosing Spondylitis or radiographic axial spondyloarthritis), nr-axSpA (non-radiographic axial spondyloarthritis), PsO (Psoriasis), AIH (Autoimmune Hepatitis), PSC (Primary Sclerosing Cholangitis), PBC (Primary Biliary Cholangitis), GvHD (Graft-vs-Host disease), GBS (Guillain-Barre Syndrome), PM (Polymyositis), DM (Dermatomyositis), GCA (Giant Cell Arteritis), NIU (Non-infectious uveitis), SLE (Systemic lupus erythematosus), LN (Lupus Nephritis), SSc (Systemic Sclerosis), JIA (Juvenile Idiopathic Arthritis), PPP (Palmo-plantar pustulosis), GPP (Generalized Pustular Psoriasis), BC (Breast Cancer, NSCLC (Non-small cell lung carcinoma), GC (Gastric Cancer), RCC (Renal Cell Carcinoma), A-HCC (Alcohol-related Hepatocellular Carcinoma), MIR (Myocardial ischaemia and reperfusion)

Source: Clinical and scientific publications, MoonLake

MLTX will expand its portfolio of **SLK indications in Derm & Rheum**

MoonLake

- **MLTX has a robust late-stage development program ongoing**
  - HS Phase 3
  - PsA Phase 3
  - Commercialization-enabling data in 2025/2026

- **Portfolio expansion is driven on the strengths of MLTX**
  - Focus on building the leadership of SLK in Derm & Rheum (vs. "opening" new TAs)
  - Significant value that can be unlocked with our Nanobody® against IL-17 A&F
  - Where elevating treatment goals with stellar science can make a real difference

Source: MoonLake

How the new indications **drive value for MLTX**

MoonLake

Derm

PPP
(Phase 2)

- **"HS-like" disease,** key priority for Derms, large unmet need
- **Up to ~10-15% of PsO patients have palmoplantar involvement**[1]
- **IL17 A&F** relevance shown through BKZ case series[2]

New indication

Rheum

1 Merola J. et al. (2018). *Dermatologic Therapy;* 31:e12589. doi.org/10.1111/dth.12589 and Chimenti et al. (2020). *Biologics;14:53-75.* doi: 10.2147/BTT; 2 Passeron et al. (2023). *JAMA Dermatol.* doi:10.1001/jamadermatol.2023.5051;
3 Limited disease control – even at lower levels: ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data; 4 Based on BE MOBILE trial results

Source: MoonLake

PPP: Elevating position as the leading innovator in Derm

MoonLake

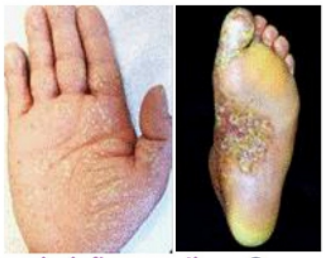
SLK can be highly differentiated…

IL-17 A&F is **most promising MoA** considering BKZ cases[1] and previously shown relative performance of SLK vs BKZ

Nanobody benefit given **deep-tissue location of lesions** (similarly to HS tunnels, pustules in deep skin)

Potential to be **first-to-market** in U.S. and US, and add yet another **distinctive therapy for Derms**

… in a severe disease without effective treatments…



Chronic inflammation: Crops of pustules causing pain & bleeding[2]

No approved therapy

Multiple MoAs failed (e.g., IL-1, IL-12/23s, IL-36, IL-17)

…by breaking new ground where others have given up

ppPASI as primary endpoint to elevate the bar vs previous attempts

Objective inflammation endpoints as additional scores to establish broader treatment goals

Competitive **number of patients** in trial, with **attractive design** for the **main PPP sites**

Deemed as sufficient to **move to Phase 3 or even approval** with successful read-outs

Market size

0.3% Global prevalence

4+ USD bn sales beyond 2037

Unmet Needs

~10-15% Of PsO patients with palmoplantar involvement[3]

