

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): June 26, 2023



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

Cayman Islands
(State or Other Jurisdiction
of Incorporation)

001-39630
(Commission File Number)

98-1711963
(IRS Employer Identification No.)

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

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

On June 25, 2023, MoonLake Immunotherapeutics (the “Company”) issued a press release announcing positive top-line results from its global Phase 2 MIRA trial (M1095-HS-201) evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with moderate-to-severe hidradenitis suppurativa. The Company hosted a webcast today, Monday, June 26, 2023 at 8:00 am, Eastern Time, to discuss the data results.

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

Item 9.01. Financial Statements and Exhibits.

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

Exhibit Number	Exhibit Title or Description
99.1	<u>Press Release, dated June 25, 2023</u>
99.2	<u>Slide Presentation, dated June 26, 2023</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Date: **June 26, 2023**

MOONLAKE IMMUNOTHERAPEUTICS

By: /s/ Matthias Bodenstedt

Name: Matthias Bodenstedt

Title: Chief Financial Officer

MoonLake Immunotherapeutics achieves landmark milestone with positive Phase 2 results for Nanobody® sonelokimab in hidradenitis suppurativa

- First placebo-controlled randomized trial in HS to report positive topline results using HiSCR75 as the primary endpoint
- Primary endpoint HiSCR75 met with 29 percentage points (ppt) delta vs placebo ($p=0.0002$) at week 12, setting a new bar in HS
- HiSCR50 met with 38 ppt delta vs placebo ($p<0.0001$), greater delta than observed for any other molecules
- Other secondary endpoints also reached statistical significance with clinically meaningful improvements at week 12, including HiSCR90, IHS4 and various patient reported outcomes
- Safety results of sonelokimab consistent with previously reported studies with no new observed safety signals
- These topline data will be discussed on Monday 26th June, at 2pm CEST/8am EDT, via webcast (registration link below)

ZUG, Switzerland, June 25, 2023 – MoonLake Immunotherapeutics (“MoonLake”; Nasdaq: MLTX), a clinical-stage biotechnology company focused on creating next-level therapies for inflammatory diseases, today announced positive top-line results from its global Phase 2 MIRA trial evaluating the efficacy and safety of the Nanobody® sonelokimab in patients with moderate-to-severe hidradenitis suppurativa (HS).

The MIRA trial (M1095-HS-201), which recruited 234 patients, is the first randomized, double-blind, placebo-controlled trial to use Hidradenitis Suppurativa Clinical Response (HiSCR) 75 as its primary endpoint, a higher measure of clinical response versus the HiSCR50 measure used in other clinical trials, therefore representing a landmark milestone in HS clinical development.

The trial met its primary endpoint with a significantly greater proportion of patients treated with both sonelokimab 120mg and 240mg achieving HiSCR75 compared to those on placebo at week 12. The primary analysis was based on the most stringent type of analysis for such trials, intent-to-treat non-responder imputation (ITT-NRI). Both doses performed similarly, with the 120mg dose providing the highest delta on HiSCR75 and HiSCR50. The 120mg dose achieved a 29 ppt delta to placebo on HiSCR75 ($p=0.0002$) and a 38ppt delta to placebo on HiSCR50 ($p<0.0001$). The results suggest that, as early as week 12, the Nanobody® sonelokimab, relative to placebo, reaches the highest clinical activity among all other therapies tested in similarly stringent pivotal-like trials.

In addition, other clinically relevant secondary endpoints, such as HiSCR90, improvements in International Hidradenitis Suppurativa Severity Score System (IHS) 4, abscess/nodule and draining tunnel counts as well as patient reported pain and quality of life outcomes also reached statistical significance at week 12. The high performance of the Nanobody® at 120mg, the dose found to be optimal in psoriasis, demonstrates the advantage of using a smaller biologic with albumin-binding capacity to inhibit IL-17A and IL-17F for the treatment of inflammatory diseases.

The safety profile of sonelokimab was consistent with previously reported studies with no new safety signals observed. Overall, sonelokimab continues to show a favorable safety profile, in line with the known profile of IL-17 inhibitors.

Jorge Santos da Silva, PhD, Founder and Chief Executive Officer at MoonLake, said: *"As part of our efforts to elevate outcomes for patients, we set an ambitious goal for our Nanobody® sonelokimab to 'meet or beat' the best results shown in pivotal-like trials of competitors. We have achieved our 'beat' goal with the positive outcome of the Phase 2 MIRA trial. In doing so, we have raised the bar for what can be accomplished for HS and these positive topline data provide us with even greater confidence as we look forward to our next steps and our aspiration to become a leader in the inflammation and immunology space."*

Kristian Reich, MD, PhD, Founder and Chief Scientific Officer at MoonLake, commented: *"The positive topline results from the MIRA trial establish a new era in the treatment of chronic inflammatory diseases, as our Nanobody® sonelokimab indicates a new bar versus what was achieved previously with monoclonal antibodies. Importantly, the results confirm the advantage of the Nanobody's smaller size versus traditional antibodies in the treatment of diseases in which high-level improvements depend on optimal tissue penetration such as hidradenitis suppurativa and likely psoriatic arthritis. The data also validate sonelokimab's unique mode of action to efficiently inhibit IL-17F in addition to IL-17A. The positive outcome of the MIRA trial would not have been possible without the support and participation of the patients and investigators to whom we are grateful."*

Alexa B. Kimball, MD, MPH, lead investigator of the MIRA trial, investigator at Beth Israel Deaconess Medical Center, Massachusetts, US, and Professor of Dermatology at Harvard Medical School, added: *"Hidradenitis suppurativa is a chronic, inflammatory, recurrent, and debilitating skin disease that has profound and wide-ranging impacts across many aspects of patient's lives. As a physician, I see tremendous need for new treatment options for people living with HS, particularly for treatments to reach high thresholds of response in clinical trials (e.g., HiSCR75 and beyond). The positive high clinical responses observed with sonelokimab in the Phase 2 MIRA trial are encouraging, demonstrating its promise as a potential future treatment option."*

These topline data will be discussed on Monday June 26, 2023 at 2pm CEST/8am EDT before the Nasdaq market opens, via webcast at:

<https://onlinexperiences.com/Launch/QReg/ShowUUID=AF1A77F1-F560-4D58-AE3B-00698698C741&LangLocaleID=1033&GroupID=Onyx>

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

The MIRA trial proceeds to week 24, with a 4-week safety follow-up. Important data is being collected regarding longer-term efficacy and safety of sonelokimab, as well as results from switching to sonelokimab from the placebo and the adalimumab arms. Full results from the MIRA trial will be submitted for publication in a peer-reviewed medical journal and for presentation at an upcoming scientific meeting.

Sonelokimab has already been successfully assessed in a randomized, placebo-controlled, Phase 2b trial ([NCT03384745](https://clinicaltrials.gov/ct2/show/study/NCT03384745)) in 313 patients with moderate-to-severe plaque-type psoriasis in which it demonstrated a rapid and durable skin clearance (PAS100) with no unexpected safety findings.

Sonelokimab is currently being evaluated in a Phase 2 trial ([NCT05640245](https://www.clinicaltrials.gov/ct2/show/NCT05640245)), 'ARGO', in patients with active psoriatic arthritis with the primary end-point readout expected in Q4 this year.

Sonelokimab is not yet approved for use in any indication.

- Ends -

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 $\geq 75\%$ 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 (IHSS4), 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 MoonLake Immunotherapeutics

MoonLake Immunotherapeutics is a clinical-stage biopharmaceutical company unlocking the potential of sonelokimab, a novel investigational Nanobody® for the treatment of inflammatory disease, to revolutionize outcomes for patients. Sonelokimab inhibits IL-17A and IL-17F by inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers that drive inflammation. The company's focus is on inflammatory diseases with a major unmet need, including hidradenitis suppurativa and psoriatic arthritis – conditions affecting millions of people worldwide with a large need for improved treatment options. MoonLake was founded in 2021 and is headquartered in Zug, Switzerland. Further information is available at www.moonlaketx.com.

