



# MoonLake Immunotherapeutics

R&D Day

San Diego, during AAD

March 10<sup>th</sup> 2024

## Logistics

**Date:** March 10th, 2024

**Time:** 09.00-11:30 PST

**Location:** Westin San Diego Bayview  
(Webcast also available)



## Agenda

Topic	Sub-topics	Speaker	Timing
<b>Introduction</b>	- Welcome & session details	Matthias Bodenstedt	5 mins
<b>PsA</b> <i>Going beyond in Rheumatology</i>	- PsA, a multi-domain challenge - SLK in a competitive context - ARGO data read-out (24 weeks) - Next steps on Ph 3 program	Prof. Joseph Merola Kristian Reich	40 mins
<b>HS</b> <i>A franchise building indication in Derm</i>	- HS, a devastating disease - The MIRA data in context - Regulatory feedback & Ph 3 program - Market size & potential	Prof. Ken Gordon Kristian Reich Jorge Santos da Silva	40 mins
<b>New frontiers for SLK and MLTX</b>	- Unlocking the value of SLK - New Indications - Path forward catalysts 2024/2025	Jorge Santos da Silva	20 mins
<b>Moving Forward</b>	- Financials & next steps - Next steps for MLTX	Matthias Bodenstedt	5 mins
<b>Q&amp;A session</b>			To end

## Forward Looking Statements

Certain statements in this presentation may constitute “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding our expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: plans for preclinical studies, clinical trials and research and development programs; the anticipated timing of the results from those studies and trials; potential market opportunities, estimates of market size, and estimates of market growth; potential indications; the timing of regulatory meetings; the occurrence and timing of market engagement; expectations regarding the time period over which our capital resources will be sufficient to fund our anticipated operations; the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts; and effects on liquidity and capital resources, including cash position. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “might”, “plan”, “possible”, “potential”, “predict”, “project”, “should”, “strive”, “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that such statement is not forward looking. Forward-looking statements are based on current expectations and assumptions that, while we and our management consider reasonable, as the case may be, are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management’s control including general economic conditions and other risks, uncertainties and factors set forth in the section entitled “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in our Annual Report on Form 10-K that was filed with the U.S. Securities and Exchange Commission (the “SEC”) on February 29, 2024, as well as factors associated with companies, such as MoonLake Immunotherapeutics, that operate in the biopharma industry. Nothing in this presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this presentation, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. We neither undertake nor accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in our expectations or in the events, conditions or circumstances on which any such statement is based. This presentation does not purport to summarize all of the conditions, risks and other attributes of MoonLake Immunotherapeutics.

## Industry and Market Data

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

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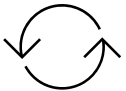
## Instructions for this session



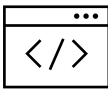
Please **take note of the disclaimer** on the previous page



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



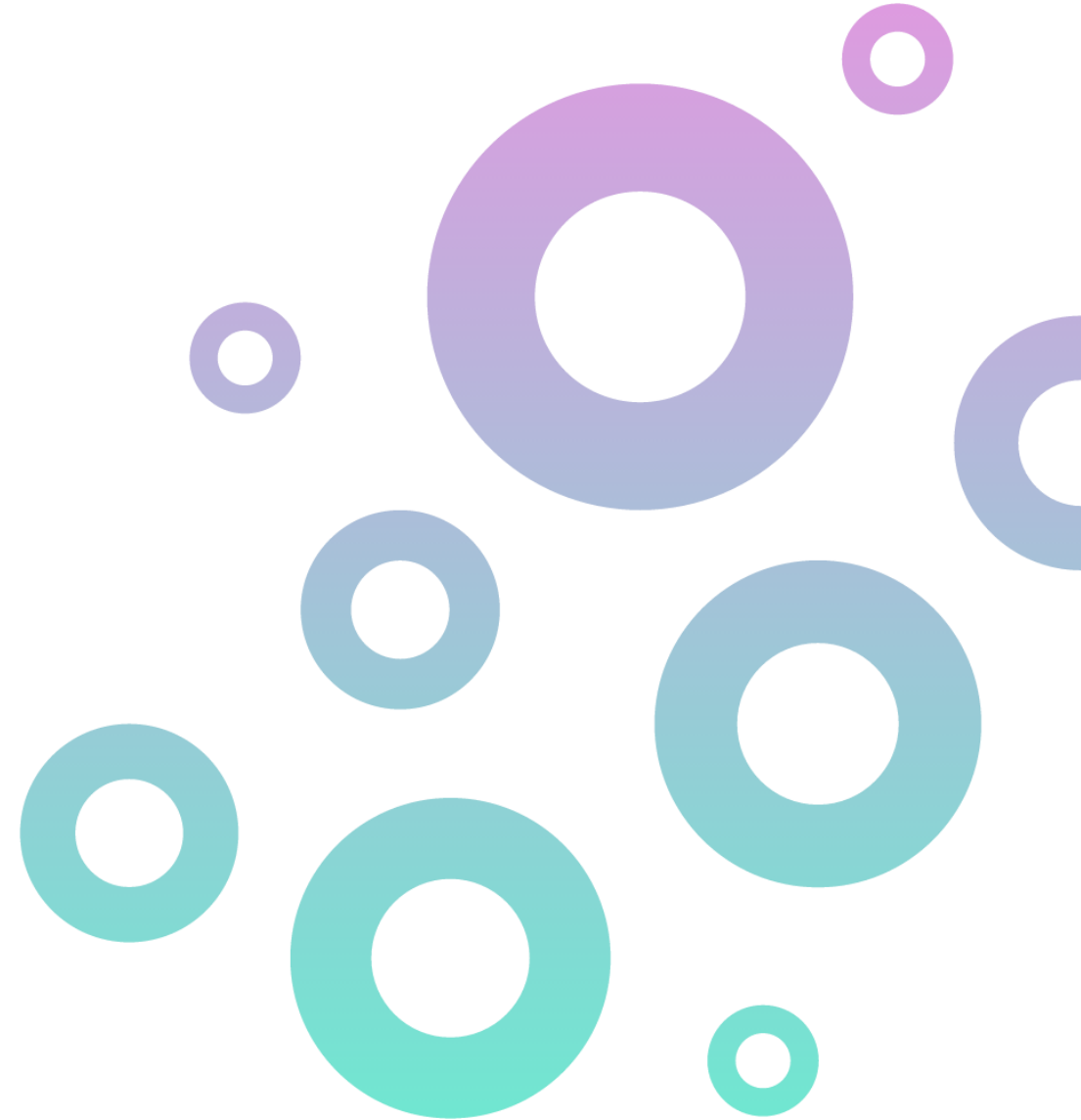
**The presentation** and a **replay** will be made available on our IR website



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



**Other requests** should be directed to [ir@moonlaketx.com](mailto:ir@moonlaketx.com) or [media@moonlaketx.com](mailto:media@moonlaketx.com)

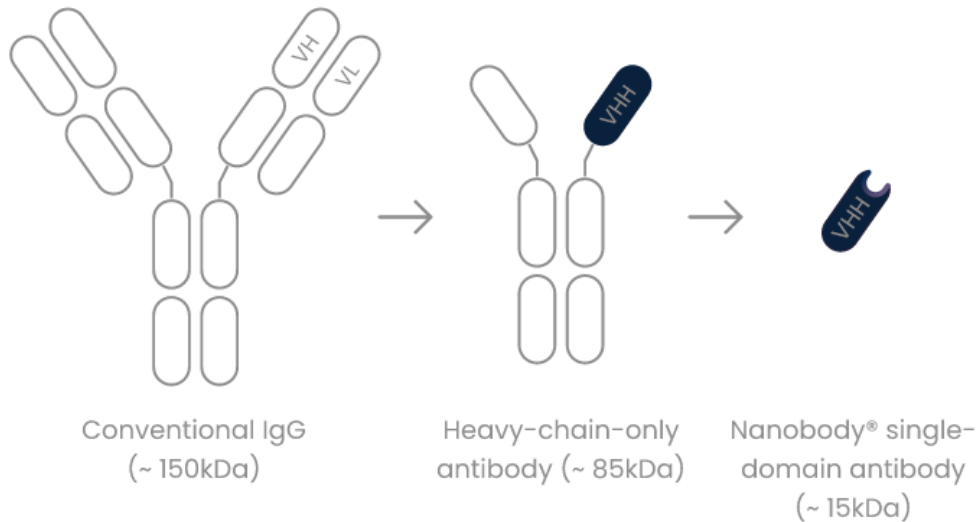


- **Founded in 2021** in Switzerland
- **Nanobody® technology** licensed in initial private round
- **Unique molecule with sonelokimab**, tri-specific IL-17A & IL-17F Nanobody® to elevate treatment in inflammation in a **\$40bn+ market**
- **Public on Nasdaq** since April 2022 and **~\$750m raised**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

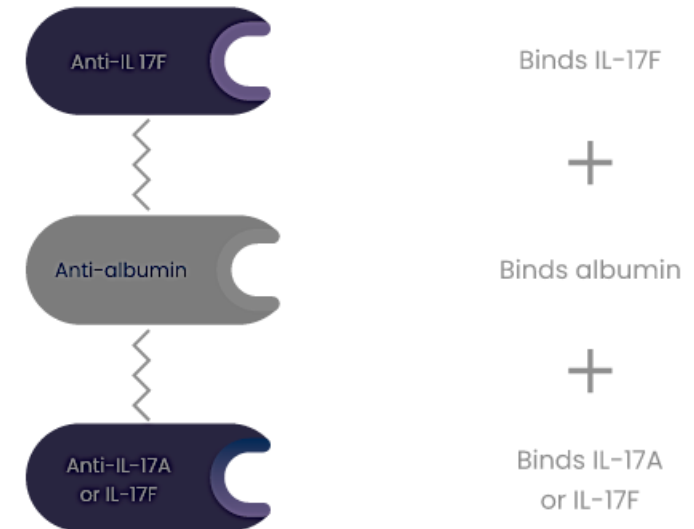


# A differentiated molecule – Do you still Antibody?

Nanobodies® are much smaller than traditional antibodies



They can be designed to have multiple and different binding domains



## IL-17A & IL-17F

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

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

Subcutaneous administration, Q4W

# It's all about the dimers

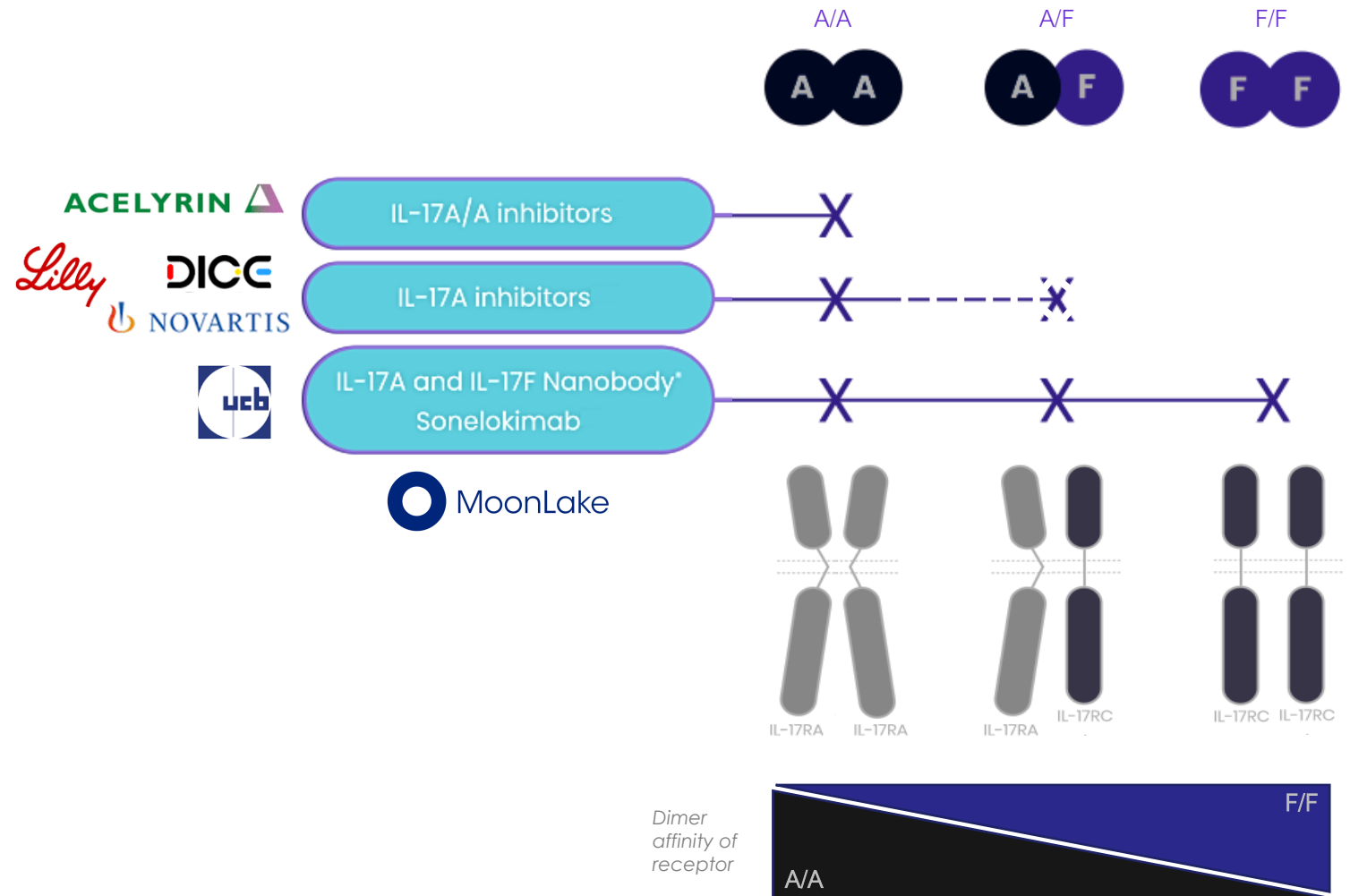
*Illustrative*

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**



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

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

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



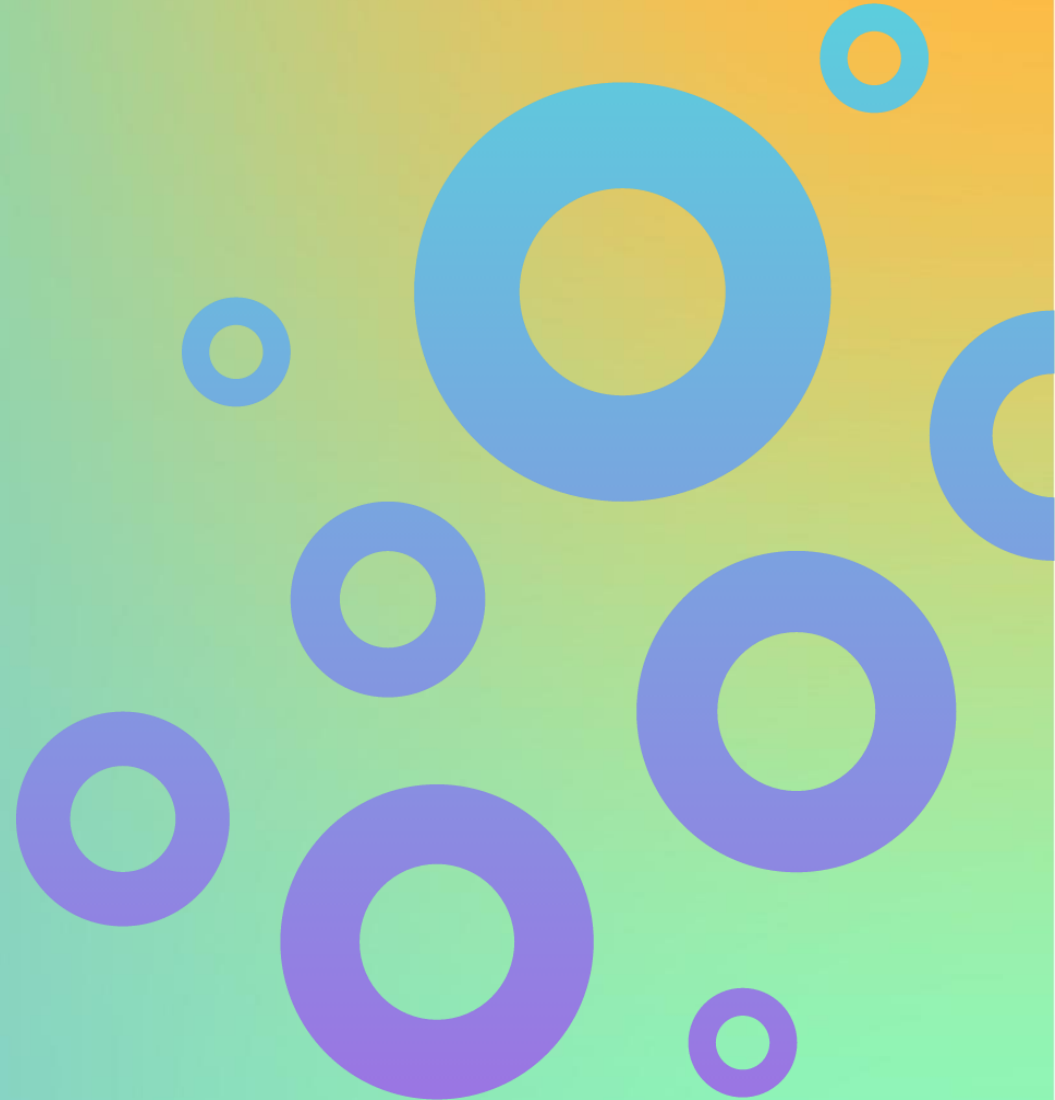


# PsA

*Going beyond in Rheumatology*

# PsA – A multidomain challenge

Prof. Joseph F. Merola

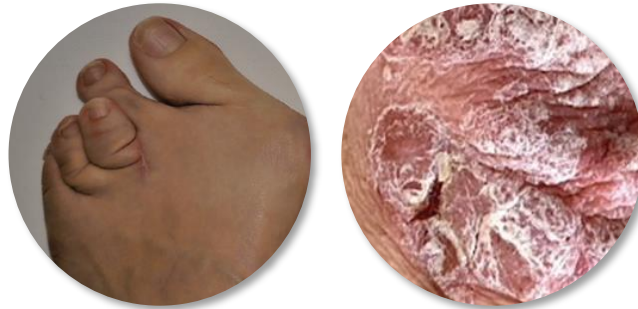


**Prof. Merola is a consultant and/or investigator for** Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, AbbVie, Eli Lilly, Novartis, Janssen, UCB, Sanofi, Regeneron, Sun Pharma, Biogen, Pfizer, MoonLake Immunotherapeutics

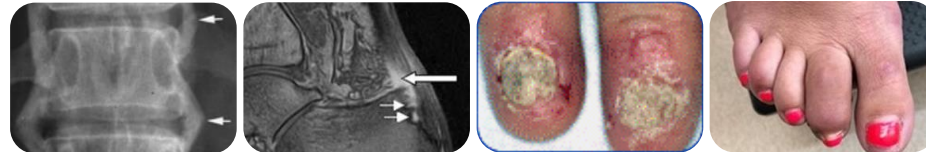
## PsA is a multidomain disease

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>**



## 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



### ACR + PASI Response in joints + skin



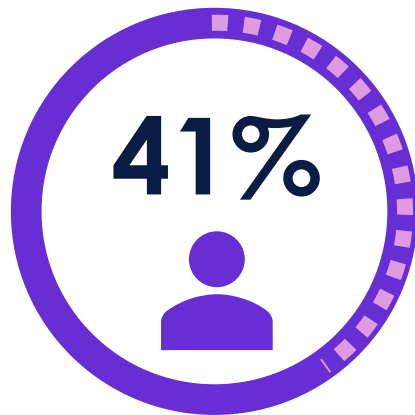
**Can we elevate to ACR70 + PASI 100?**

<sup>1</sup> Coates et al Nat Rev Rheumatol 2022;18:465–479 | Dactylitis and nai/skin images courtesy of Prof. Joseph F. Merola and Prof. Kristian Reich, respectively (please do not reproduce) | Other images reproduced (CC-BY licenses) from Mochizuki et al Case Rep Rheumatol 2018;2018:4216938, Jurik Insights Imaging 2011;2:177–191, McQueen et al Arthritis Res Ther 2006;8:207      <sup>2</sup> Gossec et al J Rheumatol 2018;45:6–13

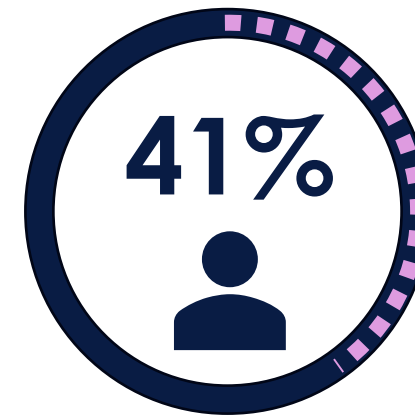
## PsA is common

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

## However, PsA is often underdiagnosed or undertreated



**~2 in 5 patients with PsA were underdiagnosed**  
in the PREPARE non-interventional study<sup>4</sup>



**~2 in 5 patients diagnosed with PsA are not on biologics**  
in a recent international survey<sup>5</sup>

★ **New research at AAD 2024**

Among surveyed US patients with PSO:

**41%** already had joint symptoms, but in most cases had not discussed treating these symptoms with their doctor<sup>6</sup>

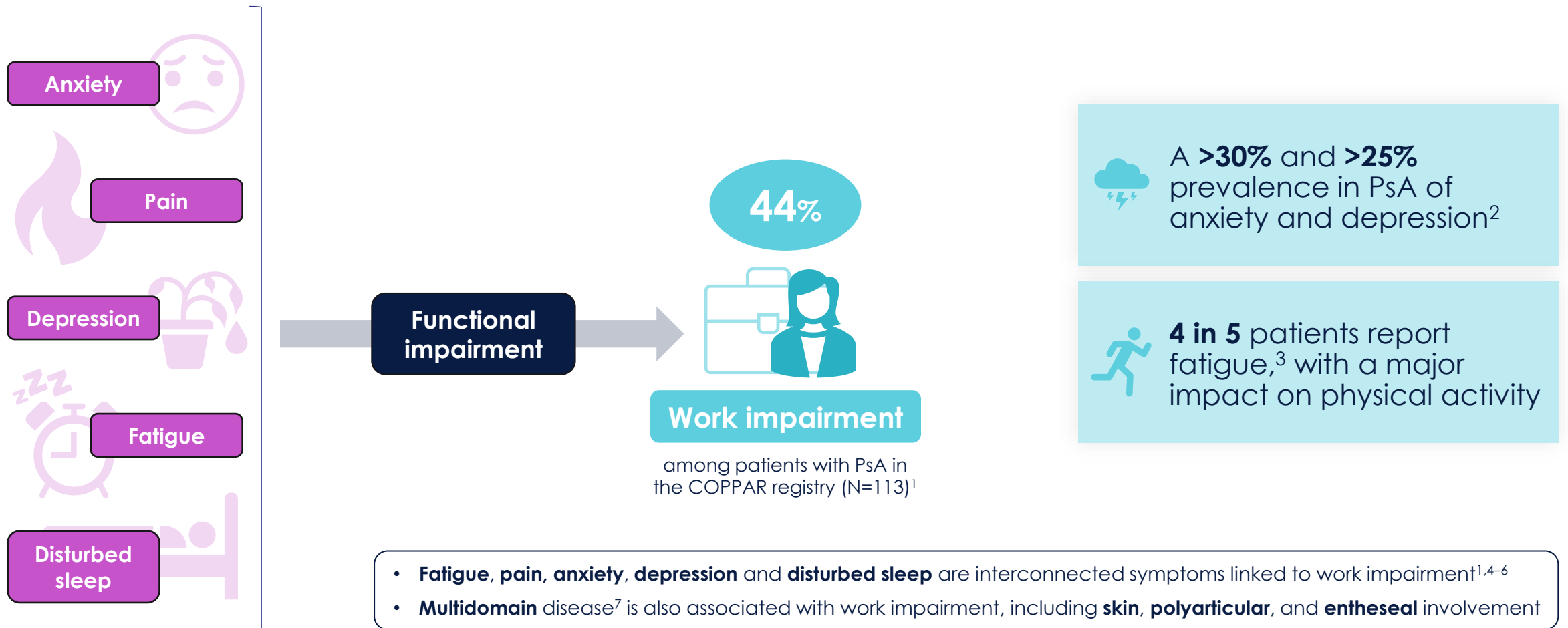
<sup>1</sup> Johns Hopkins Medicine [https://www.hopkinsarthritis.org/arthritis-info/psoriatic-arthritis] Accessed Mar 2024  
Am Acad Dermatol. 2013;69:729–35

<sup>5</sup> Tillett et al Rheumatol Ther 2020;7:617–37

<sup>6</sup> Luce et al AAD 2024;Poster 50361

<sup>2</sup> National Psoriasis Foundation [https://www.psoriasis.org/psoriasis-statistics] Accessed Mar 2024

<sup>3</sup> Merola et al Dermatol Ther 2023;13:2635–2648 <sup>4</sup> Mease et al. J



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

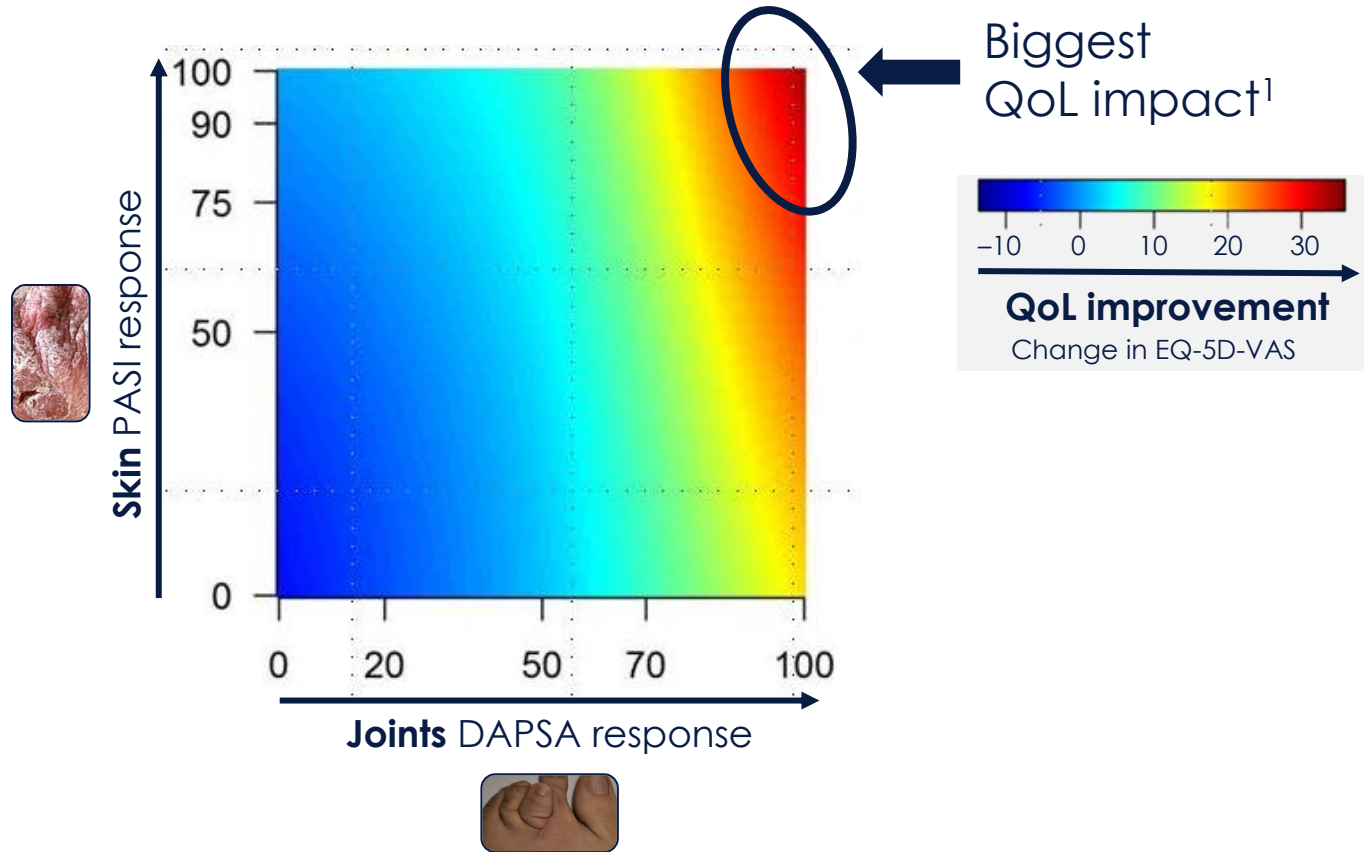
1 Shadick et al ACR 2023;Poster 0488  
Rheum Dis 2020;79 (suppl 1):AB0821