0 Approved or effective treatment options

1. Passeron et al. (2023). *JAMA Dermatol.* doi:10.1001/jamadermatol.2023.5051; 2 Brunasso A. & Massone C (2021). *Fac Rev.*; Twelves et al. (2019. *J Allergy Clin Immunol. 143(3):1021-1026.* and Misiak-Galazka, M. (2020). *Am J Clin Dermatol 21, 355–370.*; 3 Merola J. et al. (2018). *Dermatologic Therapy; 31:e12589.* doi.org/10.1111/dth.12589 and Chimenti et al. (2020). *Biologics;14:53-75.* doi: 10.2147/BIT

Source: MoonLake team

How the new indications **drive value for MLTX**

MoonLake

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- **IL17 A&F** relevance shown through BKZ case series[2]

New indication

Juv HS
(Phase 3)

- **First clinical trial in juvenile HS**, addressing critical gap for derms
- **Opportunity** to control progressive disease pre-irreversible damage
- **Parallel to adult HS Ph 3,** allowing further differentiation as "HS leader"

Strengthen indication

Rheum

1 Merola J. et al. (2018). *Dermatologic Therapy*; 31:e12589. doi.org/10.1111/dth.12589 and Chimenti et al. (2020). *Biologics*;14:53-75. doi: 10.2147/BTT; 2 Passeron et al. (2023). *JAMA Dermatol*. doi:10.1001/jamadermatol.2023.5051;
3 Limited disease control – even at lower levels: ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data; 4 Based on BE MOBILE trial results

Source: MoonLake

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Strengthen indication

Rheum

axSpA
(Phase 2)

- **Multi-bn markets** (r/nr-axSpA) with limited efficacy of current SoC[3]
- With PsA allows MLTX to further **lead in seronegative Spondylarthritis**
- **IL17 A&F** relevance shown through BKZ cases[4], small size an advantage

New indication

1 Merola J. et al. (2018). *Dermatologic Therapy*; 31:e12589. doi.org/10.1111/dth.12589 and Chimenti et al. (2020). *Biologics*;14:53-75. doi: 10.2147/BTT; 2 Passeron et al. (2023). *JAMA Dermatol*. doi:10.1001/jamadermatol.2023.5051;
3 Limited disease control – even at lower levels: ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data; 4 Based on BE MOBILE trial results

Source: MoonLake

axSpa: Broadening leadership in Rheum by elevating care in axSpA

MoonLake

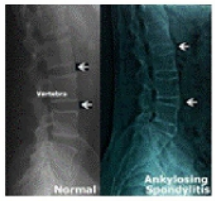
SLK to elevate care to new efficacy levels…

Strong rationale for **SLK to elevate care in axSpA**

- Winning MoA, with IL-17A&F inhibition showing most durable responses
- Strong SLK PsA data in joints and nails as proxy for spinal inflammation
- Nanobody benefit in difficult-to-treat deep inflammation and co-morbidities[1]

With PsA allows MLTX to further **lead in seronegative Spondylarthritis**

… in a disease with high unmet need…

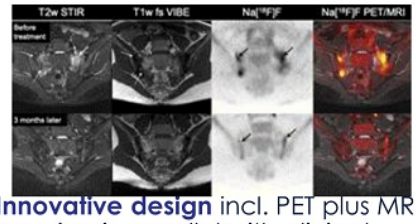


Chronic inflammation of axial skeleton

Large **unmet needs**, at least 1.5M US patients diagnosed & treated in 2015-2023[2]

Limited disease control for SoC – even at lower levels[3]

…with innovative imaging to redefine outcome measurements



Innovative design incl. PET plus MRI imaging in parallel with clinical read-outs

Accelerated path to Phase 3

Competitive **number of patients** in trial, with **attractive design** for the **specialized sites**

Market size

1.5% As current upper level of global prevalence

10+ USD bn market potential in next 10 yrs

Unmet Needs

40% Of pts do not reach relevant improvements with current therapies[3]

30% As current upper limit of nr-axSpA patients that progress to r-axSpA[4]

1. BKZ with durable response and effective in treating co-morbidities (i.e., uveitis) based on BE MOBILE trial results; 2. Based on U.S. claims data and estimations for AS: Unique patients diagnosed between 2015-2023 (ICD-10 code: M45.*) and assuming 50:50 split between AS and nr-axSpA as per literature; 3. ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data; 4. Ruderman E. et al. (2013). Arthritis Rheum. 2013;65:S1052–S1053.