About Nanobodies®

Nanobodies® represent a new generation of antibody-derived targeted therapies. They consist of one or more domains based on the small antigen-binding variable regions of heavy-chain-only antibodies (VHH). Nanobodies® have a number of potential advantages over traditional antibodies, including their small size, enhanced tissue penetration, resistance to temperature changes, ease of manufacturing, and 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 Sonelokimab

Sonelokimab (M1095) is an investigational ~40 kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible glycine-serine spacers. With two domains, sonelokimab selectively binds with high affinity to IL-17A and IL-17F, thereby inhibiting the IL-17A/A, IL-17A/F, and IL-17F/F dimers. A third central domain binds to human albumin, facilitating further enrichment of sonelokimab at sites of inflammatory edema.

Sonelokimab has been assessed in a randomized, placebo-controlled Phase 2b study in 313 patients with moderate-to-severe plaque-type psoriasis. Sonelokimab demonstrated a rapid and durable clinical response (Investigator's Global Assessment Score 0 or 1, Psoriasis Area and Severity Index 90/100) in patients with moderate-to-severe plaque-type psoriasis. Sonelokimab was generally well tolerated, with a safety profile similar to the active control, secukinumab (Papp KA, et al. Lancet. 2021; 397:1564-1575).

In an earlier Phase 1 study in patients with moderate-to-severe plaque-type psoriasis, sonelokimab has been shown to decrease (to normal skin levels) the cutaneous gene expression of pro-inflammatory cytokines and chemokines (Svecova D. J Am Acad Dermatol. 2019;81:196–203). Currently, a global phase 2 trial in psoriatic arthritis (NCT05640245, M1095-PSA-201, "ARGO") including multiple arms and over 200 patients is ongoing (announced on Dec 14, 2022).

About Hidradenitis Suppurativa

Hidradenitis suppurativa 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.

Cautionary Statement Regarding Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding MoonLake's expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for clinical trials and research and development programs; and the anticipated timing of the results from those trials, including completing the MIRA trial; and 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 such statement is not forward looking.

Forward-looking statements are based on current expectations and assumptions that, while considered reasonable by MoonLake and its management, as the case may be, are

inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with MoonLake's business in general and limited operating history, difficulty enrolling patients in clinical trials, and reliance on third parties to conduct and support its clinical trials, and the other risks described in or incorporated by reference into MoonLake's Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the Securities and Exchange Commission.

Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. MoonLake does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or in the events, conditions or circumstances on which any such statement is based.

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MoonLake Immunotherapeutics

R&D Day Webcast

Presentation Document – Results MIRA trial
June 26th 2023

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W: moonlaketx.com | E: info@moonlaketx.com



Date: June 26th, 2023
Time: 8am EDT
Location: Webcast



Topic	Sub-topics	Lead	Timing
Intro	- Key messages	Jorge Santos da Silva	5 mins
HS – MIRA trial Primary Endpoint Readout	- MIRA's pivotal profile, incl. baseline - Efficacy data at primary endpoint - Safety data & other secondaries - Discussing what it means for HS & Derm	Kristian Reich	30 mins
Moving Forward	- Conclusions - Overall value of MLTX - Path forward	Jorge Santos da Silva	10 mins
Q&A		Matthias Bodenstedt	To end

Instructions for this session



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



You can **submit your questions** through the Q&A function in the **bottom left** – questions are only visible to the moderators – we will address **as many questions as possible** at the end of this session



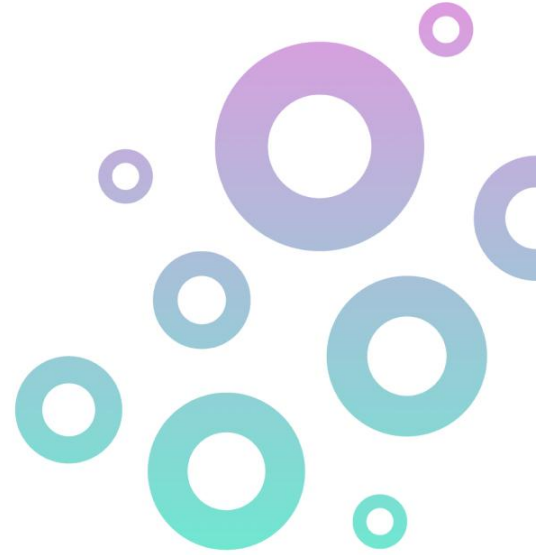
The presentation and a **replay** will be made available on our IR website



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



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



Forward Looking Statements

Certain statements in this presentation may constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding our expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for clinical trials and research and development programs; the anticipated timing of the results from those trials; and expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate", "believe", "continue", "could", "estimate", "expect", "intend", "may", "might", "plan", "possible", "potential", "predict", "project", "should", "strive", "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that such statement is not forward looking. Forward-looking statements are based on current expectations and assumptions that, while we and our management consider reasonable, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with our business in general and limited operating history, difficulty enrolling patients in clinical trials, and reliance on third parties to conduct and support our clinical trials, and the other risks described in or incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings with the Securities and Exchange Commission. Nothing in this presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this presentation, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. We neither undertake nor accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in our expectations or in the events, conditions or circumstances on which any such statement is based. This presentation does not purport to summarize all of the conditions, risks and other attributes of MoonLake Immunotherapeutics.

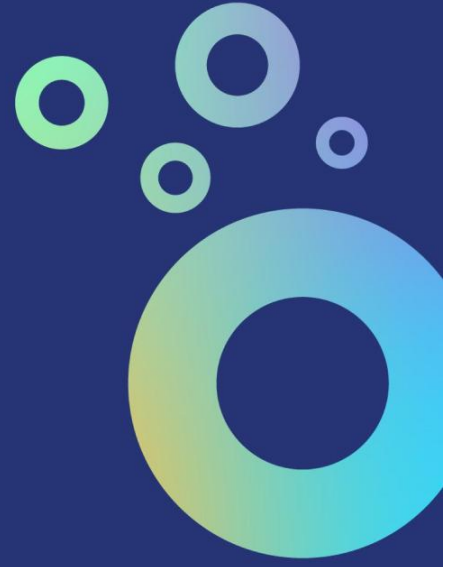
Industry and Market Data

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

Trademarks

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

Introduction



Primary Analysis		HiSCR75 (Delta of best dose to PLC, ppt) ¹			
		Trial A	Average	Trial B	
1	Bimekizumab (Bimzelx)	ITT-mNRI (All-ABX) (mNRI-HS-ABX)	15 (22) <small>BE HEARD I</small>	17.5 (22.5) <small>WEEK 16</small>	20 (23) <small>BE HEARD II</small>
2	Adalimumab (Humira)	ITT-NRI	11 <small>PIONEER I</small>	16 <small>WEEK 12</small>	21 <small>PIONEER II</small>
3	Secukinumab (Cosentyx)	ITT-mNRI	- <small>SUNSHINE</small>	-	- <small>SUNRISE</small>
	Sonelokimab (SLK)	ITT-NRI (+ITT-mNRI)		> 20 <small>MIRA WEEK 12</small>	Other expectations: + Monthly Dosing + Higher Primary Endpoint ? No new safety signals ? Lower Thrush (<i>Candida</i>)

Note: Data is not based on Head-to-Head comparisons. ¹ HiSCR75 response for best dose and placebo, respectively; Bimekizumab (320mg Q2W/Q2W), 40% and 18% (BE HEARD I), 39% and 16% (BE HEARD II); Adalimumab (40 mg), 23% and 14% (Pioneer I), 33% and 14% (Pioneer II); Secukinumab, no HiSCR75 responses available
Source: MoonLake Corporate

MLTX's MIRA trial is a SUCCESS – Setting a new bar in HS

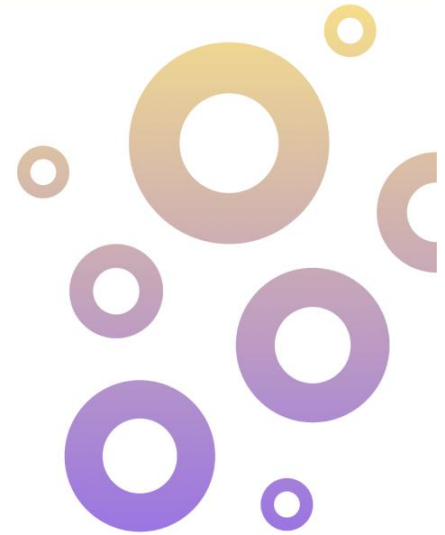
- HiSCR75 at wk 12 primary end point met – *first time ever, "Beat" scenario, landmark data*
- Other end points met at wk 12, early wk16 data promising – *impact of SLK for HS patients is clear*
- No new safety signals – *continued favorable safety profile*