2 Vestergaard et al RMD Open 2024;10:e003412  
6 Spindler et al J Am Acad Dermatol 2021;85:910-922

3 Gossec et al J Rheumatol 2022;49:1221-8  
7 Walsh et al Joint Bone Spine 2023;90:105534

4 Haugeberg et al Arthritis Res Ther 2020;22:198

5 Gossec et al Ann



## Multidomain PsA leads to more pronounced QoL impairment<sup>2</sup>

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

→ Assess response in both joints + skin

ACR + PASI



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

Image credits: skin—courtesy of Prof. Kristian Reich, joints—Mochizuki et al Case Rep Rheumatol 2018;2018:4216938

<sup>1</sup> Quality of life data from 402 patients with PsA and moderate-to-severe skin involvement ( $\geq 3\%$  BSA) after 24 weeks on therapy/placebo in the SPIRIT Phase 3 clinical study program (heat map image reproduced with permission from Prof. Merola) | Kavanaugh et al Arthritis Rheumatol 2017;69[suppl 10]:AB2539 <sup>2</sup> Tillett et al Rheumatol Ther 2020;7:617–37

**>3 in 4 patients do not achieve MDA**  
within 6 months of biologic initiation<sup>1</sup>



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

**Patients who do not achieve MDA may also have a higher overall disease burden, e.g.:**<sup>2</sup>

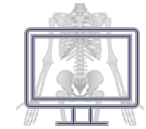
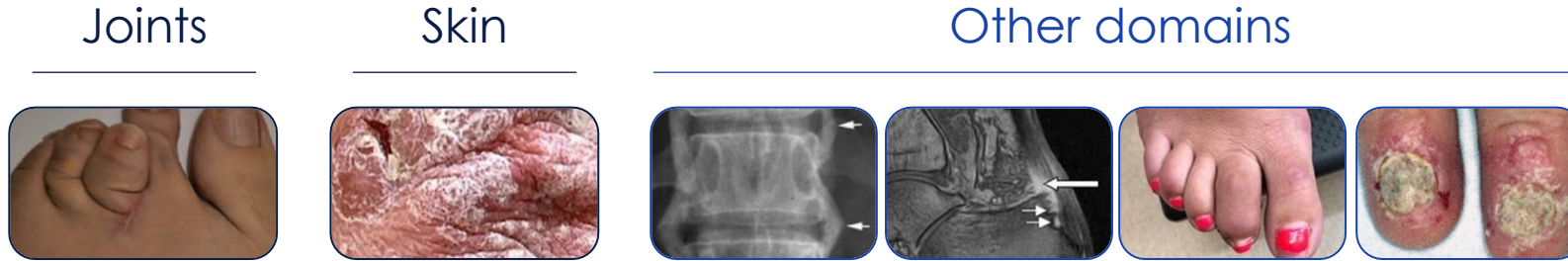
- More fatigue
- Worse physical function
- Worse mental function
- Greater quality of life impact

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

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



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



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

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

# Can we optimize IL-17 inhibition?

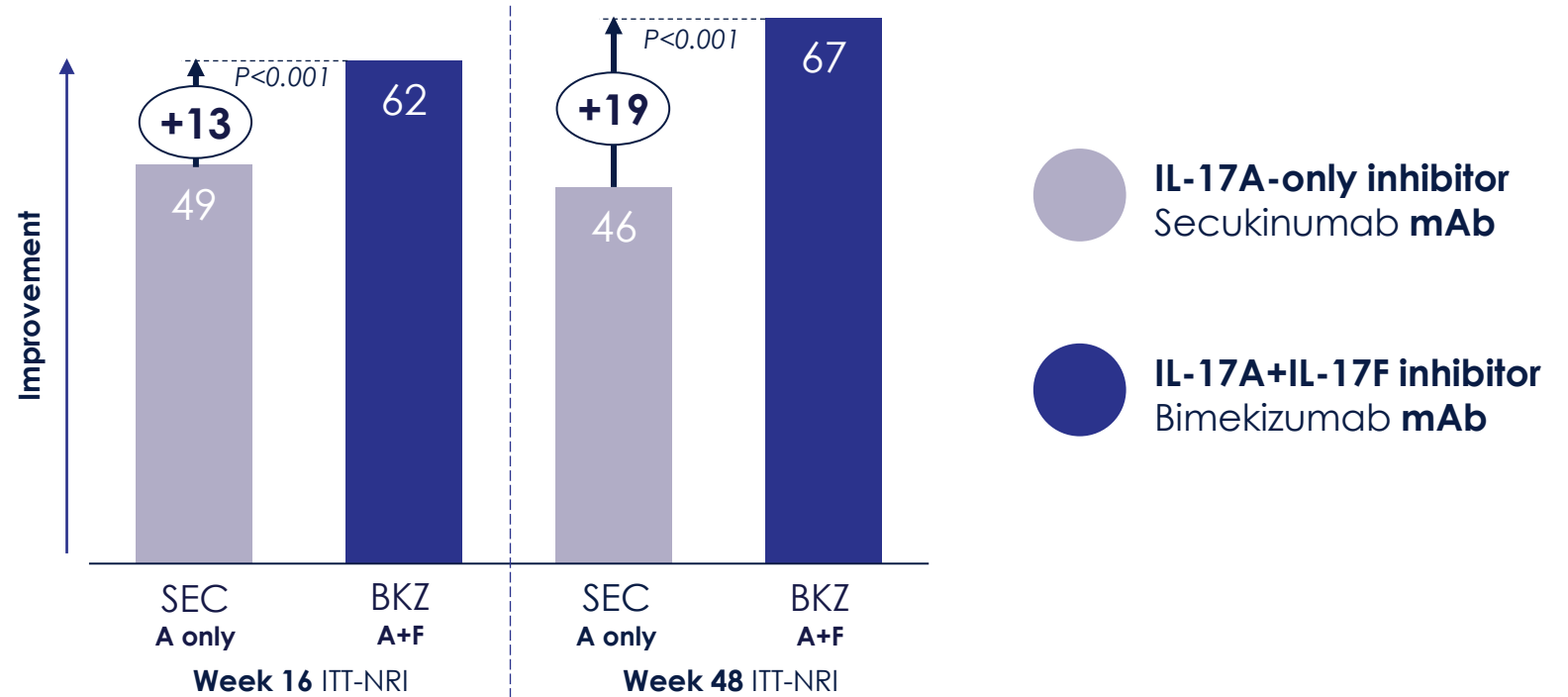
As the class of choice for addressing all domains in PsA, **innovation on MOA is centered on optimizing IL-17i**, based on increasing evidence that IL-17F drives psoriatic inflammation alongside IL-17A...



**Skin: Plaque psoriasis**  
(Moderate-to-severe)

Primary endpoint:  
PASI 100 at Week 16

**PASI 100 BE RADIANT Phase 3b H2H BKZ vs SEC<sup>1</sup>**



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

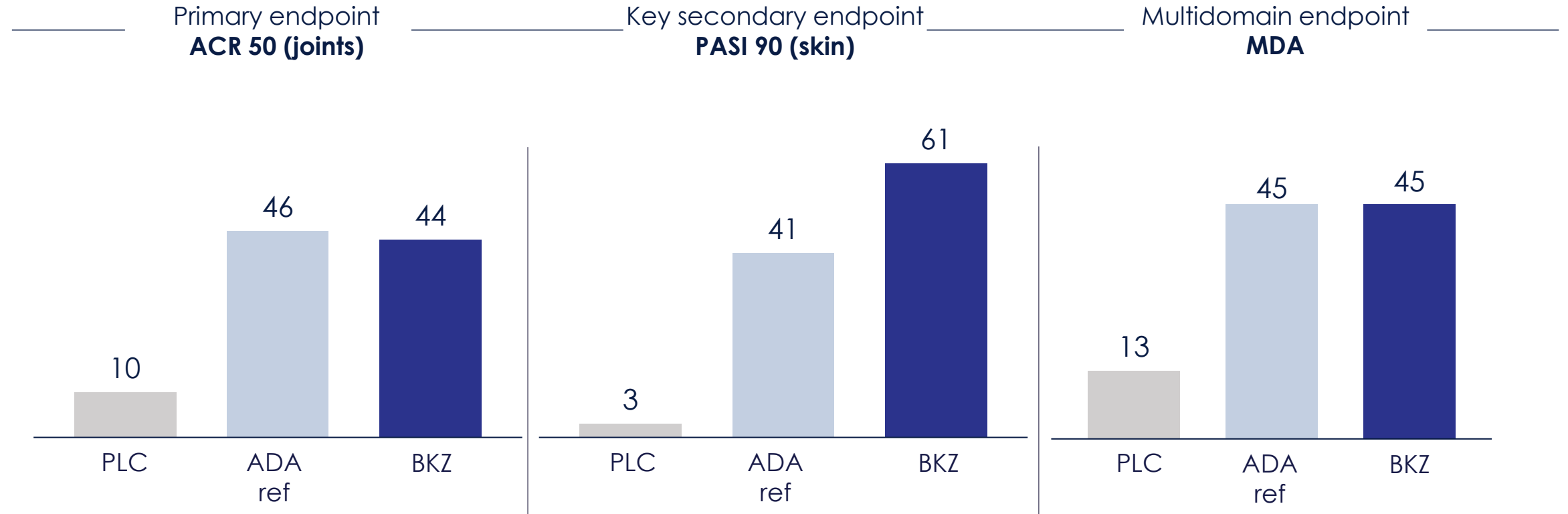
A study in patients with moderate-to-severe psoriasis; only a subset of participants had PsA and the clinical significance of the findings is unclear (there are no head-to-head studies of these two MOAs in PsA); Reich et al N Engl J Med 2021;385:142-152  
Image of skin courtesy of Prof. Kristian Reich

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

**Bimekizumab** IL-17A and IL-17F inhibitor (160 mg Q4W) | BE OPTIMAL (Phase 3 **PsA**)<sup>1</sup>

**Week 16** NRI-ITT

- Patients enrolled in the study were biologic-naïve — similar results were seen in a TNF-IR study<sup>2</sup>



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

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

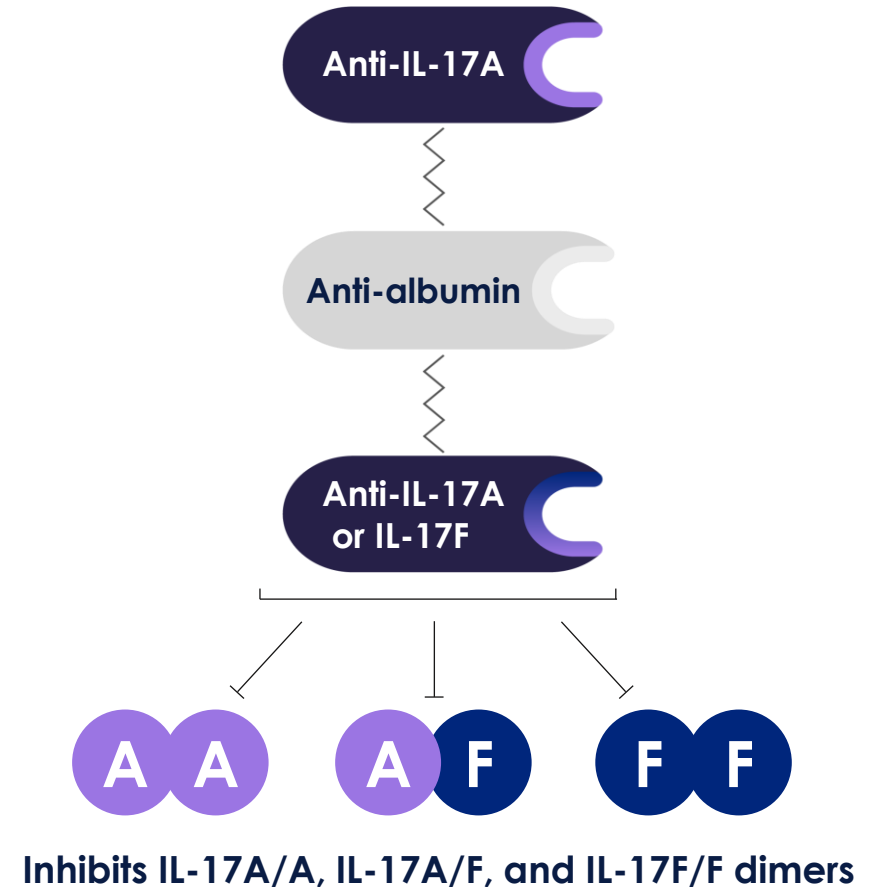
As a **Nanobody<sup>®</sup>**, **sonelokimab (SLK)** is designed to penetrate difficult-to-reach tissues and directly target sites of inflammation:<sup>1,2</sup>

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

## Sonelokimab Phase 2b in psoriasis<sup>1</sup>

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

**Sonelokimab Nanobody<sup>®</sup>** ~40 kDa<sup>1,2</sup>



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

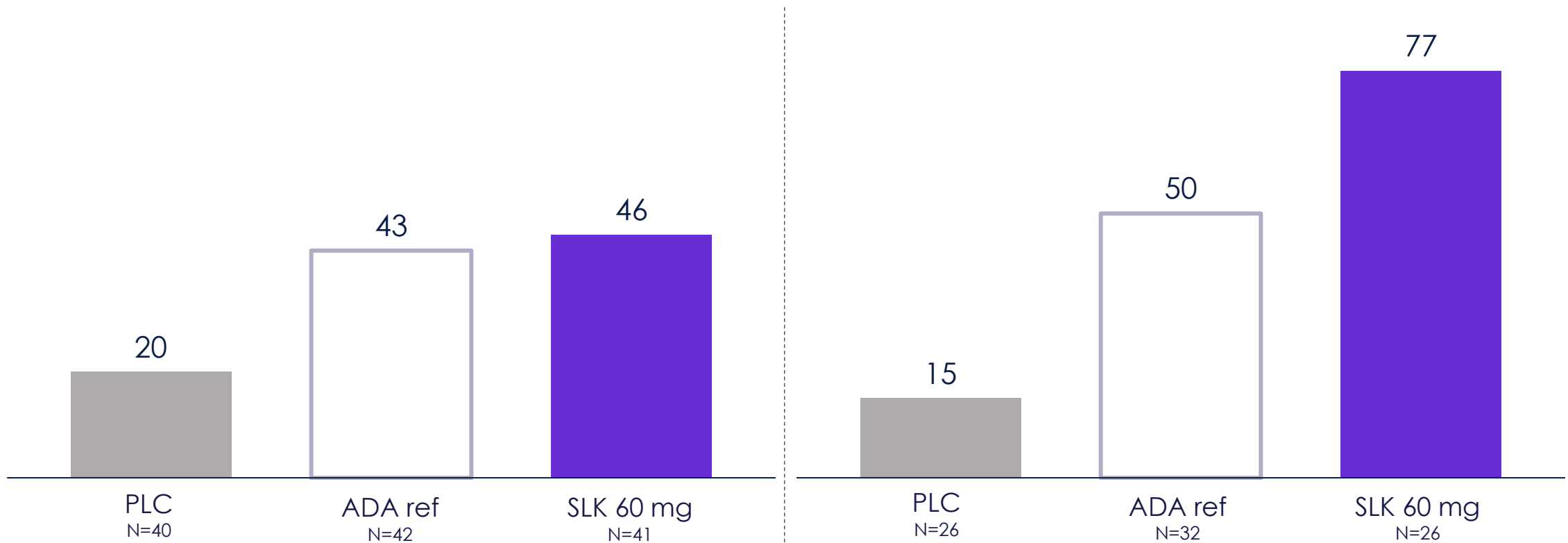
**Sonelokimab** IL-17A and IL-17F inhibitor (Nanobody®) | ARGO (Phase 2 PsA)

**Week 12 NRI-ITT**

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

Primary endpoint  
**ACR 50 (joints)**

Key secondary endpoint  
**PASI 90 (skin)**



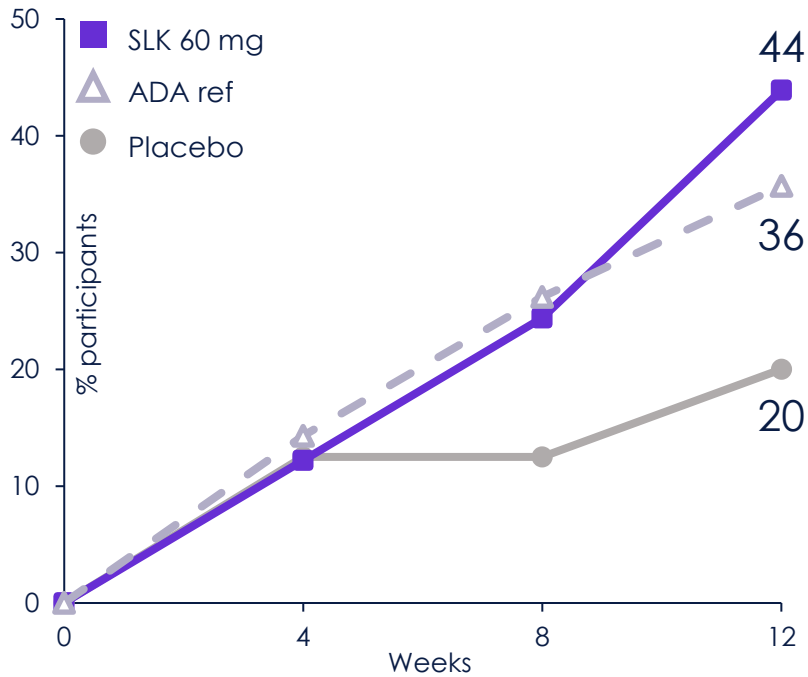
Inhibition of IL-17A and IL-17F with a Nanobody® showed promising efficacy in both joints + skin

# The SLK Nanobody® also showed promising responses in composite scores

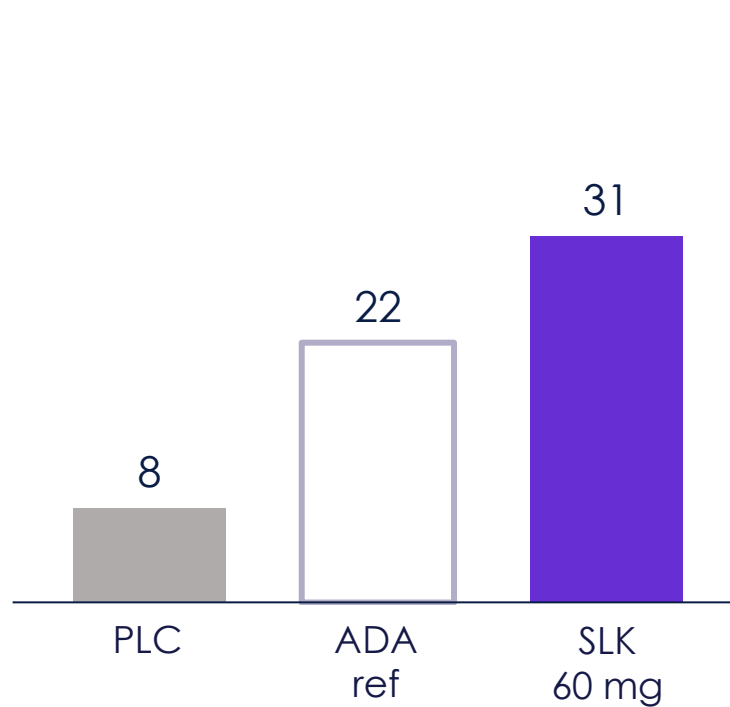
Sonelokimab ARGO

Week 12 ITT-NRI

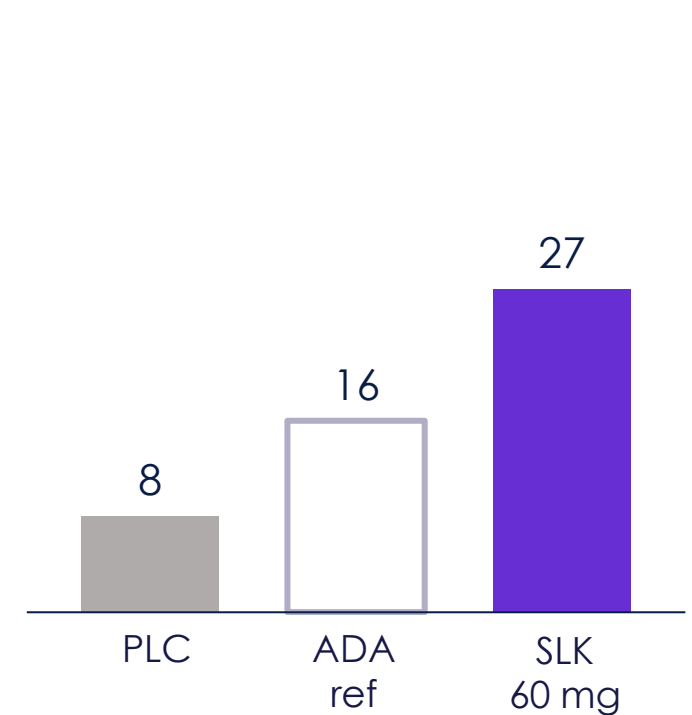
Multidomain endpoint  
**MDA**



Joints + skin composite  
**ACR 50 + PASI 100**



Higher threshold  
**ACR 70 + PASI 100**



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

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

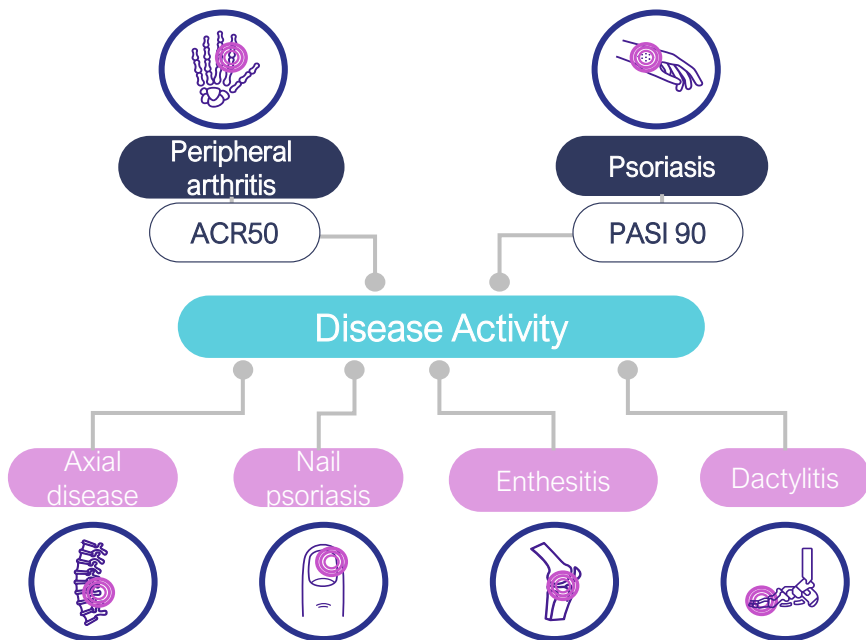
Week 12 data in the ARGO trial **set high expectations of continuing increases in key endpoints, as well as multidomain composites**, to Week 24 with SLK treatment

# ARGO trial 24 wk data

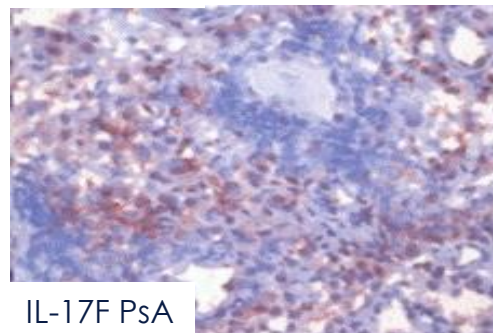
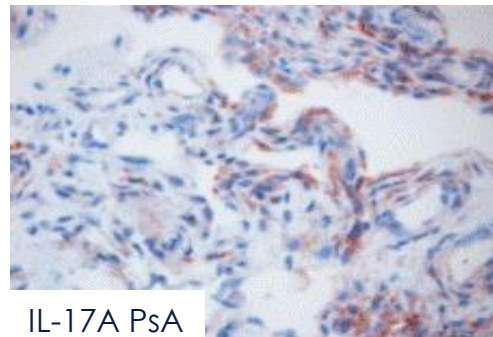
Kristian Reich



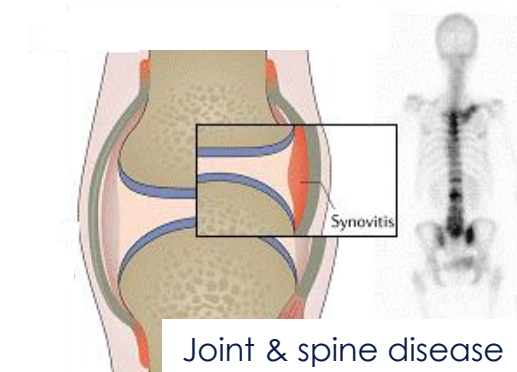
## PsA is a multi-domain deep-tissue disease...