Source: MoonLake team; Lubrano (E.) (2018). *Clin Rev Allergy Immunol*; 9298.; Tahir H. et al. (2021). *J Exp Pharmacol*. 2;13:627-635; MyAS;

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- **Multi-bn markets** (r/nr-axSpA) with limited efficacy of current SoC[3]
- With PsA allows MLTX to further **lead in seronegative Spondylarthritis**
- **IL17 A&F** relevance shown through BKZ cases[4], small size an advantage

New indication

PsA
(Phase 2)

- **Double down on PsA** (and spondyloarthritis) by elevating bar on outcomes
- **Innovation to measure disease-modification** in joints, enthesitis, dactylitis
- **Parallel to current Ph 3,** further enabling commercial success

Strengthen indication

1 Merola J. et al. (2018). *Dermatologic Therapy*; 31:e12589. doi.org/10.1111/dth.12589 and Chimenti et al. (2020). *Biologics*;14:53-75. doi: 10.2147/BTT; 2 Passeron et al. (2023). *JAMA Dermatol*. doi:10.1001/jamadermatol.2023.5051;
3 Limited disease control – even at lower levels: ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data; 4 Based on BE MOBILE trial results

Source: MoonLake

New indications provide sizeable **opportunity in multi-bn markets**

MoonLake

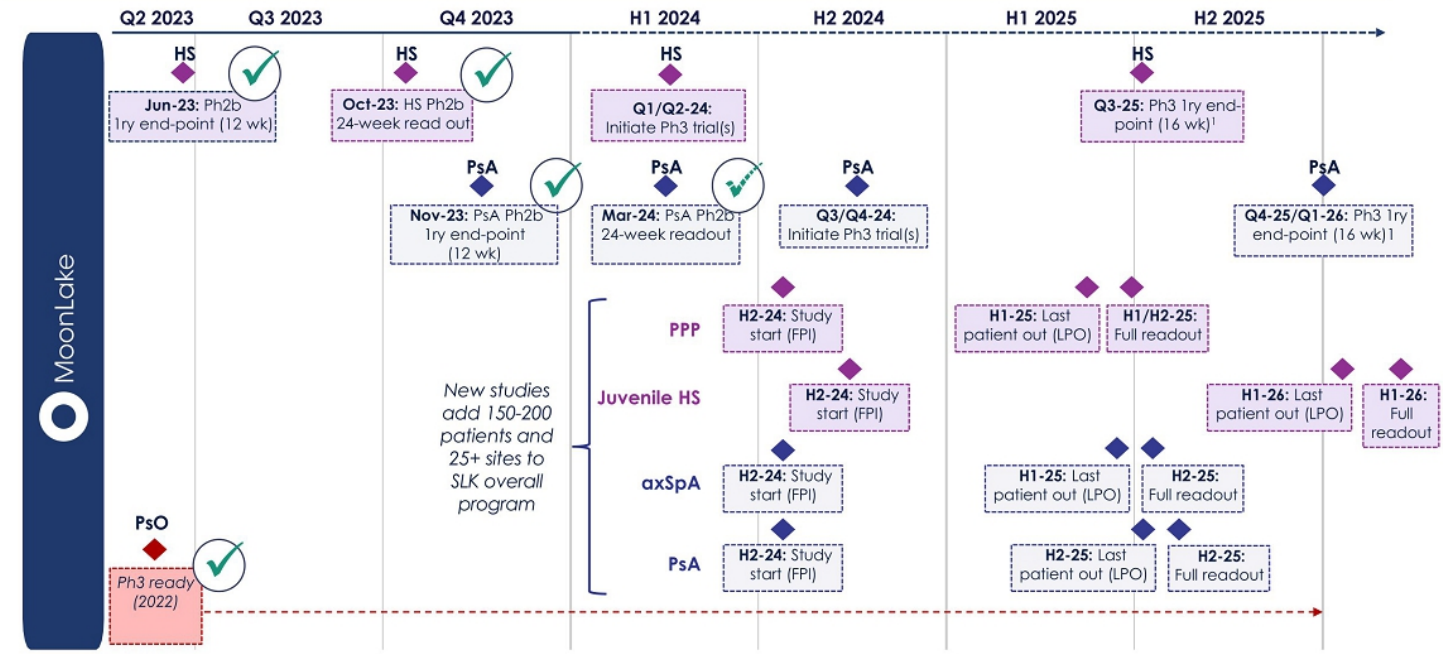
		Leading MoA	Prevalence (%)	Mkt size ($, 2035)	Key challenge
Derm	 **PPP** *(Phase 2)*	IL-17A&F[1]	0.3%	3.5-4bn (12% growth from '22)	*No approved or effective therapy*
	 **Juv HS** *(Phase 3)*	IL-17A&F TNF (no trial)	1%	USD 1-2bn (9% growth from '22)	*No clinically studied product*[4]
Rheum	 **axSpA** *(Phase 2)*	IL-17A&F[2] TNF & IL-17A	1.5%	USD 10-12bn (6% growth from '22)	*Limited efficacy of SOC*[5]
	 **PsA** *(Phase 2)*	IL-17A&F TNF & IL-17A	1%	USD 15bn (5% growth from '22)	*Outcomes sub-optimal (e.g., ACR)*