MLTX's SLK Nanobody® opens a new era in therapy

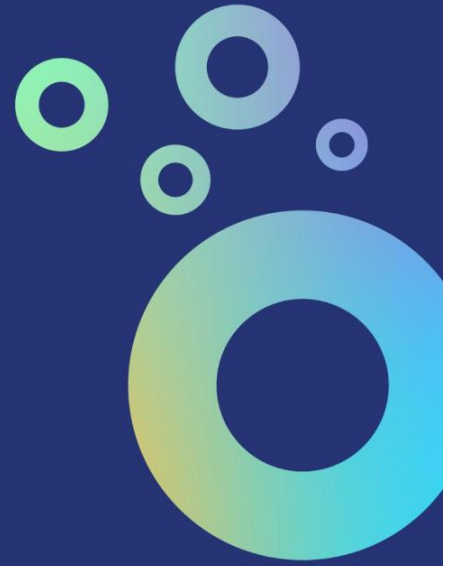
- SLK reaches high clinical goals deep in tissue, with its unique MoA
- Our view: SLK now leading asset in HS, a multi-bn market (\$10bn+)
- Remember: leading efficacy/safety in PsO (\$25bn+)
- And: PsA trial progressing well and we believe trial de-risked (~\$10bn)

MLTX becomes a leader in I&I

- Soon Ph3-ready in 3+ TAs – planning launch in 2027 with price first in HS
- A wealth of potential indications to further pursue (\$30bn+)
- Solid financial position allows Phase 3 to be prepared on MLTX's terms



MIRA Trial *Results*



Blockage of apocrine glands... ...creates deep tissue lesions... ...rich in IL-17F... ...and causing devastating damage

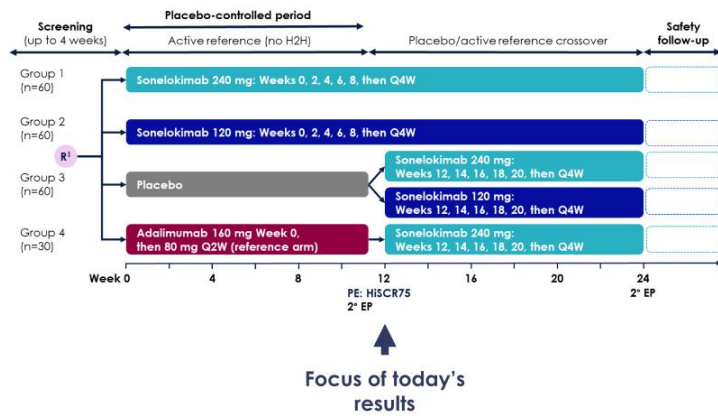
(essentially an "apocrinitis")

[vicious circle between IL-17 release and keratinocyte proliferation and activation]

Market size		Unmet Needs							
2%+	Global prevalence	7	avg # of years to diagnosis, globally	10+	USD billion sales by 2035	1	Drug approved (Humira)	50%	Improvement for half of pts only

Picture from <https://plasticurgerykey.com/the-folliculopiloosebaceous-unit-the-normal-fpsu/>; Accessed December 2022; von Laffert M et al. Br J Dermatol 164:367-71, 2011; Navrazhina K, et al. J Allergy Clin Immunol 2021;147:2213-24

Source: MoonLake Corporate © 2023 | Proprietary | MoonLake TX 9



Key design elements of MIRA

- Global study (North America and Europe) with approx. 60 sites
- Double-blind, placebo-controlled, active reference arm
- N=234 patients randomized
- Moderate-to-severe HS (≥ 5 lesions, Hurley 2 and 3, previous biologic use)
- HiSCR75 as primary endpoint
- ITT-NRI as primary analysis, secondary analyses include mNRI, logistic regression with MI, as observed
- Antibiotic use for HS imputed as NR
- Stratification for Hurley stage and previous biologic use

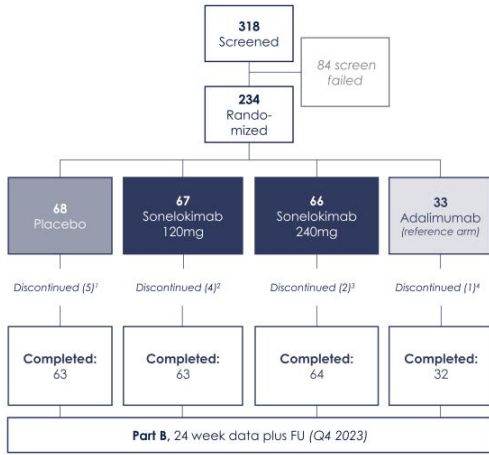
Study element	PIONEER I / II ¹ (Humira®)	SUNSHINE/ SUNRISE ² (Cosentyx®)	BE HEARDI / II ³ (Bimzelx®)	MIRA (Sonelokimab)
Stage	Phase 3	Phase 3	Phase 3	Phase 2
Size	n=307 / n=326	n=541 / n=543	n=505 / n=509	n=234
Design	R, DB, PC	R, DB, PC	R, DB, PC	R, DB, PC (AR)
Dose arms	1 ADA, placebo	2 SEC, placebo	3 BKZ, placebo	2 SLK, placebo (ADA)
Key inclusion criteria - Baseline AN count - Hurley stage	≥3 II and III	≥5 I, II and III	≥5 II and III	≥5 II and III
Primary endpoint	HiSCR50 W12	HiSCR50 W16	HiSCR50 W16	HiSCR75 W12
Stratification	Hurley stage and concomitant ABX (PII)	Region, concomitant ABX, and body weight	Hurley stage and concomitant ABX	Hurley stage and prior biologic use
Primary analysis	ITT-NRI Cochran-Mantel-Haenszel ^{1a}	ITT-mNRI (MI) Logistic regression ^{1b} (Hurley stage, baseline AN)	ITT-mNRI (MI) Logistic regression ^{1c}	ITT-NRI Cochran-Mantel-Haenszel^{1a}
Previous biologic use	not allowed	allowed	allowed	allowed
Concomitant ABX	not allowed / allowed	allowed	allowed	allowed
Handling of new ABX - any ABX - for HS	included NRI	included Data handling rules ⁵	NRI (2 ^o included) ⁴ NRI	incl. NRI

Notes: ^{1a}including the stratification factors; ^{1b}including the stratification factors and other covariates; ^{1c}only NRI if AN count ≥50% compared to baseline; ²primary analysis mNRI ALL-ABX, secondary analysis mNRI HS-ABX; A=abscis, ABX=antibiotics, AR=active reference, DB=double blind, DF=draining tunnel, IT=intention-to-treat, PC=placebo-controlled, N=node, NRI=non-responder imputation, mNRI=modified NRI (only patients with missing data due to lack of efficacy or safety), R=randomized

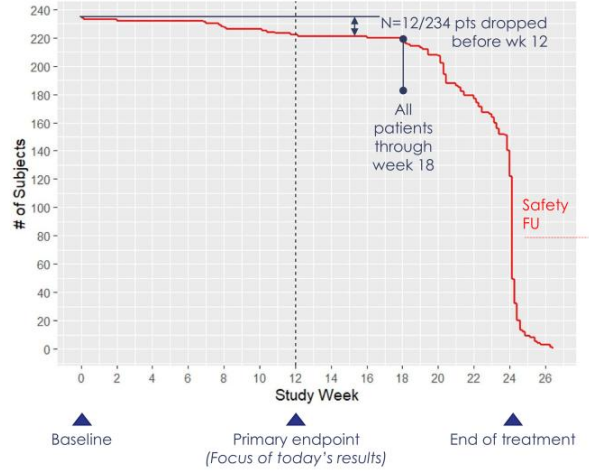
¹ Kimball AB, et al. N Engl J Med. 2014; 375:422-34; ² Kimball AB, et al. Lancet. 2023; 401:747-761; ³ Kimball AB et al. Late-breaker AAD. 2023