## ...with 3x IL-17F vs IL-17A<sup>1</sup>...



## ...and causing devastating damage



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

### Market size

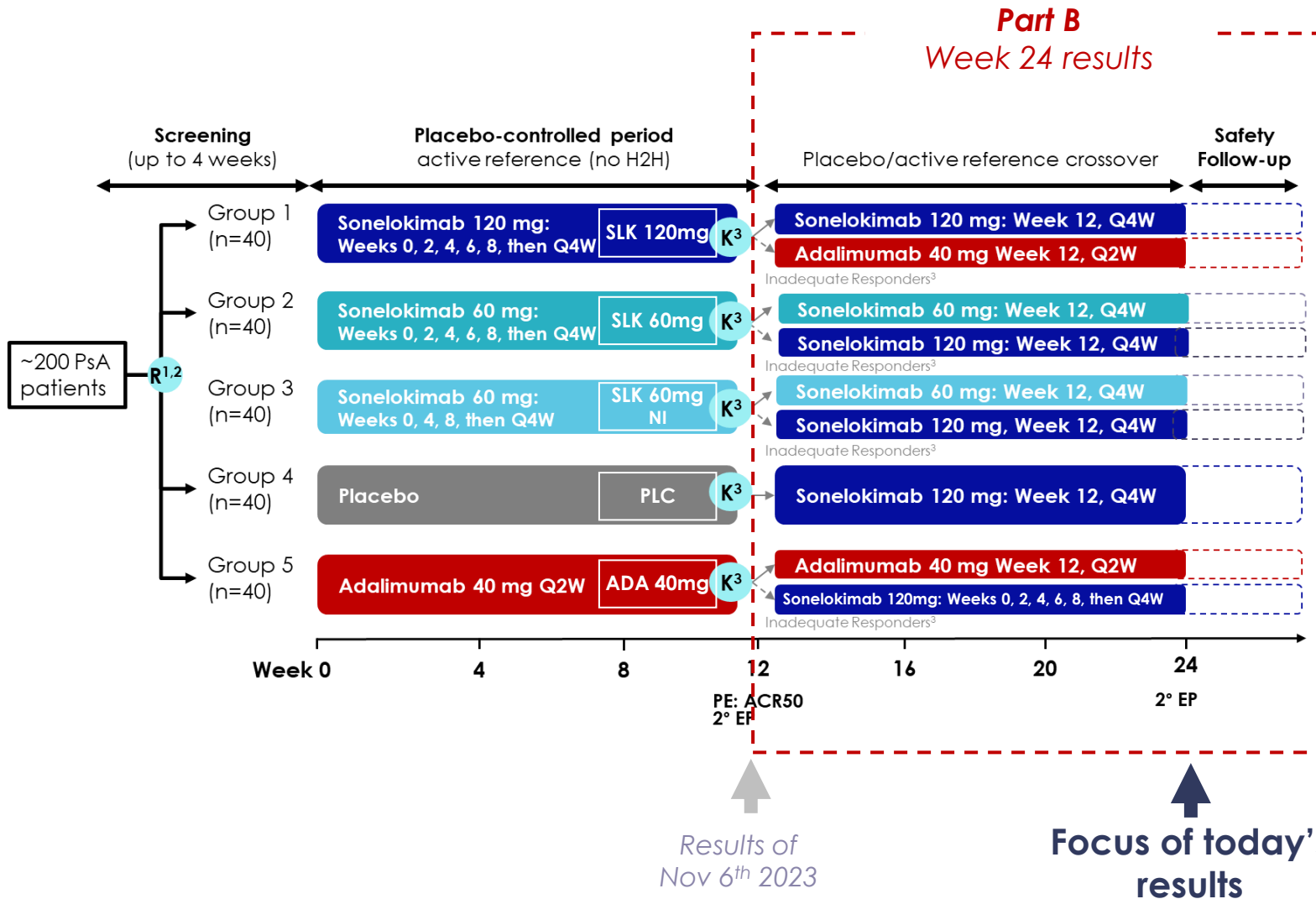
**0.5%** Global prevalence    **10+** USD bn sales beyond 2030

### Unmet Needs

**80%** or more patients with multiple disease domains    **10%** skin involvement in PsA patients – severe skin disease    **20%** is still standard ACR level of improvement

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

Source: MoonLake Medical, Clinical pictures K. Reich



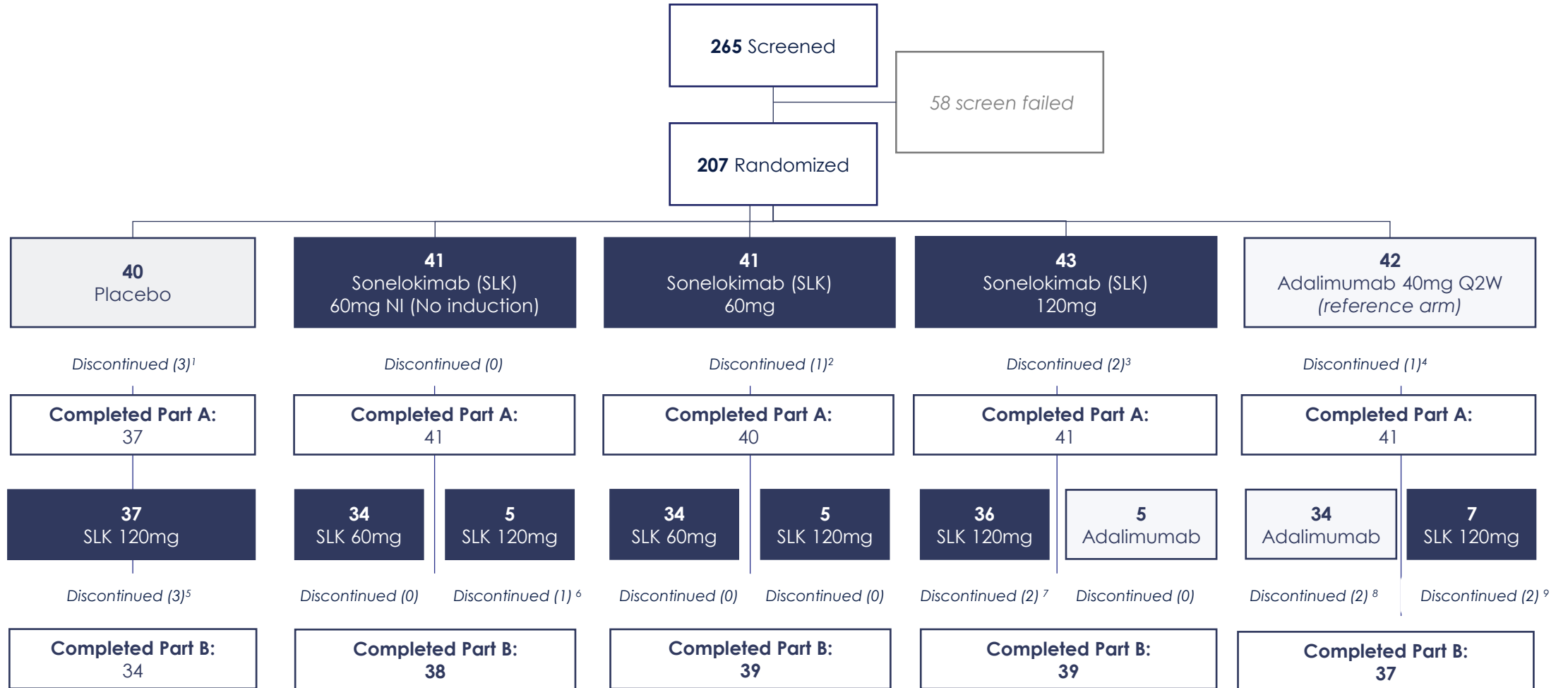
## Key design elements of ARGO

- Global study with approx. **50 sites**, with **207 patients** randomized
- **Double-blind, placebo-controlled, active reference arm**
- **Active PsA** (TJC68  $\geq 3$ , SJC  $\geq 3$ , current active PsO and/or confirmed PsO)
- **ACR50** as primary endpoint, **PASI90** as key secondary endpoint
- **ITT-NRI** primary analysis; Stratification by sex, previous bio use
- **SLK 120mg** and **SLK 60mg** reached stat sig at wk 12
- Group 3 ("SLK 60mg NI", no induction) had not reached stat sig at wk 12
- **Some crossover arms** not analyzed separately (small samples, 5-7 pts/arm)

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

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

## Disposition (Part A+B)



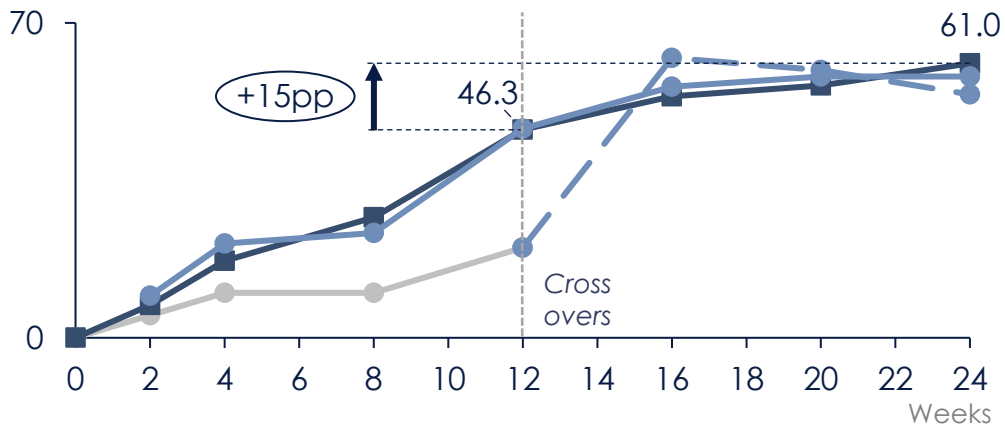
Part B Database lock 7th February 2024. AE = Adverse Event, Wdw by S = Withdrawal by Subject; Completed Part A = completed treatment up to Week 10 and completed assessments to Week 12; 3 patients did not subsequently enter part B; 1: 1x Not Treated, 1x Wdw by S & 1x Lack of Effect; 2: 1x Protocol withdrawal criteria; 3: 1x AE (not related to treatment) & 1x Wdw by S; 4: 1x Wdw by S; 5: 3 x AE; 6: 1 1x Wdw by S; 7: 1 x AE 1x Wdw by S; 8: 1 x PD 1 x Wdw by S; 9 1 x AE 1 x PD

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

● PLC ■ SLK 60mg ● SLK 120mg ● PLC->SLK 120mg

## ACR50 response (Primary endpoint)

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

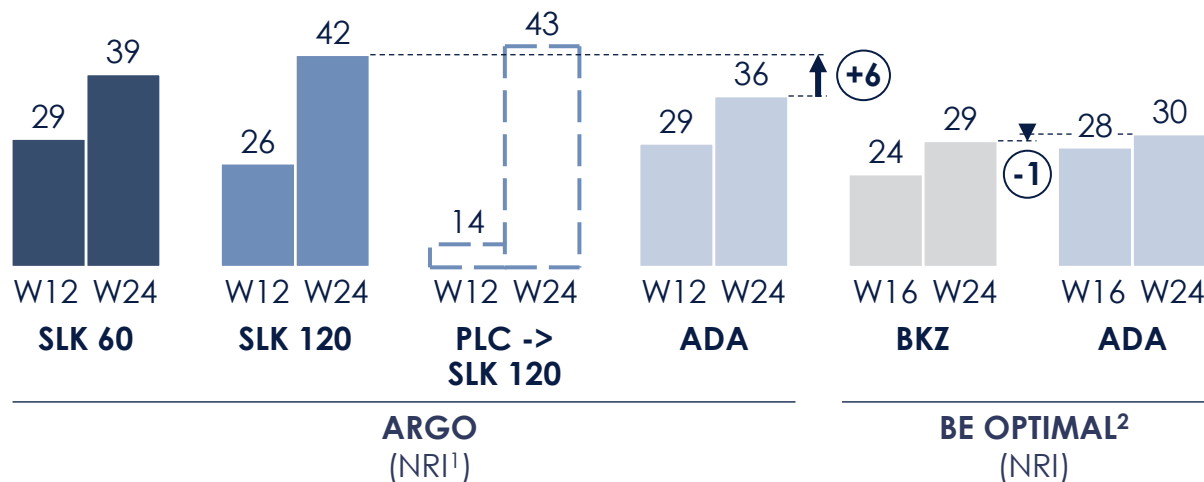
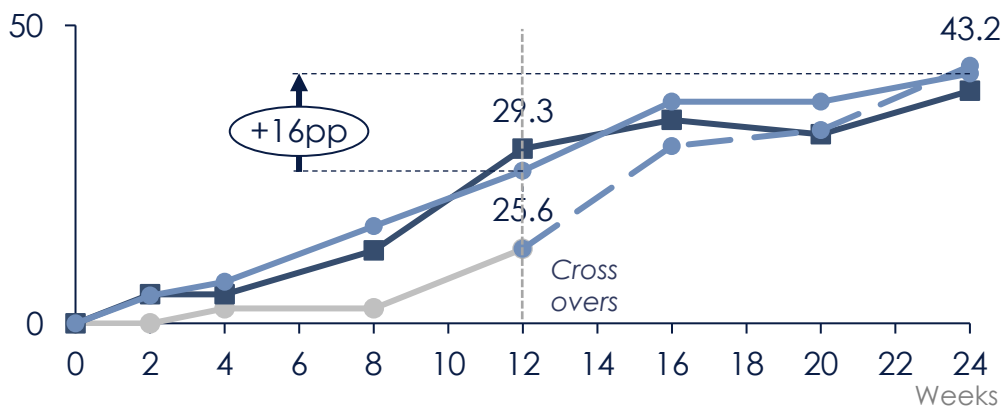


## Cross-trial comparison to BKZ



## ACR70 response (Secondary endpoint)

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



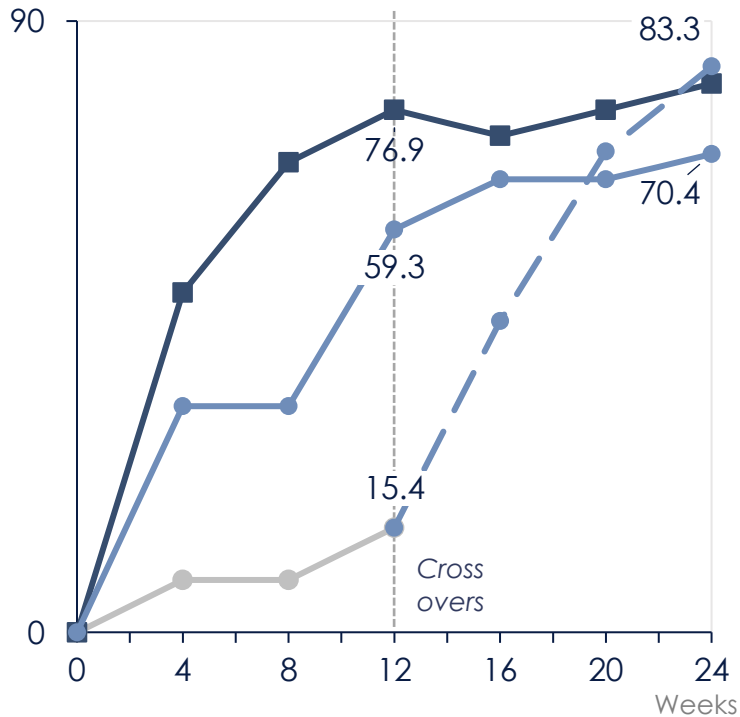
Note: Comparison across trials have inherent limitations. No head-to-head trials 1 ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from Week 12 onwards; 2 Ritchlin et al. Ann Rheum Dis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

# Skin outcomes continue to improve to wk 24, beyond competitors

● PLC ■ SLK 60 ● SLK 120 ● PLC->SLK 120

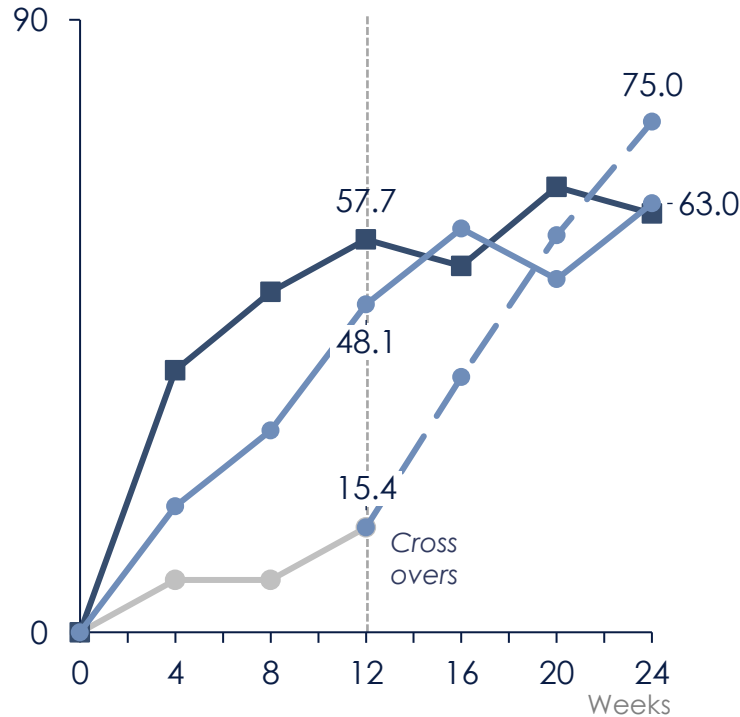
## PASI90 response

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



## PASI100 response

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



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

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

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

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

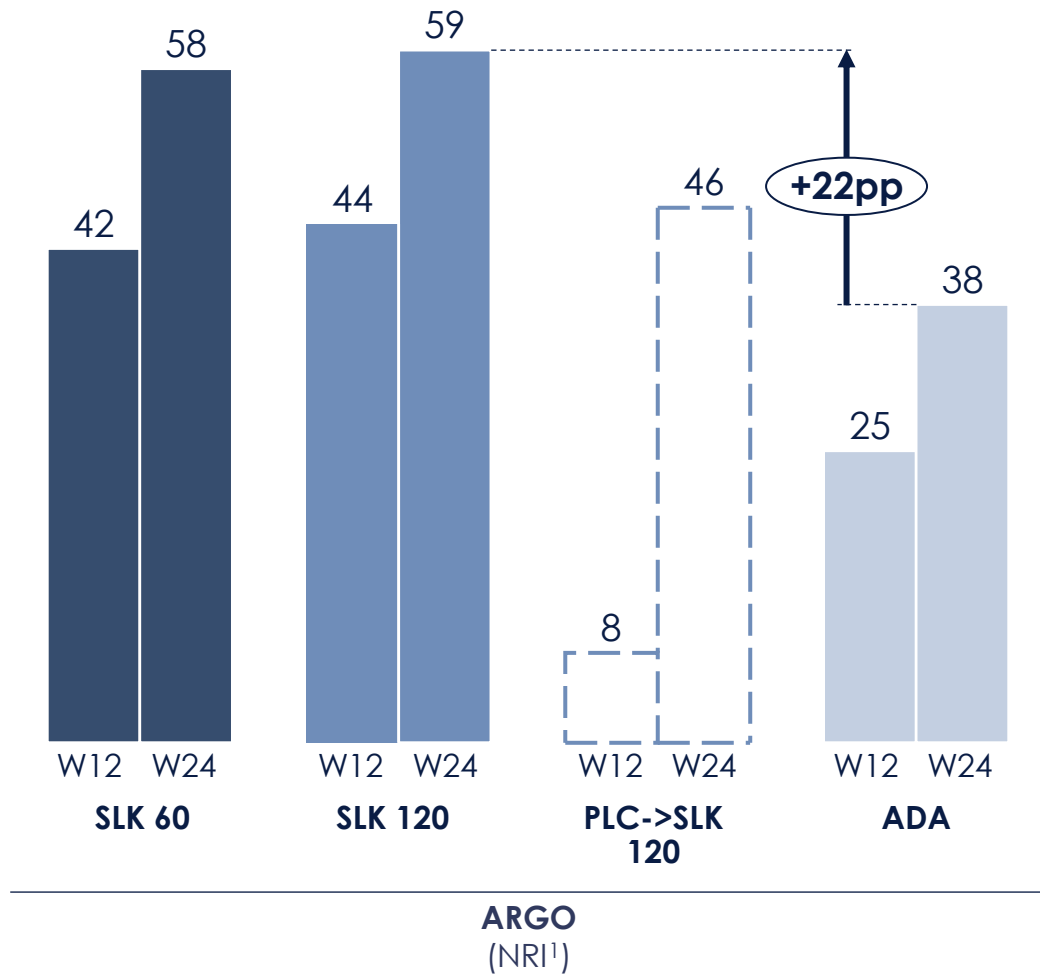
**SLK responses are numerically higher than observed with BKZ**, (73% PASI90 and 56% PASI100 in BE OPTIMAL at wk 24)<sup>2</sup>

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

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

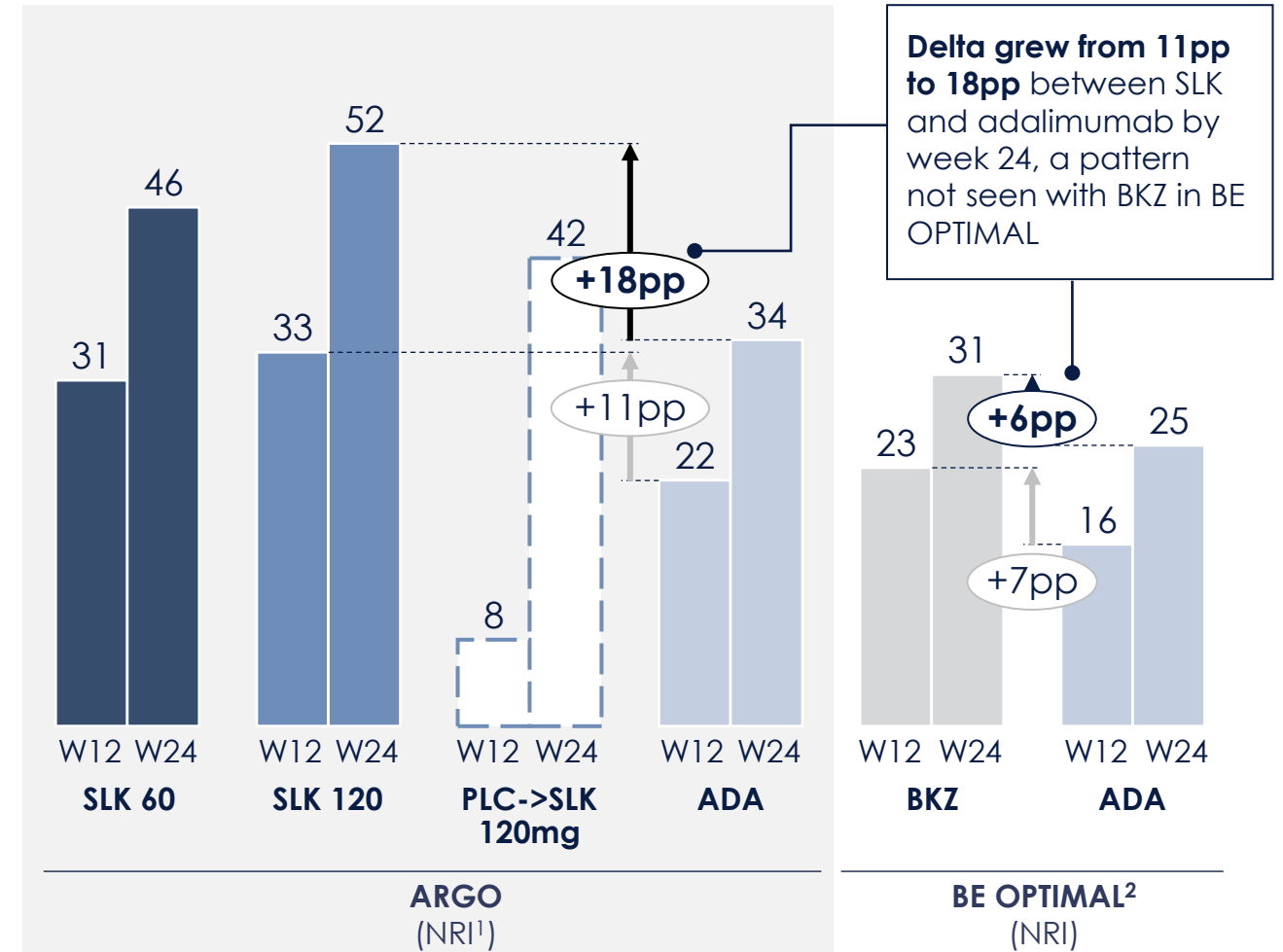
## Patients reaching both ACR50 and PASI90

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



## Patients achieving both ACR50 and PASI100

Percent (%) pts reaching score

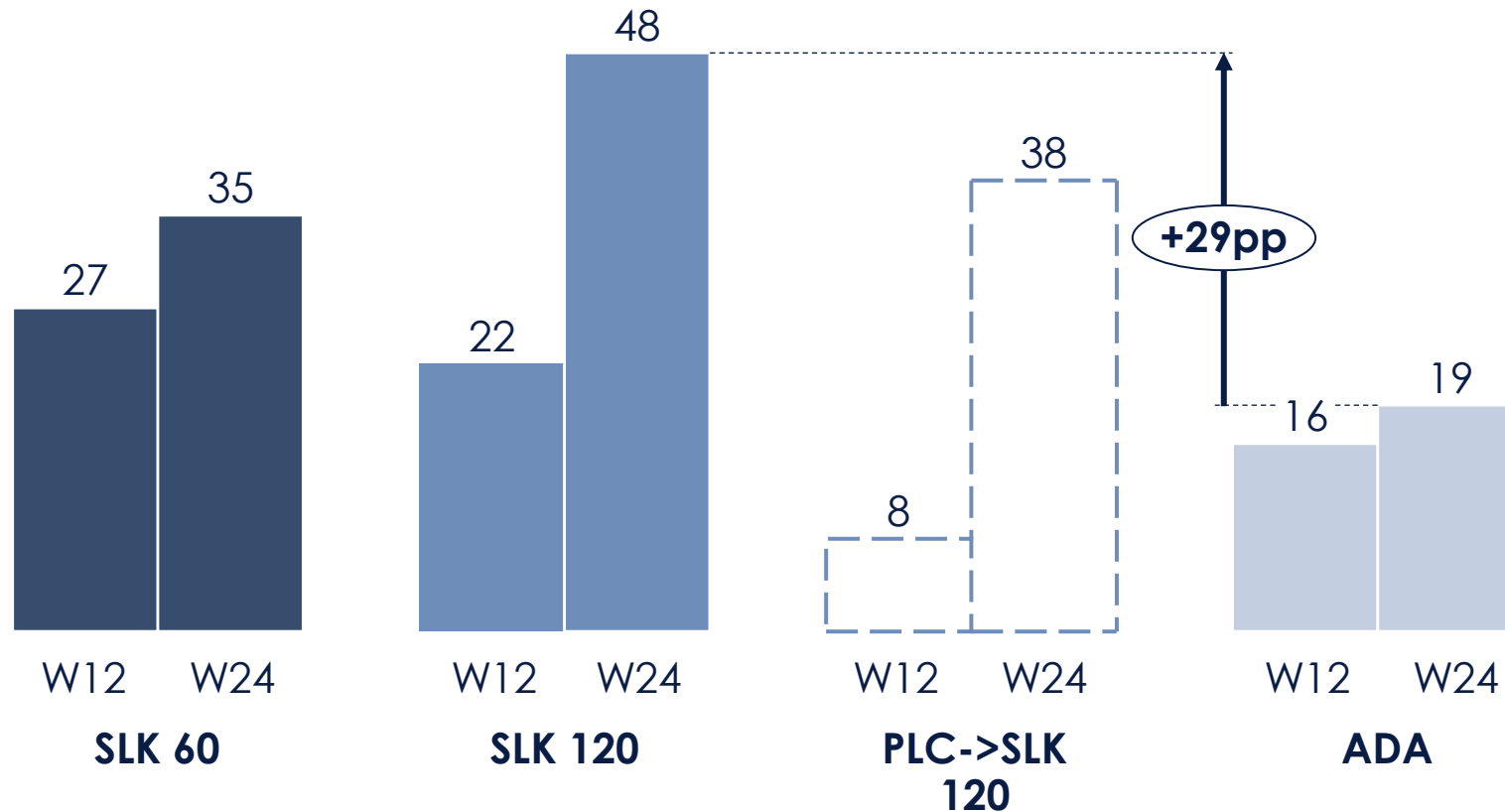


Note: Comparison across trials have inherent limitations. No head-to-head trials 1 Subset of participants with BSA >=3% at baseline, ITT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried forward from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

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

## Patients reaching both ACR70 and PASI100

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



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

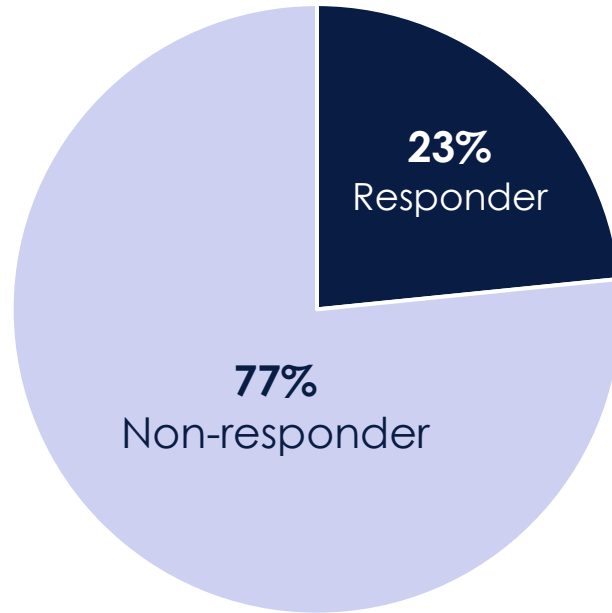
At week 24 delta to adalimumab in this **high bar composite score is close to 30pp**

Strong signal of **elevated efficacy vs adalimumab<sup>2</sup>** on this higher hurdle endpoint

<sup>1</sup> 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;

<sup>2</sup> Nominal p value, post-hoc analysis (p<0.05), study not powered for statistical comparison between SLK and ADA arms