1 See Bimekizumab case series: Passeron et al. (2023). JAMA Dermatol. doi:10.1001/jamadermatol.2023.5051; 2 Based on BE MOBILE trial results; 3 Prevalence based on literature and U.S. claims data / Global market size estimates based on forecasting historic growth in prevalence and MLTX research on key assumptions (e.g., net prices, adherence, etc.) 4. Humira label in juvenile based on safety data from other indications; 5 ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data

Source: MoonLake Internal Opportunity Model, © 2024 Komodo Health, Inc. All rights reserved. Reprinted with permission.

New indications further **enrich the potential catalyst calendar** in 2024-25

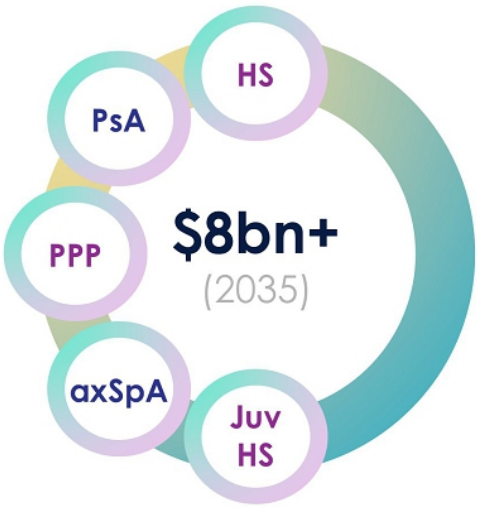
MoonLake



1 Assuming current Phase 3 planning is agreed with regulators (+/- 6 months)

Source: MoonLake team

Potential new indications could **further build out SLK's potential**



MoonLake continues to address the **most pressing unmet needs** in inflammatory diseases

The additional programs result in **USD 3Bn+,** continuing to push the potential of SLK as a leading drug in inflammation

