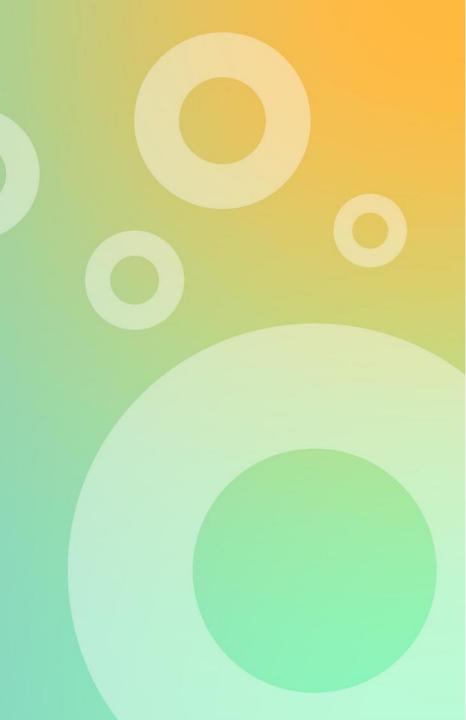


# MoonLake Immunotherapeutics

Capital Markets Update

New York

September 11th 2024



# Welcome to our Capital Markets Update



#### Logistics

Date: September 11th, 2024

Time: 09.00-10.30 EST

Location: Webcast from Nasdaq Market site, 4

Times Square, New York



#### Agenda

Торіс	Sub-topics	Speaker	Timing
Introduction and Business Update	<ul><li>Welcome</li><li>MLTX summary</li><li>SLK summary</li><li>Key points for the session</li></ul>	Jorge Santos da Silva	10 mins
R&D Update	<ul><li>R&amp;D program overview</li><li>HS &amp; VELA program update</li><li>PsA &amp; IZAR program update</li><li>New indications overview</li></ul>	Kristian Reich	30 mins
SLK – Market Opportunity	<ul> <li>HS – A franchise building indication</li> <li>PsA – Leading the pack in Rheum</li> <li>Broadening the portfolio</li> </ul>	Jorge Santos da Silva	30 mins
Moving Forward	<ul><li>Q key takeaways and ML cash runway</li><li>Path forward</li></ul>	Matthias Bodenstedt	10 mins
Q&A session	N/A	N/A	10 mins

#### Disclaimer



#### **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. Forwardlooking 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.

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## Instructions for this session



Please take note of the disclaimer on the previous page



You can **submit your questions** through the "Ask a question" function on the top right of your screen – questions are only visible to the moderators – we will address **as many questions as possible** at the end of this session



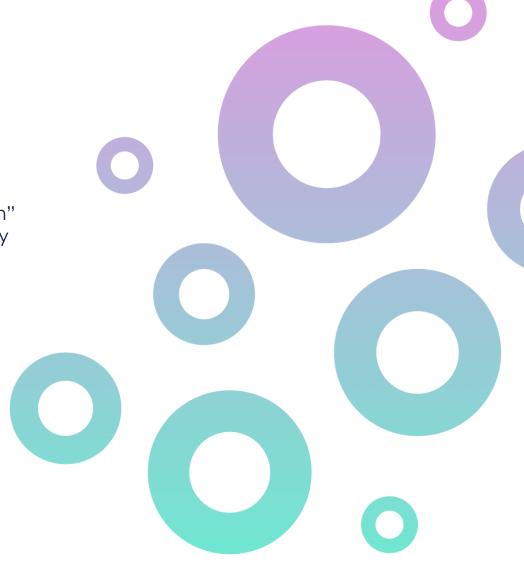
**The presentation** and a **replay** will be made available on our IR website



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



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- Founded in 2021 in Switzerland
- Nanobody® technology licensed in initial private round
- O Unique molecule with sonelokimab, trispecific 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
- O Clinical phase company successfully concluded phase 2b in HS ("MIRA", n=234), PsA ("ARGO", n=207), and also psoriasis (n=313)
- Initiated Phase 3 in 2024 plus additional indications market launch expected in 2027
- Driven by a top-tier team, target is to unlock a pipeline-in-a-product across large indications (>\$5bn in HS & PsA alone)

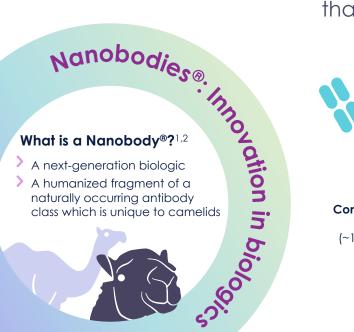


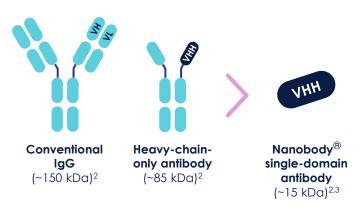
## A differentiated molecule – Do you still Antibody?

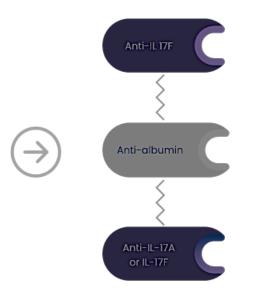


# Nanobodies® are much smaller than traditional antibodies

They can be designed to have multiple and different binding domains









#### Sonelokimab

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

Note: Ig, immunoglobulin; VH, heavy chain variable domain; VHH, variable heavy domain of heavy chain variable domain; 1 Hamers-Casterman, C., et al. Nature. 1993; 363:446–448; 2 Jovčevska I, Muyldermans S. BioDrugs. 2020;34:11–26; 3 Tijink BM, et al. Mol Cancer Ther. 2008;7:2288–2297; For reference in this presentation: the terms Nanobody® and Nanobodies® are registered trademarks of Ablynx, a Sanofi company.

Source: MoonLake Research

#### It's all about the dimers



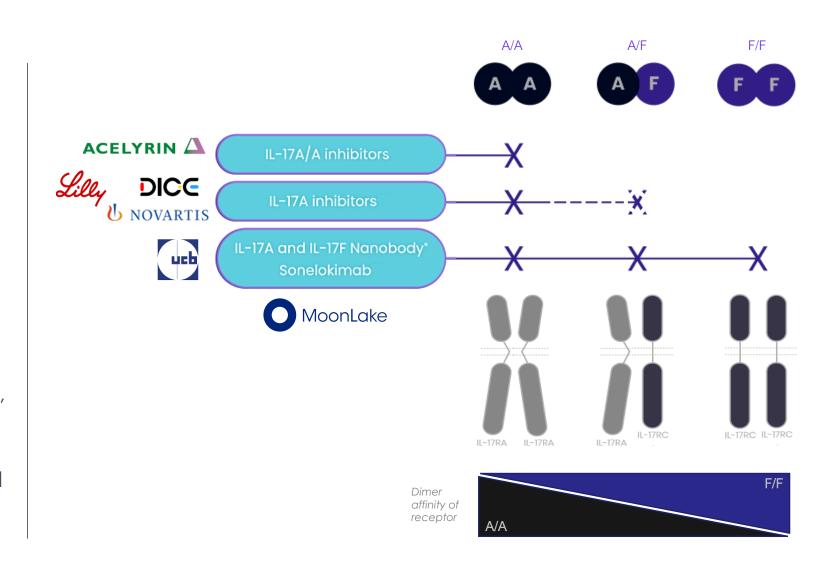
Illustrative

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<sup>1,2</sup>

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



# SLK rapidly becoming a leader in large inflammatory diseases



		Trial	Patients (n)	Leading MoA	SLK leading asset
37	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
\W	PsA	Phase 2b (ARGO)  Placebo-controlled with Humira TM	207	IL-17A & F IL-23 & IL-17A	Highest responses in skin/joints, incl. critical composite scores
Å	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	Phase 2&3  PPP, axSpA, Adolescent HS, PsA	~150	IL-17A & F Other	IL-17A & F inhibition <b>best</b> data in AS, nr-AxSpA, PPP, Adol HS

## Progress on HS and PsA discussed today, also information on new indications

Note: Comparisons across trials, with inherent limitations. No head-to-head trials

# Key points we will hit on today



MLTX **Operational Plan on course**, building on strong operational and clinical performance from 2021-2023 and Phase 2 programs

**Progress with both FDA and EMA** (end-of-Phase 2 meetings and numerous other interactions) across multiple indications

Focus on **driving the portfolio** of indications for SLK, at full speed for a 40bn+market – Ph 3 programs in **HS and PsA**, and **New indications (NI)** 

#### HS:

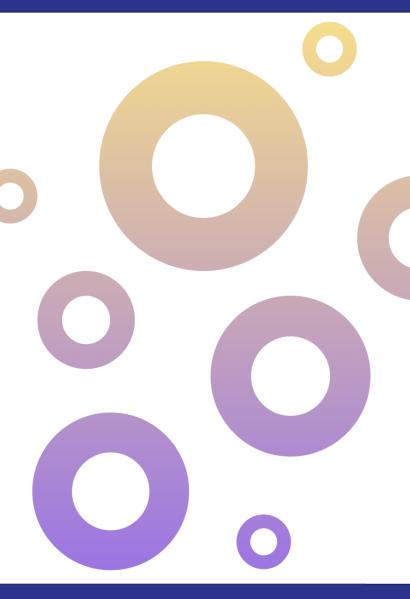
- VELA 1 and 2 recruiting on plan with an ambitious timeline (as in Ph2)
- Key inflection point as of mid-2025 with detailed endpoint readout
- Market maturation confirms multi-bn potential for SLK in a 15bn+ market by 2035
- Five ways in which SLK can differentiate from closest rival, Bimzelx™

#### PsA:

- Engines going on innovative IZAR 1 and 2 ramp-up FPI Q4 2024
- Market shifting to "multi-domain", 15bn+ market opportunity

NI: PPP ramp-up, Adol HS FDA/EMA approved, Rheum soon, data H1'25

Continued solid financial performance, **strong cash** position to at least end of 2026 as we build the **leader in Type 3 inflammation with SLK** 





# R&D Update Kristian Reich, CSO





# Summary

#### MoonLake continues to drive value from three angles

- Continued pursuit and delivery on core clinical goals (HS and PsA)
- Preparation of next waves of indications (PPP, axSpA and Adol HS)
- Ground-breaking research, guiding trials, medical strategy & IP

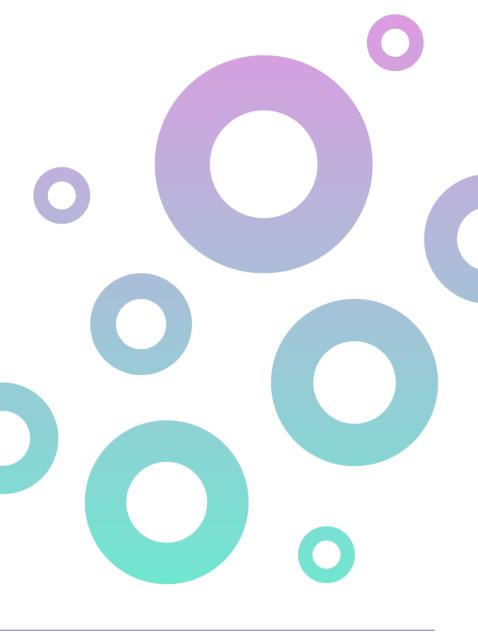
#### HS phase 3 trials (VELA-1 and -2) are running well

- Study design with positive FDA & EMA feedback (~800 pts)
- Trackability and management through unique data visualization
- Primary endpoint as of mid-2025 SLK to become new HS "gold standard"

#### PsA phase 3 trials (IZAR-1 and -2) ramping up

- Innovative design with Risankizumab arm ~1500 patients across 3 regions
- Site selection ongoing at speed
- H2 2024 is period for regulatory Ph 3 submissions & approvals FPI

#### New Indication trials to unlock additional value for MoonLake



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# Overview of R&D programs at MLTX



Resec	arch (incl. collaboration)	Next wav	<b>e</b> (Ph 3 enablir	ng)	Phase 3	(BLA enabling)
Bio- markers	IP-enabling Derm & Rheum program (2024-26)	PPP – LEDA	Phase 2 (2025)		HS – VELA	Phase 3 (2025/26)
Deep tissues	SLK penetration based on imaging and clinical sampling (2025-26)	axSpA – S-OLARIS	Phase 2 (2025)		PsA – IZAR	Phase 3 (2025/26)
New TAs	Portfolio expansion based on human models (2024-26)	PsA – P-OLARIS	Phase 2 (2025/26)		Adol HS – VELA-TEEN	Phase 3 (2025/26)

# **HS:** A challenge and an opportunity





HS is **progressive** and results in **irreversible tissue destruction** over time...<sup>1</sup>

...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...<sup>2</sup> ...we need HS therapies that provide sustained and significant improvements to patients' lives

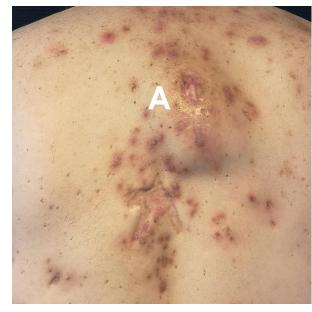


**Delayed** (and under-) diagnosis drive conservative prevalence estimates...<sup>2,3</sup>

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



Advanced disease stages with deep dermal abscess (A), tunnels (T) and scarring (S)







1 Sabat R et al. Nat Rev Dis Primers. 2020; 6:18; 2 Krueger JG et al. Br J Dermatol. 2024; 190:149-162; 3 Ingram J et al. EADV 2023, Poster P0046; pictures courtesy of Dr. N. Kirsten, France, and Prof. M. Augustin, Germany, used with permission

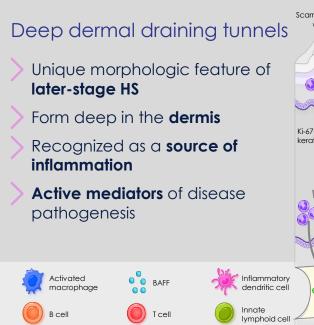
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# **HS:** Early control is key to address deep dermal inflammatory lesions





Early inflammatory nodules



Fibroblast .