**>3 in 4 patients do not achieve MDA**  
within 6 months of biologic initiation<sup>1</sup>



% of patients who were MDA responders

### MDA breakdown<sup>2</sup>

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

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

**Achievement of MDA clinical responses with any biologic remains low**

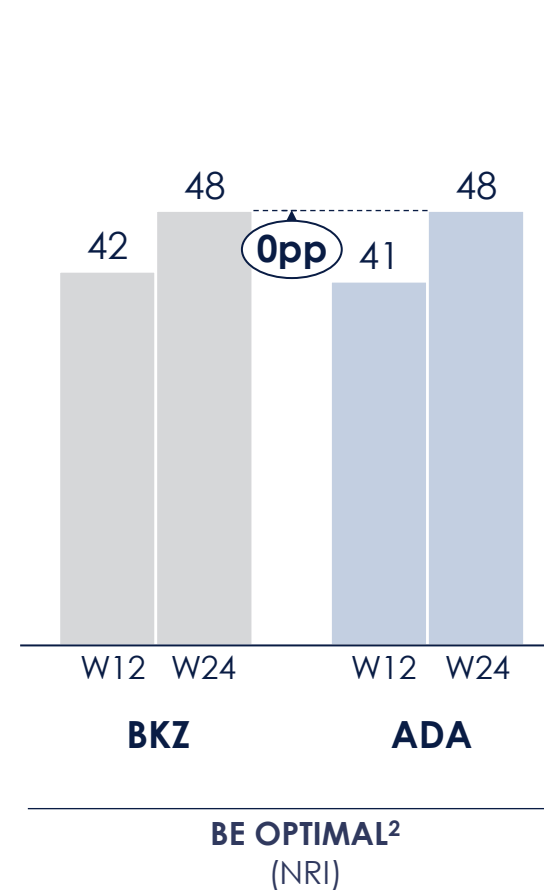
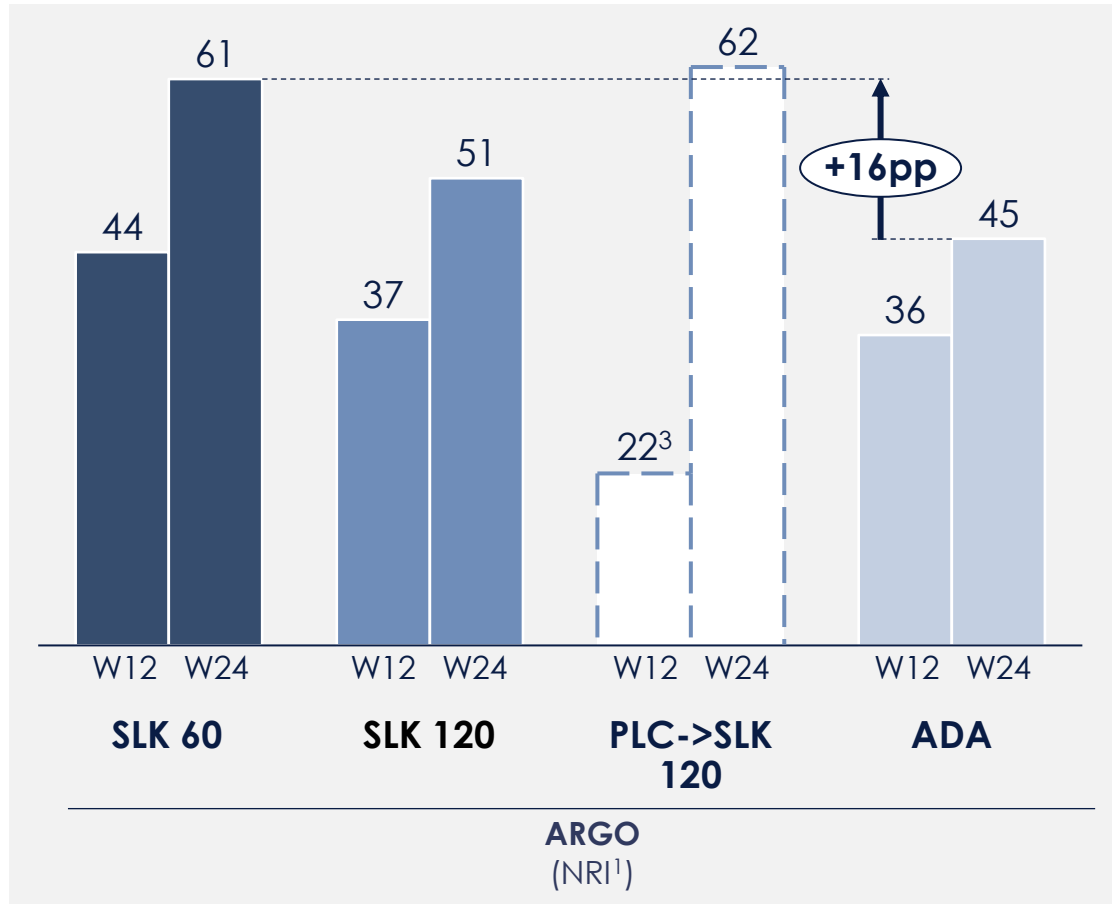
<sup>1</sup> Data from the CorEvitas registry (N=1,251); Ogdie et al. ACR 2021; abstract 1344; <sup>2</sup> BSA, body surface area; HAQ-DI, Health Assessment Questionnaire Disability Index; PASI, Psoriasis Area and Severity Index; PRO, patient-reported outcome; S/TJC, swollen/tender joint count; VAS,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



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

## Patients reaching Minimal Disease Activity (MDA)

Percent (%) pts reaching score



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

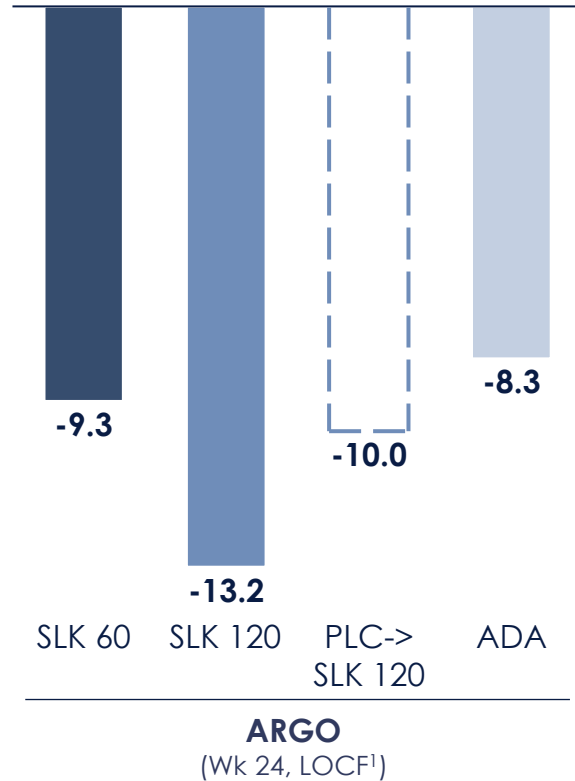
**Delta to adalimumab was observed (up to 16pp) within the trial, which has not been the case with BKZ in the trial that incl. the same reference arm**

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

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

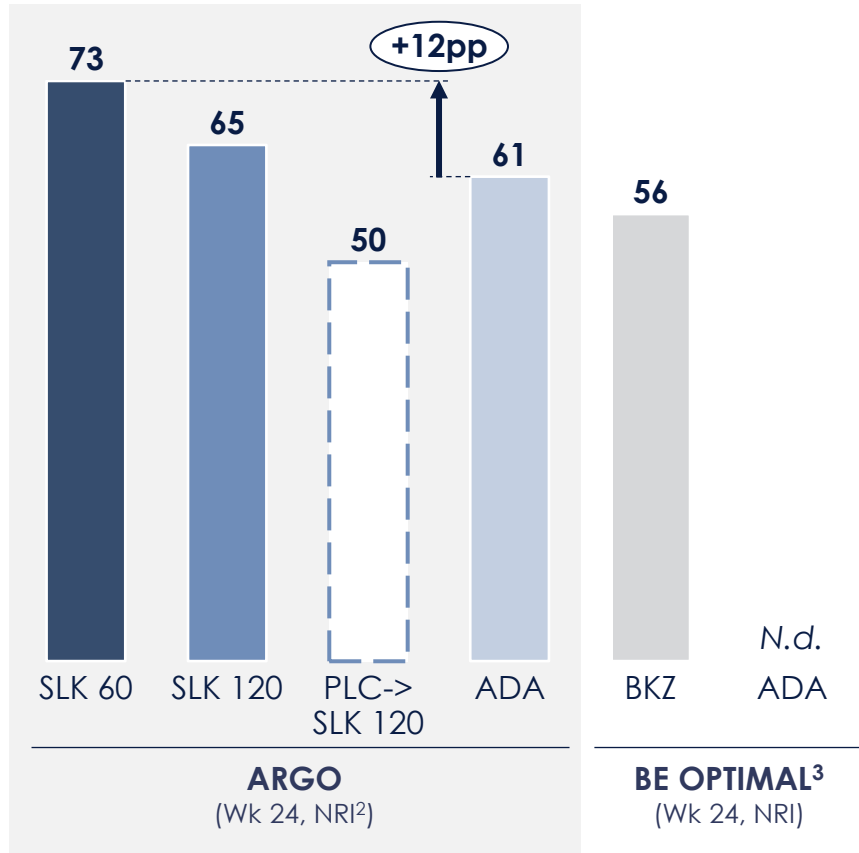
## Nail PsO Severity (mNAPSI)

Mean change from baseline



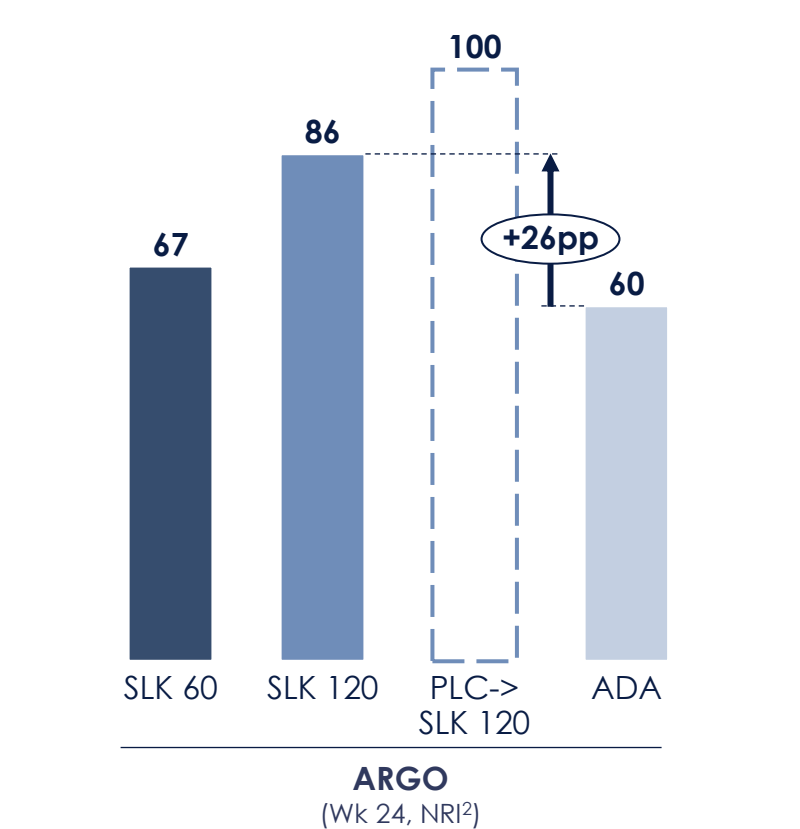
## Nail PsO Resolution (mNAPSI=0)

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



## Leeds Enthesitis Index (LEI)

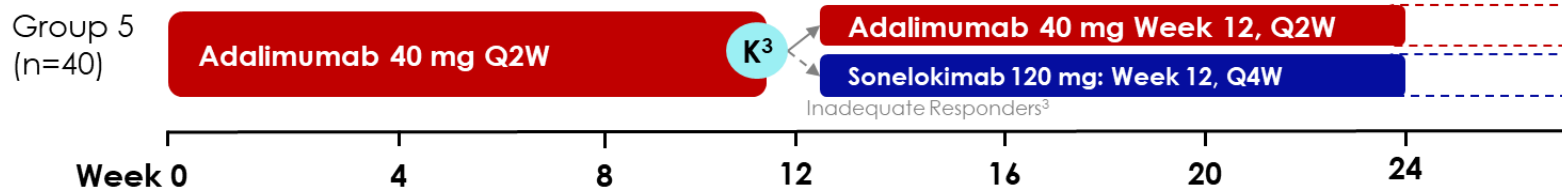
Percent (%) of pts with LEI 2+ at baseline that improved 2+ pt



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

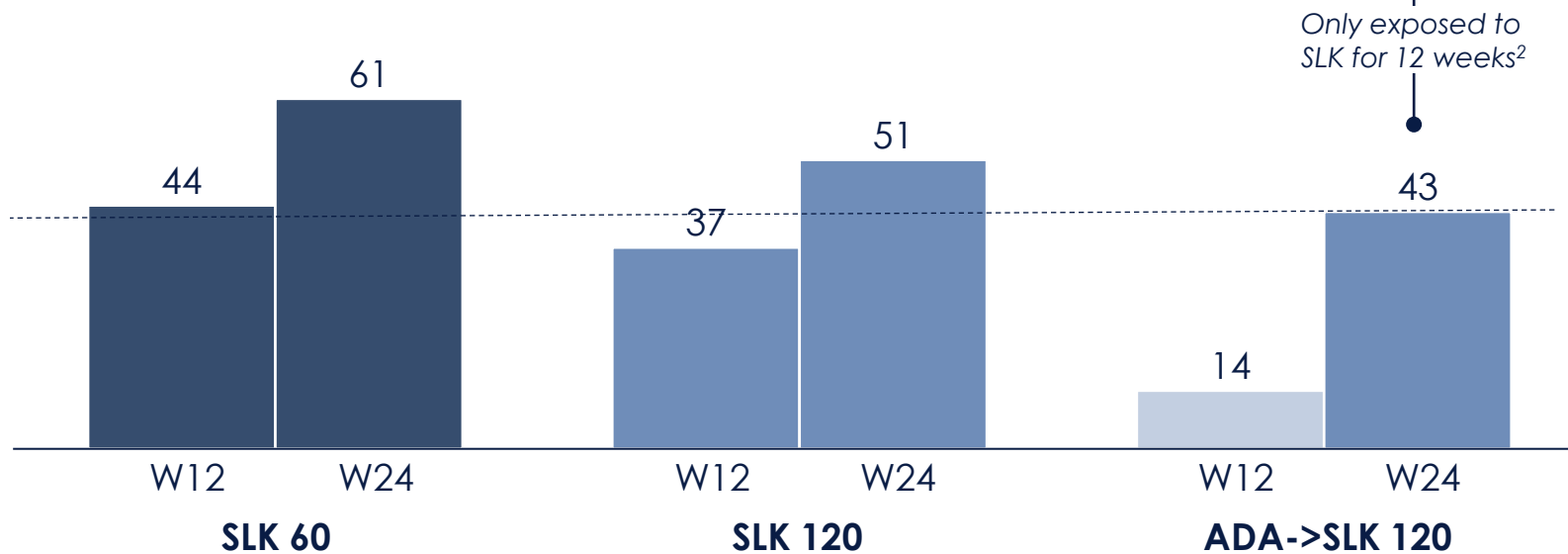
Note: Comparison across trials have inherent limitations. No head-to-head trials. 1 Last observation carried forward for all missing values; 2 IIT-NRI up to Week 24, except that participants who were re-assigned from their original treatment arm at Week 12 as per protocol had last observation carried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

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



## Patients reaching Minimal Disease Activity (MDA)

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



- 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

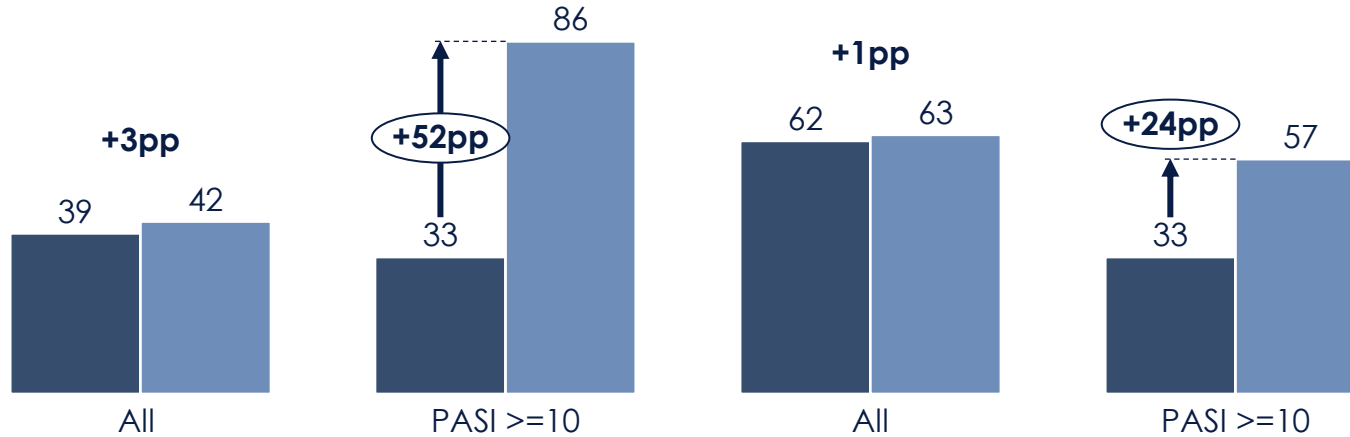
# Higher 120mg efficacy in key subgroups

## Response rates at week 24 (subgroups)

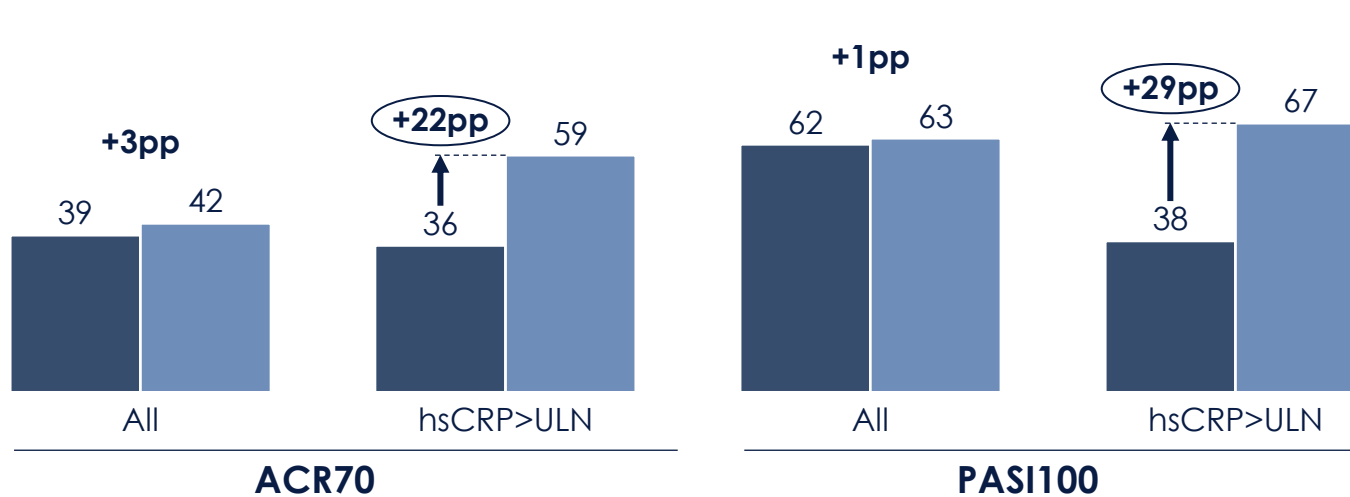
Percent (%) of pts, NRI<sup>1</sup>

■ SLK 60mg ■ SLK 120mg

Moderate-to-severe psoriasis



High level of inflammation



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

<sup>1</sup> 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;

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



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

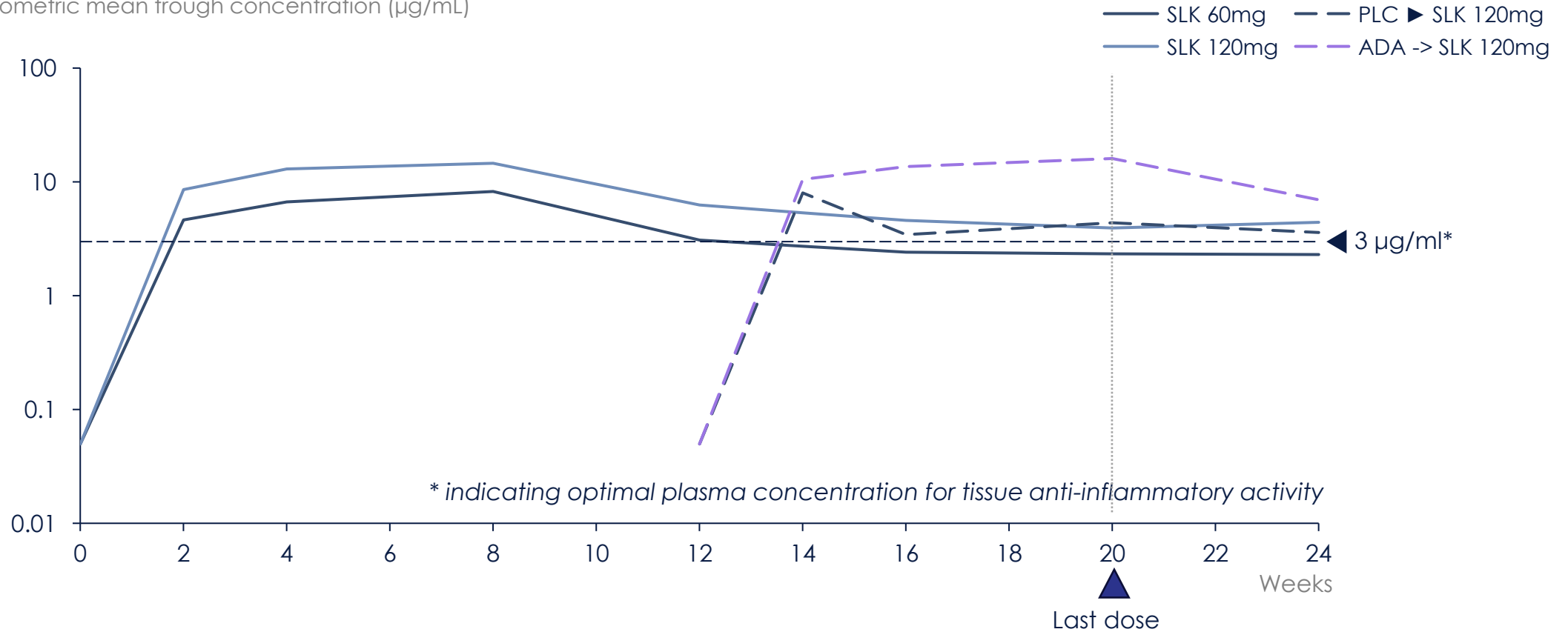
ALT, Alanine aminotransferase and AST, Aspartate transaminase; IBD, inflammatory bowel disease; MACE, major adverse cardiovascular event; SAE, serious adverse event; TEAE, treatment-emergent adverse event; ULN, upper limit of normal; 1 Top three most frequent AEs in the SLK groups. Note: The adalimumab therapy used in the MIRA trial was the originator drug (citrate-free formulation); 2 No SAEs judged to be treatment related; 3 One case with elevated transaminases >3x ULN in adalimumab arm reported as an AE; one case of transient elevated transaminases and CK concurrent with a reported event of exercise-related muscle inflammation in SLK 60 mg; 4 TEAEs leading to discontinuation included 1 x tonic-clonic seizure, 1 x Furuncle, 1 x Pharyngeal abscess & Subcutaneous emphysema, 1 x Tonsillar inflammation, 1 x Epididymitis, 1 x Arthritis

Source: MoonLake Clinical

© 2024 | Proprietary | MoonLake TX

## SLK trough concentrations

Sonelokimab geometric mean trough concentration ( $\mu\text{g/mL}$ )



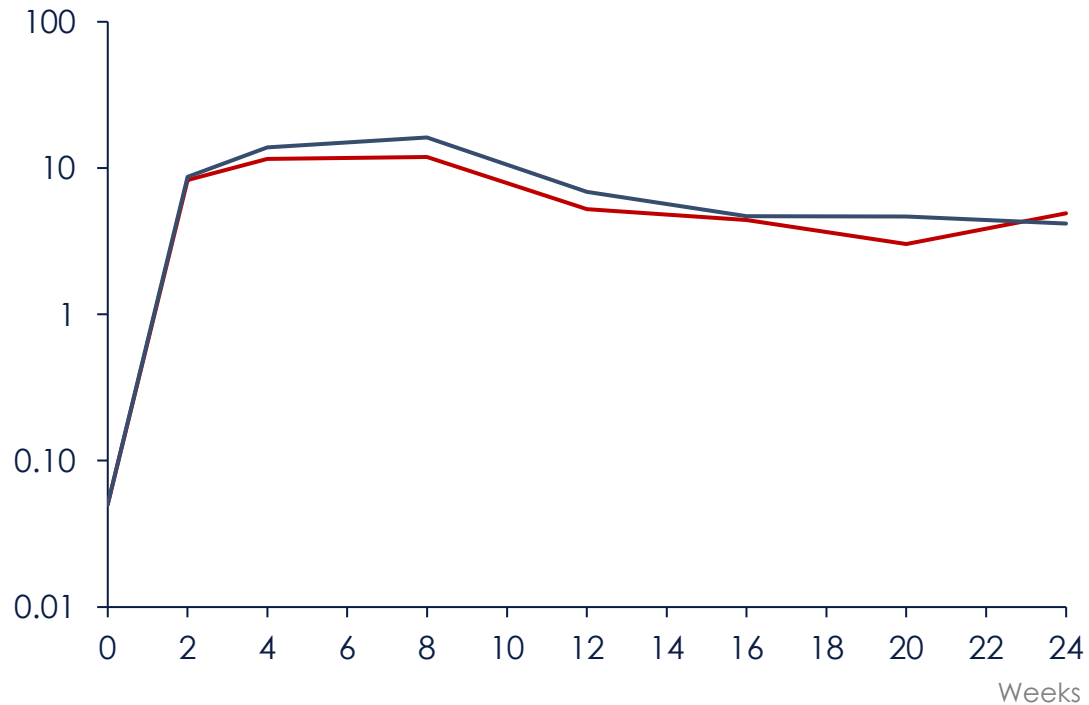
Trough concentrations of crossed over arms **replicate data** from first 12 weeks, **rapidly bringing SLK above** optimal plasma concentration (to reduce large amounts of target) and **remaining above level** as patients move to maintenance dose

# No signs of clinically relevant immunogenicity

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

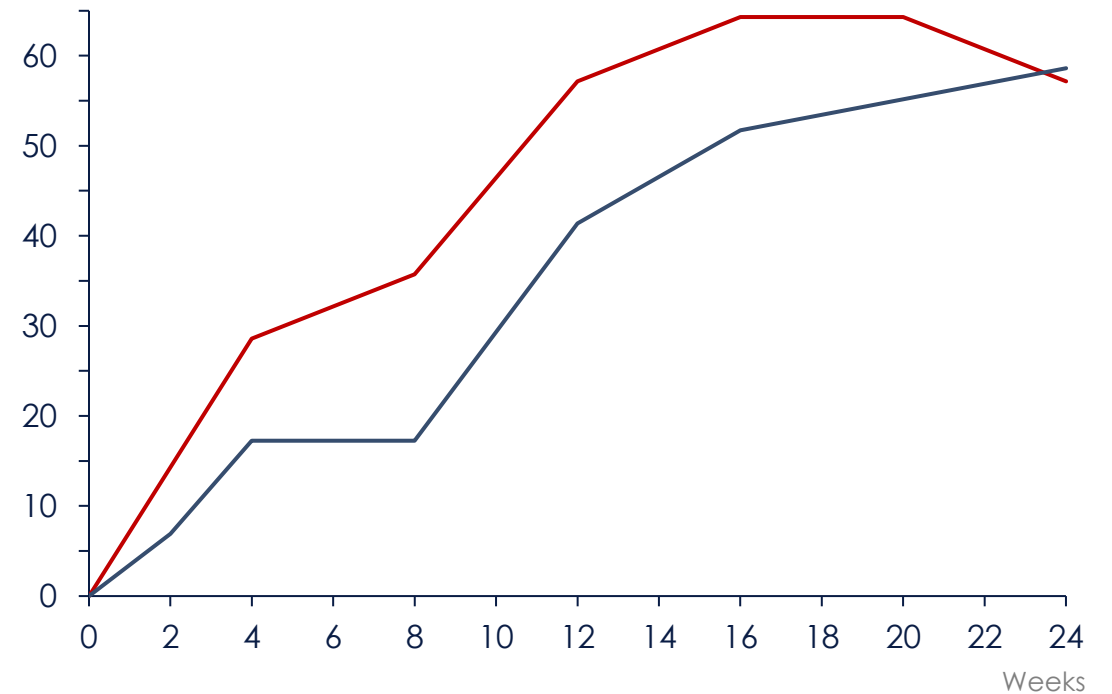
## SLK trough concentrations were unaffected by treatment-emergent ADA status

SLK 120mg geometric mean trough concentration ( $\mu\text{g/mL}$ ) by ADA status



## Furthermore, clinical response was unaffected by anti-drug antibodies<sup>1</sup>

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



Similar for 60mg dose

## What know now from ARGO

- **Dose-response pattern in line with findings** in plaque-type Psoriasis (PsO, 313 patients) and Hidradenitis Suppurativa (HS, 234 patients)
- Doses with **optimal benefit-risk profile** identified for PsA – **60 mg & 120mg** (with induction)
- Support of **favorable safety profile**
- Main ARGO study design **elements will be replicated in Phase 3** design
- **Larger program size** (potentially ~1,100-1400) expected to **reduce variations** driven by small groups
- **Sub-groups** with up-titration potential identified
- **Endpoints confirmed** for Phase3 – ACR50 & PASI90 – but with expected **primary endpoint at week 16 and emphasis on composite secondaries**
- Currently planning **two trials**
  - **TNF-IR** trial
  - **Bio-naïve** trial