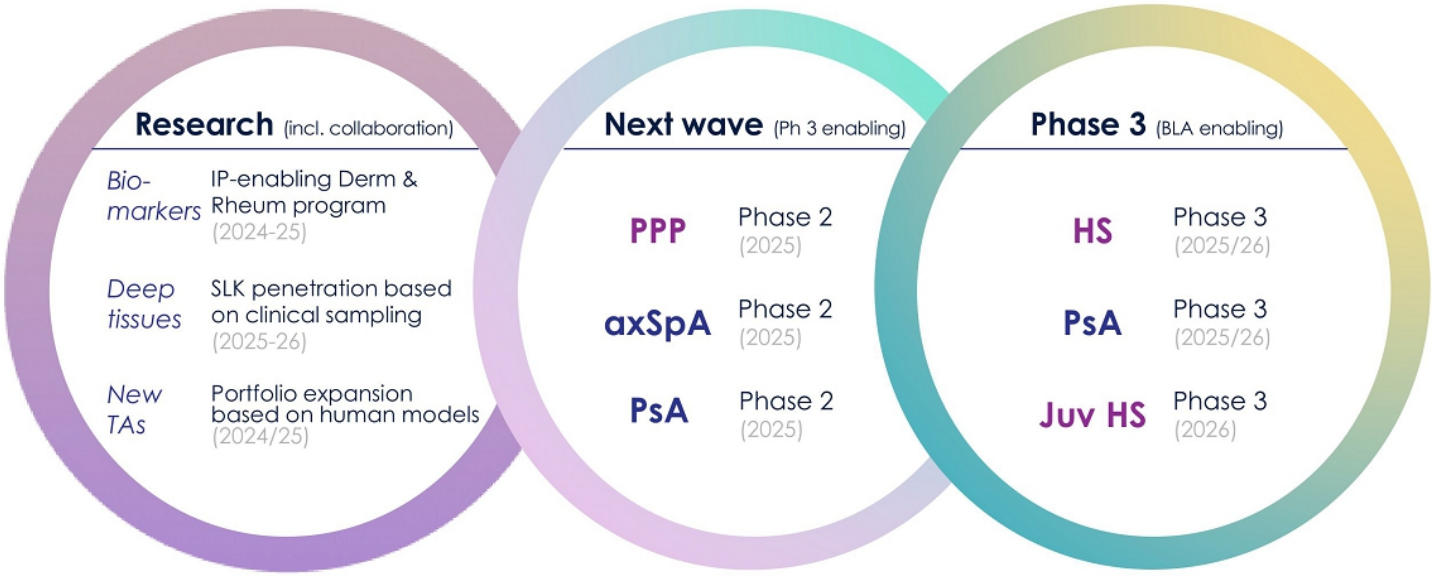
Risk profile of company remains similar as **data supports portfolio expansion** and operations can be scaled up from current structured

MLTX comfortably **financed to support development plan** and growth into market launch

Source: MoonLake Corporate

Taking a step back: Overview of R&D programs at MLTX

MoonLake



Source: Moonlake Clinical

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Moving Forward

SLK combines properties like no other asset

MoonLake

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 MDA, 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

Strategic path forward remains unchanged

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Current owner

Better owner

Source: MoonLake

Operating from a position of strength: over $500m in cash on the B/S

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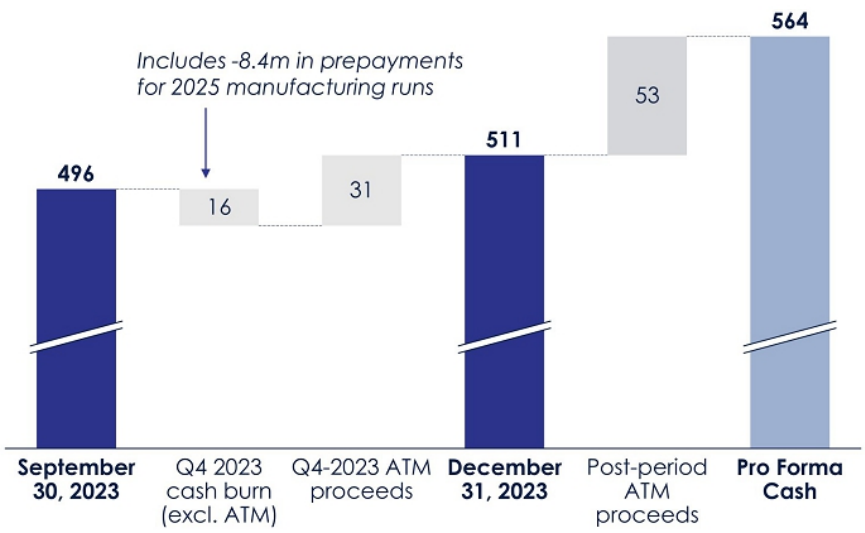
Cash, cash equivalents and short-term marketable debt securities
in USD M