Source: MoonLake Clinical

Disposition



Patient exposure



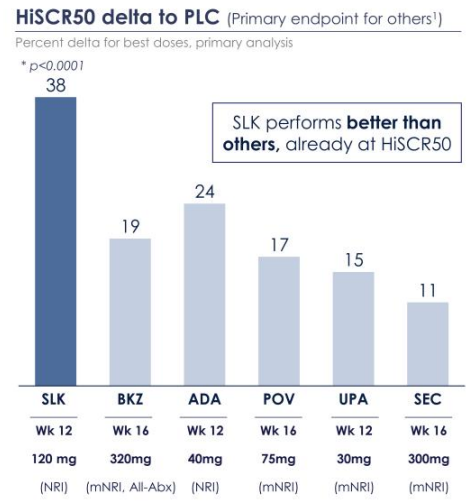
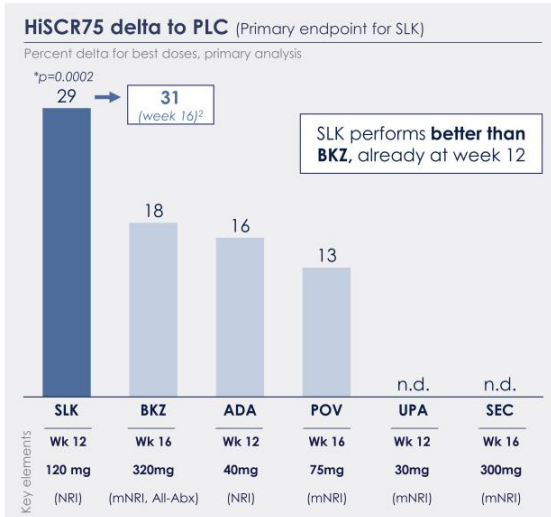
Notes: Exposure on 20 June 2023 (MoonLake Data on File); AE = Adverse Event; Phy Dec = Physician Decision; Wdw by S = Withdrawal by Subject; Prot. Viol = Protocol Violation; Completed = received the study treatment at Week 10 or a later visit: 1 AE (1), Phy Dec. (1), Wdw by S (2), Prot. Viol (1) 2 Lost to FU (1), Phy Dec. (1), Wdw by S (2) 3 Lost to FU (1), Wdw by S (1) 4 Prot. Viol (1)
 Source: MoonLake Clinical © 2023 | Proprietary | MoonLake TX

Patient characteristic	PIONEER I / II ¹	SUNSHINE / SUNRISE ²	BE HEARD I / II ³	MIRA
Age (years), mean	34.9 – 37.8	35.5 – 37.3	36.7 / 36.6	37.6
Gender , female, %	59.5 – 69.3	54 – 57	63.0 / 50.7	59.8
Race , White, %	75.8 – 87.7	74 – 81	77.8 / 81.5	85.0
BMI , kg/m ² , mean	31.3 – 34.5	31.4 – 32.8	33.8 / 32.3	33.7
Smoking , current, %	52.9 – 67.3	50 – 58	43.0 / 48.1	46.6
Duration of HS , years, mean	8.8 – 9.9	6.6 – 8.2	9.0 / 7.0	8.5
Lesions , mean				
- AN count	10.7 – 14.4	12.6 – 13.9	16 / 16.5	14.0
- DT	3.0 – 4.6	3.2 – 3.6	3.8 / 3.4	3.5
Hurley stage , %				
- I	0	2 – 6	0	0
- II	52.3 – 54.6	51 – 60	50.3 / 61.1	63.7
- III	45.4 – 47.7	28 – 46	49.7 / 38.9	36.3
DLQI , mean	14.1 – 16.3	<i>not given</i>	12.0 / 10.8	12.0
Prior biologic use , %	0	20 – 26	25.0 / 13.2	17.5
Concomitant ABX use , %	0 / 19	10 – 14	7.9 / 9.0	10.7

¹ Kimball AB, et al. N Engl J Med. 2016; 375:422-34; ² Kimball AB, et al. Lancet. 2023; 401:747-7613; ³ Kimball AB, et al. Late-breaker AAD 2023; Data based on MoonLake Clinical Data on file

Source: MoonLake Clinical

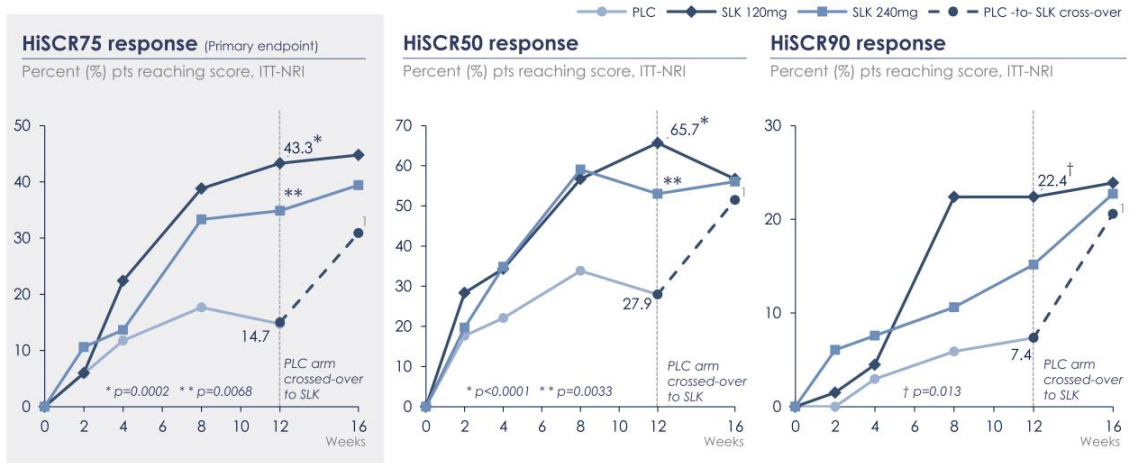
Patient characteristics	Overall MIRA (n=234)	Main arms			Active reference
		Placebo (n=68)	Sonelokimab 120mg (n=67)	Sonelokimab 240mg (n=66)	Adalimumab (n=33)
Age , yrs, mean (SD)	37.6	39.3 (13.1)	37.6 (10.5)	36.2 (11.6)	37.1 (10.6)
Gender , female, n (%)	59.8	36 (52.9%)	42 (62.7%)	42 (63.6%)	20 (60.6%)
Race , White, n (%)	85.0	59 (86.8%)	57 (85.1%)	54 (81.8%)	29 (87.9%)
BMI , kg/m ² , mean (SD)	33.7	32.7 (7.2)	35.0 (7.8)	33.5 (6.8)	33.9 (8.4)
Smoking , current, n (%)	46.6	37 (54.4%)	26 (38.8%)	29 (43.9%)	17 (51.5%)
Duration of HS , yrs, mean (SD)	8.5	8.3 (8.5)	8.8 (8.7)	8.4 (8.3)	8.3 (8.4)
Lesions , mean (SD)	14.0	14.6 (11.6)	14.5 (11.9)	12.3 (8.8)	15.2 (13.4)
- AN count	3.5	3.7 (3.4)	3.7 (4.4)	2.9 (3.4)	3.6 (3.9)
Hurley stage , %					
- I	0	0 (0%)	0 (0%)	0 (0%)	0 (%)
- II	63.7	42 (61.8%)	44 (65.7%)	42 (63.6%)	21 (63.6%)
- III	36.3	26 (38.2%)	23 (34.3%)	24 (36.4%)	12 (36.4%)
DLQI , mean (SD)	12.0	10.8 (6.4)	12.3 (6.7)	12.7 (6.9)	12.8 (7.0)
Prior biologic use , n (%)	17.5	12 (17.6%)	13 (19.4%)	12 (18.2%)	4 (12.1%)
Concomitant ABX use , n, (%)	10.7	5 (7.4%)	9 (13.4%)	8 (12.1%)	3 (9.1%)



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 plateaued already from week 8) and the wk 16 response for the 120mg arm; PLC, Placebo; SLK, Sonelekimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD III); ADA, Adalimumab (pooled PIONEER III); POV, Povorciclimab (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE)

Source: MoonLake Clinical

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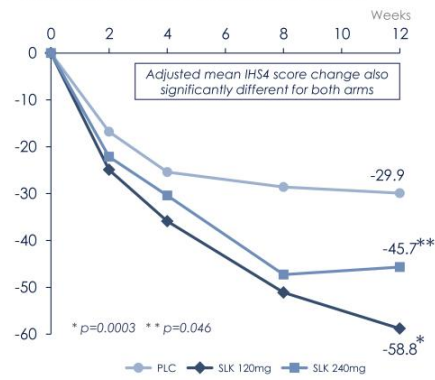
Both doses perform similarly well, depending on treatment goal, time point etc. – the Psoriasis dose (SLK 120mg) is sufficient to rapidly achieve highest scores in HS, emphasizing the likely **size advantage of SLK** over other molecules including BKZ