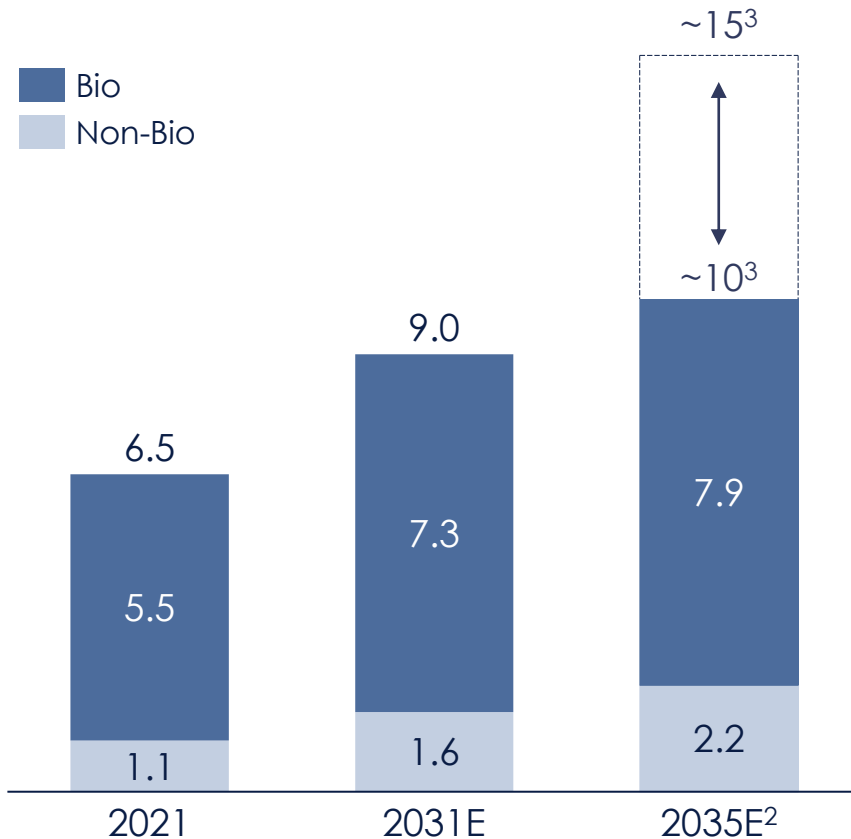
## Planned FDA EoP2 timeline (parallel with EMA):

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



## PsA market size estimates<sup>1</sup>

USD m









## Key notes

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

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



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

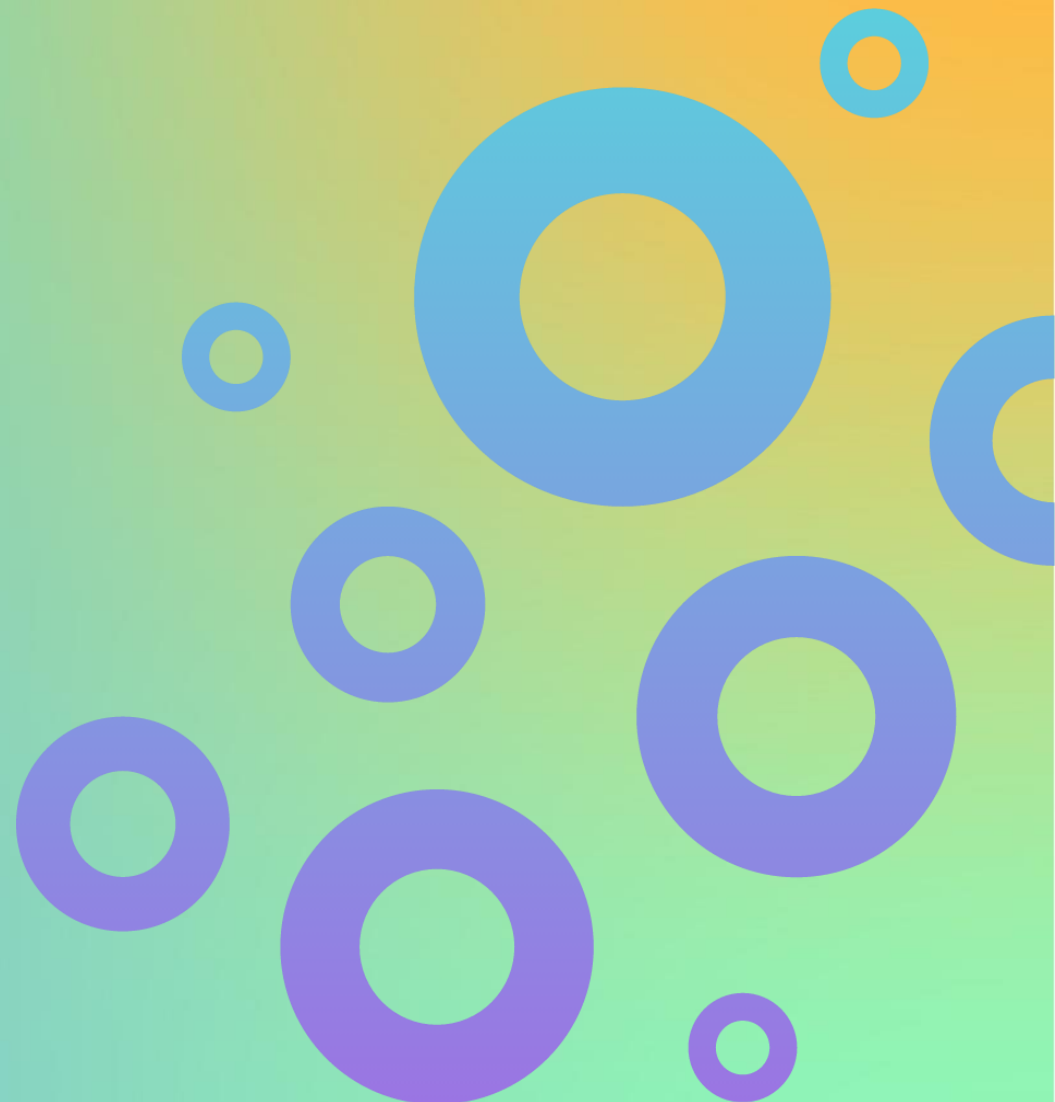


# HS

*Franchise building indication*

# HS – A devastating disease

Prof Kenneth B. Gordon

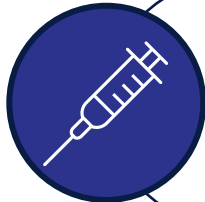


**Prof Gordon has received honoraria and/or research support from the following pharmaceutical companies:** AbbVie, Amgen, Arcutis, Bristol-Myers Squibb, Boehringer Ingelheim, Dermavant, DICE, Incyte, Eli Lilly, Janssen, LEO Pharma, MoonLake Immunotherapeutics, Novartis, Pfizer, Protagonist, UCB, Union



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>

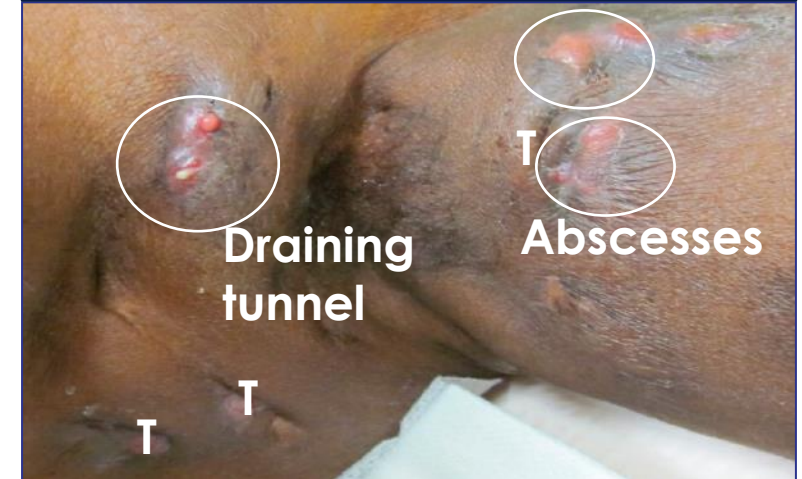
...we need HS therapies that provide **sustained and significant improvements** to patients' lives



**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 with deep abscesses and tunnels<sup>4</sup>



Late-stage disease with extensive scarring and ulceration<sup>4</sup>



<sup>1</sup> Sabat et al Nat Rev Dis Primers 2020;6:18

<sup>2</sup> Krueger et al Br J Dermatol 2024;190:149–162

<sup>3</sup> Ingram et al EADV 2023;Poster P0046

<sup>4</sup> T, tunnel | Pictures courtesy of Prof. Kenneth B. Gordon and Dr Gretchen M. Roth

## Symptoms<sup>1</sup>

Key symptoms include...

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

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

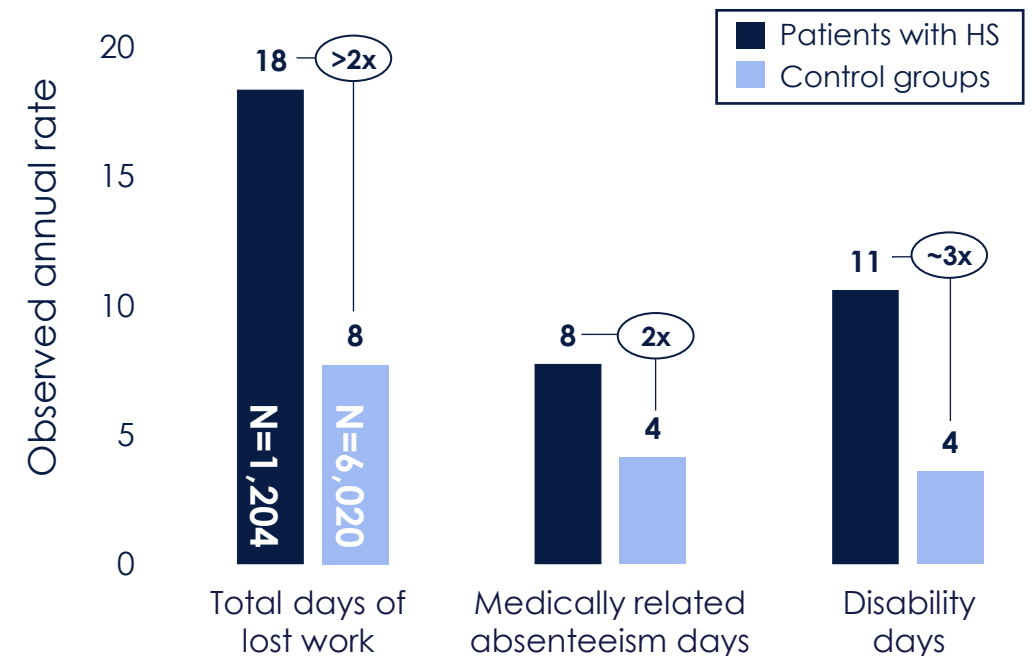
## Hospitalizations

Hospitalization and ER visits are common for patients with HS<sup>2</sup>

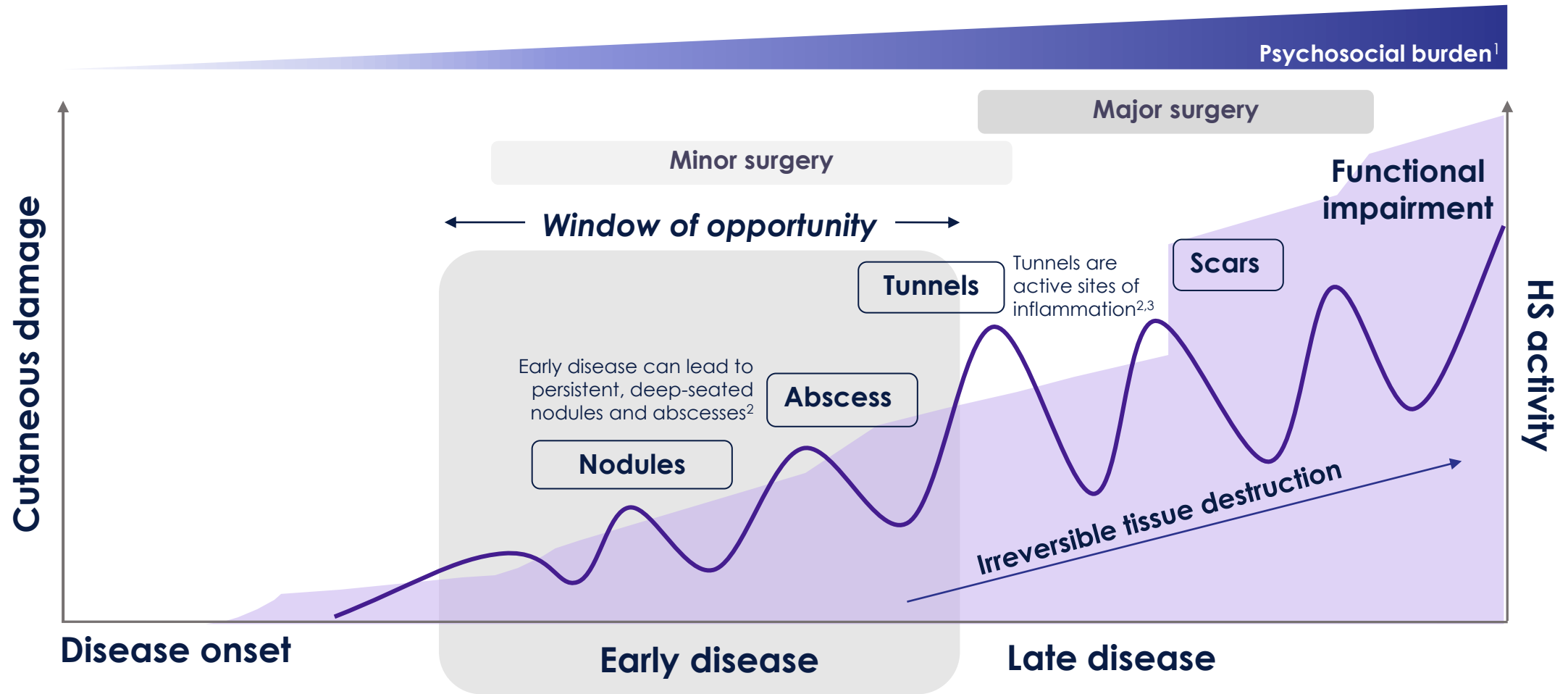
- **30% of patients with HS were hospitalized** as an inpatient on  $\geq 1$  occasion, in a US claims database covering 2016–2019<sup>2</sup>
- **6 days in hospital** and **\$33k costs** represent a typical hospitalization of a patient with HS, according to NIS data<sup>3</sup>

## Work and employment burden

In the US, HS leads to **>2x days of lost work** and nearly **3x** disability days vs. controls<sup>4</sup>



A similarly severe impact on work and employment is seen in Europe<sup>5</sup>



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

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

1 Ooi et al JAAD Int 2023;10:89-94

2 Sabat et al Nat Rev Dis Primers 2020;6:18

3 Navrazhina et al J Allergy Clin Immunol 2021;147:2213-2224



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

We need

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

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

## Only 2 biologics are approved for HS

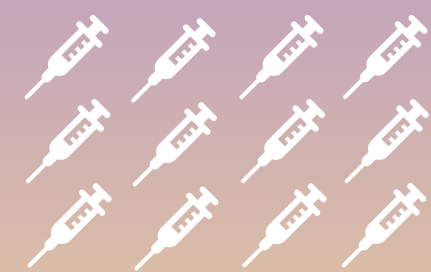
FDA-approved biologic therapies<sup>1</sup>

HS

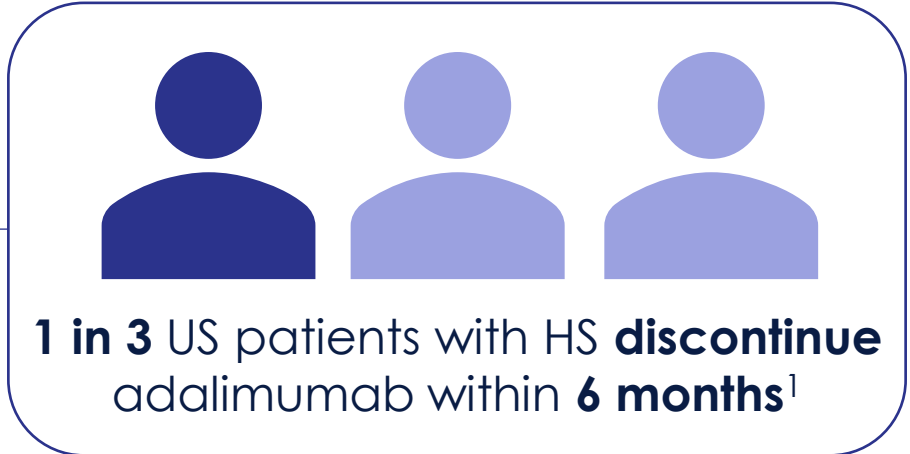
2

12

Psoriasis



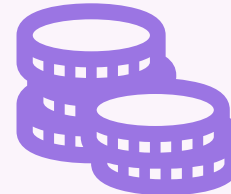
**Median drug survival**  
Adalimumab in US  
patients with HS<sup>1</sup>



**Patient groups with the highest  
burden of drug discontinuation...**<sup>1</sup>



Women



Medicaid  
coverage



Younger  
adults



Recent  
surgery

→ Similar rates observed in Europe: median drug survival reported from 8–9 months (Denmark) to 18 months (Netherlands)<sup>2</sup>

<sup>1</sup> Kimball et al EHSF 2024;T6-P-08

<sup>2</sup> Data also available for Austria | Ring et al JAMA Dermatol 2022;158:184–188, Prens et al Br J Dermatol 2021;185:177–184, Wiala et al EADV 2023;P0134, Ring et al Br J Dermatol 2024;doi:10.1093/bjd/ljae042



**Sustained efficacy is key for both derms and patients<sup>1,2</sup>**  
and is central to other aims of treatment



### **Hospitalizations<sup>3,4</sup>**

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



### **Symptoms<sup>6</sup>**

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



### **Work and employment burden<sup>5</sup>**

- Enable employment
- Increase personal happiness and social integration



**Established safety profile<sup>1,6</sup>** — Risk of serious adverse events is another important consideration for both derms and patients

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

1 Ingram et al EHSF 2023;T6-O-15

2 Ring et al Br J Dermatol 2024;doi:10.1093/bjd/ljae042

3 Garg et al J Am Acad Dermatol 2020;82:366-376

4 Krueger et al Br J Dermatol 2024;190:149-162

5 Schneider-Burrus et al Br J Dermatol 2023;188:122-130

6 Willems et al Patient 2023;16:153-164

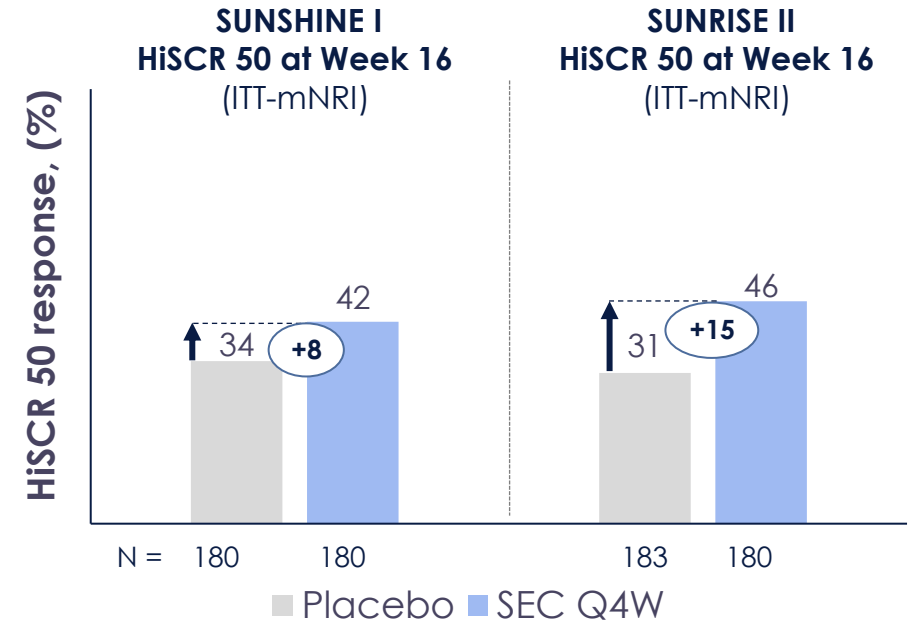
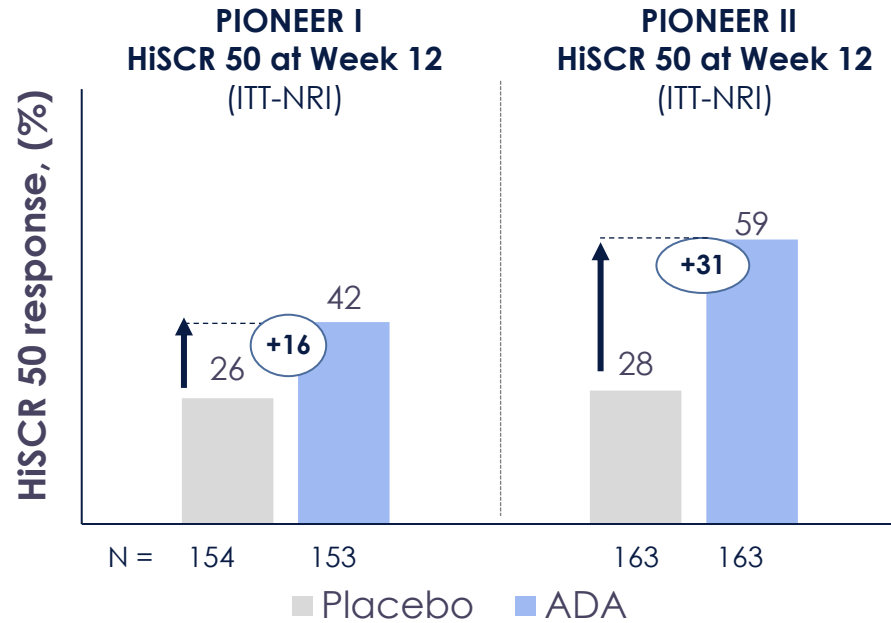
# Treatment goals have not been advanced in eight years

## Adalimumab (Humira®<sup>1</sup>) FDA HS approval 2015<sup>1</sup>

- **TNF inhibitor** Traditional mAb (~148kDa)

## Secukinumab (Cosentyx®<sup>3</sup>) FDA HS approval 2023<sup>2</sup>

- **IL-17A inhibitor** Traditional mAb (~150 kDa)



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

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

**Additional therapeutic options with alternative mechanisms of action and higher levels of response are urgently needed**

<sup>1</sup> ITT-NRI, non-responder imputation in an intention-to-treat population | Humira® Prescribing Information, Kimball et al N Engl J Med 2016;375:422-434

<sup>2</sup> ITT-mNRI, modified non-responder imputation in an intention-to-treat population | Cosentyx® Prescribing Information, Kimball et al. Lancet 2023;40:747-761

## Bimekizumab (Bimzelx®)

- IL-17A and IL-F inhibitor Traditional mAb (~150kDa)

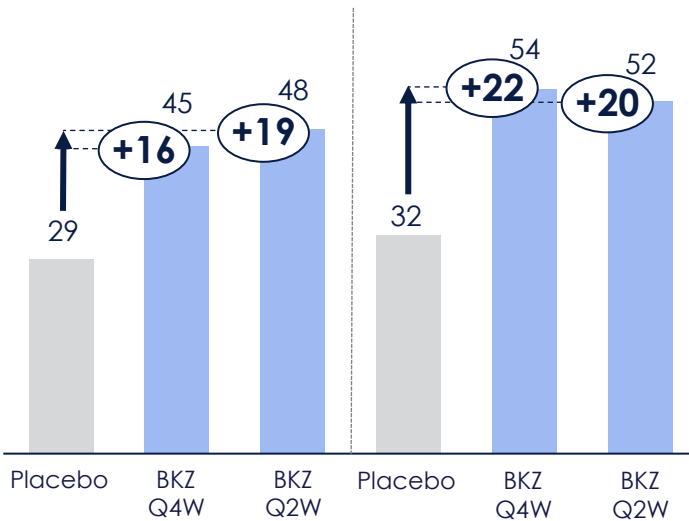
### Primary endpoint

HiSCR 50 at Week 16 (ITT-mNRI)

BE HEARD I

BE HEARD II

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



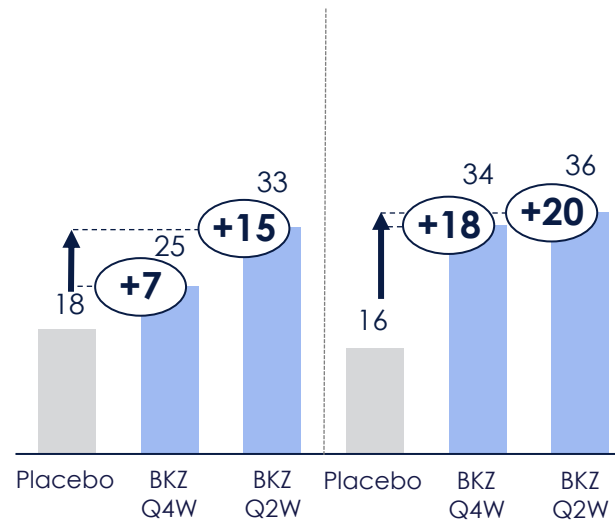
### Secondary endpoint

HiSCR 75 at Week 16 (ITT-mNRI)

BE HEARD I

BE HEARD II

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



## Elevating trial endpoints

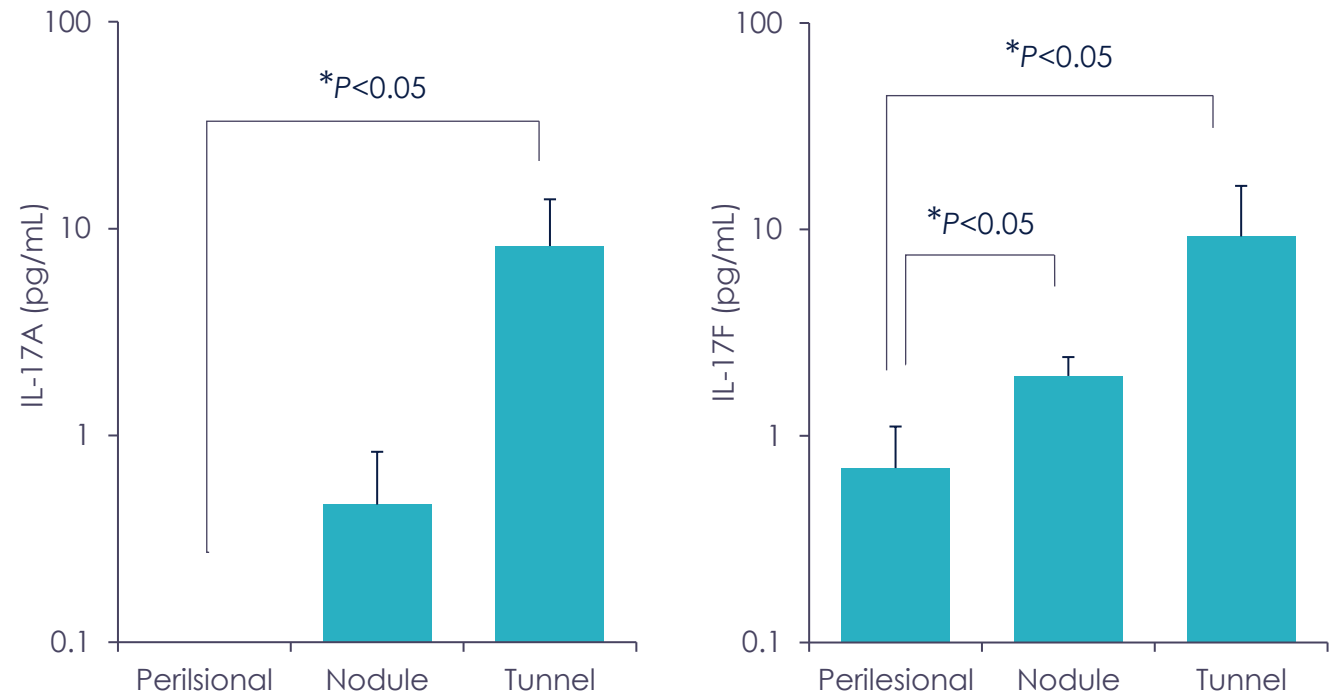
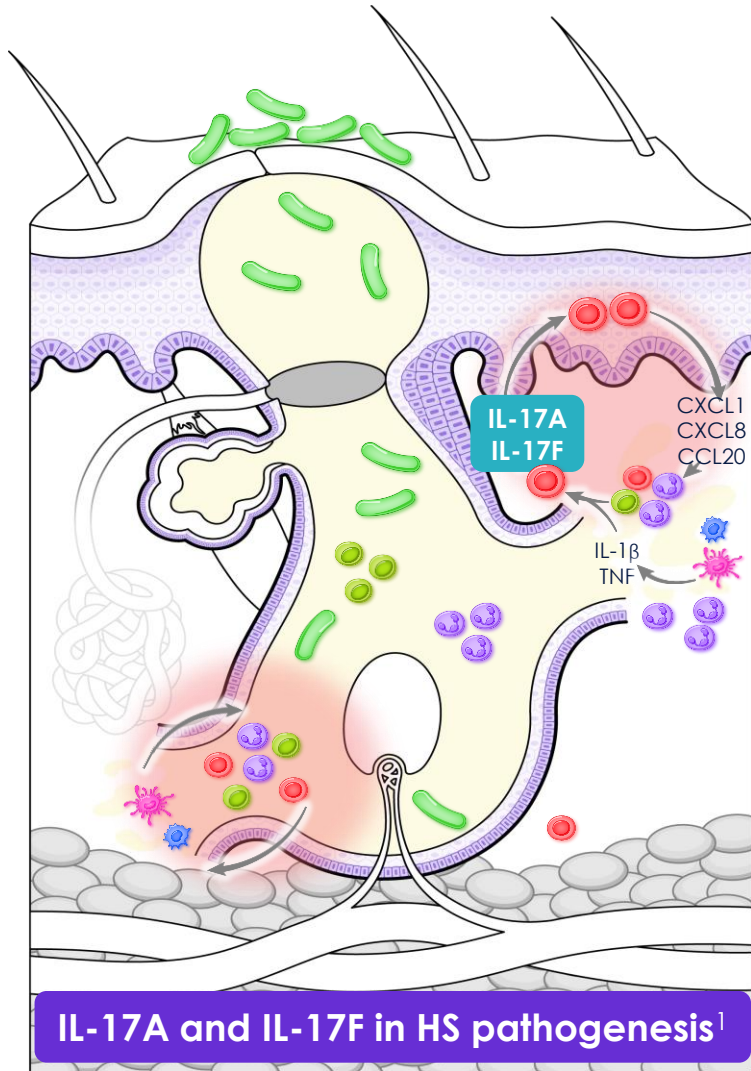
- Primary endpoint response was within the range of reports from earlier HS trials
- HiSCR 75 data suggested possibility of achieving higher threshold responses in HS than HiSCR 50