Bacterium

Hyperplasia inflammatory epithelium Tissue destruction/ CXCL8 CXCL8 Bacterial biofilm



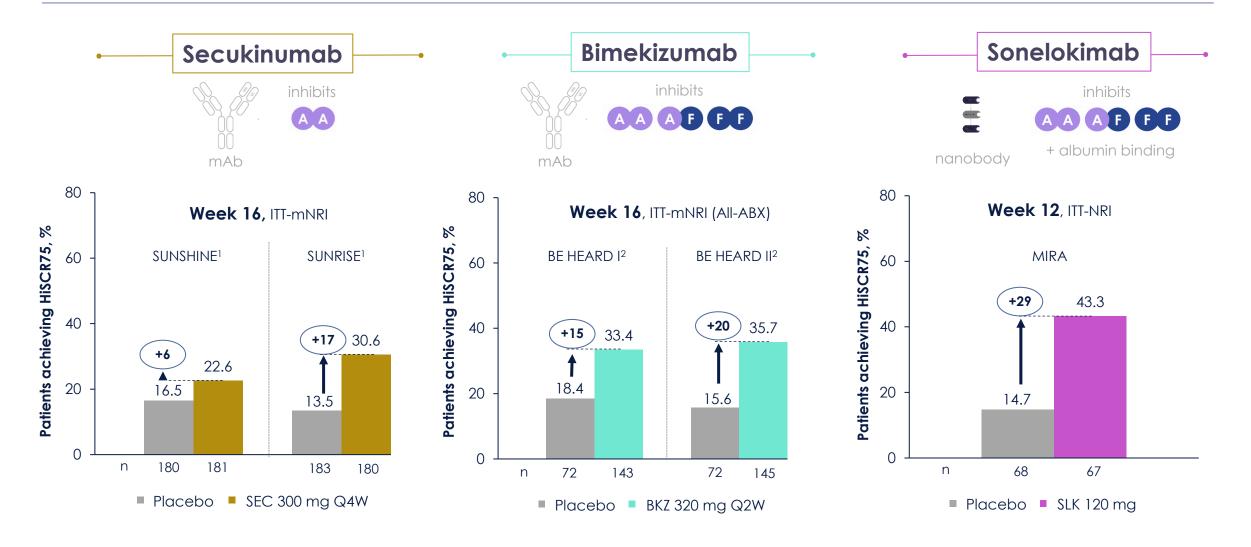
Inflammatory nodules, abscesses, scars and tunnels

Pathophysiology figure adapted from Krueger JG, et al. Br J Dermatol. 2023; doi: 10.1093/bjd/ljad345. Licensed under the Creative Commons CC-BY license (https://creativecommons.org/licenses/by/4.0/); clinical pictures courtesy of Dr. N. Kirsten, France, used with permission; DDIL, deep dermal inflammatory lesions

Source: MoonLake Medical Affairs and Research

# **HS:** Molecular advantages of SLK translates into high clinical response





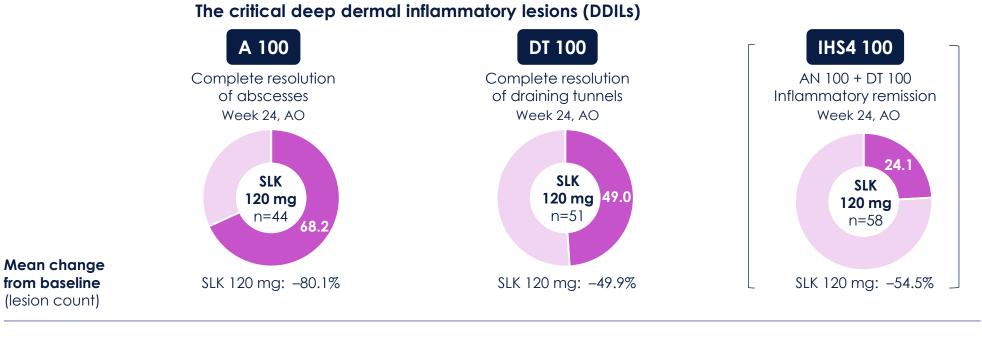
Note: Comparisons across trials, with inherent limitations. No head-to-head trials. 1 Kimball A et al. EADV 2023; 2 Kimball A et al. Lancet 2024; 403:2504-2519

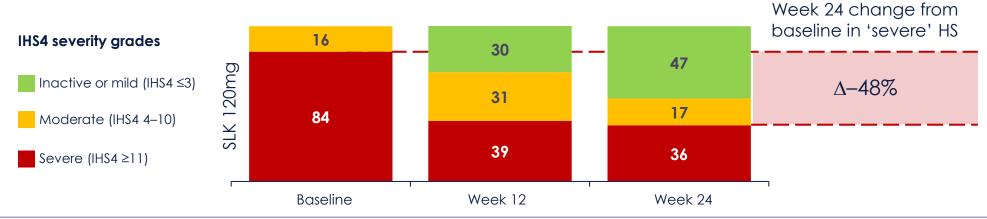
MoonLake Clinical

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## **HS:** Extensive resolution of deep dermal lesions is a hallmark of SLK







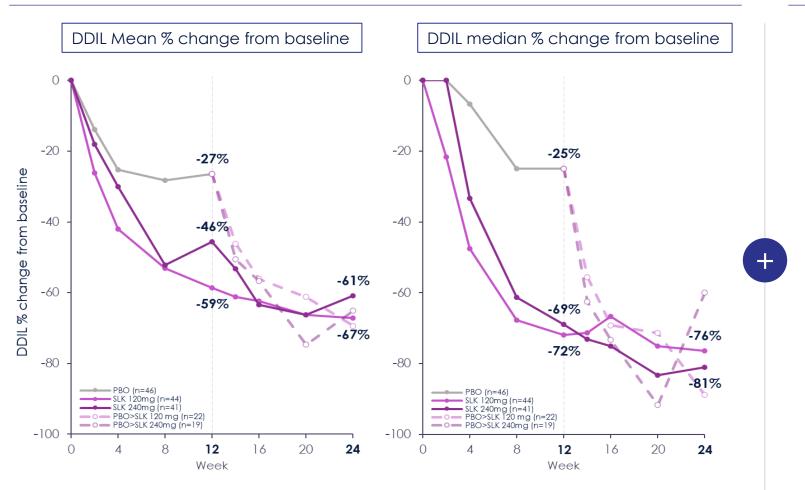
Data are as observed. In refers to the number of patients with data at W24. At baseline, 67 and 66 patients were randomized to receive sonelokimab 120mg and 240mg, respectively. At baseline, mean abscess count (in patients with ≥1 abscess) was 4.5 (PBO), 5.1 (SLK 120 mg), and 3.7 (SLK 240 mg), mean DT count (in patients with ≥1 DT) was 4.0 (PBO), 4.4 (SLK 120 mg), and 3.7 (SLK 240 mg). IHS4 data reported as observed. Where values do not sum to 100%, this is due to rounding

ource: MoonLake Medical © 2024 | Proprietary | MoonLake TX

# **HS:** SLK rapidly impacts deep dermal inflammatory lesions (DDILs)



#### SLK resulted in rapid and substantial improvements in DDILs (A+DT)



# Complete resolution of DDILs in ~40% of patients at Week 24 (A+DT)



Porter J et al. abstract in preparation for AAD 2025; DDIL, deep dermal inflammatory lesions (abscesses and draining tunnels)

Source: MoonLake Medical © 2024 | Proprie

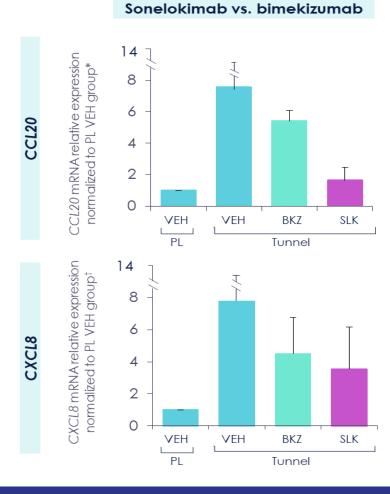
# **HS:** SLK with greater inhibition of inflammation vs. Bimzelx<sup>™</sup> in tunnels



#### Bespoke 24h ex vivo HS lesional tissue culture model



Representative example of organ culture of HS perilesional/tunnel biopsy **from HS patient** under air-liquid interface conditions





Ex vivo, SLK demonstrated greater inhibition of CXCL8 and CCL20 vs. vehicle control and BKZ in HS DDIL tissues

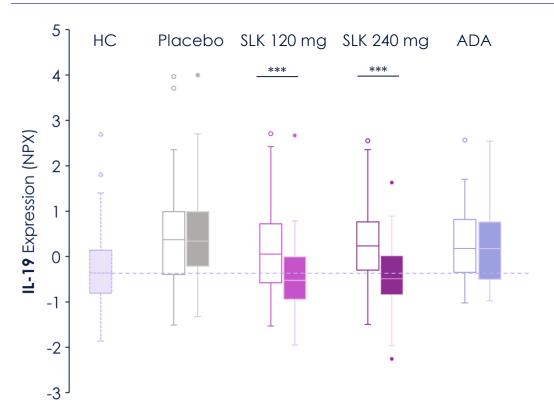
# **HS:** Biomarkers reflect deep dermal molecular responses to SLK

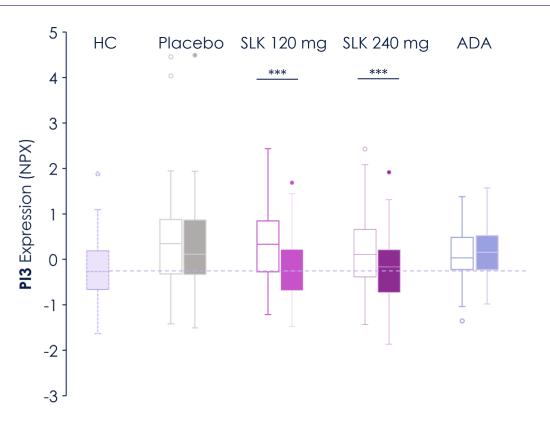


Week 12

Baseline

#### Normalization of IL-19 and PI3 levels by Wk 12 in the MIRA trial





IL-19 and PI3 associated with increased disease activity in HS, especially in draining tunnels SLK pharmacodynamic effects: Normalization of IL-19 and PI3 to levels of healthy control by week 12

Note: Comparisons across trials, with inherent limitations. No head-to-head trials. Significant decrease of IL-19 and PI3 seen at Wk 12 (paired t-test). Healthy controls were purchased from Discovery Life Sciences and matched the participants' age, sex, and ethnicity; HC, healthy controls; BL, baseline; SLK, Sonelokimab; ADA, Adalimumab; IL-19, Interleukin-19; PI3, Elafin

Source: MoonLake Medical

# **HS:** An impressive "cheat sheet" from Phase 2 MIRA



Approximate response level for different parameters in HS after SLK 120 mg treatment (week 24)

HiSCR75

60%

**IHS4-75** 

50%

HISCR90

40%

**IHS4-90** 

40%

HiSCR100

30%

IHS4-100

25%

HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4, International Hidradenitis Suppurativa Severity Score System

## **HS:** What is real impact? Helping to alleviate pain and suffering of millions



# HS patients are in intense pain and suffering...

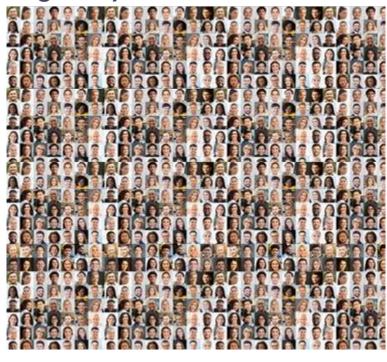
"...patient who was **weeping**: **how many days can she take off** from work? [...]

...really, really common that patients even quit their jobs because they can't sit down because it's so painful. [...]

...their intimate lives are destroyed ... pus leaking out from their bodies"

- U.S. KOL interview

# ...millions of lives affected every single day...



Millions of patients in the US alone suffering from HS

# ...yearning to get the treatment they need and deserve

SLK holds the promise to **transform lives** – **millions of times**<sup>1</sup>:

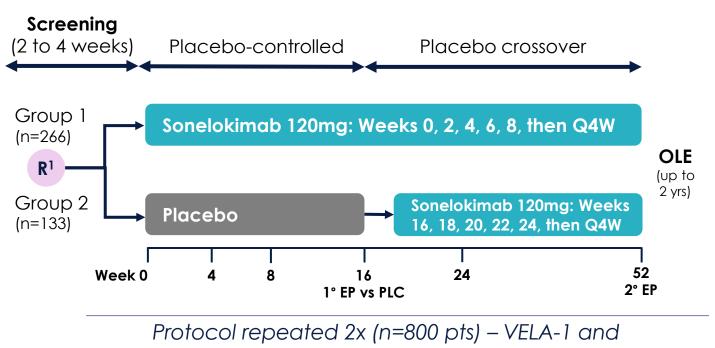
e.g., MIRA week 24

- 7 in 10 have no more abscesses
- 1 in 2 have no more draining tunnels
- 1 in 4 have no more lesions at all
- 4 in 10 report absent / min disease

# **HS:** Very positive FDA & EMA EoP2 meeting



#### Phase 3 protocol post FDA EoP2 meeting



VELA-2 (both follow the same protocol)

FDA and EMA assessments (incl. EU CTR) successfully completed First patient announced in May 2024

- One dose phase 3 FDA & EMA agree 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**
- Allows being more explicit with primary endpoint already in mid 2025, launch in 2027 (within ~24 months of BKZ launch)
- **Protocol** is similar to Phase 2 and with two arms only (historically, Phase 2 and 3 results similar when protocols don't change, incl. in Derm)

## HS: VELA aligned with FDA and EMA and progressing as planned



23



- 400 patients each and about 100 sites each
- Expected recruitment rate of ~0.35 patients/site/month (for reference: MIRA Phase 2 was ~0.45; industry is ~0.26)

VELA trials progressing as per our ambitious plan, in line with Phase 2 experience – all sites from Phase 2 involved now, first patients through week 12

MoonLake currently recruiting adults with moderate-to-severe HS for two global Phase 3 trials: VELA 1 NCT06411899 & VELA 2 NCT06411379

IRB, Institutional Review Board; FDA, Food and Drug Administration; HC, Health Canada; MHRA, Medicines and Healthcare products Regulatory Agency; REC, Research Ethics Committee; EU CTR, European Union Clinical Trials Regulation

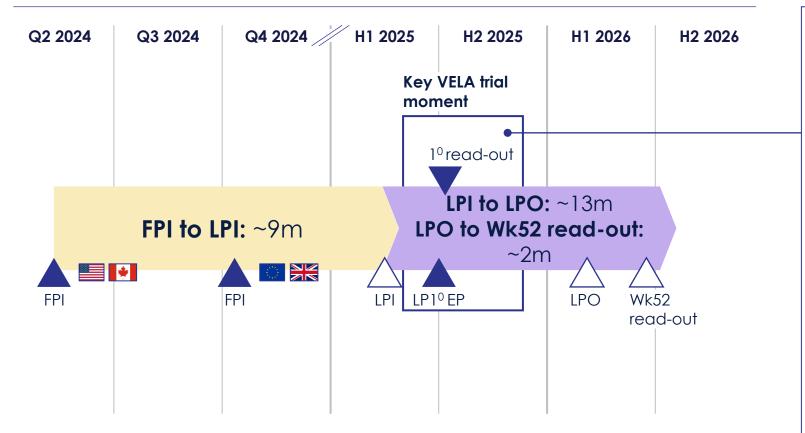
Source: MoonLake Clinical © 2024 | Proprietary | MoonLake TX

# HS: Primary VELA endpoint read-out as of mid-next year



Timelines indicative - not scaled

#### **VELA** clinical trial timeline



#### **VELA** endpoints

#### Primary endpoint:

HiSCR75 at week 16

# **Key secondary endpoints** (efficacy):

- HiSCR50 at week 16
- IHS4 score at week 16
- DLQI total reduction of ≥4 at week
   16 among participants with
   baseline of DLQI ≥4
- ≥30% reduction and ≥2-unit reduction at week 16 in the NRS30 for pain in PGA – among participants with baseline of NRS ≥3

**Safety** (similarly to MIRA primary endpoint readout)

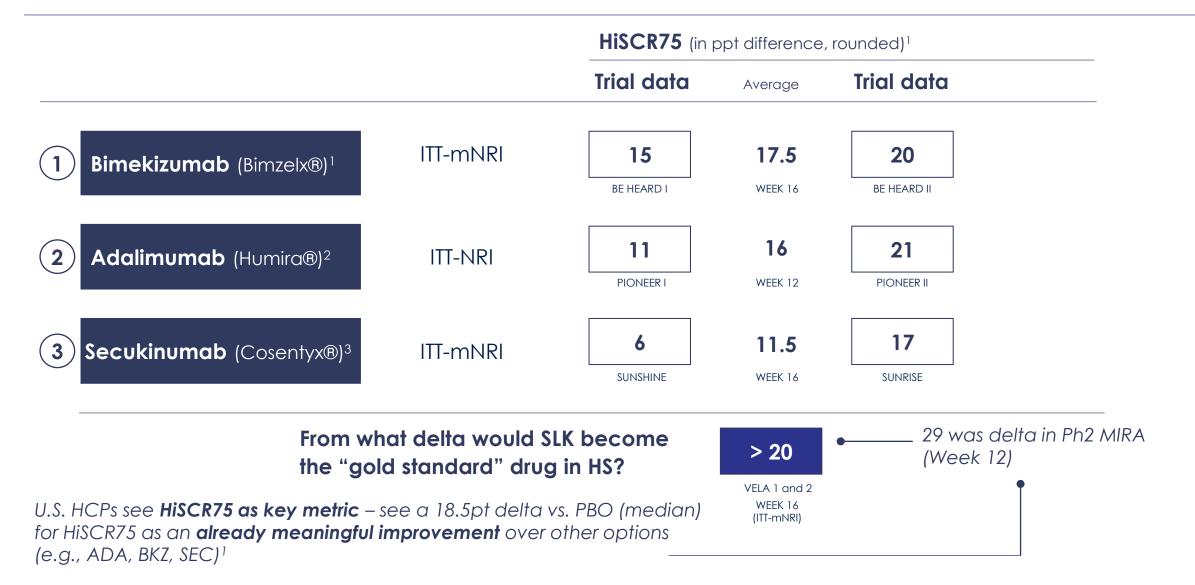
Quality ("placebo") control - Building on Ph 2 experience with ~80 sites - Stringent survey site selection, individual site training, site level QC throughout

HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4, International Hidradenitis Suppurativa Severity Score System; DLQI, Dermatology Life Quality Index; NRS30, Numerical Rating Scale; PGA, Physician Global Assessment

Source: MoonLake Clinical © 2024 | Proprietary | MoonLake TX

# HS: Framing the primary endpoint for VELA Phase 3 program





Moonlake Commercial, Moonlake Clinical

# **HS:** Leading presence at the upcoming EADV conference



#### Oral Presentations

#### **HS: Translational Research**



Inflammatory mechanisms underlying HS, including in deep dermal tunnels

Presenting author: Kristian Reich

Date and time: Thursday September 26, 08:40–08:50

**Location:** Open stage

#### **HS: Clinical Research**



Inflammatory lesion resolution over 24 weeks of the Phase 2 MIRA trial

Presenting author: Martina J. Porter

Date and time: Thursday September 26, 08:50–09:00

Location: Open stage



IHS4 outcomes over 24 weeks of the Phase 2 MIRA trial

Presenting author: Brian Kirby

Date and time: Thursday September 26, 09:00–09:10

Location: Open stage











### > e-Poster presentations

#### **HS: Clinical Research**



Patient-reported outcomes over 24 weeks of the Phase 2 MIRA trial

Presenting author: Martina J. Porter

Poster number: P0015



Inflammatory lesion resolution over 24 weeks of the Phase 2 MIRA trial Presenting author: Martina J. Porter

Poster number: P0009



IHS4 outcomes over 24 weeks of the Phase 2 MIRA trial

Presenting author: Brian Kirby

Poster number: P0084

#### **PsA: Clinical Research**



Skin, nail & multidomain outcomes at Week 12 of the Phase 2 ARGO trial

Presenting author: Joseph F. Merola

Poster number: P3108

#### **HS: Translational Research**



Inflammatory mechanisms underlying HS, including in deep dermal tunnels

Presenting author: Kristian Reich

Poster number: P0016

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# HS: MLTX collaboration with key experts in the field



Br J Dermatol 2024; **190**:149–162 https://doi.org/10.1093/bjd/ljad345 Advance access publication date: 16 September 2023 BJD
British Journal of Dermatology
Review Article

# Hidradenitis suppurativa: new insights into disease mechanisms and an evolving treatment landscape

James G. Krueger,<sup>1</sup> John Frew,<sup>2,3,4</sup> Gregor B.E. Jemec,<sup>5,6</sup> Alexa B. Kimball,<sup>7,8</sup> Brian Kirby<sup>1</sup>,<sup>9,10</sup> Falk G. Bechara,<sup>11</sup> Kristina Navrazhina,<sup>1,12</sup> Errol Prens,<sup>13</sup> Kristian Reich,<sup>14,15</sup> Eva Cullen<sup>15</sup> and Kerstin Wolk<sup>16</sup>



To read the full review, please scan the QR code

And leading presence in all key Derm meetings with presentations and posters, including for example, ESDR, EADV, SHSA, EHSF, AAD 2025 in preparation



BJD, British Journal of Dermatology; HS, hidradenitis suppurativa.; Krueger JG et al. Br J Dermatol. 2024; 190:149–162

Source: BJD, MoonLake Medical © 2024 | Proprietary | MoonLake TX

# PsA: 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<sup>1</sup>





Other clinical domains<sup>1</sup>









Axial

**Enthesitis** 

Nail

Dactylitis

Patient-reported outcomes<sup>2</sup>



Function e.g. HAG





Disease severity e.g. PGA

#### Multidomain composite outcomes<sup>2</sup>

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

ioints



Swollen

ioints



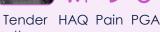
Skin

**lesions** 









ACR + PASI

Response in joints + skin

entheses







ACR50

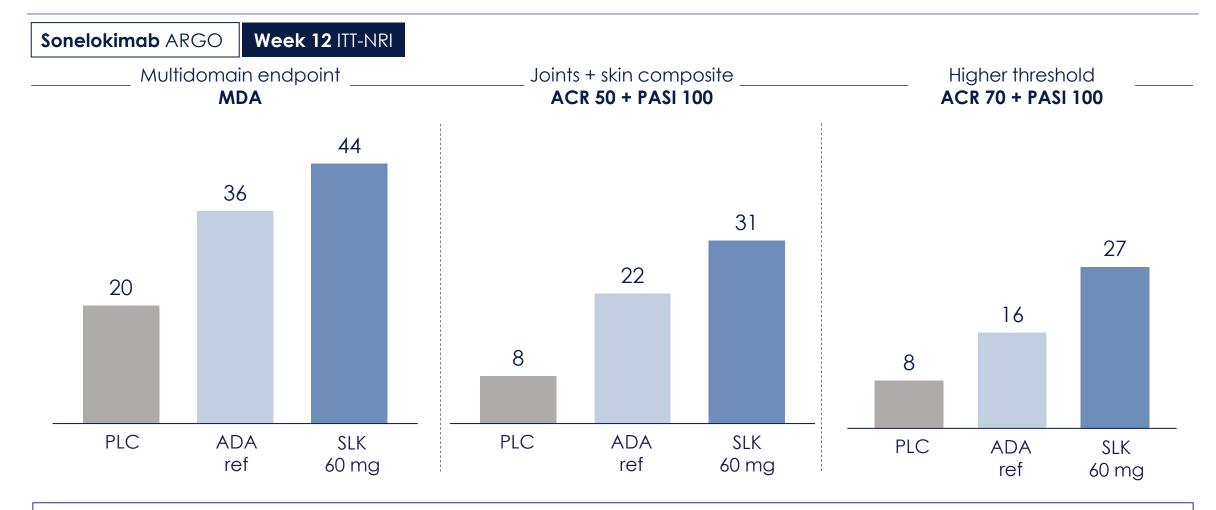
PASI100

Can we elevate to ACR70 + PASI100?

Source: MoonLake Medical

# **PsA:** SLK Nanobody<sup>®</sup> showed exciting responses in composite scores





Primary endpoint (ACR50) and key secondary endpoint (PASI90) met at wk12, with higher response that Adalimumab (in the same trial) unlike what was seen for bimekizumab in BE OPTIMAL

Note: Comparisons across trials, with inherent limitations. No head-to-head trials

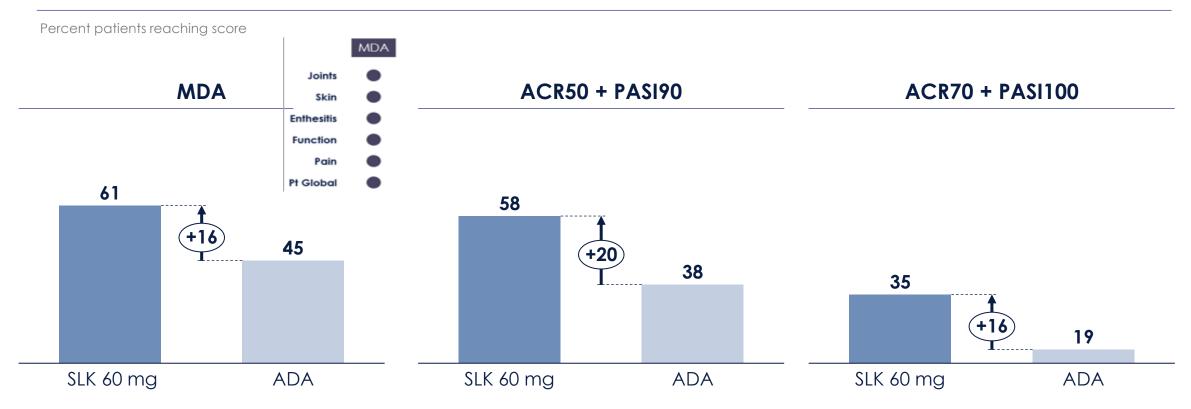
# PsA: Responses with SLK improve over time



**Sonelokimab** ARGO

**Week 24** AO

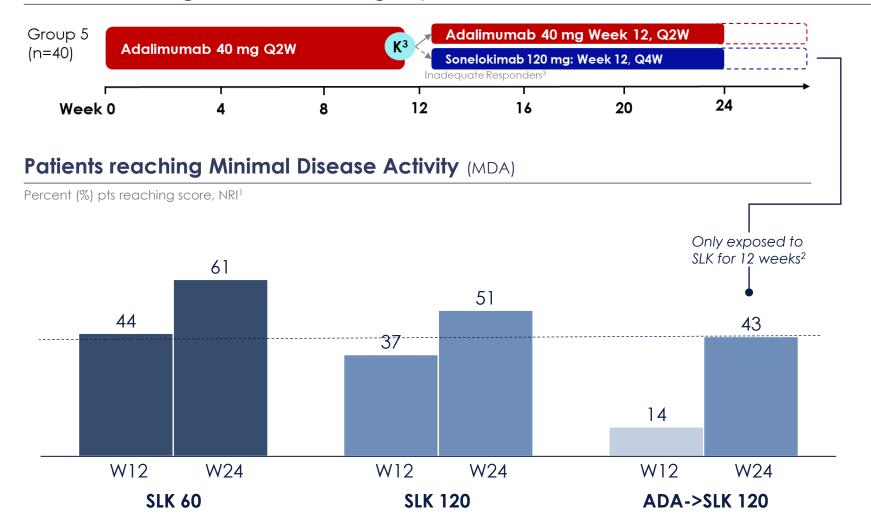
## Response level for PsA after sonelokimab and adalimumab treatment at Week 24



# PsA: Crossovers signal potential of SLK in TNF non-responders



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



- 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

ource: MoonLake Clinical © 2024 | Proprietary | MoonLake TX

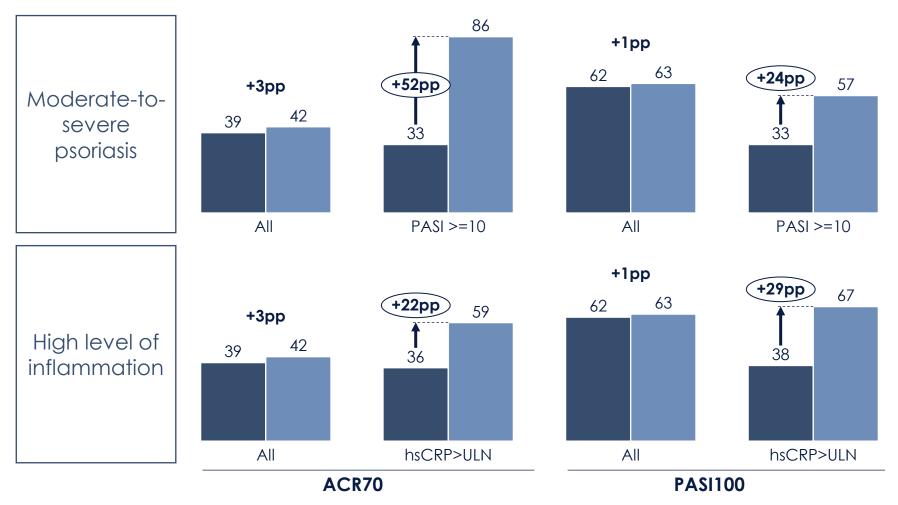
# **PsA: Higher 120mg efficacy** in key subgroups



#### Response rates at week 24 (subgroups)

SLK 60mg SLK 120mg

Percent (%) of pts, NRI<sup>1</sup>



- Key subgroups may further benefit with 120mg vs 60 mg
- Incl. those with high level of skin involvement (moderateto-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 "catchesup" in many patients at wk 24 - up-titration likely a case-bycase 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

MoonLake Clinical Source:

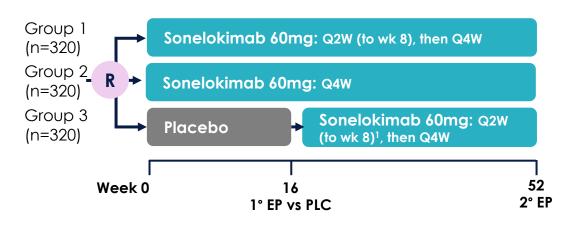
<sup>1</sup> ITI-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards

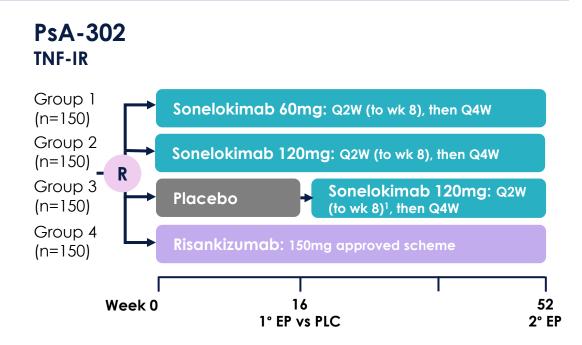
# **PsA:** IZAR is an innovative Phase 3 program in Rheumatology



#### Phase 3 protocol post regulatory advice

# PsA-301 Bio-naïve & radiographic



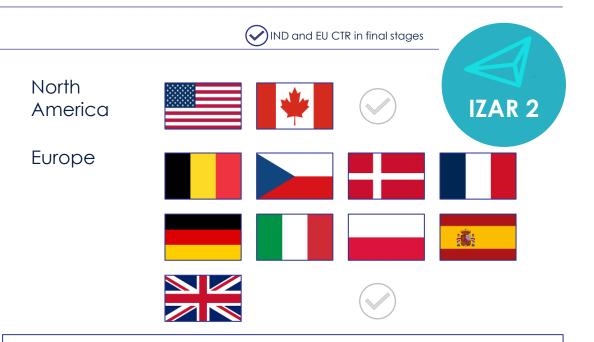


- Both doses for approval: 60 (bio-naïve/TNF-IR) & 120mg (TNF-IR) with sufficient pts for safety database (60mg, 120mg) & 90%+ power for key endpoints incl. radiographic progression
- A novel Risankizumab (Skyrizi®) comparator arm throughout the trial (first IL-23 to IL-17 comparison in PsA) study powered for comparison vs. placebo, but also aiming to show meaningful separation vs. Skyrizi
- Read-out of 1° endpoint at week 16 (around 1500 pts in total) allowing direct comparison with competitors

## PsA: IZAR has a strong geographic footprint across all major PsA sites







- Around 1500 patients across the program (960 in IZAR-1 and 600 in IZAR-2)
- First feedback on design and level of excitement with IZAR program is extremely positive – PsA currently less competitive for clinical trial patients
- Skyrizi should be beatable SLK shows ~2x higher ACR, ~2x higher PASI90 and ~2.5x higher MDA responses for SLK (ARGO) vs. Risankizumab (best of KEEPsAKE)

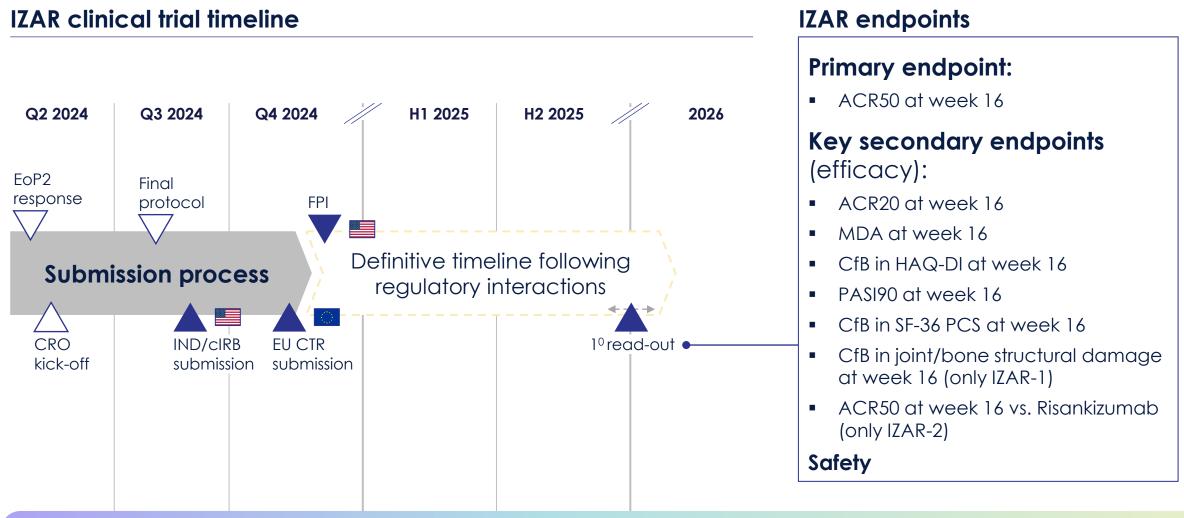
IND, Investigational New Drug; EU CTR, European Union Clinical Trials Regulation