Expected sufficient cash runway until the end of 2026, covering

- Ph3 program in HS
- Ph3 program in PsA
- Additional indication work
- Submission of BLA
- All other base spend

Low cash burn continues to demonstrate cost-efficient set up and focus of MLTX

$85.0m added via ATM at minimal dilution to double down on SLK development – no current plans for further raises

Source: MoonLake

Focus on strengthening the story of SLK as leader in Type 3 diseases

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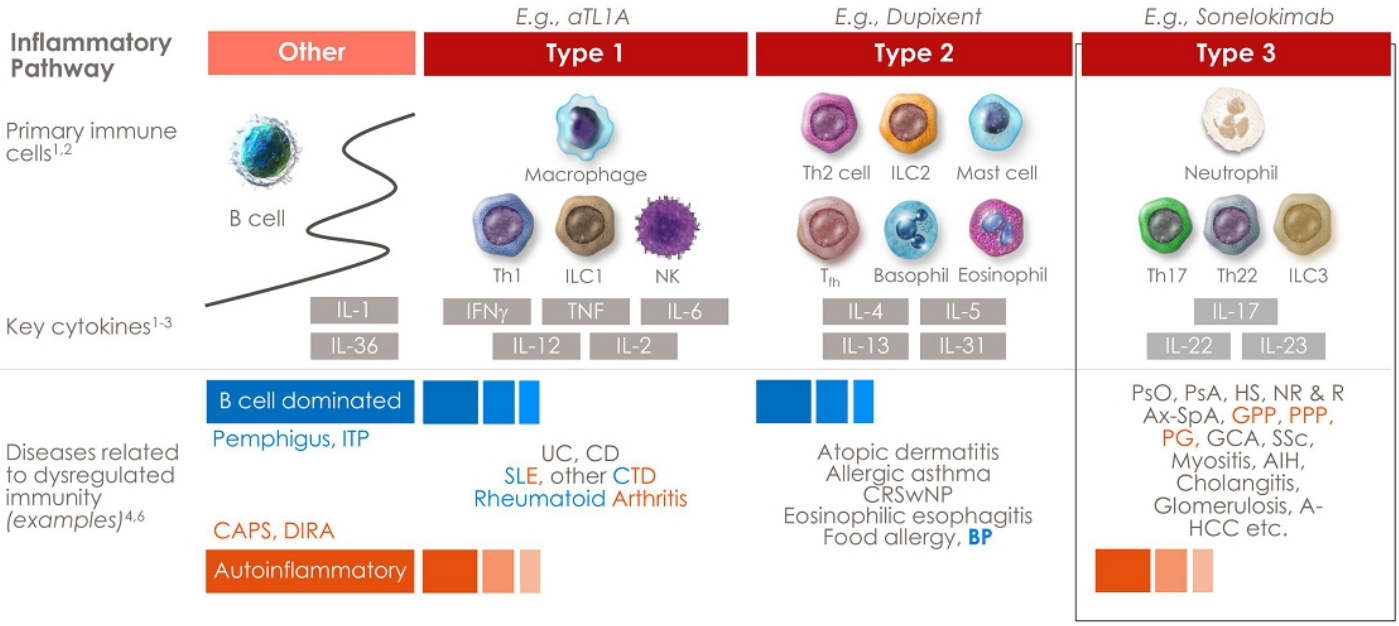

Note: Simplified depiction based on key published information, not meant to be exhaustive in nature. AD, atopic dermatitis; IFNγ, interferon gamma; IL, interleukin; ILC, innate lymphoid cell; NK, natural killer; Tfh, follicular helper; Th, T helper.

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

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Q & A

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