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

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

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

MoonLake research<sup>2</sup>



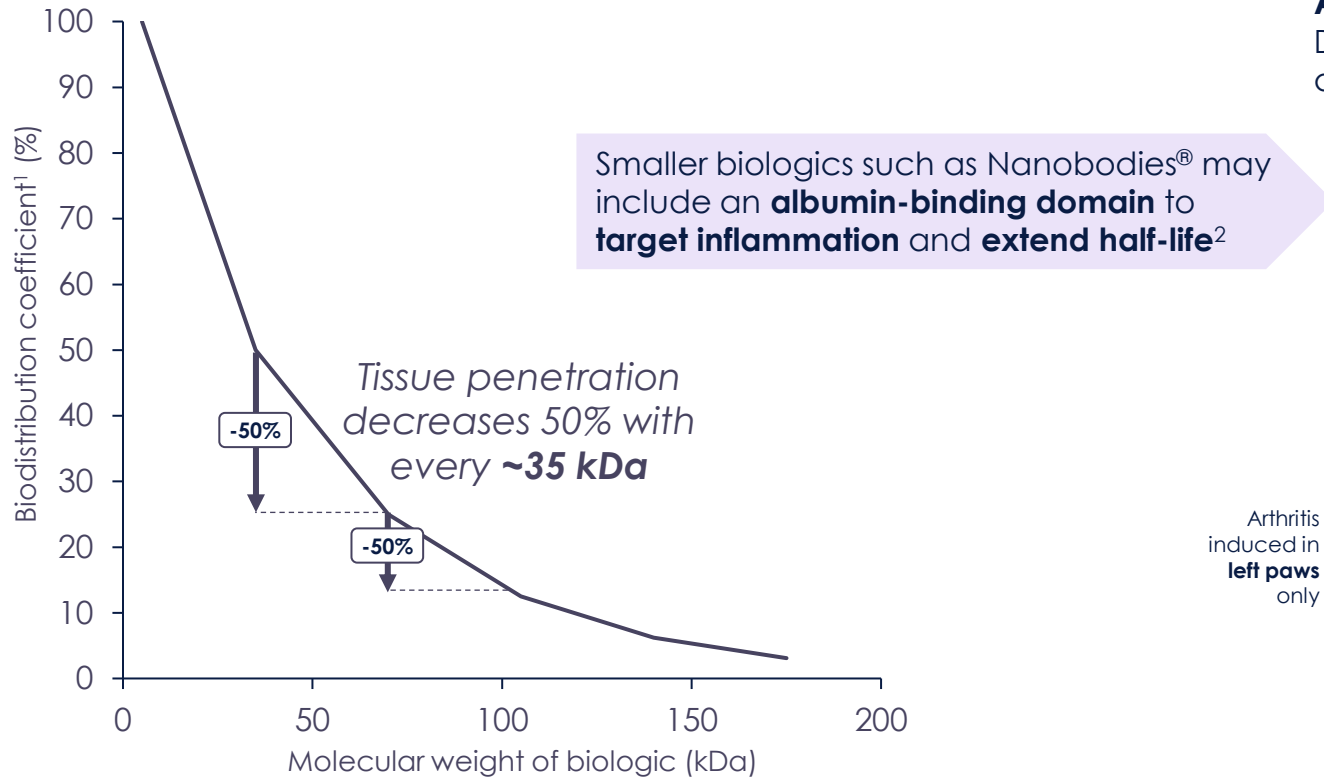
**IL-17A and IL-17F protein levels measured by cytokine array**

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

<sup>1</sup> Figure reproduced under the terms of the CC-BY license | Krueger et al Br J Dermatol 2024;190:149-162

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

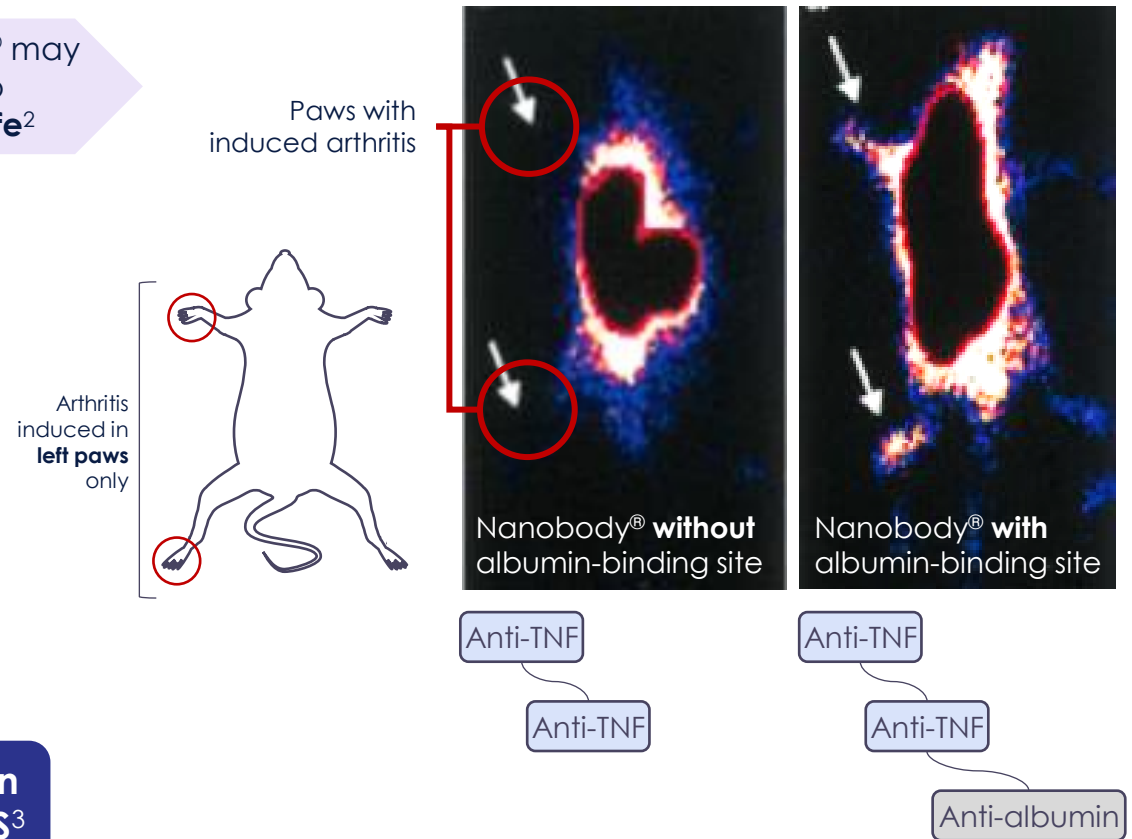
Smaller biologics → higher tissue uptake<sup>1</sup>



**Nanobodies® are designed to directly target sites of inflammation in difficult-to-reach tissues, such as the deep dermal tunnels in HS<sup>3</sup>**

Albumin-binding domains target inflammation

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



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

## MIRA efficacy at Week 12

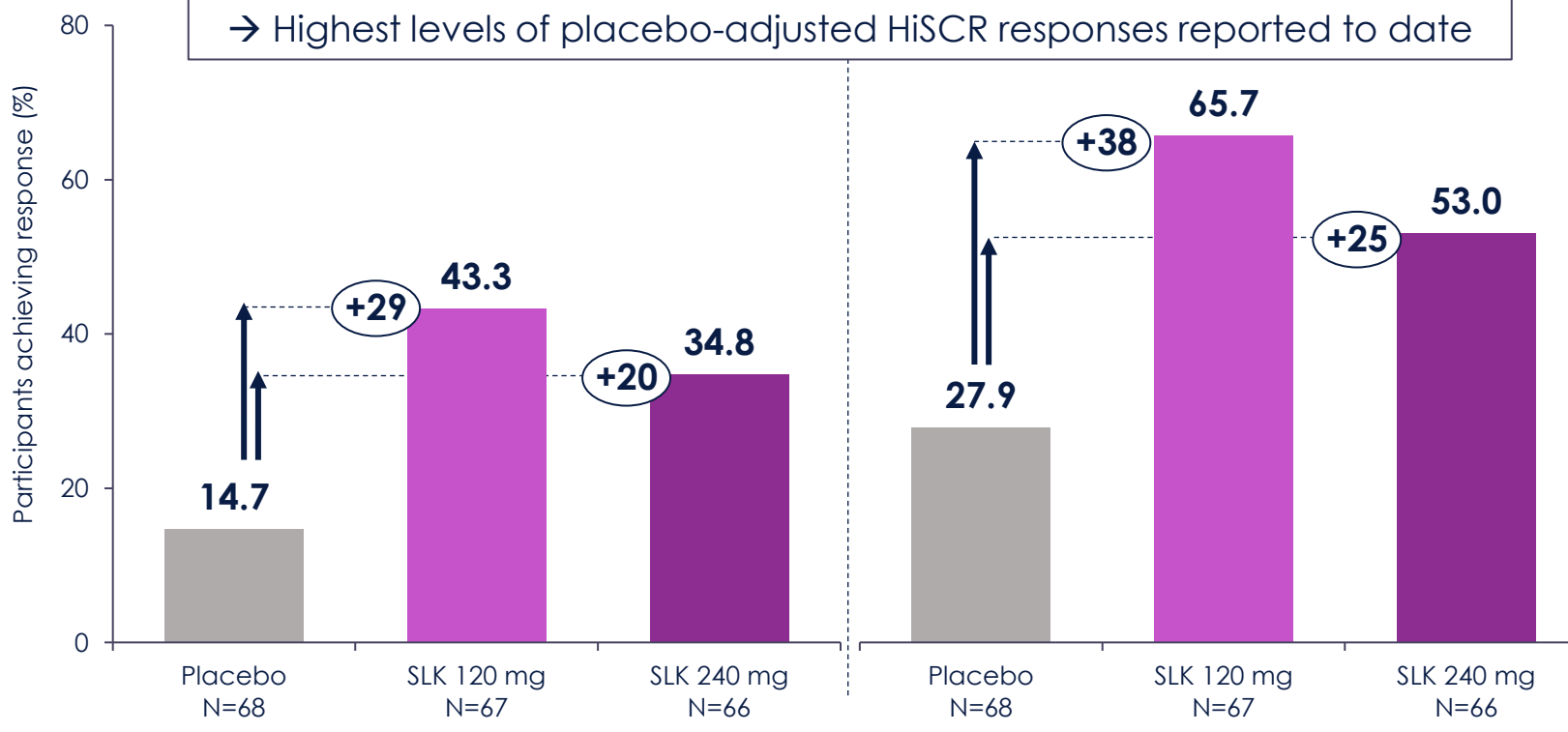
Primary endpoint 1<sup>st</sup> time in an HS trial

Key secondary endpoint

### HiSCR 75 (ITT-NRI)

### HiSCR 50 (ITT-NRI)

→ Highest levels of placebo-adjusted HiSCR responses reported to date

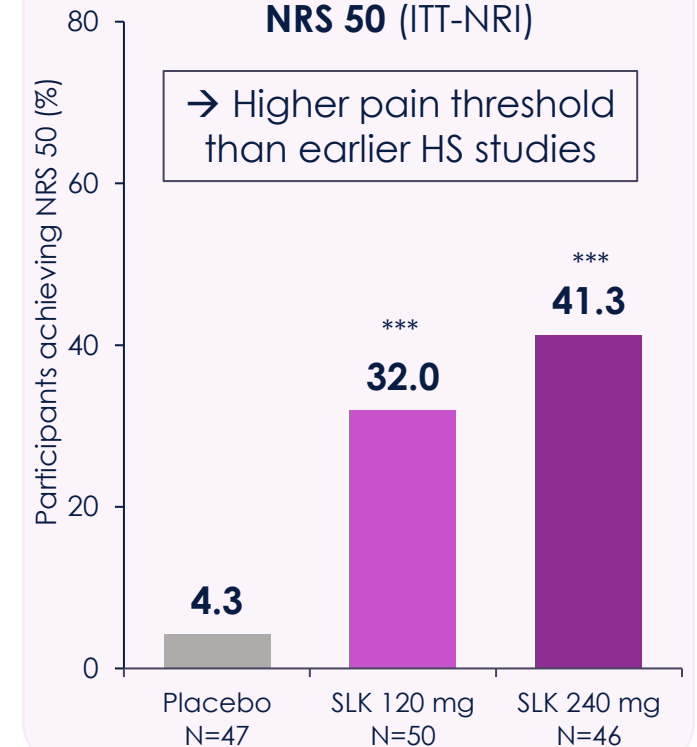


## Pain at Week 12

SLK achieved pain responses at the high threshold of NRS 50

### NRS 50 (ITT-NRI)

→ Higher pain threshold than earlier HS studies

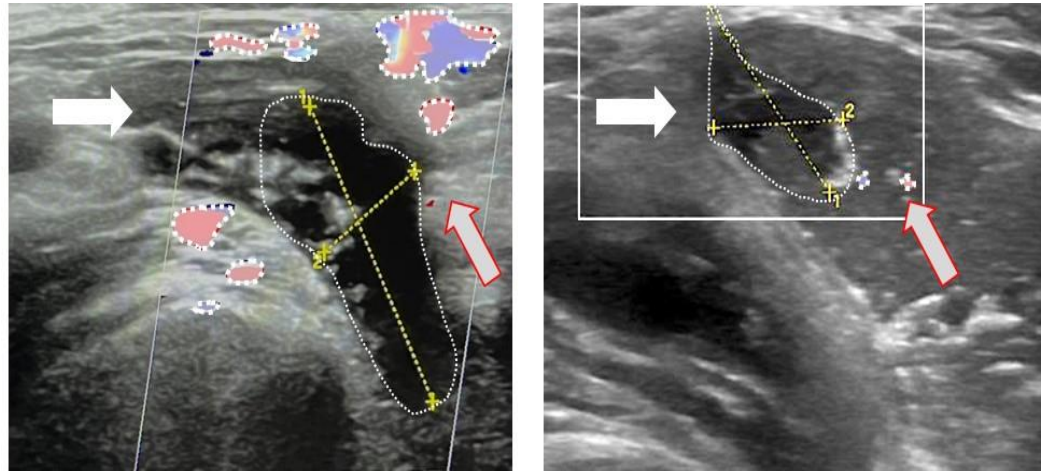


Sonelokimab was well tolerated with no unexpected safety findings

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



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

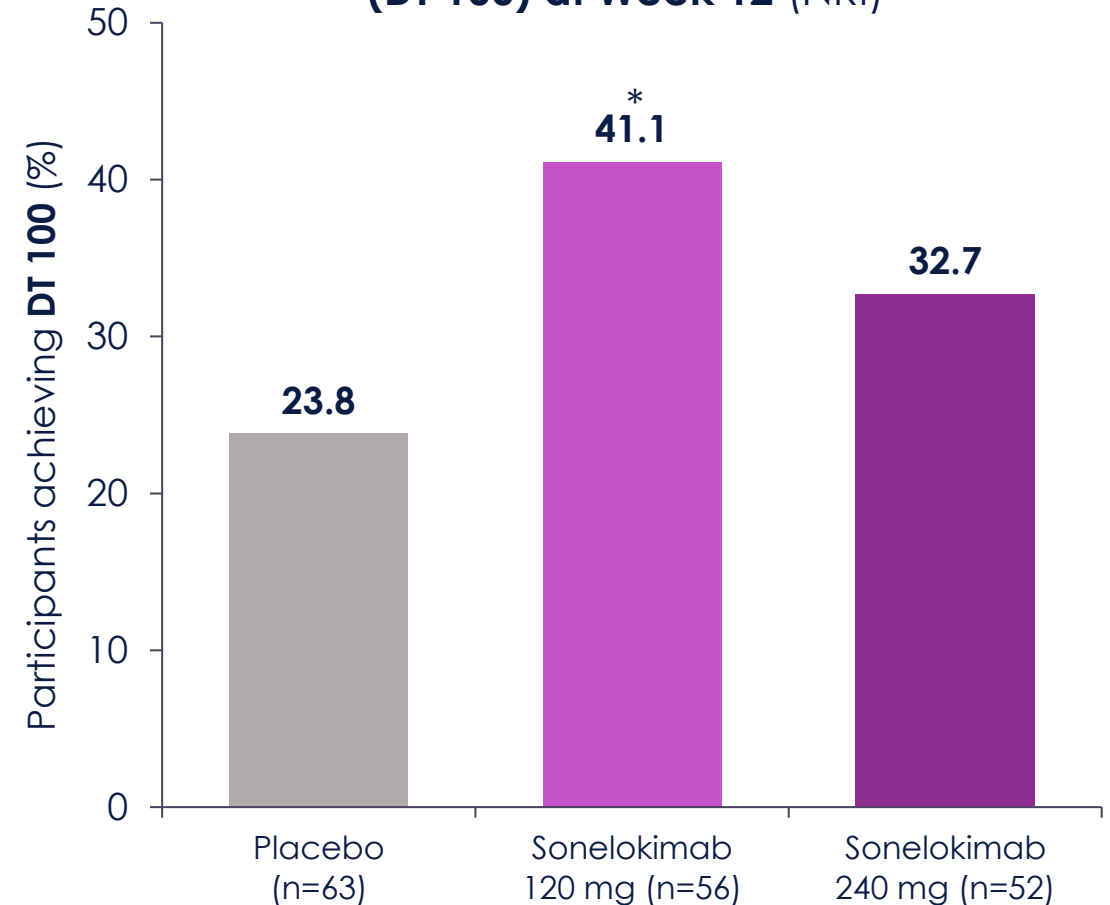


Baseline

Week 12


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

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



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

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



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



**MAINTENANCE OF RESPONSE**  
Assessing the **longevity** of treatment effect is critical




**PATIENT POPULATION**  
**Baseline disease severity** is key for interpreting results



**OPTIMAL DOSE**  
Dose based on **risk-benefit** evidence per **regulators**



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

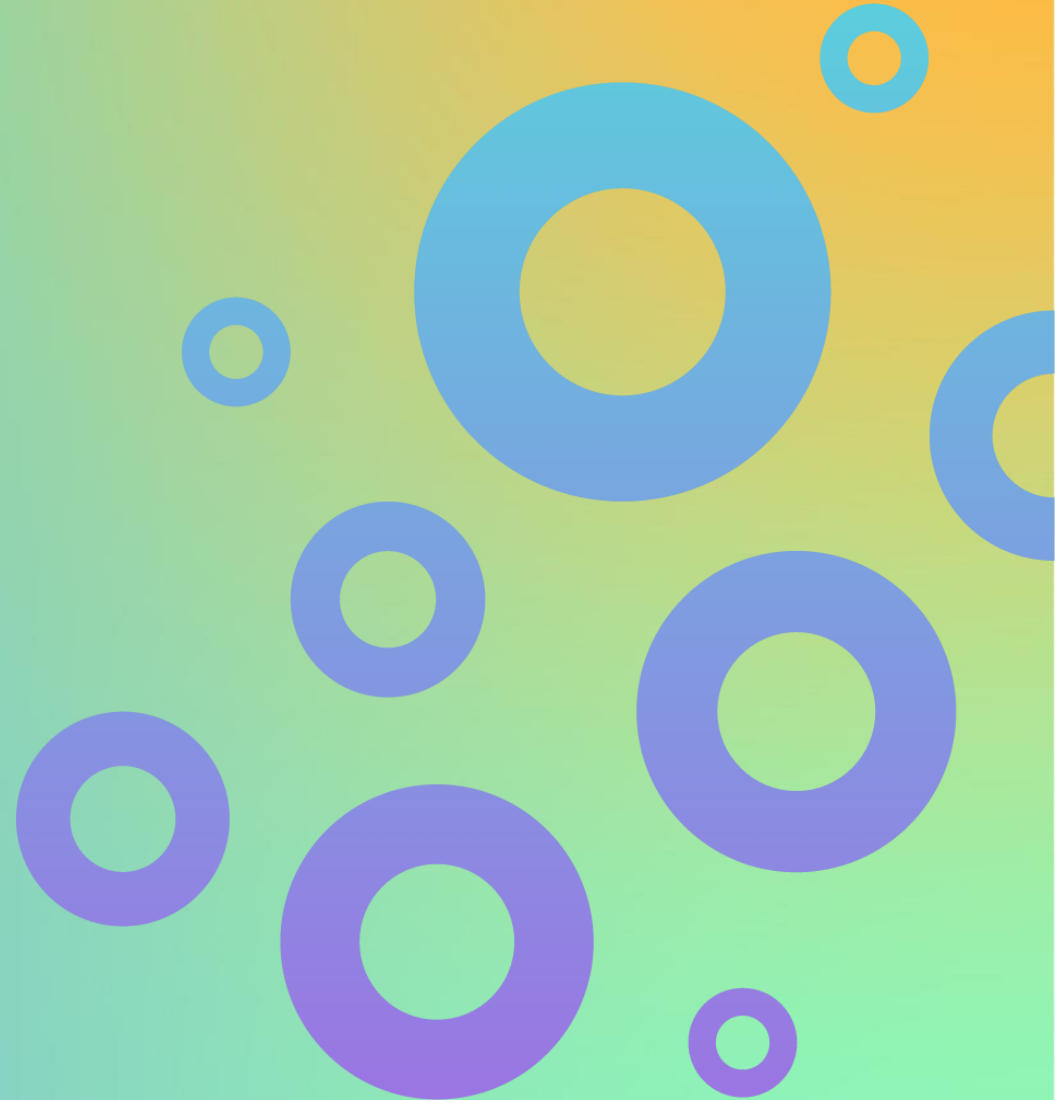


**COHORT SIZE**  
Enroll **sufficient number of patients** to satisfy regulators

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

# SLK differentiation & Phase 3 program

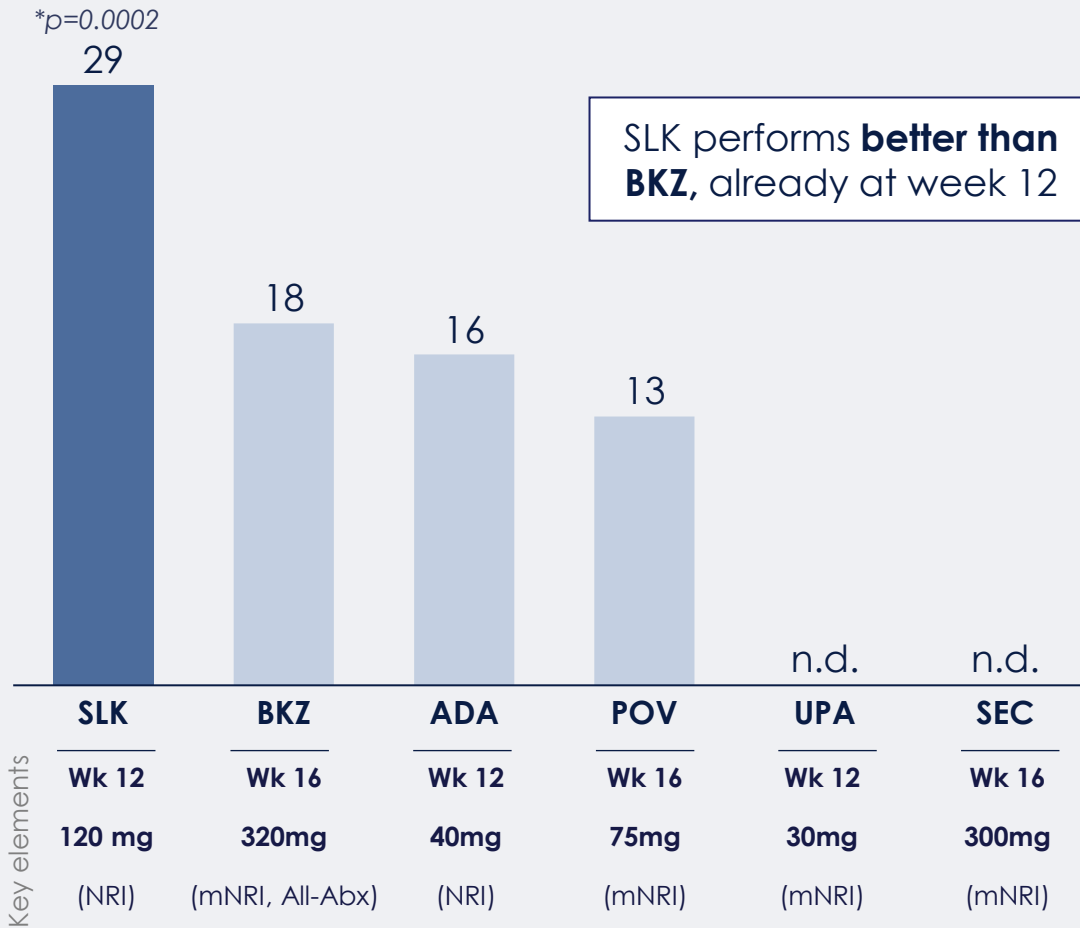
Kristian Reich



# Recap: Setting a new bar in HS for primary endpoints

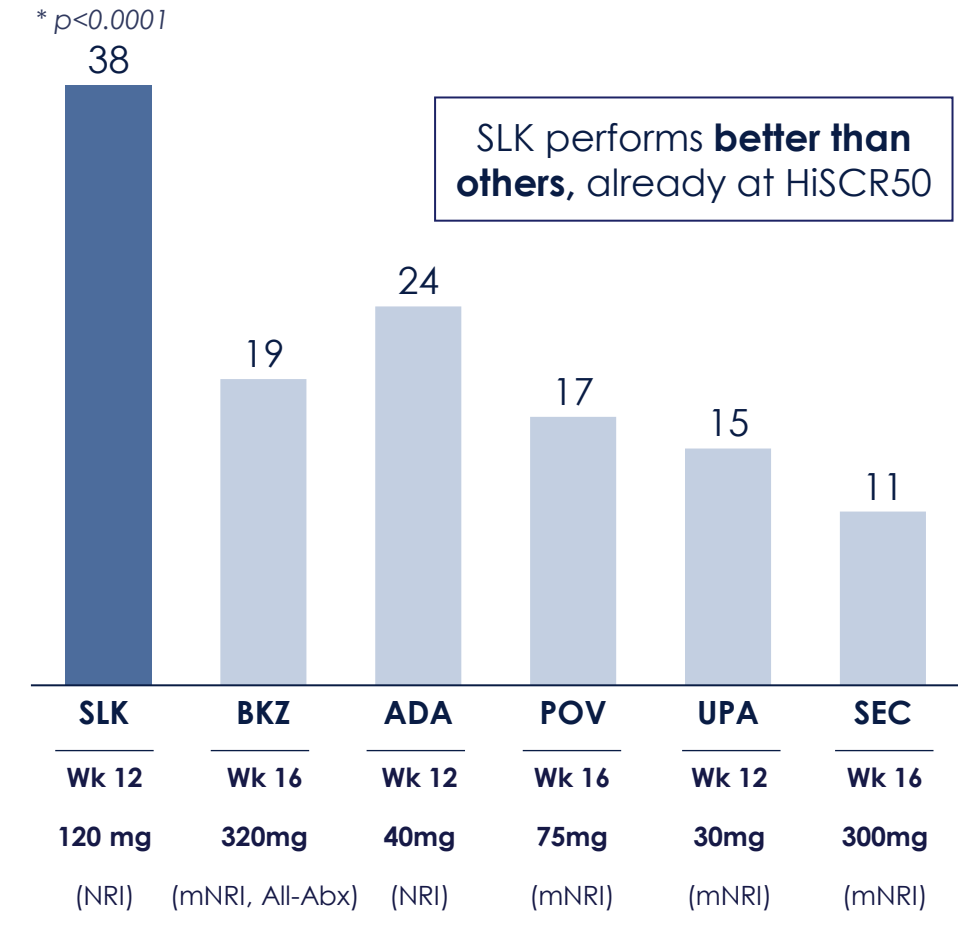
## HiSCR75 delta to PLC (Primary endpoint only for SLK)