MoonLake Clinical

## PsA: Submission of IZAR to authorities in Q3/Q4 2024



Timelines indicative - not scaled



Over 30% of sites already in Site Visit process across both trials (and over 80% of key priority sites) - large trial but progress well on track

ACR, American College of Rheumatology; MDA, Minimal Disease Activity; CfB, Change from Baseline; HAQ-DI, Health Assessment Questionnaire – Disability Index; PASI, Psoriasis Area and Severity Index; SF-36, Short-form-36; PCS, Physical Component Summary; IND, Investigational New Drug; cIRB, Central Institutional Review Board; EU CTR, European Union Clinical Trials Regulation

Source: MoonLake Clinical

### **PsA:** MLTX scientific and clinical leadership – a multi-domain disease



36

#### **Presented**

# Presenting author Prof Iain McInnes (Glasgow)





# Week 12 ARGO data — Multidomain outcomes

- Primary (ACR50) and key 2ary (ACR20, PASI90) endpoints
- MDA and ACR+PASI composites
- Skin & nail outcomes
- PsAID-12 patient QoL

#### **Oral presentation**

**Presenting author** 



#### Week 12 ARGO data — For a SpA KOL audience

- Refresher on Primary (ACR50), key 2ary (ACR20, PASI90) and ACR+PASI endpoints
- Focus on multidomain disease activity outcomes: PhGADA, DAPSA, MDA

#### Accepted

#### Poster presentation



Presenting author
Prof Joe Merola (UTSW)



#### Week 12 ARGO data — For a dermatology audience

- Primary (ACR50) and key 2ary (ACR20, PASI90) endpoints
- MDA and ACR+PASI composites
- Skin & nail outcomes



Presenting author
Prof Iain McInnes (Glasgow)



#### Week 24 ARGO data — Topline & Multidomain outcomes

- First disclosure of Week 24 data in the ARGO trial
- Key endpoints
- MDA
- ACR+PASI

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### **New indications:** IL-17A & F is at the crux of inflammation pathways

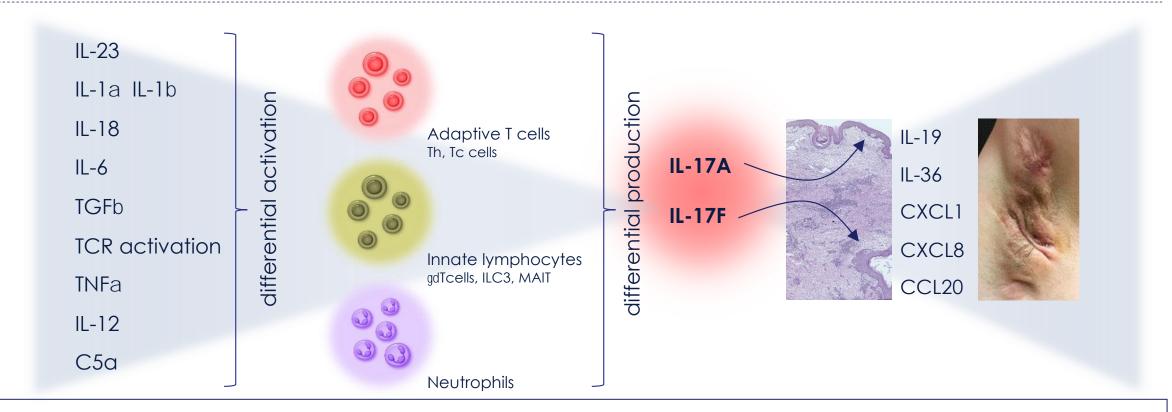


Multiple stimuli induce subsets of immune cells to produce IL-17A and F

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

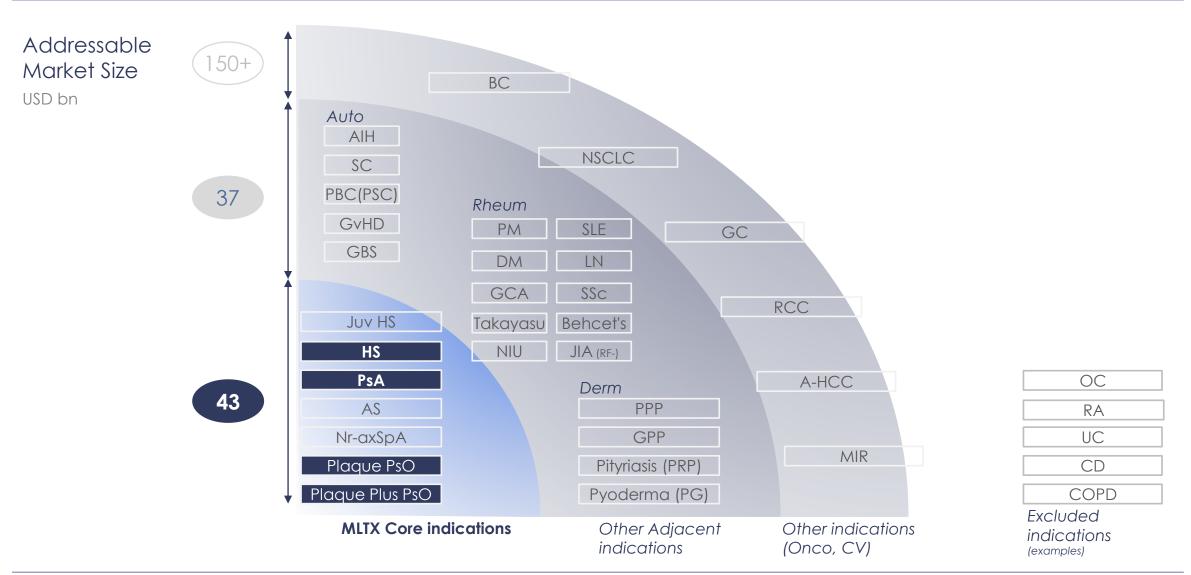


Targeting upstream or downstream pathways to IL-17A and F has led to several failures as pathways are redundant

MoonLake Clinical

## **New indications:** Many diseases involve IL-17A & F as a key pathway





HS, Hidradenitis suppurativa; PsA, psoriatic arthritis; AS, Ankylosing Spondylitis or adiographic axial spondyloarthritis; PsC, Primary Sclerosing Cholangitis; PsC, Primary Sclerosing Cholangitis; PsC, Primary Biliary Cholangitis; GvHD, Graft-vs-Host disease: GBS, Guillan-Barre Syndrome; PM, Polymyositis; DM, Dermatomyositis; GCA. Giant Cell Arteritis: NIU. Non-infectious uveitis; SLE, Systemic Sclerosis; JIA, Juvenile Idiopathic Arthritis; PPP, palmoplantar 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 Clinical and scientific publications, MoonLake Corporate

### MLTX expands its portfolio of SLK indications in Derm & Rheum



- 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

Derm









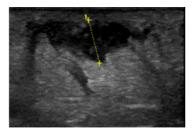


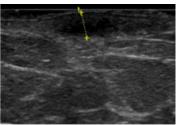
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### Across indications there is a high unmet need



#### **Adolescent HS**





Tunnel (before treatment) Week 12 (120mg SLK)

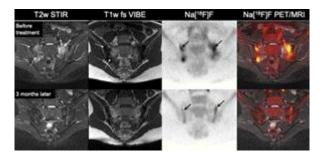
- Window of opportunity in adolescent with first and only studied HS treatment in adolescent 12+
- SLK elevates bar on HiSCR-75 and beyond
- Rapid pain reduction
- Preventing scarring and cumulative life course impairment

#### PPP<sup>1</sup>



- Painful inflammatory disease, inaccessible to larger biologics
- Nanobody may have advantage especially in poorly accessible inflamed palmoplantar tissue
- No positive trial in this indication (ex-Japan)
- There is no approved option for derms to treat PPP (in US and EU)
- There is an opportunity for an agent with high level of clinical response

PsA<sup>2</sup>



- Transferable opportunity as SLK already shown high level of clinical response in SpA (ARGO data)
- Nanobody may have advantage in difficult-to-access axial sites
- There is an opportunity to break the treatment ceiling by penetrating into inflamed tissue
- IL-17 A&F MoA has promising data for axSpA comorbidities (e.g., uveitis)

1 Images courtesy of Prof. Kristian Reich (please do not reproduce); 2 Images reproduced with permission from the authors (Bruckmann NM et al. Arthritis Rheumatol. 2022; 74(9):1497-1505)

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



## Derm



PPP (Phase 2) **Mkt size** (\$, 2035)

3-4bn (12% growth from '22) No approved or effective therapy

Challenge

Focus for today



1-2bn (9% growth from '22) No clinically studied product<sup>1</sup>

## Rheum



axSpA (Phase 2)

10-15bn (6% growth from '22) Limited efficacy of SoC<sup>2</sup>



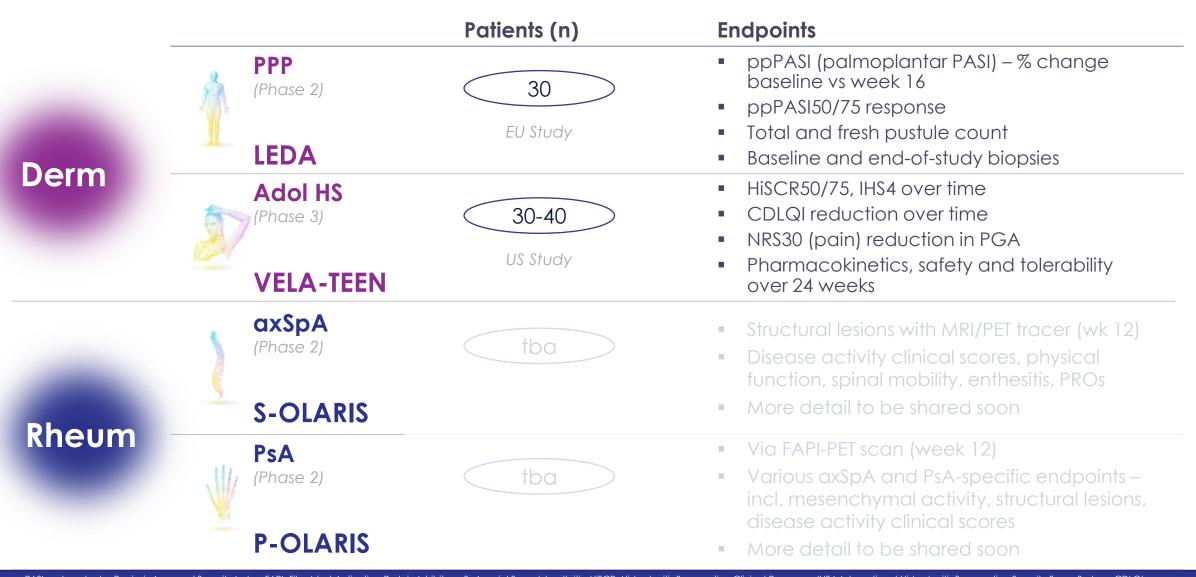
PsA
(supporting
Phase 2)

10-15bn (6% growth from '22) Outcomes suboptimal (e.g., ACR)

<sup>1</sup> Humira label in adolescent based on safety data from other indications; 2 ~40% of Humira pts do not reach ASAS20 at w12 based on ATLAS trial data

### **New indications:** Current focus on new Derm trials





ppPASI, palmoplantar Psoriasis Area and Severity Index; FAPI, Fibroblast Activation Protein InhibitoraxSpA, axial Spondyloarthritis; HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4, International Hidradenitis Suppurativa Severity Score System; CDLQI, Children's Dermatology Life Quality Index; NRS30, Numerical Rating Scale; PGA, Physician Global Assessment

ce: MoonLake Clinical © 2024 | Proprietary | MoonLake TX

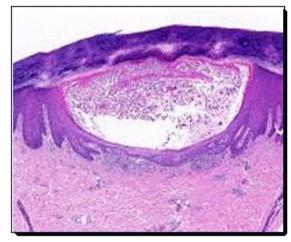
## **PPP:** An attractive new dermatology indication for SLK



#### Palmoplantar pustulosis is not palmoplantar psoriasis



PPP phenotype



PPP micro-anatomy



PP phenotype

#### In a nutshell

PPP is a pustular inflammation and a very painful **dermatitis** – sterile pustule formation in upper **epidermis** 

It may occur with or without psoriasis

**Prevalence is likely as high as 0.3% –** majority of patients also have plaque-type psoriasis on the body

There are no tested and approved specific PPP **drugs** – some efficacy has been shown for apremilast, guselkumab and IL-17 (e.g., BKZ)

Penetration into upper epidermis is regarded as limitation for mAbs

Treatments used include **non-specific psoriasis therapies** 

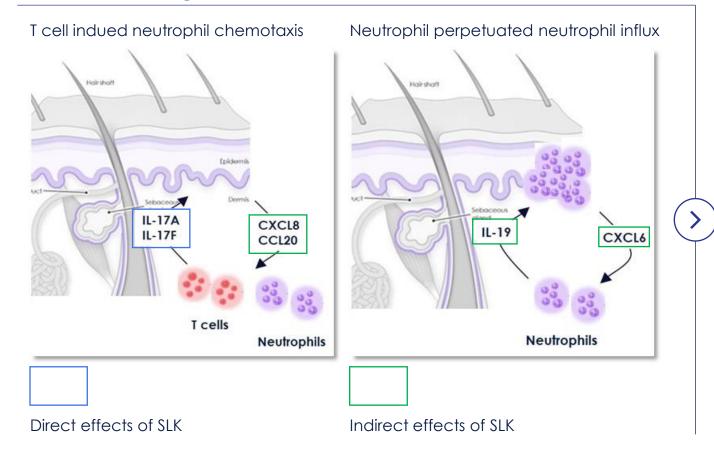
New treatments may receive **fast-track designation** 

PPP has positive collateral effects on HS story – SLK as prime therapy for neutrophilic skin disease

## PPP: Science supporting indication selection – and ClinDev



#### Pathophysiological concepts in PPP



#### PPP and integrated ClinDev

Current concept<sup>1</sup>: **Once neutrophils are attracted by IL-17-induced chemokines, a vicious circle evolves**in which IL-19 derived from neutrophils
activates CXCL6 in KCs to further
enhance neutrophil influx (via
CXCR1/2)

**Biomarker-controlled OL study as POC** with peripheral proteomics and biopsy analyses – opening door to another neutrophilic dermatitis with link to PsO

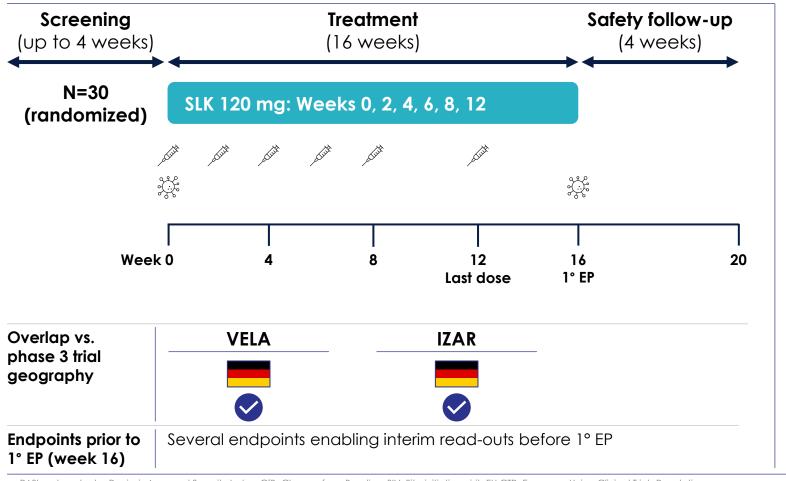
## **LEDA:** Understanding SLK in palmoplantar pustulosis (PPP)