† Week 16 data for PLC arm crossed over to SLK 120mg or 240mg; data not yet formally validated

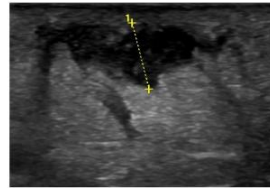
*, ** multiplicity-controlled p-values and † nominal p-value from a Cochran-Mantel-Haenszel test stratified by Hurley Stage and prior biologic use

IHS4 adjusted mean change

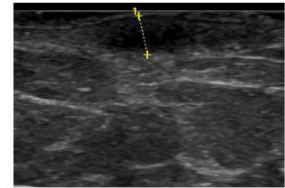
Percent (%) change from baseline over time, ITT



Direct evidence of DT changes



Deep dermal tunnel at baseline (before treatment)



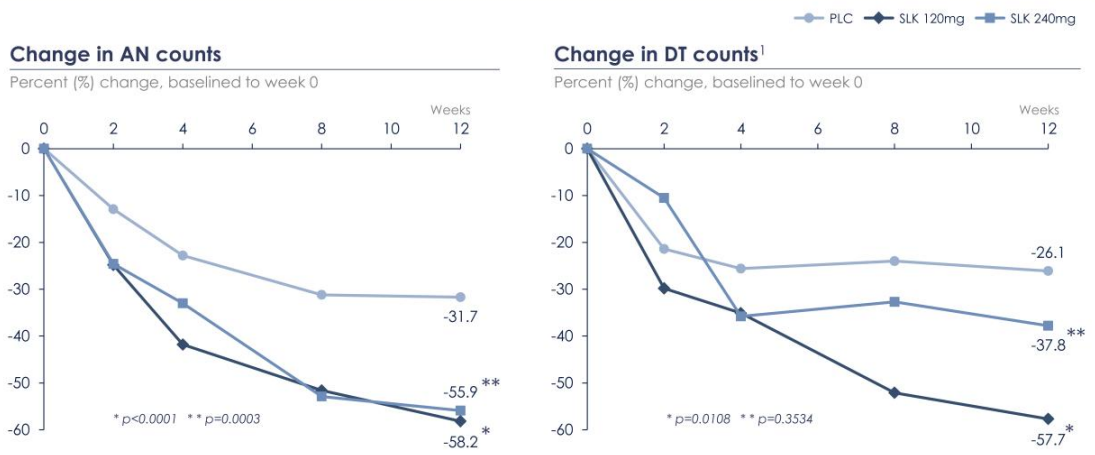
Week 12 (120mg sonelokimab)

- Case from ultrasound sub-study
- Confirming reduction of tunnel activity and morphology in patients receiving sonelokimab
- Reduction of lumen observed, as well as disappearance of neutrophil influx ("pus")

SLK improves the IHS4, a weighted composite score that quantifies **changes in tunnels, nodules and abscesses** – indicates that SLK reduces draining tunnels in patients, the **most complex inflammatory lesion** in HS

¹ IHS4 score is calculated as $\sum (n \text{ of nodules } \times 1, n \text{ of abscesses } \times 2, n \text{ of draining tunnels } \times 4)$

*,** nominal p-values, from MMRM including co-variables: baseline IHS4; Hurley Stage; prior biologic use; visit; treatment and visit-by-treatment interaction



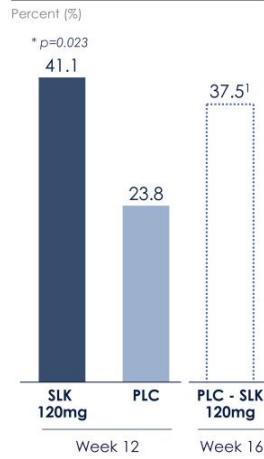
Looking beyond the composite scores, **SLK reduces individual lesions** at week 12, especially **reducing draining tunnels by half**

*, **, - p values are nominal from MMRM including co-variables: baseline lesion count; Hurley Stage; prior biologic use; visit; treatment and visit-by-treatment interaction ¹ In subjects with at least one draining tunnel at baseline

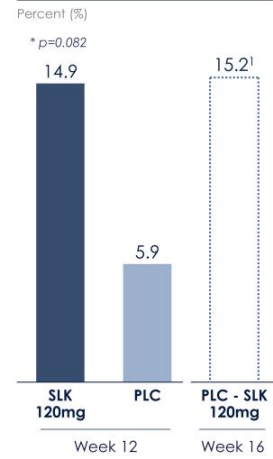
Lesion counts as a measure of remission

- **"Inflammatory remission"** best measured by direct counts of relevant lesions that should be "cleared", such as draining tunnels (DT100), and Abscesses and Nodules (AN100)
- **HiSCR measures reduction of AN count**, with no increase in abscess count and no increase in draining tunnels **vs baseline**
- HiSCR100 is therefore **not "clearance"** as even if AN count is down to zero vs baseline, tunnels can be present (even in high number)
- **Confusion** about "HiSCR100" – misleading perception of "clearance" in HS

Patients reaching DT100



Patients reaching AN100

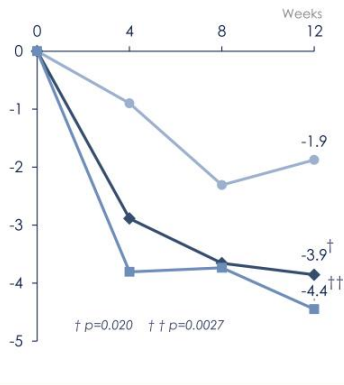


¹ Week 16 data for PLC arm crossed over to SLK 120mg or 240mg; data not yet formally validated
 Source: MoonLake Clinical

* Nominal p-value from a Cochran-Mantel-Haenszel test stratified by Hurley Stage and prior biologic use

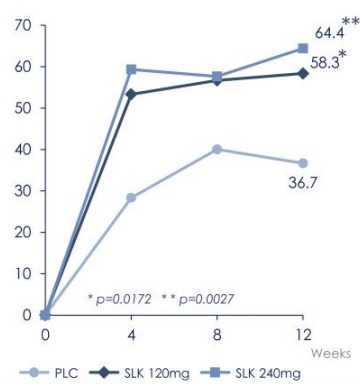
DLQI adjusted mean

Score change from baseline, ITT



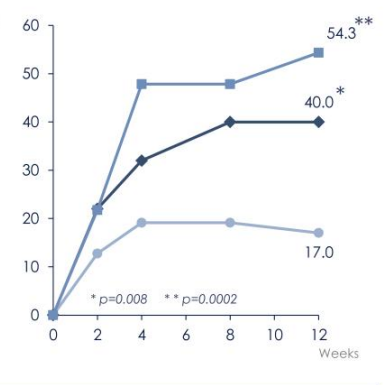
DLQI improvement ≥ 4 points¹

Percent (%) responders per arm, ITT-NRI



PiGA Pain NRS30 response rates

Percent (%) responders per arm, ITT-NRI



Important improvements in pain in ~ 50% of patients and in health-related quality of life in ~ 60% of patients

¹ Absolute DLQI ≤ 5 response rate was also a secondary endpoint, with SLK 120mg reaching 27% and SLK 240mg reaching 34% at week 12, and placebo reaching 22% (no statistically significant difference). For DLQI improvement ≥ 4 points only patients with baseline DLQI ≥ 4 were included. For PiGA pain NRS30 only patients with baseline NRS ≥ 3 were included. ***, nominal p-value from a Cochran-Mantel-Haenszel test stratified by Hurley Stage and prior biologic use; †, †† p-values are nominal from MMRM including co-variables: baseline DLQI; Hurley Stage; prior biologic use; visit; treatment and visit-by-treatment interaction. Source: MoonLake Clinical © 2023 | Proprietary | MoonLake TX 20