Percent delta for best doses, primary analysis



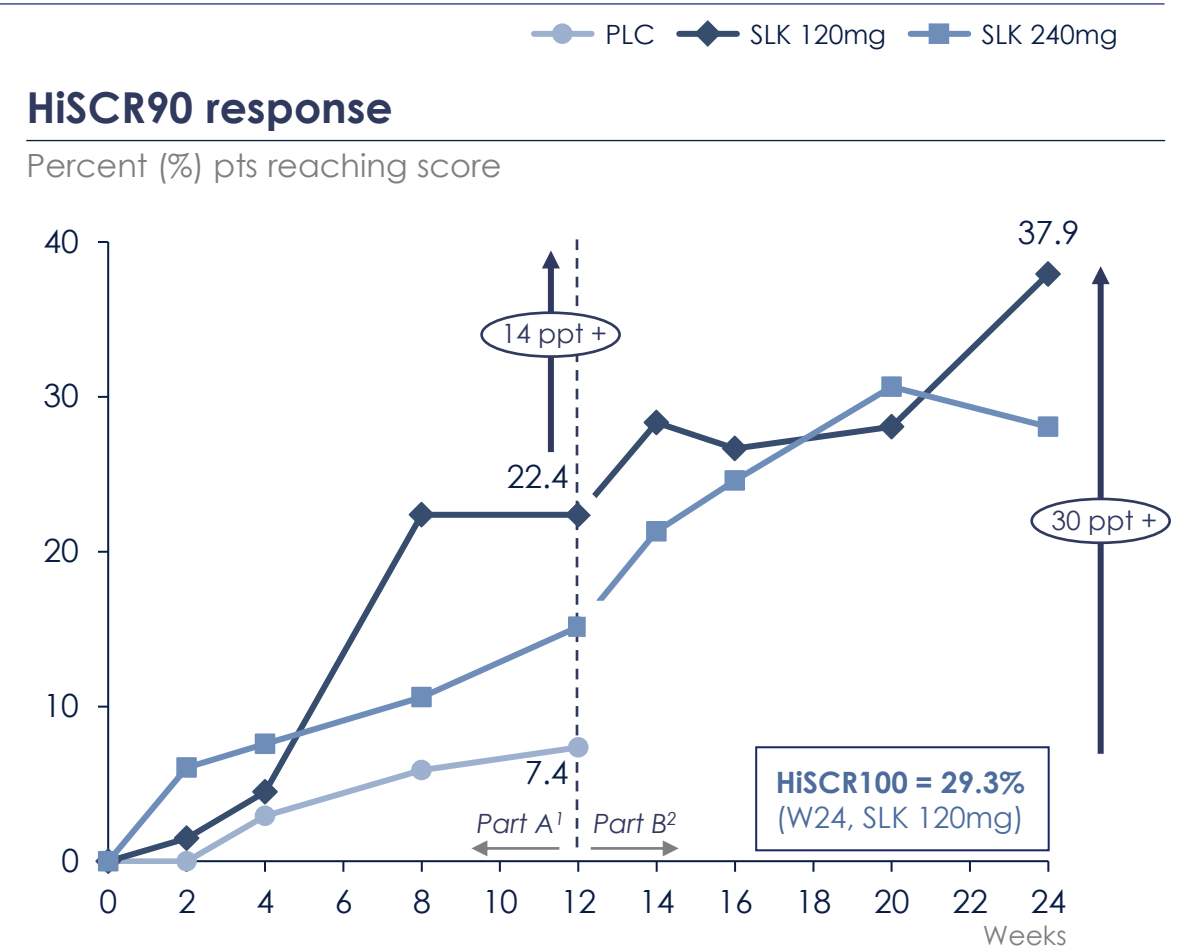
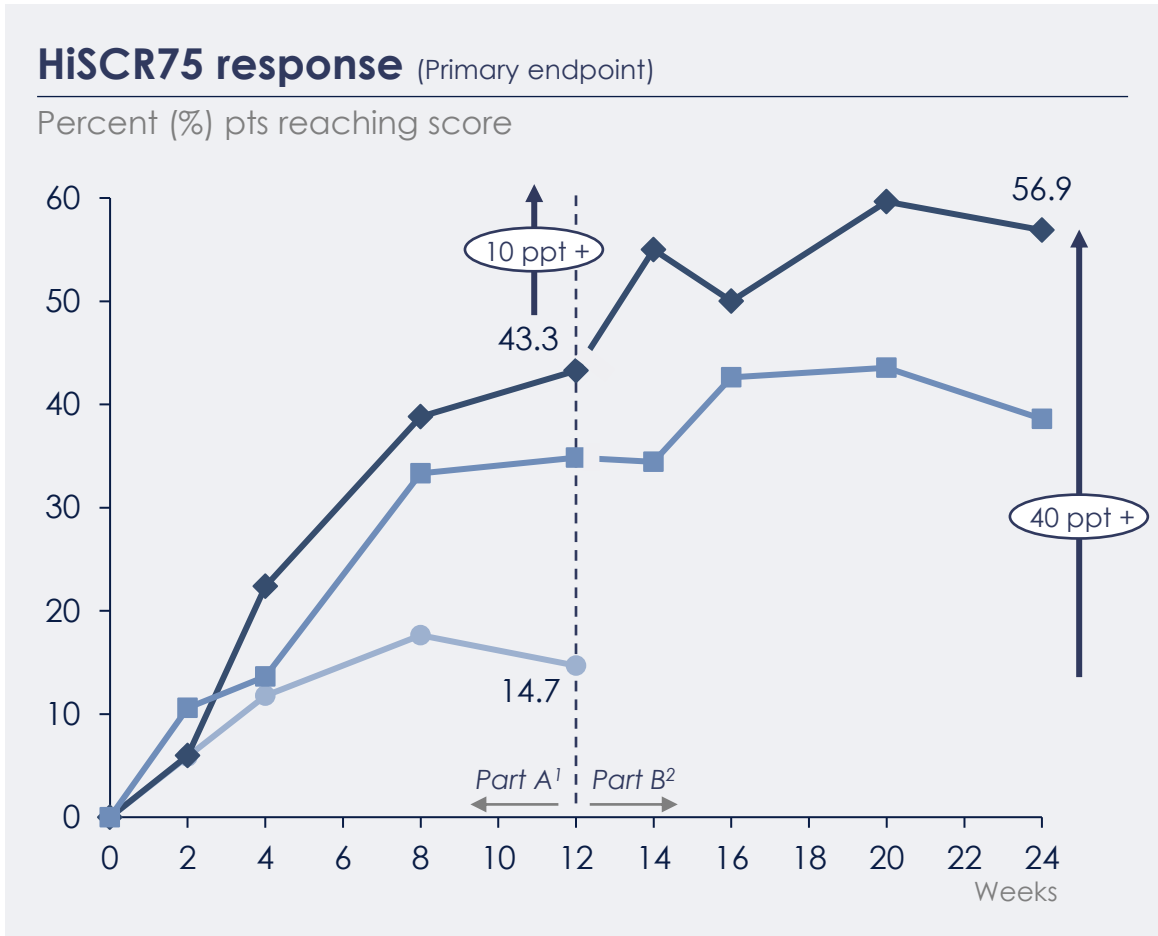
## HiSCR50 delta to PLC (Primary endpoint for others<sup>1</sup>)

Percent delta for best doses, primary analysis



Note: This is a comparison across trials, with inherent limitations. No head-to-head trials. 1 POV used mean AN count reduction as primary endpoint 2 Estimation of HiSCR75 delta to PLC at wk 16 using the avg. response of the 2 crossed-over groups from PLC to SLK doses at wk 12 (PLC plateaus already from week 8) and the wk 16 response for the 120mg arm; PLC, Placebo; SLK, Sonelokimab (MIRA study); BKZ, Bimekizumab (pooled BE HEARD I/II); ADA, Adalimumab (pooled PIONEER I/II); POV, Povorcitinhib (NCT04476043); UPA, Upadacitinib (NCT04430855); SEC, Secukinumab (pooled SUNRISE/SUNSHINE)  
 Source: MoonLake Clinical (R&D Day June 27<sup>th</sup> 2023)

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



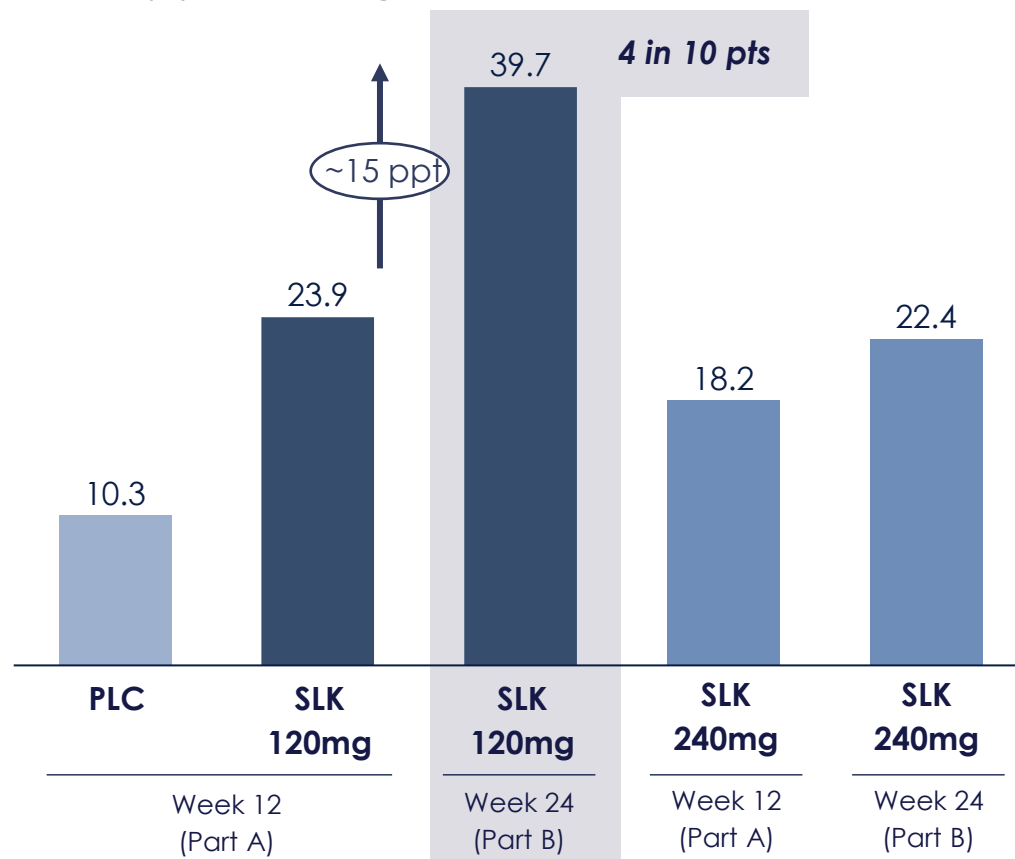
Significant increase in number of patients **reaching HiSCR75** with convenient **monthly injection**  
**Deepening of responses** with monthly maintenance dosing, as close to **40% of patients reach HiSCR90** by week 24

1 IIT-NRI data up to Wk 12 (Part A)

2 As observed data from Wk 14-24 (Part B)

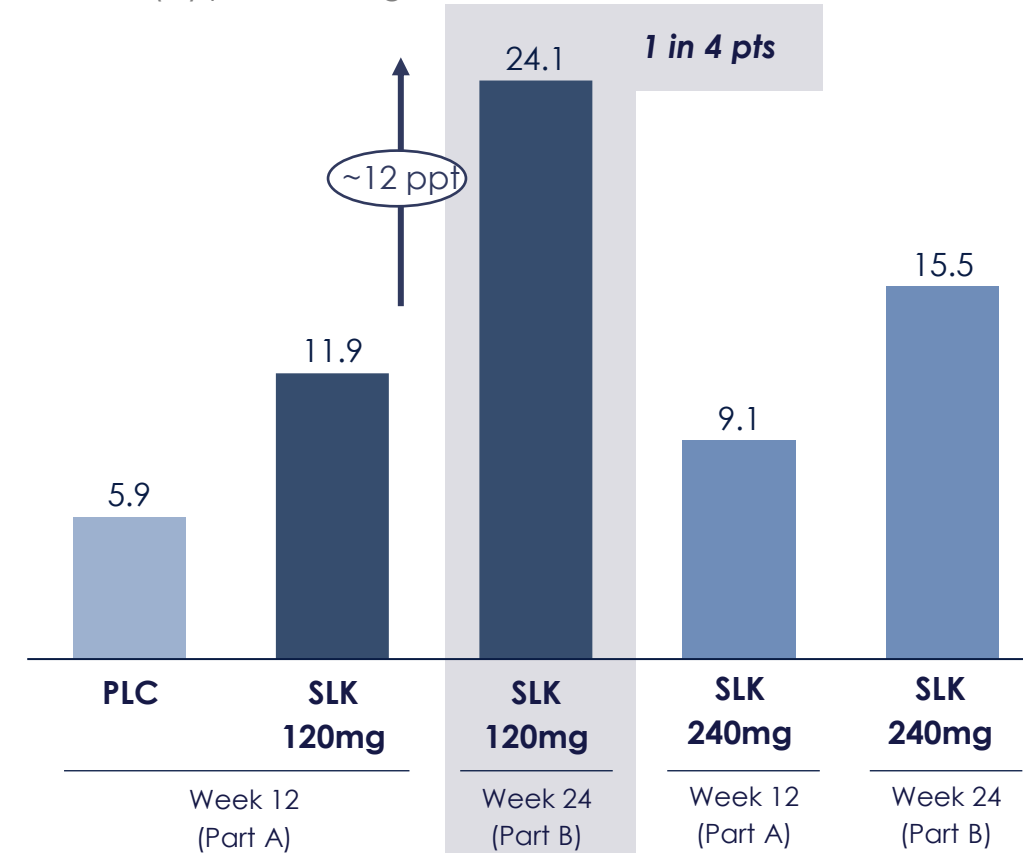
## IHS4-90 response

Percent (%) pts reaching score<sup>1</sup>



## IHS4-100 response

Percent (%) pts reaching score<sup>1</sup>









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

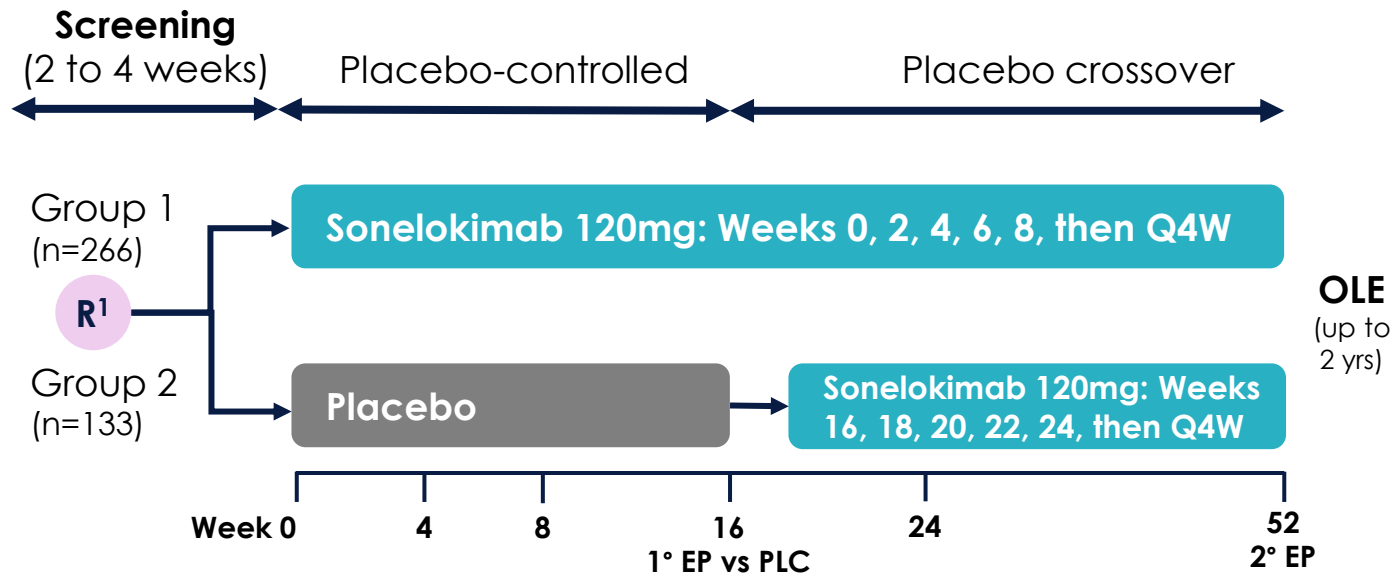
<sup>1</sup> IIT-NRI data up to Wk 12; as observed data after week 12

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



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

## Phase 3 protocol post FDA EoP2 meeting



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

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

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

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



## 2. HS: VELA builds on the success of MIRA



Announcing Phase 3 HS program:



**VELA I**  
**VELA II**

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

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

**BKZ Ph2<sup>1,2</sup> n=90**

**BKZ Ph3 (BH II)<sup>3,4</sup> n=509**

**MLTX Ph2 (MIRA) n=234**

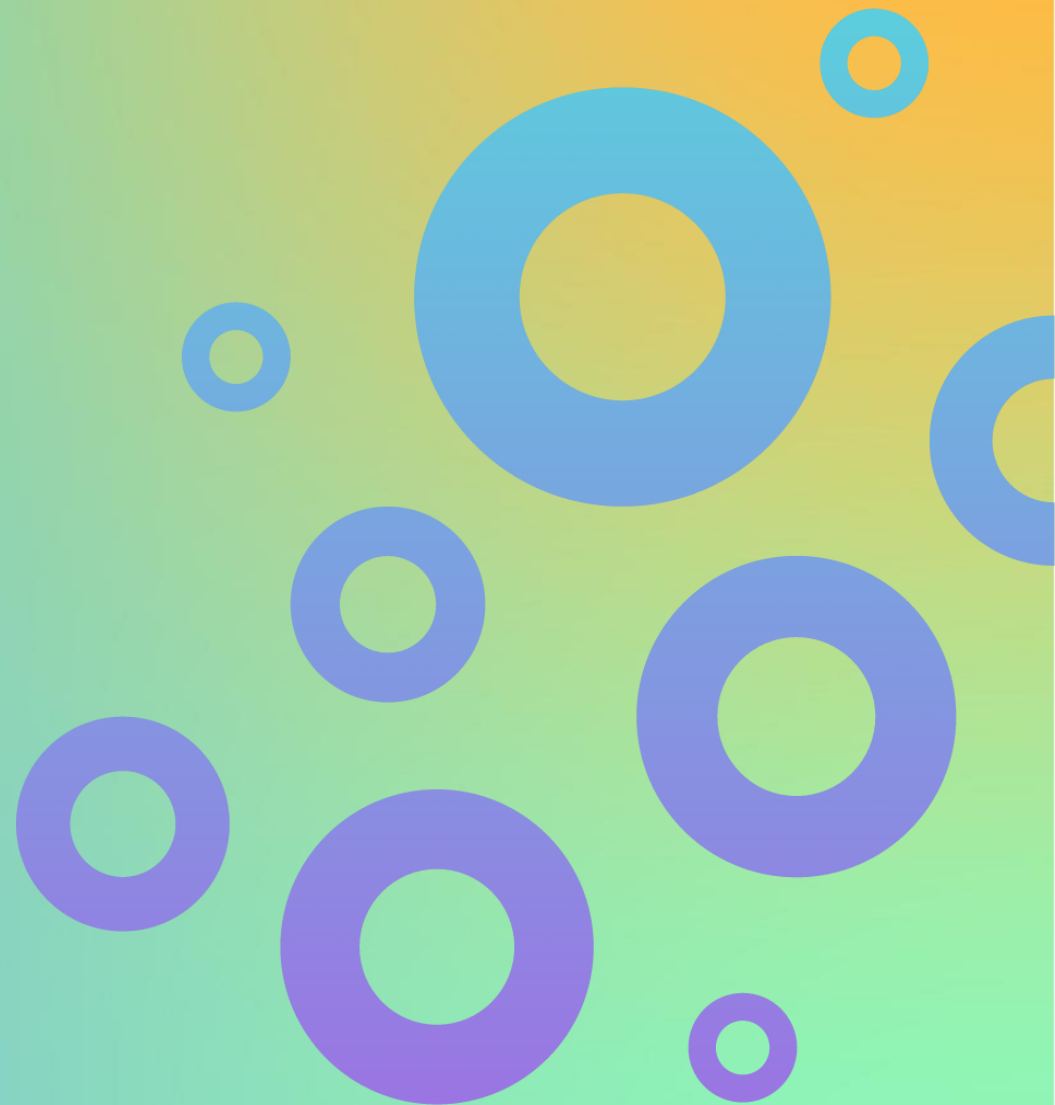
**MLTX Ph3 (VELA) n=800**

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

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

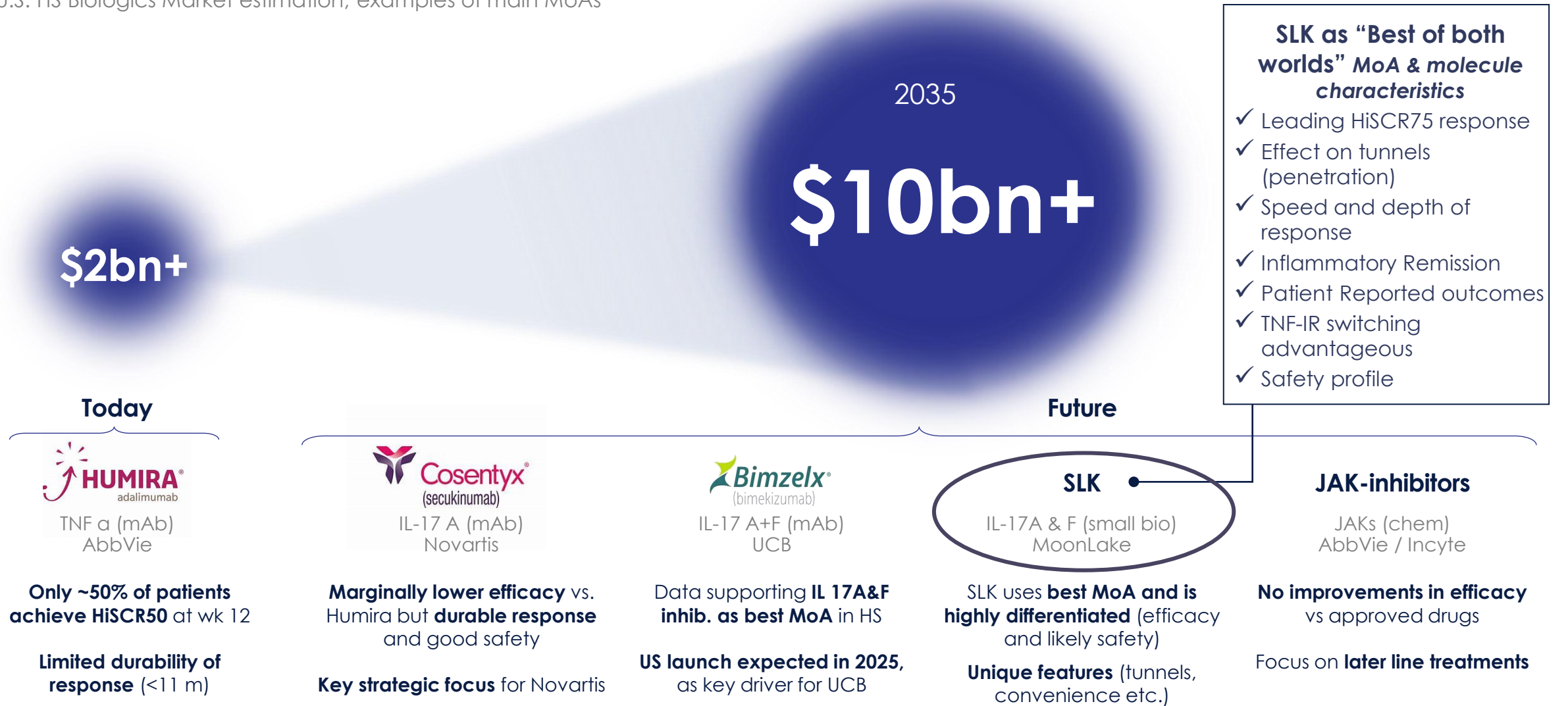
# HS is the next large indication in Derm

Jorge Santos da Silva



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

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



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

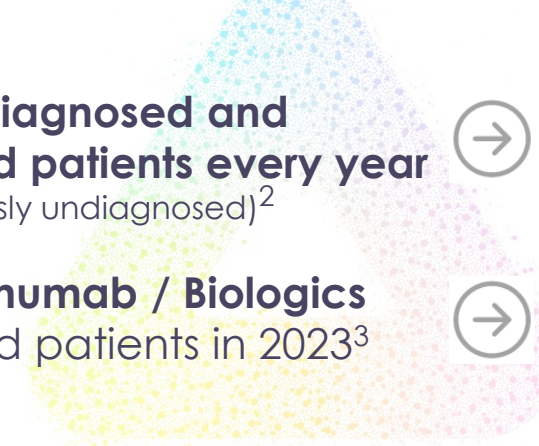
# Market: Large market size is substantiated by real-world data

U.S. adult HS patients

## Claims methodology

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

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

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

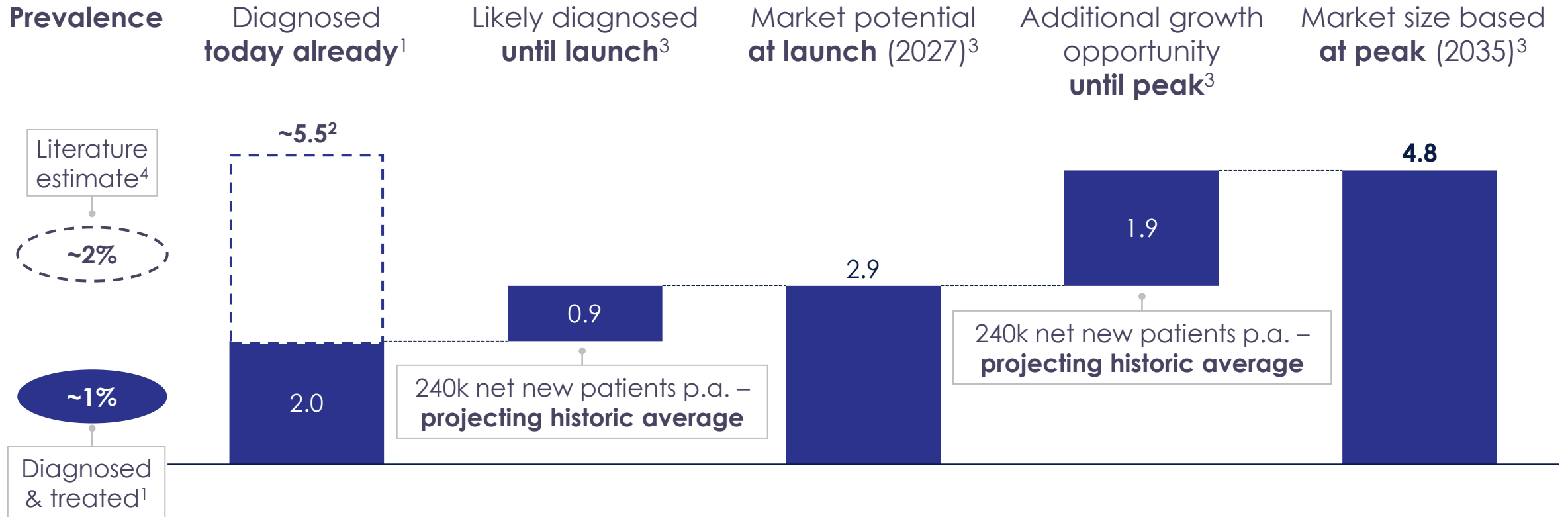
1

2

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

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

U.S. adult HS patients



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

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

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



U.S. adult HS patients

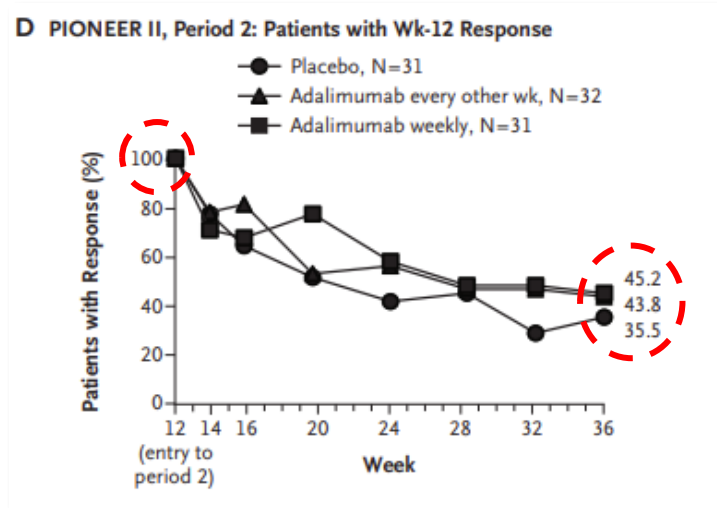
	Therapy post HS diagnosis	
	Year 1 <sup>1</sup>	Year 2-3, of year 1 <sup>2</sup>
<b>Patients on antibiotics or steroids</b> – most continue longer-term	<b>55%+</b>	<b>65%+</b>
<b>Patients visiting an emergency room</b> – most continue to have visits	<b>30%+</b>	<b>55%+</b>
<b>Patients that undergo HS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