## A Phase 2, multicenter, biomarker-controlled study of sonelokimab in patients with moderate-to-severe palmoplantar pustulosis



#### Endpoints and major milestones

#### Primary endpoint:

CfB of ppPASI at week 16

#### Key secondary endpoints

- ppPASI50 at week 16
- ppPASI75 at week 16

#### Major milestones:

- EU CTR approval & first SIV : Q3/Q4 2024
- FPI (screened): Q4 2024
- LPI: Q2 2025
- Data: As of early 2025

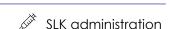
ppPASI, palmoplantar Psoriasis Area and Severity Index; CfB, Change from Baseline; SIV, Site-initiation visit; EU CTR, European Union Clinical Trials Regulation

Source: MoonLake Clinical © 2024 | Proprietary | MoonLake TX

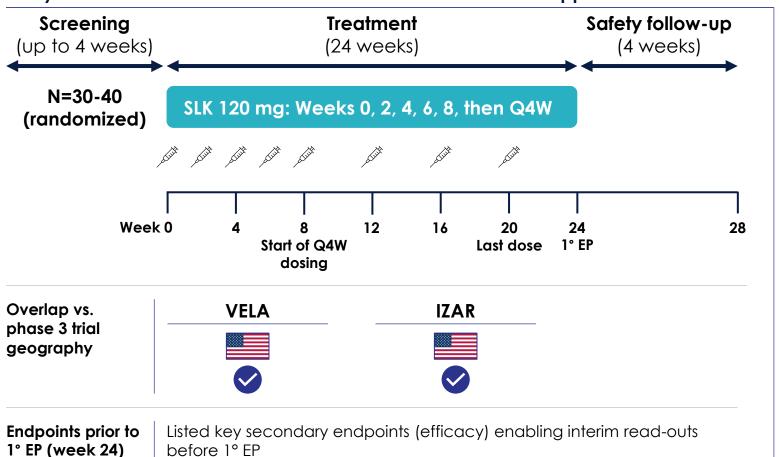
### **VELA-TEEN:** Understanding SLK in adolescent HS patients



**VELA-TEEN** protocol in finalization



An open-label, single-arm study to evaluate the pharmacokinetics and safety of subcutaneous (SC) sonelokimab in adolescents aged  $\geq 12$  to  $\leq 17$  years at the time of study inclusion with active moderate to severe hidradenitis suppurativa



#### **Endpoints and major milestones**

**Primary endpoint –** pharmacokinetics, safety and tolerability over 24 weeks to allow extrapolation to adult data

#### Key secondary endpoints (efficacy):

- HiSCR50/75, IHS4 over time
- CDLQI total reduction of ≥4 over time among participants with baseline of DIQI≥4
- ≥30% reduction and ≥2 unit reduction over time in the NRS30 for pain in PGA – among participants with baseline of NRS ≥3

#### **Major milestones:**

- FDA submission: Q3/Q4 2024
- FPI: Q1 2025
- LPI: Q3 2025
- Data: From mid-2025 with topline in Q1 2026

Q4W, every 4 weeks; HiSCR, Hidradenitis Suppurativa Clinical Response; HIS4, International Hidradenitis Suppurativa Severity Score System; CDLQI, Children's Dermatology Life Quality Index; NRS30, Numerical Rating Scale; PGA, Physician Global Assessment

Source: MoonLake Clinical

## **New Indications:** S-OLARIS/P-OLARIS elevating SLK impact



#### **S-OLARIS:** Sonelokimab and PET-MRI (NaF) in patients with axSpA

- Detects activated osteoblasts
- Measures pathological bone formation in axSpA

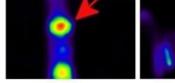
#### FDG PET<sup>1</sup>



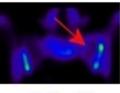
Patient 1

Patient 2

#### Naf PET<sup>1</sup>

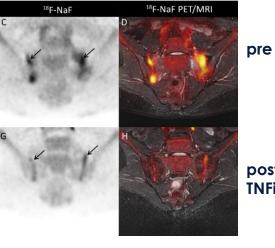


Patient 1



Patient 2

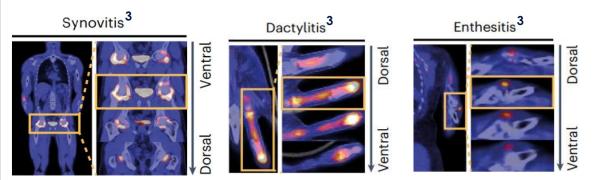
#### Treatment response<sup>2</sup>



#### post **TNFi**

#### P-OLARIS: Sonelokimab and PET-CT (FAPI) with MRI in patients with PsA

- Detects activated fibroblasts
- Measures inflammation in PsA and axSpA
- Marks inflammation in **multiple PsA** domains
- Good agreement with **clinical scores** & Tx success
- **Broad applicability** with/without structural changes



High-profile collaboration: Leading rheumatology/nuclear medicine physicians – incl. Georg Schett (TIME100 Health)

Ground-breaking science: Quantifying depth of tissue inflammation and reduction of inflammatory activity

**Brand-new insights:** Deeper understanding of Sonelokimab's impact on diseases beyond general clinical scores

1 Bruijnen S et al. Arthritis Research & Therapy, 2012; 14:R71; 2 Bruckmann NM et al. Arthritis Rheumatol, 2022; 74(9):1497-1505; 3 Rauber S et al. Nat Immunol, 2024; 25(4):682-692; Images reproduced with permission from the authors (footnote 2 and 3) or under a CC-BY licence (footnote 1; licensed under the Creative Commons CC-BY license (https://creativecommons.org/licenses/by/2.0/)); FAP, Fibroblast Activation Protein

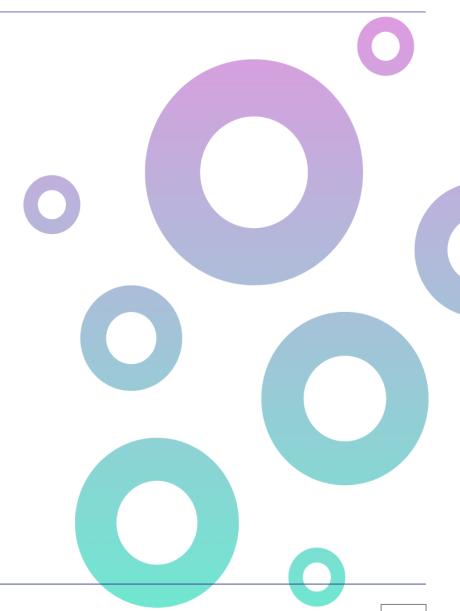
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## The commitment of MLTX to elevating care in inflammatory diseases



#### Our clinical development program

	INDICATION	PHASE	TRIAL NAME
Dermatology	Hidradenitis suppurativa	PHASE 3	VELA-1
	Hidradenitis suppurativa	PHASE 3	VELA-2
	Adolescent hidradenitis suppurativa	PHASE 3	VELA-TEEN
	Palmoplantar pustulosis	PHASE 2 LEDA	
	Psoriasis	PHASE 3 READY	
	Psoriatic arthritis	PHASE 3	IZAR-1
Rheumatology	Psoriatic arthritis	PHASE 3	IZAR-2
Rheum	Axial spondylarthritis	PHASE 2	S-OLARIS
	Psoriatic arthritis	PHASE 2	P-OLARIS



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# SLK

Differentiated, multi-indication blockbuster Jorge Santos da Silva, CEO





HS A franchise building indication





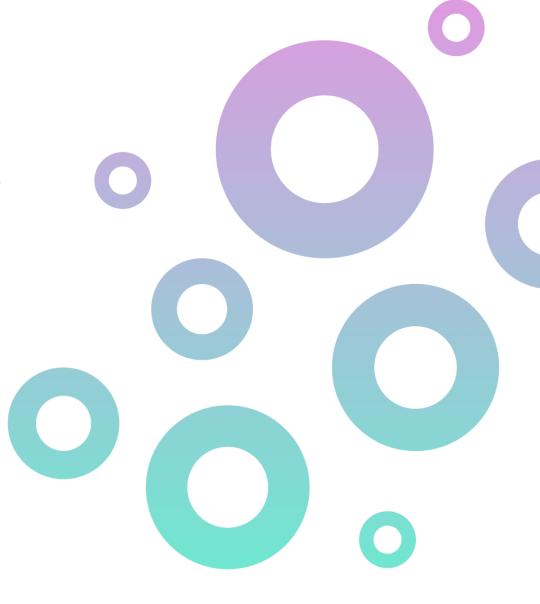
## HS: Three key questions we hear

- A) What makes us believe there is really an HS market?

  Cosentyx™ launch successfully driving excitement & understanding of size (10-15bn), Bimzelx™ following suit
- B Why is market large?

  Unequivocal evidence of a larger-than-expected prevalence (2%+), pricing and case for biologics use
- C How can MLTX win with SLK in HS?

  HS is not a winner-takes-all market, and provides unique commercial and access options to play



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## **HS:** Market is expected to growth to \$10bn+ by 2035



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

\$2bn+

\$10-15bn+

(1.7-2% prev / 8-10% biol)

# 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** 



Only ~50% of patients achieve HiSCR50 at wk 12

Limited durability of response (<15 m)



UCB expects HS market to reach \$5bn by 2029

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

**Key strategic focus** for Novartis



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

**Future** 

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. Biologics includes advanced therapies; 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



## HS: What needs to happen so view on market size keeps building



# Cosentyx™ US performance

- Launch without review delays on Nov 1st 2023
- Fast launch more patients in treatment, more patients biologics, new patients + switch patients
- Continued momentum post 6 months + KOLs continued excitement with IL-17A & F and SLK

# Cosentyx™ EU performance

- Similar trajectory to the US so far similar 50% NBRx in DE
- Competitive or better with biosimilars of ADA in new patients
- KOLs continued excitement with IL-17A & F and SLK

#### Bimzelx™ EU launch

- MA following CHMP positive opinion on Apr 22<sup>nd</sup> 2024
- Fast penetration in 2024 (also vs. Cosentyx™)
- Mix of new patients and switches from existing ones

# Bimzelx™ US approval

- Progression of sBLA process for launch in 2025
- Any delay that precludes launch in early 2025

#### From our side

- Build continuous market insights that will differentiate our play, via Komodo partnership
- "Broadcast" real and detailed insights to remain one step ahead of competitors
- Be ready to react to competitor statements (e.g., NVS Q1 news, UCBs prevalence statements)

ource: MoonLake Commercial © 2024 | Proprietary | MoonLake TX



## NVS expects **HS launch to drive Cosentyx** to \$7bn+ global sales



#### Cosentyx U.S. YoY quarterly revenue growth, %



#### Novartis earnings call takeaways

- "HS is the 2<sup>nd</sup> largest derm indication after PsO" – Vas Narasimhan, CEO NVS
- Potential for multi-bn market –
   opportunity to drive Cosentyx to a \$7bn
   drug (up from global \$5bn+ in FY 2023)
- Cosentyx financial outperformance primarily driven by HS launch: >60% NBRx in U.S. (and >50% NBRx in Germany)

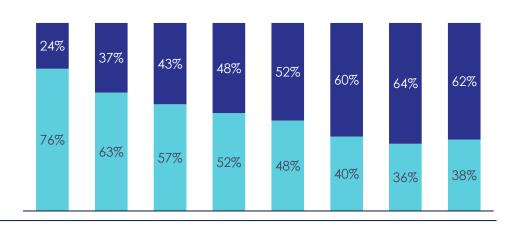


## High HS unmet need & disease severity enables Cosentyx uptake



#### Monthly patients in HS<sup>1</sup>, %





- Given high unmet need, disease severity and care gap in HS, new treatments are heavily anticipated
- Despite limited efficacy and ~8 years later to market, Cosentyx rapidly achieved >60% NBRx share in U.S.

# Total patients



Clinically differentiated and durable new treatment options have potential to achieve disease leadership in HS despite being later to market

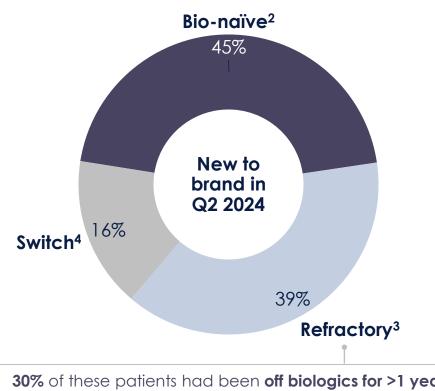
Note: Totals extrapolated based on ~75% avg. claims coverage rate; 1 Data cut-off date: Jun 8, 2024; 2. Refers to "new to brand" patients



## A) Share of Cosentyx across all patient segments



#### Cosentyx new patients in HS by treatment experience<sup>1</sup>, %



30% of these patients had been off biologics for >1 year showing that Cosentyx is able to reactivate HS patients

- Cosentyx sizable bio-naïve share shows that **Humira's entrenched market position** as previously only approved biologic is coming under pressure
- High share of **refractory patients** further indicates unmet need with existing treatment options
- Share of switch patients show that patients and physicians rapidly consider new options

biologics for HS before; 3 Refers to patients with previous biologics exposure in HS that had a treatment break <3m; 4 Refers to patients with previous biologics exposure in HS that had a treatment break <3m



## Cosentyx patients keep growing for both new and total patients



#### Total Cosentyx patients per month in HS<sup>1</sup> (k)



- Continued increase of new and total patients for Cosentyx
- Despite initial bolus of TNF-experienced patients, no plateau in Cosentyx monthly patients treated
- More recent months likely still underestimated given collection lag in claims counts (not extrapolated for claims collection lag)

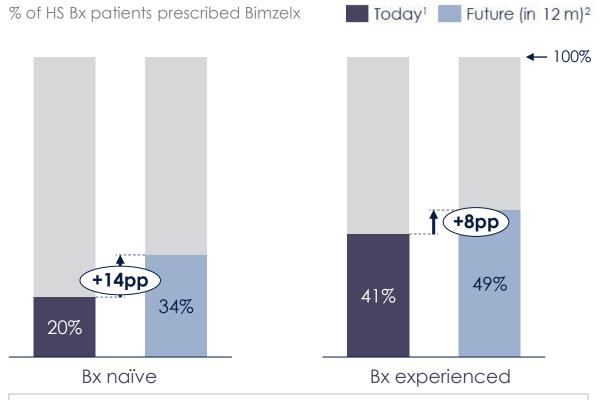


## EU market research shows high potential for BKZ and SLK





HCP survey: Bimzelx HS market share in Bx-naïve/experienced patients in Germany (N=30)



Even without launch experience, HCPs in the US are expecting to prescribe BKZ for ~28% of Bx-naïve patients and ~36% of Bx-experienced patients over the next 12 months

- Bimzelx<sup>™</sup> has rapidly captured a **meaningful**market share across Bx-naïve (20%) and Bxexperienced patients (41%)
  - Building on early momentum, HCPs expect to further increase prescriptions in highlighting:
    - Strong market growth in HS, as they become increasingly familiar with the drug
    - IL-17A/F as the winning MoA across most settings (incl. vs IL-17A)
    - Continued need for new options to adequately address disease burden
  - "~60% of my new patients will likely go to BKZ, although **BKZ** is not yet the gamechanger we need in HS" German top KOL

Source: Primary Market Research, Moonlake Commercial © 2024 | Proprietary | MoonLake TX

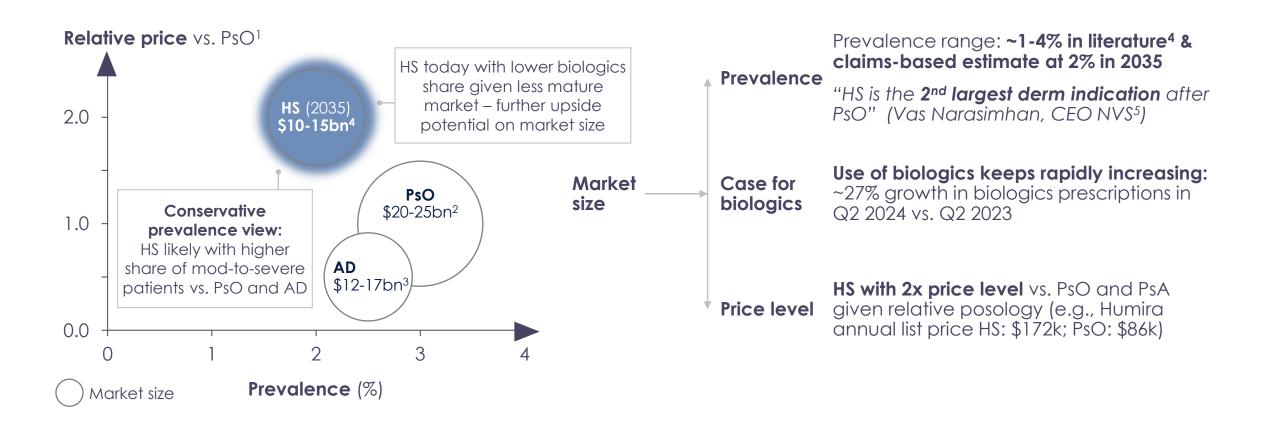
<sup>1.</sup> Considering responses to the question: Considering your last 10 moderate to severe HS patients, what proportion were treated with the following biologics? 2. Considering responses to the question: When treating moderate to severe HS patients in 12 months' time (i.e., end of 2025), what biologic are you most likely to choose?