Patients with events ¹ , n (%)	Main arms			Active reference
	Placebo (N=68)	Sonelokimab 120 mg (N=67)	Sonelokimab 240 mg (N=66)	Adalimumab (N=33)
Any TEAE	45 (66.2)	53 (79.1)	52 (78.8)	27 (81.8)
Any SAE	2 (2.9)	2 (3.0)	1 (1.5)	0 (0.0)
Any TEAE Leading to Treatment Discontinuation	1 (1.5)	3 (4.5)	0 (0.0)	0 (0.0)
Fatal TEAE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infections & Infestations				
Nasopharyngitis	10 (14.7)	10 (14.9)	6 (9.1)	2 (6.1)
Upper respiratory tract infections	3 (4.4)	4 (6.0)	7 (10.6)	4 (12.1)
Oral Candidiasis	0	4 (6.0)	8 (12.1)	0
Oropharyngeal Candidiasis	0	0	0	0
Oesophageal Candidiasis	0	0	0	0
Vulvovaginal Candidiasis	0	2 (3.0)	0	0
Skin Candidiasis	0	0	1 (1.5)	0
Genital Candidiasis	0	1 (1.5)	0	0
Cardiac disorders				
Atrial fibrillation	0	0	0	1 (3.0)
Cardiac failure chronic	1 (1.5)	0	0	0
Gastrointestinal disorders				
IBD	0	0	0	0
Diarrhoea	1 (1.5)	1 (1.5)	2 (3.0)	2 (6.1)

All Candida cases were mild to moderate, no case led to treatment withdrawal

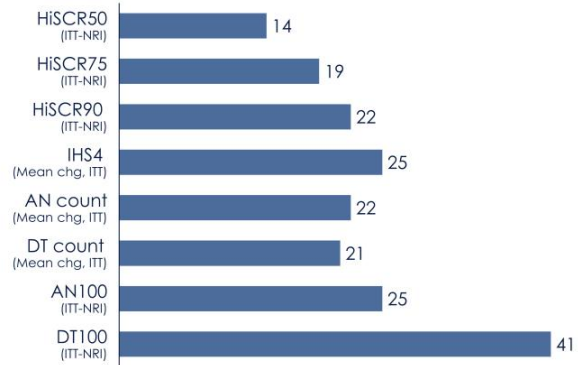
¹ All terms in the table are system organ classes (SOCs) and preferred terms (PTs) as per MEDRA (v26), selected SOCs and PTs are shown

Reference arm performance

- A small (n=33) patient arm was run in parallel with the main arms to
 - **Control placebo** responses for HiSCR responses and other endpoints
 - Test adalimumab **in our hands to collect information** for Phase 3 (incl. a potential superiority Ph 3 trial)
- While small and not built for any statistical analysis, **adalimumab seemed to behave as expected** from the 2015 Pioneer trials
- Values (placebo, HiSCRs) **are similar to Pioneer**, which is closest to MIRA from a baseline perspective

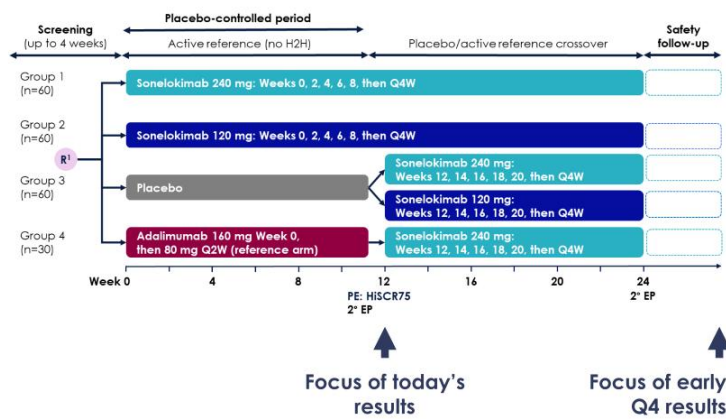
Difference in response between SLK and ADA

Percent (%) improvement for each score, between SLK 120mg main arm and ADA 80mg Q2W active reference arm, the ADA active reference arm scores represent the baseline (0)



Shows how many more % of patients reach the goal with SLK

MLTX will continue collecting data from Part B in HS, as well as the ARGO trial (PsA), to define detailed plan for Phase 3



24-week results planned for early Q4

- Early unverified data from Week 16 suggests **cross-over of patients from placebo elevates responses** across different end-points – this and its extent will be analyzed in Part B
- Similarly, for the **adalimumab cross-overs**, albeit with a small n (only qualitative information will be collected, especially around TNF-IR due to small n)
- It appears the **responses on the SLK arms are either maintained or improved** at week 16 – this will be analyzed to week 24 in Part B
- Results will be shared either through a presentation like today – as of **early Q4 this year** – or through a conference
- A **peer-reviewed publication** is expected in due course

Research & Clinical Summary

A new bar, a new era

The scientific rationale for a unique molecule

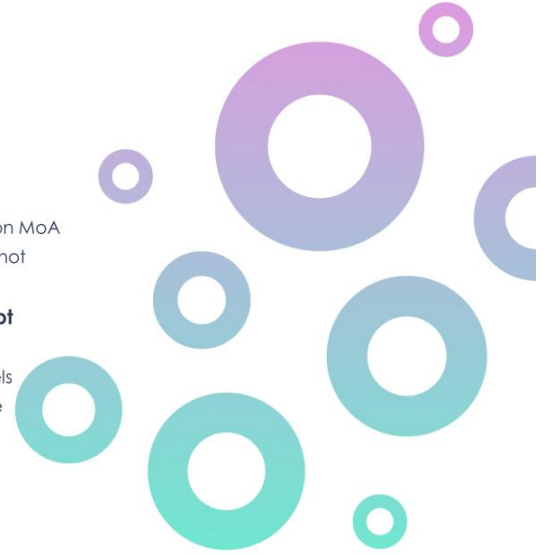
- SLK has unique IL-17F and A binding properties, a key inflammation MoA
- SLK has enhanced tissue penetration, reaching where mAbs cannot

What MIRA shows – clinical validation of the Nanobody® concept

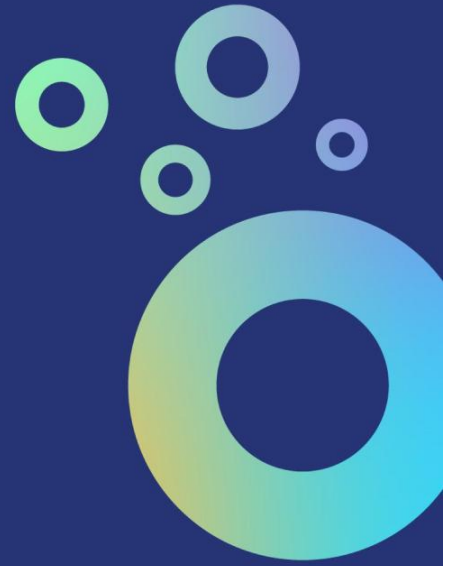
- HiSCR75 and HiSCR50 deltas to PLC above all other trials
- Significant effects on the deepest inflammatory lesions, the tunnels
- Impact on what matters to patients: pain, quality of life, drainage
- Favorable safety tolerability profile, as observed previously

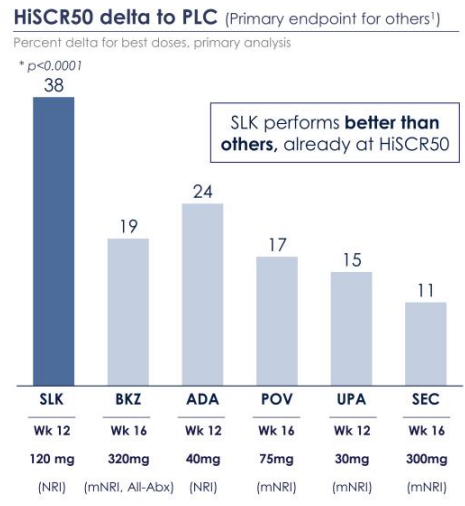
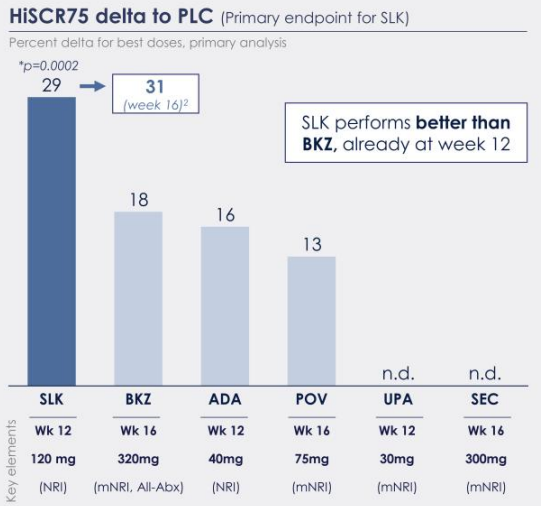
Optimal outcome for fast clinical development