## **HS:** Why is HS opportunity this large?



U.S. HS Biologics Market estimation in 2035





## Prevalence: New data confirms insights and continued growth



U.S. adult HS patients

**Key insights** 

Large existing prevalence:

Unique diagnosed & treated patients<sup>1</sup>

**Strong growth in new patients:**New diagnosed and treated patients (previously undiagnosed)<sup>2</sup>

**Strong growth in biologics treatment:** Biologics treated patients<sup>3</sup>

**Higher Biologics share** despite increased growth in new diagnoses: Share in Biologics treated patients

**From** (data as of **Q4 2023**)

**~2.0m** (Q4 2015-Q4 2023)

~260k

(in 2023)

~56k (CY 2023<sup>3</sup>)

~2.8% (CY 2023)

>

**To** (data as of **Q2 2024**)

+10%

~2.2m

(Q4 2015-Q2 2024)

+15%

~300k

(LTM Jun 2024)

+28%

~72k

(LTM Jun 2024<sup>3</sup>)

+18%

~3.3%

(LTM Jun 2024)



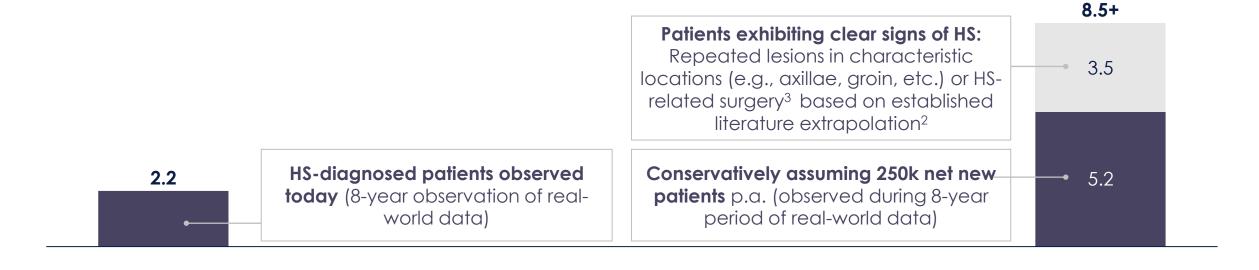
## **Prevalence:** ~5M+ diagnosed & treated patients expected in 2035



U.S. adult HS patients



Estimated
Diagnosed and
treated in 2035



% of U.S. adult patients

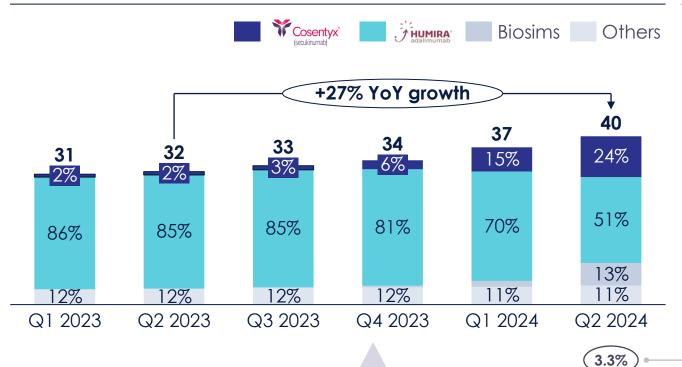
% of U.S. adult patients



## Bx-share: Share already increasing after Cosentyx launch



#### HS biologics patients in U.S. (k)<sup>1</sup>



Cosentyx approval

#### Key takeaway

- Cosentyx is expanding the market vs. just gaining share from Humira: script data shows marked increase vs. previous years
- Humira mainly losing share to biosimilars given recent coverage decisions (e.g., CVS)
- BKZ and SLK launches as next inflection points and catalysts for HS market growth

**Further upside potential:** Higher Biologics share in analogs (e.g., ~8-15% in PsO, PsA and axSpA<sup>1</sup>)

Note: Diagnosed & treated patients with HS diagnosis (ICD-10 L73.2); Applied ~75% coverage rate of U.S. claims; Applied claims collection lag extrapolation for last 6 months; Biologics includes advanced therapies; 1. 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

Biologics

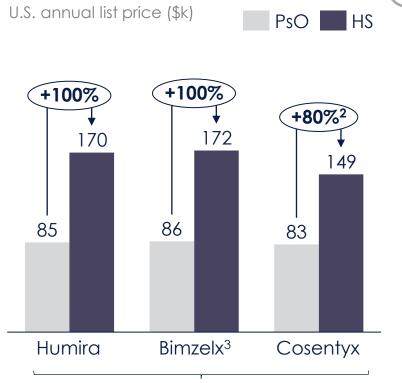
share



## Price level: HS with 2x price level vs. PsO given relative posology



HS list prices are substantially higher vs. PsO...



HS requires a higher dosing regimen vs. PsO

...driven by relative posology differences (maintenance dosing)

Dosing regimen	HUMIRA® adalimumab	Cosentyx° (secukinumab)	<b>Z</b> Bimzelx	SLK
PsO	<b>40</b> mg <b>Q2W</b>	300mg <b>Q4W</b> <sup>1</sup>	<b>320</b> mg <b>Q8W</b> (option to double for patients >120kg)	n.d. <sup>4</sup>
HS	<b>80</b> mg <b>Q2W</b>	<b>300</b> mg <b>Q4W</b> (option to double if inadequate response)	320mg Q2W / Q4W (trial arms)	<b>120</b> mg <b>Q4W</b>
Dosing in HS vs. PsO / PsA	~2x	~1.5x <sup>2</sup>	~2-3x <sup>3</sup>	~2x

<sup>1</sup> Option to give 150mg dose; 2 Assumes ~50% of patients will uptitrate based on clinical response; 3 Lower end: ~10% of PsO patients uptitrate & lower HS posology; Higher end: ~10% of PsO patient uptitrate & higher HS posology for ~50% of patients; 4 For reference: 60mg arm showed most favourable results in ARGO trials



## **HS:** How can we win with SLK in HS?



Facts
<ul> <li>HS market is sufficiently large to allow for multiple winners – top 4 drugs can average ~\$2-3bn+p.a. as seen in similar markets such as PsO</li> </ul>
<ul> <li>New entrants drive growth (e.g., 40% of PsO growth through Skyrizi™) – HS market rapidly growing with Cosentyx™ launch</li> </ul>
<ul> <li>Benefit-risk ratio matters in a severe, underserved market such as HS – even in PsO, later launches for assets with superior performance rapidly achieved market leadership</li> </ul>
• SLK has a clear profile to differentiate in HS by raising the bar and across outcomes, per KOLs
<ul> <li>HS favorable for access (vs. PsO) due to higher disease severity with irreversible damage and less competition / payer management</li> </ul>
<ul> <li>HS with a smaller Medicare share limits Part D reform exposure vs. most other portfolios and exhibits less exclusionary contracting</li> </ul>
<ul> <li>HS is highly concentrated (i.e., 12% of HCOs cover ~70% of Biologics patients within top 15 states), also driven by established HS "centers of excellence"</li> </ul>
<ul> <li>Targeted Go-To-Market approach sufficient to unlock SLK blockbuster status with Derms</li> </ul>

Potential for a highly differentiated, "gold standard" therapy in HS



## HS is no winner-takes-it-all market: Top 4 drugs can average \$2-3bn+ 🔘 MoonLake

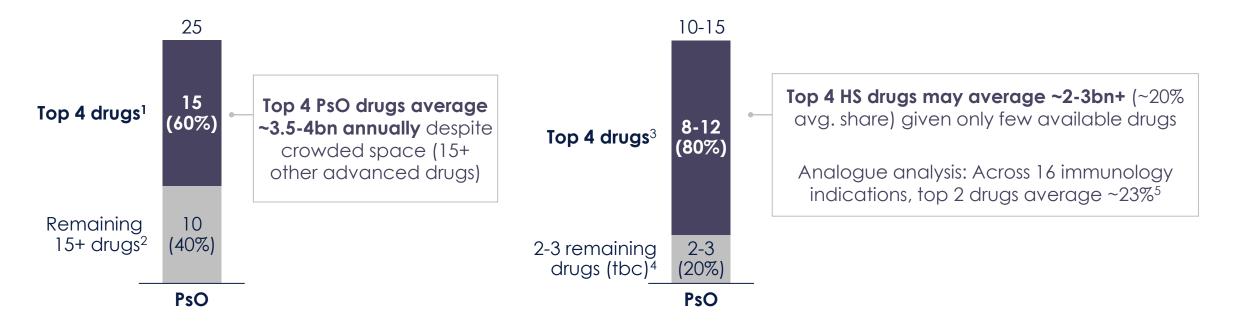


#### In crowded PsO, top 4 drugs average ~\$3.5-4bn annually

U.S. Market size in 2035, \$bn (% market share)

#### In much less crowded HS, top 4 drugs may easily capture ~80%+ of the market, averaging \$2-3bn annually

U.S. Market size in 2035, \$bn (% market share)



Given limited efficacy and durability of existing HS treatments, patients rapidly move on to new therapies (i.e., 11m median duration for Adalimumab), creating a market for multiple winner drugs

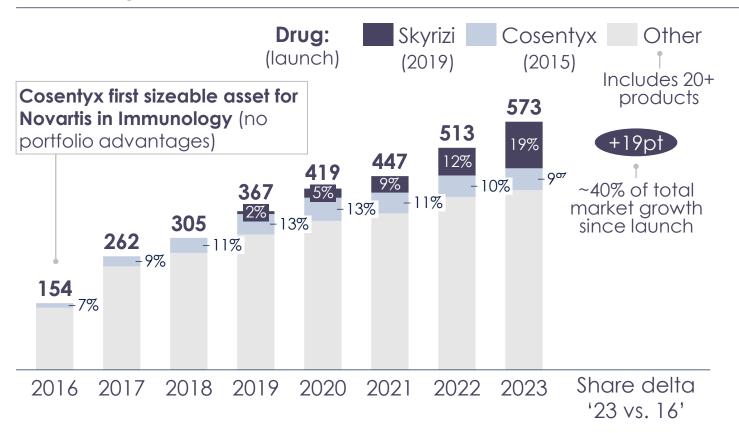
1. Includes Skyrizi and Humira; 2. Includes other approved biologics and targeted therapies (e.g., TNFs, IL12/23s, JAKs, etc.); 3. Assumed to include SLK and BKZ; 4. Subject to future approval; could include current Ph2 / Ph3 assets such as Rinvoq, Povorcitinib, Lutikizumab, etc.; 5. Considering DRG data from 16 Immunology indications: PsA, RA, Asthma, Moderate adult AD, Nr-axSpA, AS, CU, LN, SLE, PsO, COPD, Acute CD, Maintenance CD, Acute UC, Maintenance UC



### Efficacy matters: PsO shows clin differentiation wins vs. launch time



#### **PsO biologics patients** in U.S. (k)<sup>1</sup>



- Disease leadership despite later launch: Skyrizi and Cosentyx with ~30% share vs. 20+ biologics despite later launch
- Clinical differentiation matters most:
   Despite no broad immunology portfolio for NVS, Cosentyx overcame rebate walls with differentiated efficacy as BKZ is today (next page)
- New entrants are growing the market:
   Skyrizi accounts for 40% of total market growth

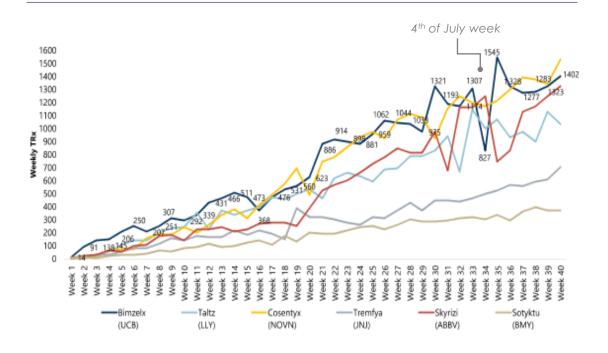
<sup>1.</sup> Patients with a biologics prescription in the respective year and a preceding PsO diagnosis;



## Efficacy matters: Bimzelx shows again that best efficacy wins in PsO



**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

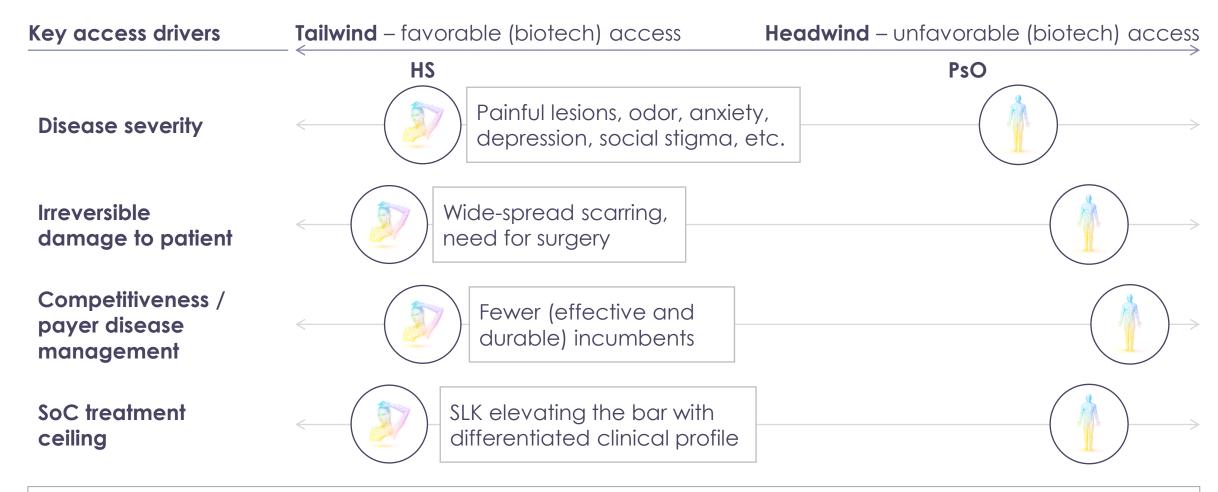
- SLK has shown leading responses at week 12 and week 24 across all relevant outcomes in HS (MIRA trial), incl. being the first to use HiSCR75 as primary endpoint, showing largest deltas to placebo in different HiSCRs, bringing one quarter of patients to inflammatory remission, demonstrating impact on tunnels etc.
- SLK shows leading responses across all relevant outcomes in PsA (ARGO trial) at week 12 and week 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, with share reaching ~35%<sup>2</sup>



Access: HS favorable for US access compared to other large derm





HS offers substantial tailwinds in market access – especially for Commercial channel, which represents the largest book of business

Source: MoonLake Commercial, Market research © 2024 | Proprietary | MoonLake TX

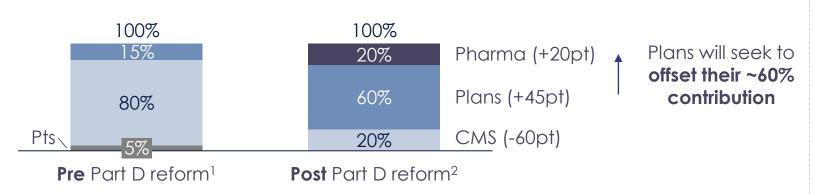


## Access: HS limits Part D reform exposure vs. most other portfolios



## Medicare profits are under intense pressure from IRA Part D reform as Pharma will have to bear ~20-50% of costs,...

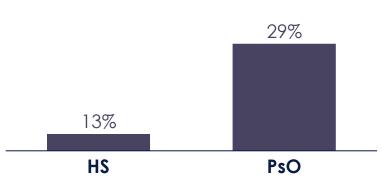
Contribution to drug cost, % of annual cost<sup>1,2</sup>



- Part D reform introduces ~20% direct Pharma contribution to annual drug cost<sup>2</sup>
- In addition, plans will seek to offset their ~60% contribution, e.g., through demand for rebates, increased step edits, etc.
- Assuming 50-50 contribution between Pharma and Plans, resulting in 30% additional contribution from Pharma

## ...making SLK an attractive asset to limit Part D reform exposure

Medicare volume, % of lives covered



SLK in HS with limited Medicare and Part
D reform exposure

<sup>1.</sup> Pre Part D reform: On annual drug cost in excess of ~\$7,400; 2. Post Part D reform: On annual drug cost in excess of \$2,000

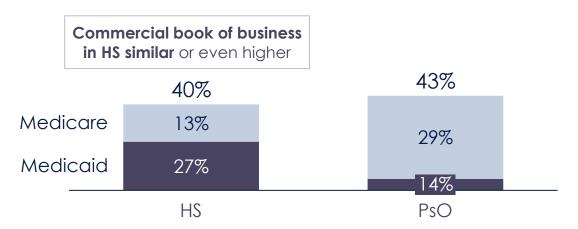


## Access: Higher Medicaid share exhibits less exclusionary contracting



#### Higher Medicaid share in HS vs. Medicare...

% of covered U.S. lives



- HS with higher Medicaid share commercial share similar to U.S. lives covered
- Similar to Commercial (managed by Commercial PBMs/ payers) – similar process and stakeholders

## ...and exhibits less exclusionary contracting vs. Medicare (based on PsO analog)

% of covered U.S. lives based on PA criteria in PsO

#### % covering multiple IL17s in PsO:



- Medicaid more frequently covers multiple drugs within a class (PsO: ~60% Medicaid lives covered have access to 3+ IL17 drugs vs. only ~3% in Medicare)
- Medicaid does not represent a GTN disadvantage for newly launched products (as long as rebate spread in Commercial is kept within reasonable bounds)

<sup>1.</sup> Limited impact from statutory 'best price' rebate as long as Commercial rebate variation is minimized; 2. Defined as covering ≥3 IL17 drugs carried on formulary

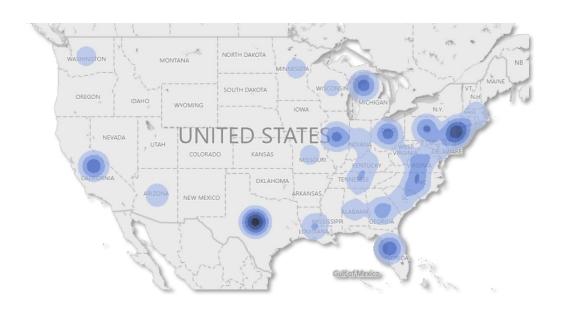


## Concentration: HS is a highly concentrated market with strong COEs



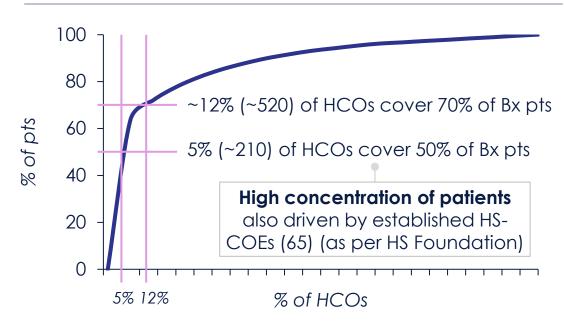
U.S. adult HS patients on biologics

#### Distribution by state



15 states in the U.S. cover ~70% of Biologics treated patients<sup>1</sup>

#### Distribution by HCO in top 15 states



12% of HCOs cover ~70% of Biologics patients<sup>1</sup> (within top 15 states)

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

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

### **HS:** Five ways in which **SLK can differentiate** from BimzelX®



# Earlier therapy

First molecule clinically tested in juvenile HS allowing earlier therapy in avoiding irreversible damage

# Elevated efficacy

Highest performance at elevated treatment goals, incl. HiSCR75, IHS4-100, plus key outcomes for patients

### Leading benefit-risk ratio

Rapid onset, durable response Nanobody® with safety profile of traditional IL-17s

# Improved convenience

Faster, lower volume, monthly Nanobody® injections vs. biweekly/high volume

Unique mode of action

Leading IL-17A & Finhibitor with unique Nanobody® binding and functional properties

Source: MoonLake Corporate © 2024 | Proprietary | MoonLake TX

# SLK is a **strong contender** to be the #1 drug in HS



Life-limiting disease with 2M US prevalence	Prevalent (~2M US) inflammatory disease with very life-limiting, painful deep dermal lesions — yet, very few Tx options with limited efficacy	Setting out the problem		
SLK elevates bar on HiSCR 75 and beyond	SLK as convenient, monthly biologic allowing rapid and unprecedented levels of clinical response, at high threshold endpoints such as HiSCR 75 (delta to PBO at w12 29% vs. at w16 BKZ 18% & SEC xx%) and beyond	Why SLK is the answer		
Nanobody advantage esp. in deep dermal lesions	Unique combination of small, albumin-binding Nanobody with high affinity and proven IL-17A+F MoA — <b>targeting inflammatory drivers: deep dermal lesions</b> (at w24 complete resolution of abscesses ~70% & tunnels ~50%)	Reason to believe		HS (adult)
Life-changing pain reduction	Patients report life-changing pain reduction (1 out of 3 achieves NRS50 at w12), symptom resolution and QoL improvement, while derms can rely on its familiar, trusted safety profile as an IL-17	Were impact really matters		
Inflammatory remission as new ambition in HS	Elevates the ambition to inflammatory remission (1 out of 4 achieves IHS4-100 at w24), giving patients hope for a future where life is not limited by HS	Outlook	Σ	



PsA
Leading the pack in Rheum



### PsA: Reasons to believe that MTLX can win with SLK in Rheum



- Breaking the treatment level
- IL-17 A&F have the potential to elevate the treatment level across domains well-positioned for leadership across entire PsA population
- PsA landscape is fragmented and depends on HCP type and patient subgroups nevertheless, many successful blockbuster drugs emerge

2 IL-17 A&F is winning MoA

- With SLK 60%+ achieve MDA at week 24, plus other multi-domain scores (ARGO)
- Currently, IL-17 and IL-23 making substantial inroads in PsA US claims show 23% IL-17 and 25% IL-23 use making the way for further success with IL-17 A&F
- Large market with high biologics use
- PsA is an established market with continued growth towards USD 10-15B in 2035
- US claims show 1.8m unique patients with an annual growth of 175k net new patients.
   Biologics share already at 15%, continuously increasing

- 4 Favorable characteristics
- PsA mirrors some similar market access characteristics like HS severe disease with irreversible damage, current SoC with treatment ceiling; competition is higher
- PsA is also a **concentrated market** (i.e., 15% of HCOs cover ~80% of patients) like HS

e: MoonLake Corporate © 2024 | Proprietary | MoonLake TX



## Breaking the treatment level – SLK is the next-gen treatment in PsA





2023 revenue  $(\$bn)^2$ 

### Treatment levels and positioning for existing products in PsA<sup>1</sup>

		Multi-domain focused		
Orals	TNFs & JAKs	IL-12 & IL-23	IL-17A only	Next gen drugs (IL-17 A&F)
ACR20	ACR50	PsA PASI100	ACR50 + PASI90	ACR (50, 70) + PASI 100
				MDA
~\$1bn	\$3bn+	\$1.5bn+	\$1.5bn+	Others
	Simponi * golimumab golimumab (Totalda) (Total	Stelara  Jistekini mab  Tremfya* (guselkumab)  Skyrizi* risankizumab-rzaa  Zingalan-t-pata	taltæ (ixekizumab)  **Cosentyx* (secukinumab)	SLK ZBimzelx
Otezla* (apremilast) 30mg	HUMIRA* RINVOQ:			
ORENCIA (abatacept)	Current SoC level			

- Historically, PsA treatments were singledomain focused – different products used for distinct patients (e.g., IBD, skin-mainly) and by different HCPs (e.g., IL-23 by derms)
- Given large PsA market size, most undifferentiated products reach \$1bn+ p.a.
- IL-17 A&F is developed to elevate the treatment ceiling across domains, wellpositioned for leadership across entire PsA
- Hence, SLK not directly competing with most PsA drugs (12+) that remain singledomain focused (more like 3-5 competitors)

<sup>1.</sup> Based on clinical efficacy and Commercial product positioning; 2 Class revenue based on MoonLake estimate of 2023 total market sales and 2023 patient share by class



# Market is split into **different segments** – IL-17A & F can lead in all



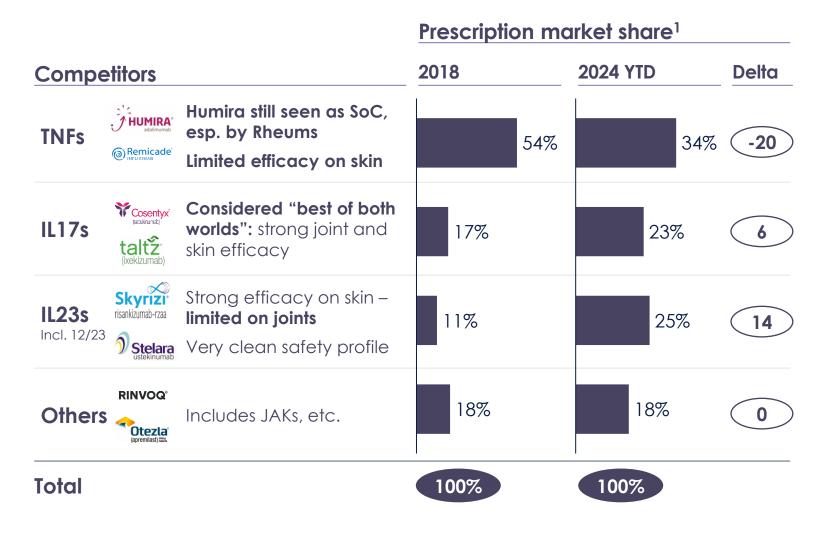
Currently favored drug by HCPs		Currently fo	avored drug by patient niche	
Rheums:	Remicade Simponi golimumab dalimumab	Joint & skin	talta (ixekizumab) **Cosentyx* (secukinumab)	Given differentiated
	talt2° (ixekizumab) Cosentyx° (secukinumab)	Skin	Skyrizi- risankizumab-rzaa -brugdilbrid spekton  Skyrizi- (guselkumab)	clinical profile across domains, SLK well-positioned to achieve PsA
Derms:	Skyrizi risankizumab-rzaa risankizumab-rzaa risankizumab-rzaa	Orals	Otezla (apremilast) ilmen. XELJANZ (tofacitinib) (tofacitinib) (ang talete	leadership across HCPs and patient niche
	talta (ixekizumab) Cosentyx (secukinumab)	IBD	Skyrizi- risankizumab-rzaa risankizumab-rzaa risankizumab-rzaa	

Even in these niches, products can generate blockbuster sales given overall PsA market size



# Shares keep moving to **innovative drugs** in this competitive market





- TNFs lose share to newer products (JAKs and others largely flat)
- IL-23s with strongest growth, despite limited clinical differentiation (e.g., ACR data)
- Goal to break treatment ceiling and shift expectations to disease remission (e.g., MDA) and higher treatment outcomes (e.g., ACR70)
- Opportunity to generate
   additional evidence to support
   IL17 A&F as "best of all worlds"

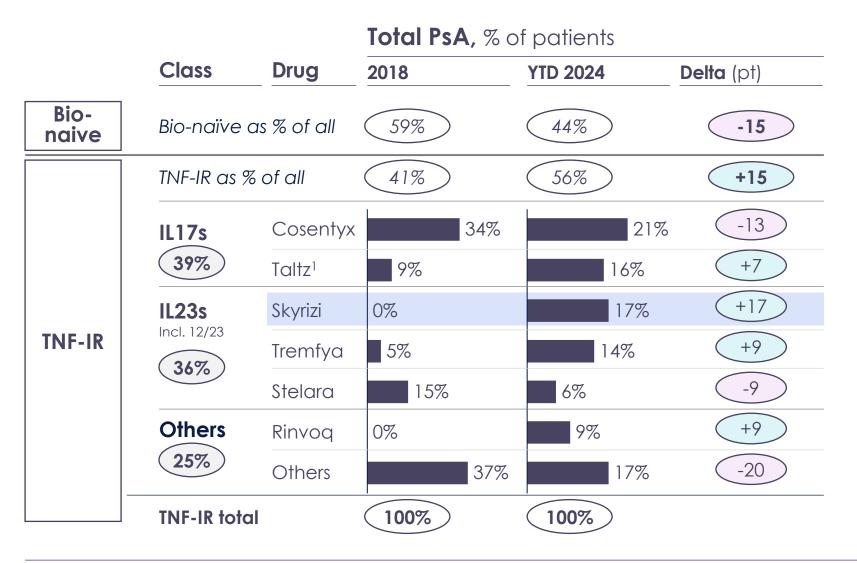
<sup>1.</sup> Based on Komodo claims data: Includes patients with a prescription of the respective drug in 2022 AND a PsA diagnosis in 2015-2022



# SLK could make strong inroads in post-TNF setting to start







- TNF-IR population growing in importance
  - Most patients (56%) have already failed on a TNF
  - TNFs expected to retain strong adoption in bionaïve patients given access and long-standing clinical experience
- Skyrizi and IL-23s with strongest share expansion in post-TNF setting
- SLK with opportunity to make strong inroads in post-TNF setting given clinical differentiation as nanobody

<sup>1.</sup> Includes Infliximab, Golimumab and TNF biosimilars; 2. Includes Abatacept, Kanakinumab, etc.