- Winning dose regimen and endpoints now known for phase III
- Builds on winning PsO data and de-risks next MLTX trials (incl. PsA)



Moving Forward





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 plateaued already from week 8) and the wk 16 response for the 120mg arm; PLC, Placebo; SLK, Sotikimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD III); ADA, Adalimumab (pooled PIONEER III); POV, Povorciclinib (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE)

Source: MoonLake Clinical

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Primary Analysis		HiSCR75 (Delta of best dose to PLC, ppt) ¹	
1	Sonelokimab (SLK)	ITT-NRI	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 29 <small>MIRA (WEEK 12)</small> </div>
2	Bimekizumab (Bimzelx®)	ITT-mNRI (All-ABX) (mNRI-HS-ABX)	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 17.5 <small>(22.5)</small> <small>BE HEARD (WEEK 16)</small> </div>
3	Adalimumab (Humira®)	ITT-NRI	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 16 <small>PIONEER (WEEK 12)</small> </div>
4	Secukinumab (Cosentyx®)	ITT-mNRI	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> - <small>SUN x</small> </div>

SLK:

- ⊕ Monthly Dosing
- ⊕ Higher Primary Endpoint
- ⊕ Favorable safety profile

Note: Data is not based on Head-to-Head comparisons. 1 HiSCR75 response for best dose and placebo, respectively; Bimekizumab, 40% and 18% (Be Heard I); 39% and 16% (Be Heard II); Adalimumab, 25% and 14% (Pioneer I); 35% and 14% (Pioneer II); Secukinumab, no HiSCR75 responses available
Source: MoonLake Corporate

US HS Biologics Market estimation



Key drivers

Overall HS True Prevalence	2.1%	2.1%	(can be up to 4%, esp. in the US)
Proportion with Mod-to-Severe disease	~55%	~55%	(as per literature ¹)
Proportion of Mod-to-Severe with HS Diagnosis	~7%	~19%	(growth as per current US claims)
Biologics Use	~7%	~13%	(as psoriasis over the last 12 years)

¹ For example, 'Hurley II Hidradenitis Suppurativa Has an Aggressive Disease Course', Annika et al., Dermatology 2018; doi: 10.1159/000491547

Source: MoonLake Corporate, DRG/Clarivate, academic journals, CBO

A winning MoA...

- **Highest efficacy**

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

- **Safer inhibition**

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

- **Only 2 molecules**

SLK & BKZ – top 2 typically get 2/3 of indication bio sales (avg. \$4bn+)¹

... and a differentiated molecule

- **Elevated Efficacy**

SLK shows highest performance at elevated treatment goals, HiSCR75 (or PASI100), as well as additional key outcomes for patients

- **Higher goals**

*Highest primary clinical endpoint with **HiSCR75**, with comparisons to gold-standard Humira® (or Cosentyx® on PASI100)*

- **Improved convenience**

*Candida ("thrush") at **lower rates** vs BKZ and **monthly injections** vs. biweekly BKZ (in HS)*

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

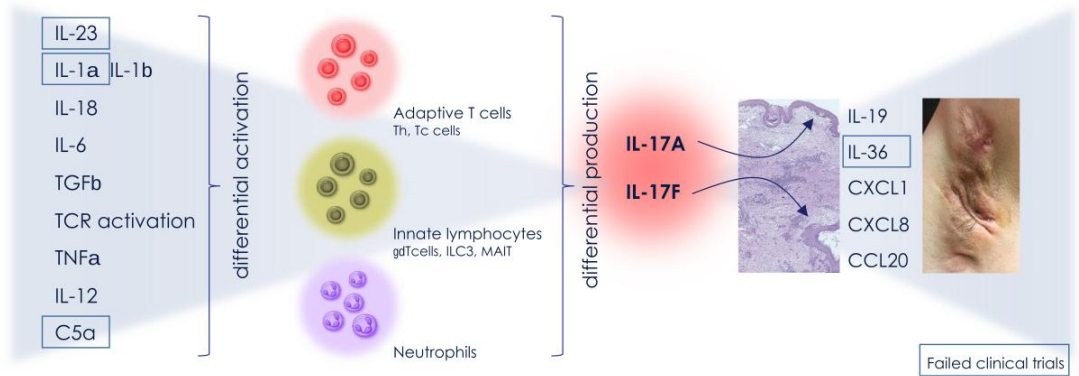
Source: DRG, MoonLake Corporate


Multiple stimuli induce subsets of immune cells to produce IL-17A and F

Different cell types preferentially produce IL-17 A and/or F

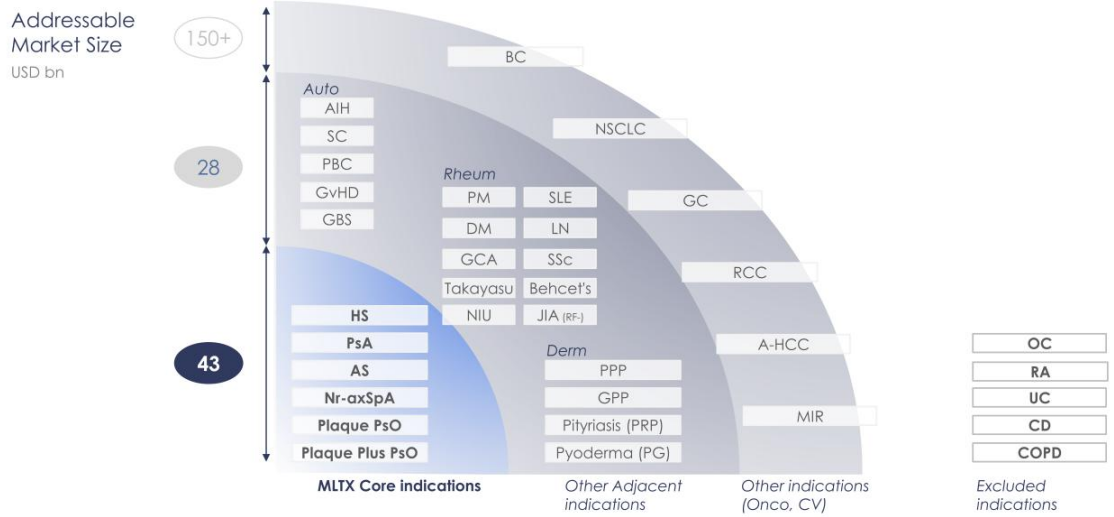
IL-17A and F as "bottleneck" in deep pathology

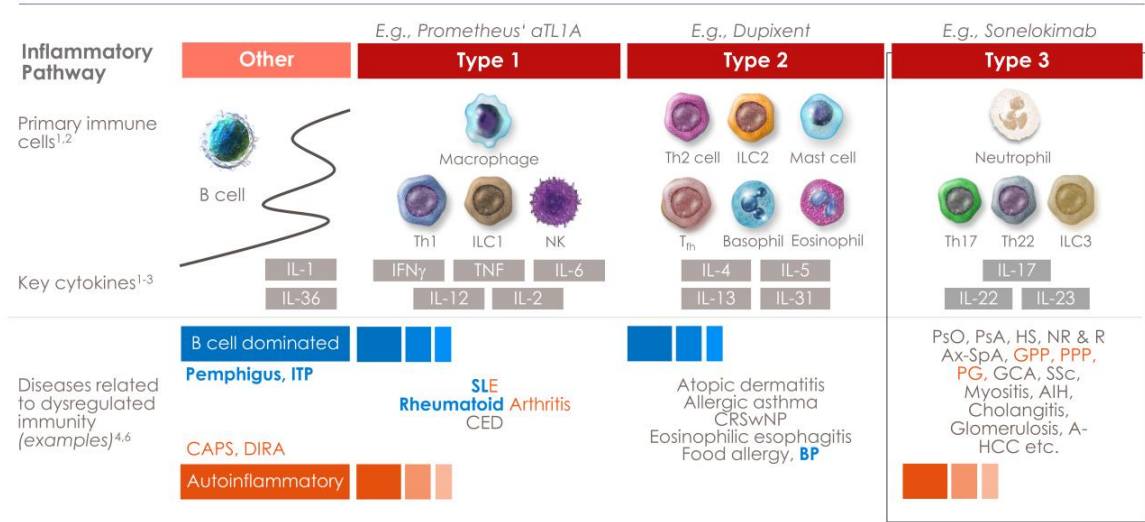
IL-17A and F induce multiple pro-inflammatory effectors, e.g. activation of keratinocytes