## PsA sizable market can be confirmed with US claims data



### Claims methodology

 Source are unique U.S. patients from prescription claims data

 ~75% coverage rate of US claims

 Diagnosed & treated patients with PsA diagnosis (ICD-10 L40.5) Key insights (extrapolated to 100% of U.S. population)

~1.8m Unique patients diagnosed and treated in Q4 2015-Q2 2024<sup>1</sup>

 $(\Rightarrow)$ 

**Confirms** large existing PsA population

~175k New diagnosed & treated patients every year (previously undiagnosed)<sup>2</sup> in Q3 2023 – Q2 2024

 $\Rightarrow$ 

Confirms underdiagnosis & future growth potential

~275k Biologics treated patients in Q3 2023 – Q2 2024<sup>3</sup>

+38%

+13%

**Confirms** todays already substantial Bx market size estimate

~15% Biologics share in Q3 2023 - Q2 20244

+2ppt

**Tower Proof of Section 2016-2023** Growth p.a. in Biologics-treated patients in 2016-2023<sup>5</sup>

 $\Rightarrow$ 

Confirms high unmet need & Bx market growth potential

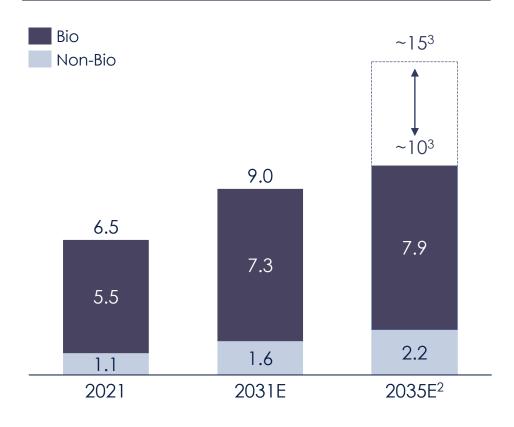


# PsA to be a ~\$15bn market in 2035



U.S. HS Biologics Market estimation in 2035

### PsA offers multi-bn adjacent Rheum opportunity in mature market



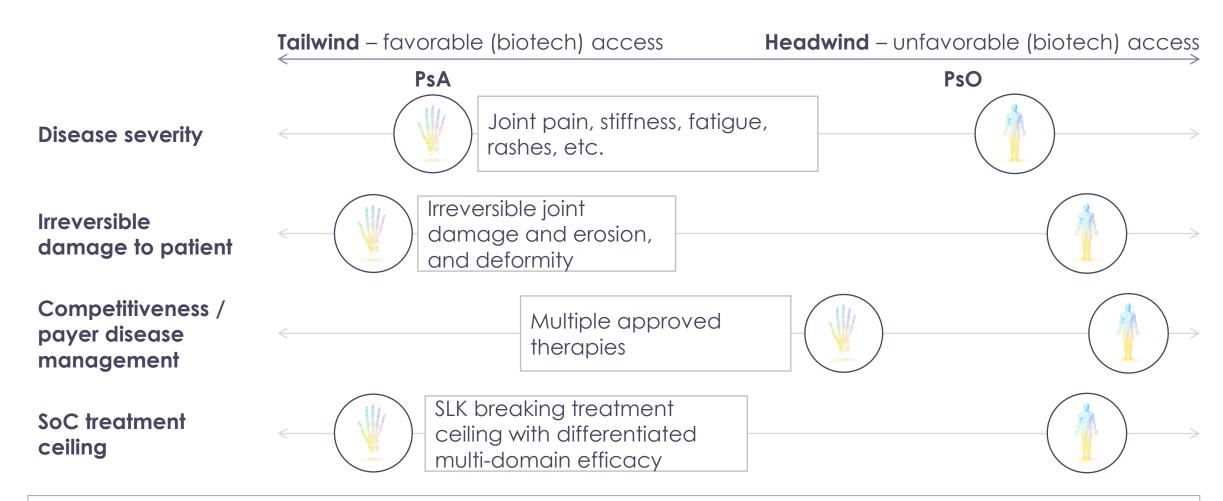
#### Key takeaways

- Multi-bn revenue opportunity for the 2-3 most differentiated molecules in a ~\$10-15bn market
- SLK elevating the treatment ceiling across domains hence, wellpositioned to become major drug in PsA
- All-analysts-average places SLK sales for PsA above blockbuster **level** (despite only assigning modest market share of ~1-15%)
- What we **need to see happening** next:
  - Good BKZ uptake (similar to PsO), incl. erosion of IL-23
  - Continuous move from ACR or PASI, to composites as the measure of success in PsA
- Good SLK transition from ARGO to Phase 3



### While more competitive, PsA has favorable access drivers





**PsA offers many of the same tailwinds in market access** as in HS given severe and progressive disease and significant unmet need to break the treatment ceiling

Moonlake Commercial, Market research



# Unlike PsO, PsA is also a highly concentrated market



#### **Biologics patient concentration** (% of biologics patients treated by top 1,000 HCPs in 2023)

% of HS Bx patients



- HS and PsA more concentrated vs. PsO, enabling successful commercialization with lean and targeted field setup
- **Higher HS concentration:** Likely driven by more specialized treatment landscape (i.e., HS Foundation Centers of Excellence)
- Higher PsA concentration: Rheums landscape more concentrated, increasing concentration vs. derm-only indications

Targeted Go-To-Market approach enables unlocking SLK opportunity forecast in concentrated PsA landscape

# Expectations for IZAR outcomes – Clearly differentiated profile in PsA



			abla abla	
Multi-domain disease – 75% do not reach MDA	Multidomain disease, with IL-17 favored for efficacy across all domains — yet 'treatment ceiling' remains: 75%+ patients do not reach MDA within 6 m <sup>1</sup>	Setting out the problem		
SLK with unprecedented response across domains	SLK produces unprecedented levels of clinical response in joints (ACR50: SLK 61% vs. BKZ 45% at w24) and multidomain, higher threshold endpoints (MDA: SLK 60% at w24 vs. RIS 25% at w24 & BKZ 25% at w16²), demonstrating differentiated efficacy across domains	Why SLK is the answer	6(	
Nanobody advantage across all domains	Unique combination of small, albumin-binding Nanobody with high affinity and proven IL-17A+F MoA — targeting psoriatic inflammation across domains, incl. difficult-to-access, poorly vascularized sites (i.e., nails)	Reason to believe	0 seconds	PsA
Rapid & durable response with disease modification	Rapid & durable responses, with disease modification (no radiographic progression) and familiar, trusted safety profile as an IL-17	Were impact really matters		
SLK breaks the treatment ceiling	Option for HCPs to break 'treatment ceiling' for the first time, with unprecedented efficacy levels across all domains and in diverse range of patients	Outlook	Ž	

1. Data from the CorEvitas registry (N=1,251); Ogdie et al. ACR 2021;abstract 1344; 2, ACR70+PASI100: SLK 48% at w24

Source: MoonLake Medical Affairs; Clinical trials © 2024 | Proprietary | MoonLake TX

## Our strategic imperatives



#### *Imperative*



# Build the HS market story

HS is a \$10-15bn+ market with high unmet need

Not "winner-takes-all"

Single asset, single category is a winning play

Elevating the bar allows for diff vs Bime into 2027



# Move PsA market to next level

Efficacy across tissues is winning play (comps, MDA)

No drug addresses multidomain as SLK, even vs BKZ

Not "winner-takes-all" \$1015bn+ market

We can dislodge incumbents



# Unlock potential beyond HS & PsA

\$bn opportunities

"Turning cards" on PPP & axSpA helps investors

Adol HS & PsA further differentiate label

BD can be option in future



# Compete with excellence

MLTX can execute big trial program in parallel success in VELA & IZAR Company creates a compelling Access story MLTX has path to become a "real" co.

85

We are not doing this in a void – NVS, UCB and others are "rowing in the same direction"

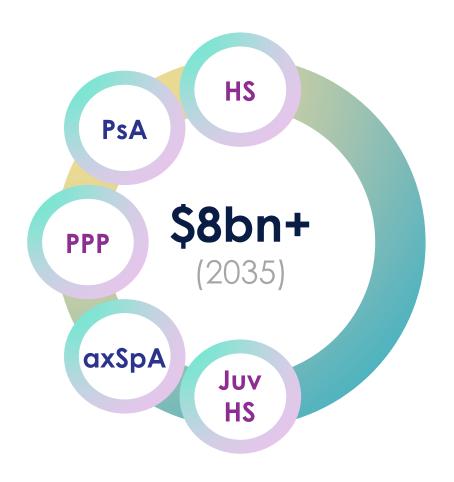


# Moving Forward Matthias Bodenstedt, CFO



### We continue to build out the potential of SLK





MoonLake continues to address the most pressing unmet needs in inflammatory diseases, incl. HS and PsA – estimated >USD 5bn in potential value)

The new indications could result in additional **USD 3Bn+ value**, continuing to push the potential of SLK as a leading therapy in inflammation

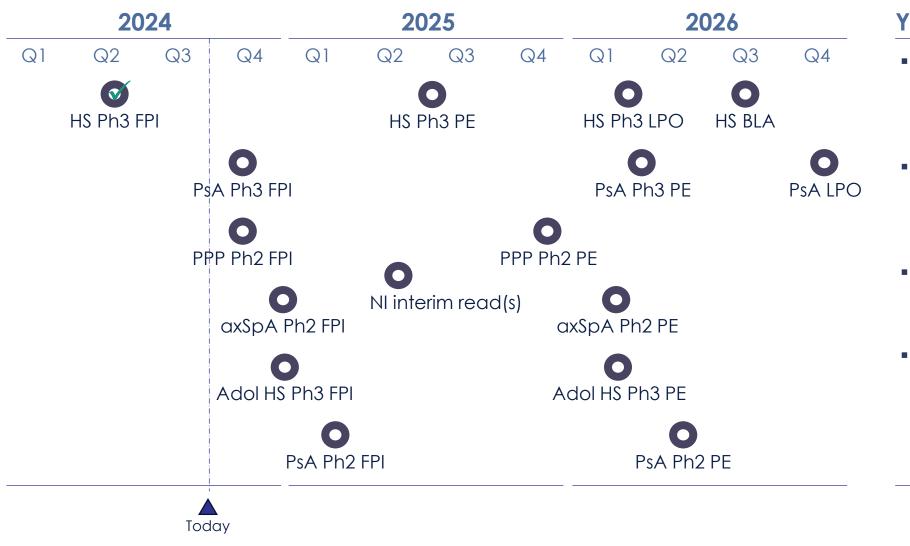
Risk profile of company remains similar as **data supports portfolio expansion** and operations can be scaled up from current structure

MLTX financed to support development plan

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# Expected timeline of important catalysts for MTLX



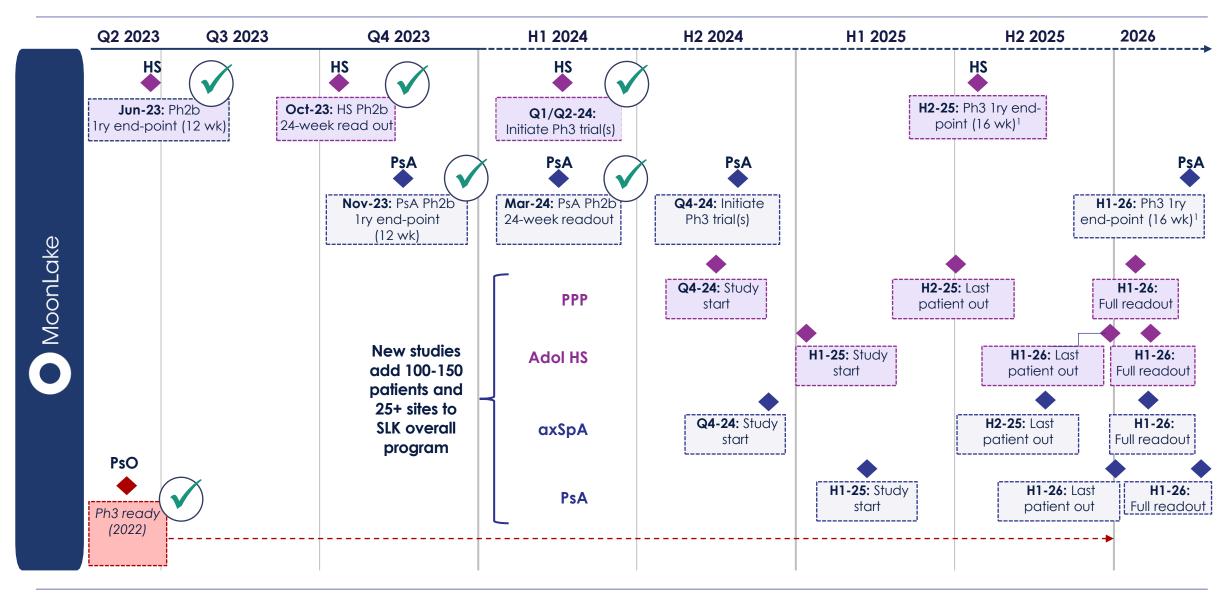


### Year-by-year view

- 2024 continues to be "execution time" with Phase 3, new Indications and BLA ramp-ups
- 2025 is "heavy on data" (incl. PE HS), moving to "next chapter on runway" and getting on with Access
- 2026 is also heavy on data, and "focus is on BLA" and field ramp up
- Over time, we will continue considering options for portfolio and MLTX with
   2027 focused on launch

### Data catalyst calendar for MLTX in 2024-25





<sup>1</sup> Assuming current Phase 3 planning is agreed with regulators – End of Phase 2 meeting on May 6<sup>th</sup> 2024 with the FDA, EMA input and feedback expected in parallel (+/- 6 months)

Source: MoonLake Clinical

# Balance sheet provides expected cash runway to at least end 2026



# Cash, cash equivalents and marketable debt securities in USD M



# Operating expenses per quarter in USD M



### **Key notes**

- Increasing R&D spend in line with expectations:
  - HS VELA program running at "full steam"
  - Initiation of PsA IZAR and Adol. HS programs will add additional expense
  - Continued growth in team size
  - Additional study work (PPP, axSpA, etc.)
     commenced as per plan
- Stable G&A expenses, as expected
- MLTX burn rate continues to be lean and closely controlled in the context of the broader Biotech space
- Guidance: at least 18 months of cash from primary endpoint of VELA
- Inflection points expected on data readouts through 2025 (main readout is primary endpoint of VELA)

### MLTX extensively covered & active at investor and scientific events



**Price Target** 

104

100

#### Select investor events



11 September Capital Markets Update



**18-19 September** New York





Investor lunch

STIFEL

**17-18 September** Virtual

Jefferies
19-21 November
London



**9 December**IR Peer meeting

#### Scientific meetings & presentations



**4-7 September** Lisbon



13 September Investigator meeting PPP



**25-28 September** Amsterdam



**12-14 November** Boston



ACR 2024

**14-19 November** Washington DC

**1-3 November** Austin, TX

WEDBUSH	Outperform	92	
<b>CANTOR</b> Pitagerald	Overweight	n/a	
GUGGENHEIM	Buy	80	
LIFESCI CAPITAL	Outperform	75	
LEERINK : PARTNERS	Outperform	73	
cîti	В∪у	72	
COWEN	Outperform	n/a	
₽BTIG	Outperform	71	
STIFEL	Виу	69	
Jefferies	В∪у	65	
Goldman Sachs	Neutral	62	
Needham	Виу	62	
W <sup>9</sup> LFE RESEARCH	Peer perform	n/a	
<b>*</b> BARCLAYS	Equal weight / pos.	55	
Bryan, Garnier & Co	Neutral	401	
An	Analyst average		

Rating

Buy

Outperform

**Analyst** 

PPENHEIMER

**M** HCW

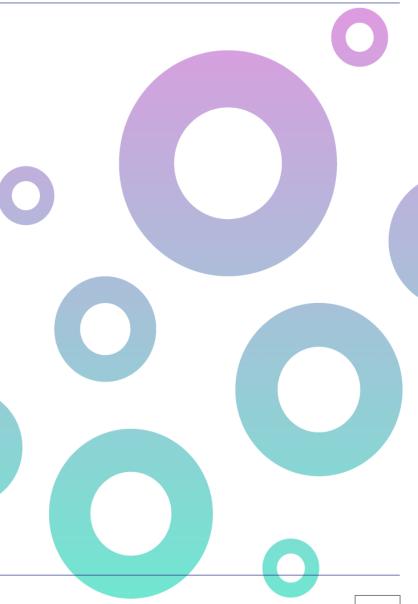
1 Excluded from average as not updated since November 2023

Source: MoonLake (last udate: September 7, 2024) © 2024 | Proprietary | MoonLake TX

# Closing remarks



- It is all about execution in 2024, so we set-up readouts well for 2025
- Our focus is and will keep being on bringing sonelokimab further in multiple indications in late-stage development
- We foresee no partnerships in the next months we do not need the cash and we see it as a distraction
- We continue to be the best steward to guide SLK through development
- The team is now in place to deliver, and any significant organizational growth will only come after the VELA primary endpoint readout
- Further guidance post our presence during JPM 2025





Q&A MLTX Management





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