	Trial	Patients (n)	Leading MoA	SLK leading asset
 HS	Phase 2b (MIRA)	234	IL-17A & F TNF	✓ Highest ever primary endpoint (HiSCR75), largest delta to placebo at HiSCR75 and 50
 PsO	Phase 2b	313	IL-17A & F IL-23	✓ Largest delta vs market leader Cosentyx™ at PASI100, compared to BKZ, IL-23, etc.
 PsA	Phase 2b (ARGO)	200+	IL-17A & F TNF	○ IL-17A & F inhibition shows best ACR/PASI data incl. TNF-IR pts
 Other Rheum & Derm	TBA	TBA	IL-17A & F Other	○ IL-17A & F inhibition best data in AS, nr-AxSpA, enthesitis...

PsA primary endpoint data for SLK expected to be announced in the coming months





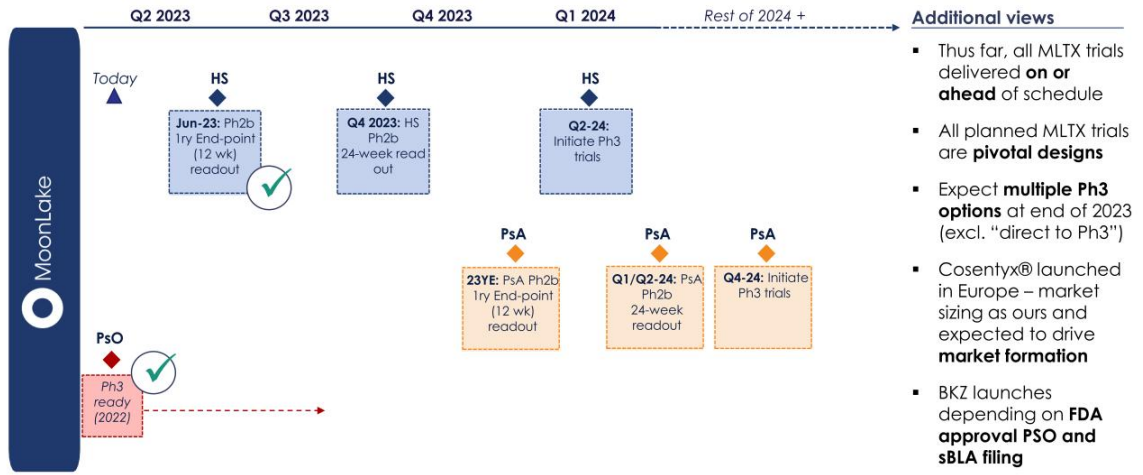
Note: Simplified depiction based on key published information, not meant to be exhaustive in nature. AD, atopic dermatitis; IFN γ , interferon gamma; IL, interleukin; ILC, innate lymphoid cell; NK, natural killer; Th, follicular helper; Th, T helper.

¹ Kaiko GE, et al. Immunology, 2008;123:326-338
2017;35:33-84

² Eyertich K, Eyertich S. J Eur Acad Dermatol Venereol, 2018;32:692-703
⁵ Coates LC, et al. Semin Arthritis Rheum. 2018;46:291-304

³ Raphael I, et al. Cytokine. 2015;74:5-17
⁶ Gandhi NA, et al. Expert Rev Clin Immunol. 2017;13(5):423-437.

⁴ Nakayama T, et al. Annu Rev Immunol.
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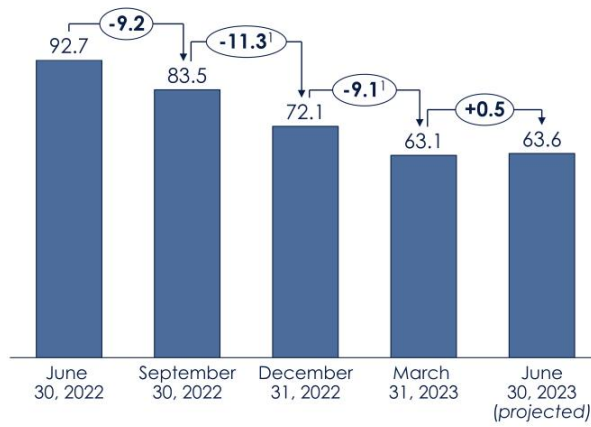


Additional views

- Thus far, all MLTX trials delivered **on or ahead** of schedule
- All planned MLTX trials are **pivotal designs**
- Expect **multiple Ph3 options** at end of 2023 (excl. "direct to Ph3")
- Cosentyx® launched in Europe – market sizing as ours and expected to drive **market formation**
- BKZ launches depending on **FDA approval PSO and sBLA filing**

Cash, cash equivalents & short-term marketable securities

USD M



• **Discipline** – Cash burn demonstrating cost-efficient set up and focus of MLTX

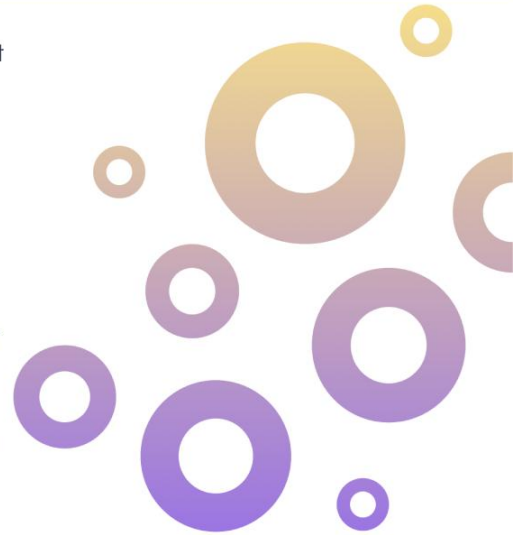
• **Strength** – Runway until the end of 2024, i.e. HS readout +18 months, covering:

- Completion of ongoing Ph2 programs in HS and PsA
- Preparation of Ph3s, End-of-Phase 2 meetings, etc.
- All other base spend

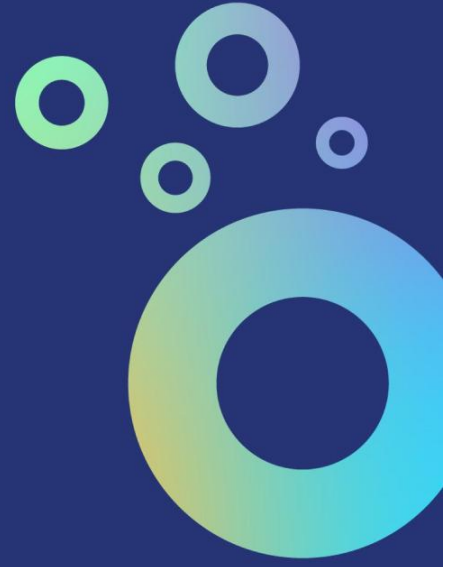
• **Optionality** – MLTX controls path forward to raise for its Phase 3 programs along several catalysts

¹ Differences may not add up due to rounding

- **Best in class** – SLK is a unique molecule among all “next gen IL-17s”, as now shown in HS and PsO
- **Rarefied air** – only two molecules can inhibit all IL-17 pro-inflammatory dimers, only SLK combines that MoA with unique molecular characteristics
- **MLTX = Robust trials** – comparing apples-to-apples is critical, esp. in diseases like HS, PsA, PsO & others, and only pivotal-like designs provide differentiating insight
- **Multi Bn drug** – SLK may impact very large markets that are growing fast now, with potential over \$70bn, as a leading asset in Type 3 inflammation
- **Our year** –MLTX has all key readouts among “next gen IL-17s” to end of 2023, and operates from a position of financial stability and strength



Q&A





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