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

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

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

## Trial results: Maintenance of response



**~55%** did not maintain response after 9m

## Claims: Duration of therapy (N=53k)<sup>1</sup>

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

xx Median duration (m) on therapy



**~11m median** duration of treatment

**Not linked to U.S. access & affordability hurdles,** given European studies show similar results<sup>2</sup>

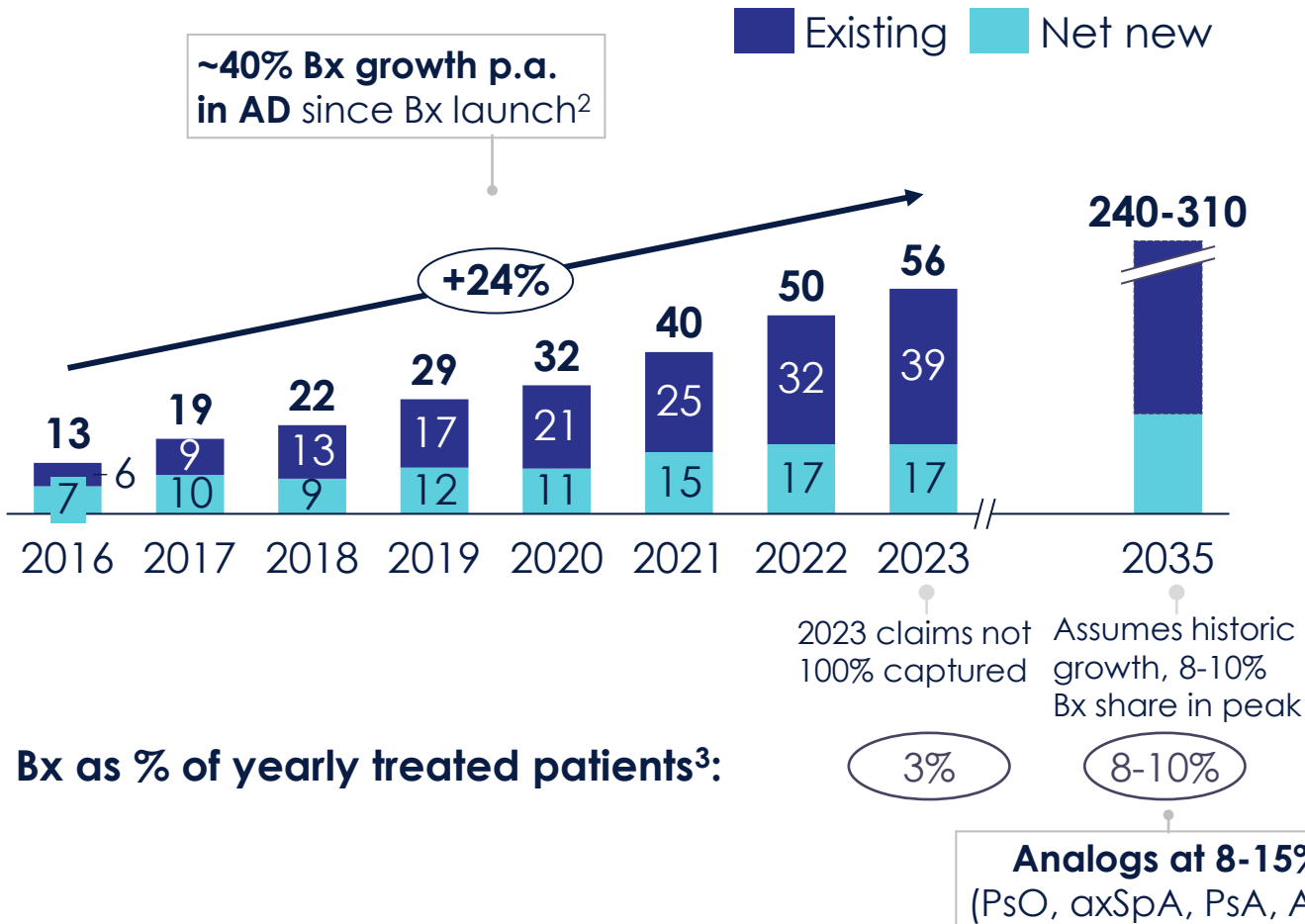
**Claims data confirms limited duration of therapy (~11m median) for Adalimumab in real-world patients, leaving them without efficacious HS treatment option**

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



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

### HS Biologics and targeted treatment patients in U.S. (k)<sup>1</sup>



### Bx as % of yearly treated patients<sup>3</sup>:

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

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

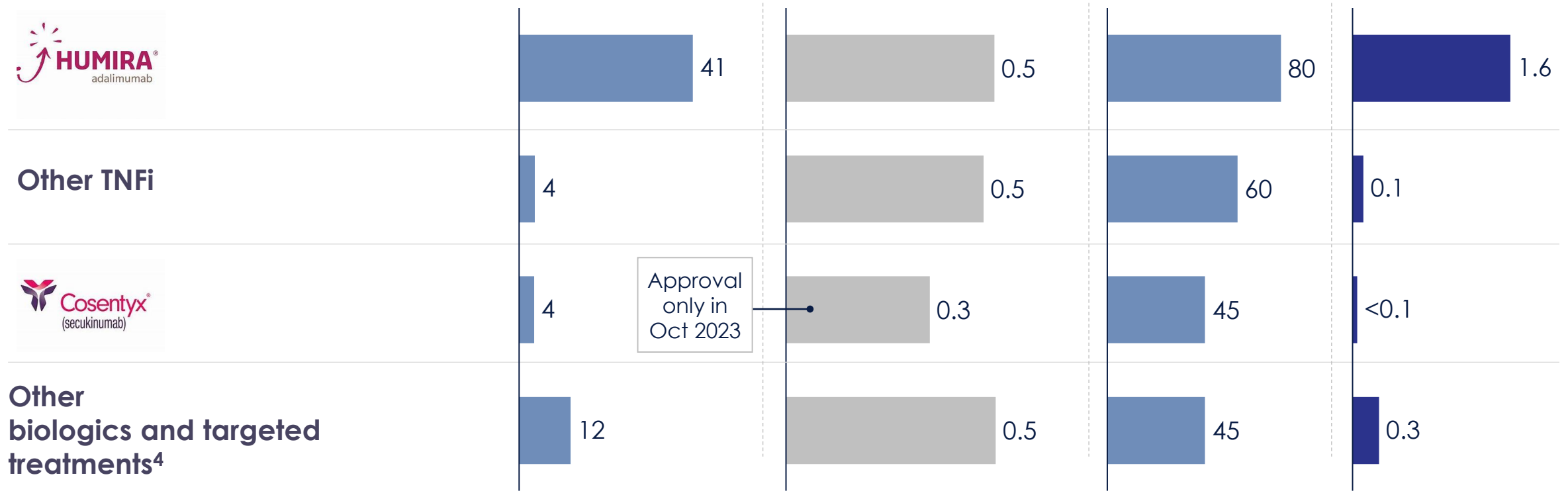
# 2 Market: Humira accounts for most of current \$2bn+ biologics market

2023 claims not 100% captured yet (time lag)

## HS market (2023 – Q4 claims not fully covered)

### Competitors

Patients treated (k)<sup>1</sup>  $\otimes$  2023 fill rate (yrs)<sup>2</sup>  $\otimes$  Net price (USDk)<sup>3</sup>  $\ominus$  Revenue (USDbn)



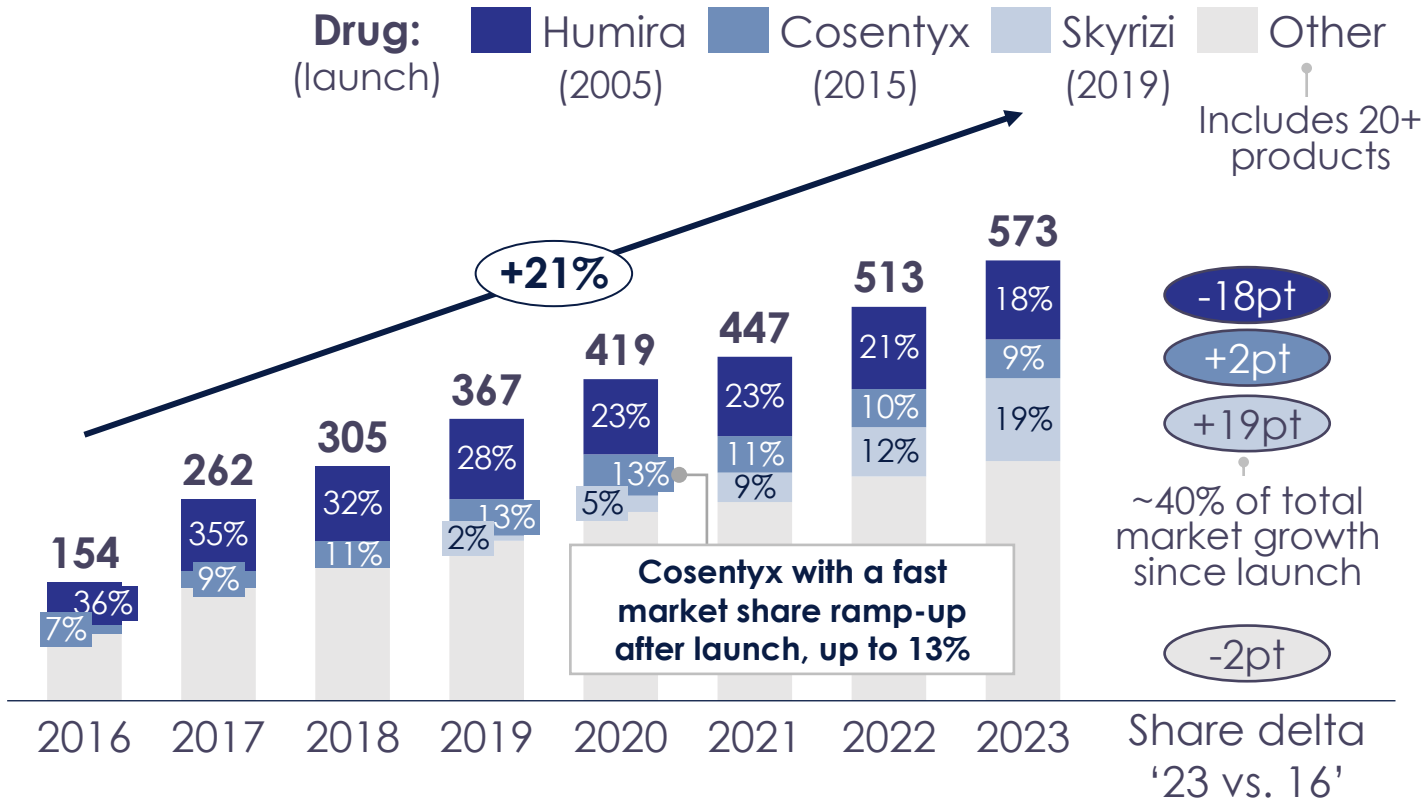
**Total**

**2.1**

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

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

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



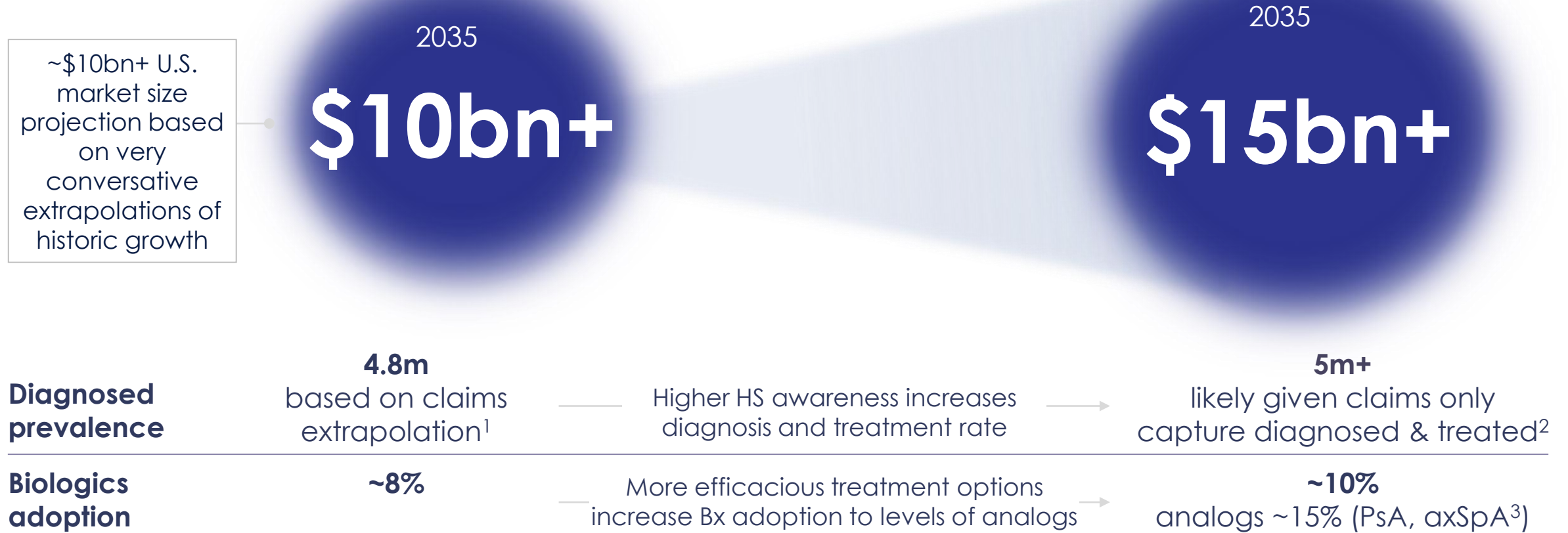
- **Better clinical profile matters most:** After their respective launches Cosentyx and Skyrizi are capturing a big share of the market
- **New entrants are growing the market:** Upon their launches the biologics market has grown substantially (Skyrizi accounted for 40% of market growth)
- **Disease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

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

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

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

U.S. adults HS Biologics Market estimation



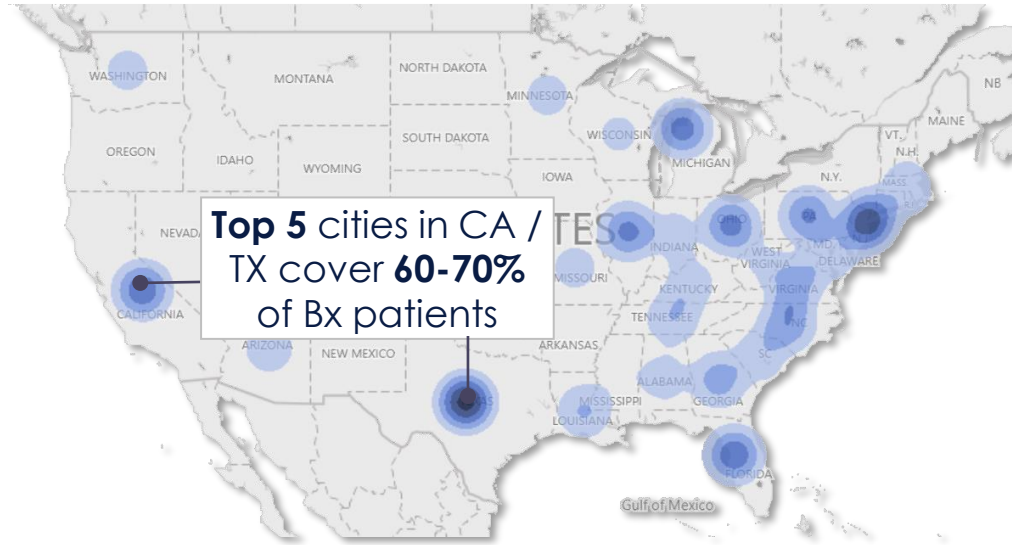
Through recent claims analyses we cannot only substantiate the projected 2035 \$10bn HS market in the U.S. but we believe the true HS market in the U.S. has potential to become \$15bn+

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

# Targeting: Achieving SLK blockbuster status in concentrated landscape

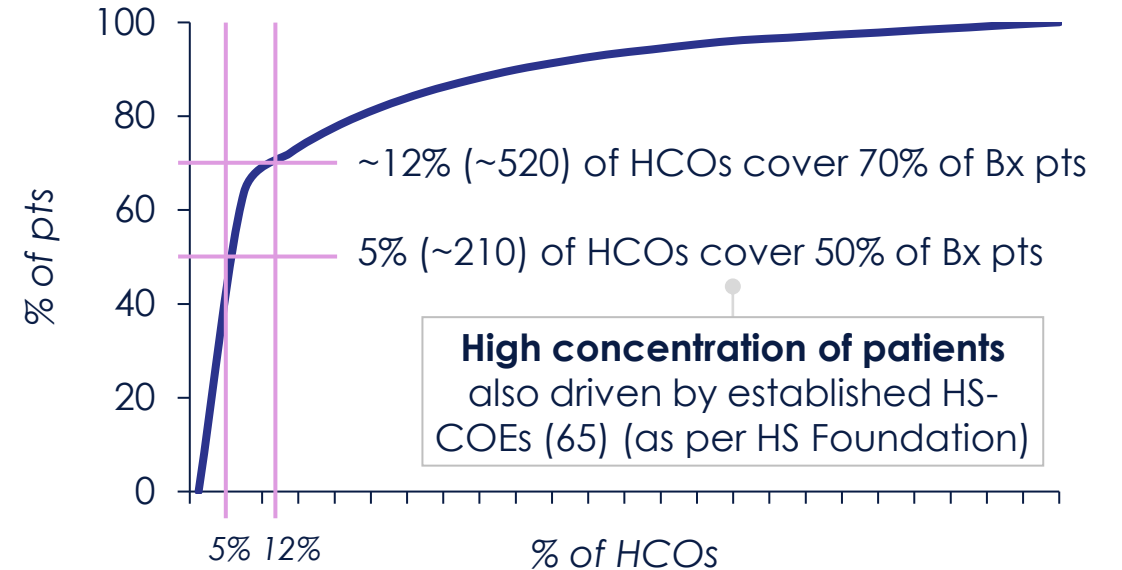
U.S. adult HS patients on biologics

## 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

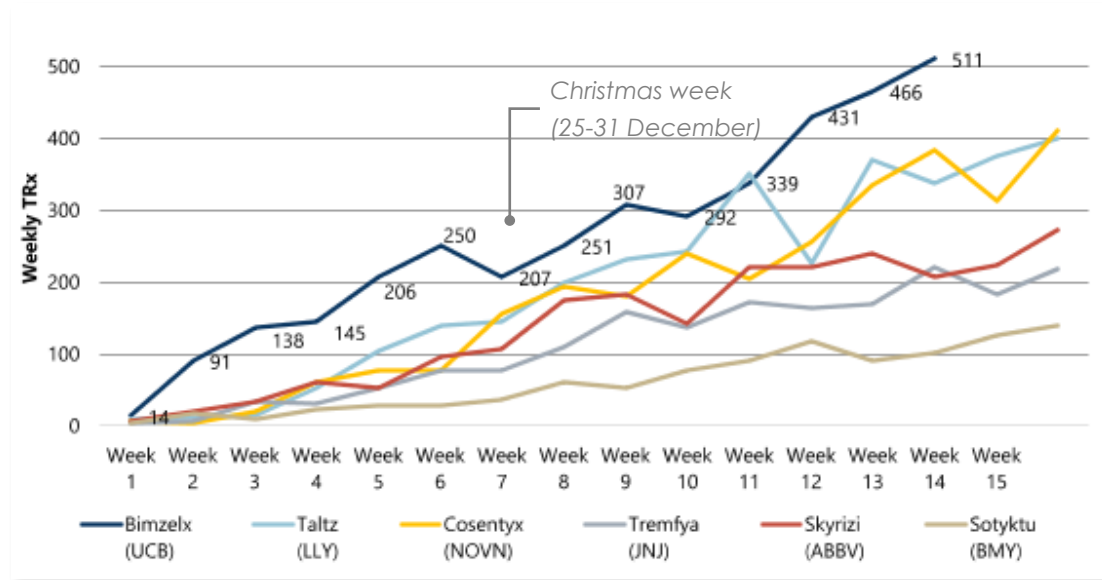


**12% of HCOs** cover **~70% of Biologics** patients<sup>1</sup> (within top 15 states)

**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

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



**SLK shows a differentiated profile across multiple trials and clinical outcomes**

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

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

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

# HS: SLK is most convenient

## Maintenance injection schedule



15s injection time  
per 1ml syringe<sup>1</sup>



15s injection time  
per 1ml syringe<sup>2</sup>

### SLK



3s injection time  
per 1ml syringe

**Substantially fewer  
and quicker injections**  
(5x faster injection)

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

Source: Product leaflets, Company information, MoonLake Commercial

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

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





# New indications

*New frontiers for SLK and MLTX*

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

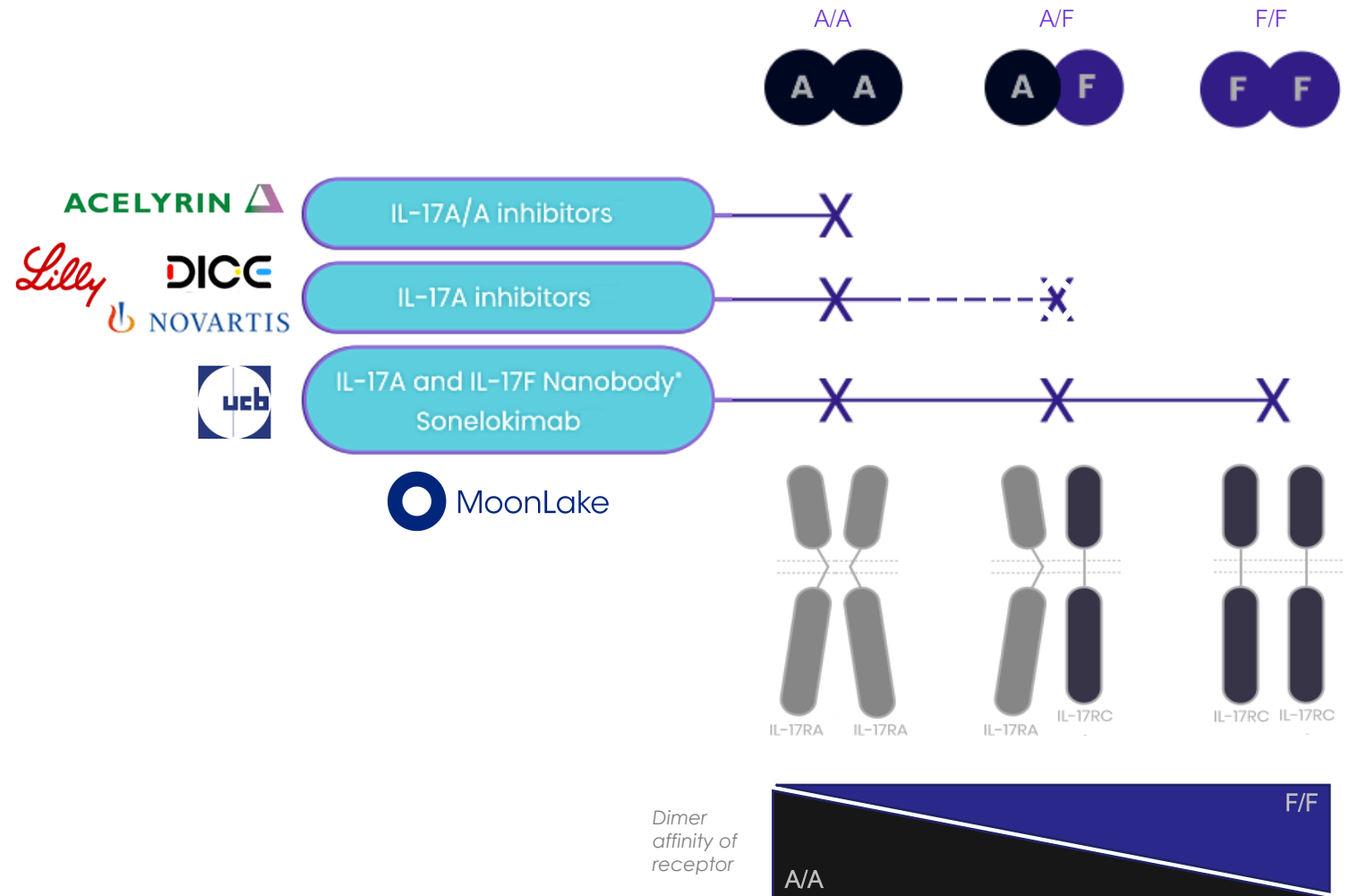
Illustrative

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

Different IL-17RA & RC chains combine to form complexes, and those have different affinity for different dimers<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**



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

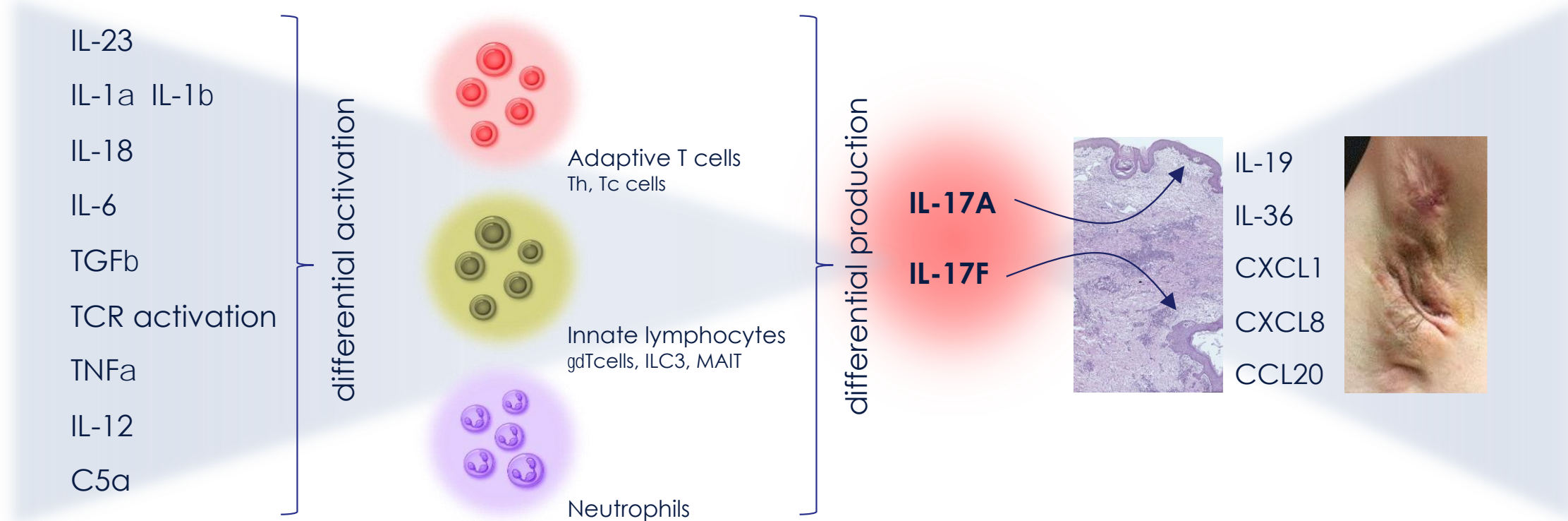
# Key MoA: IL-17A & F is at the crux of **many** inflammation pathways

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

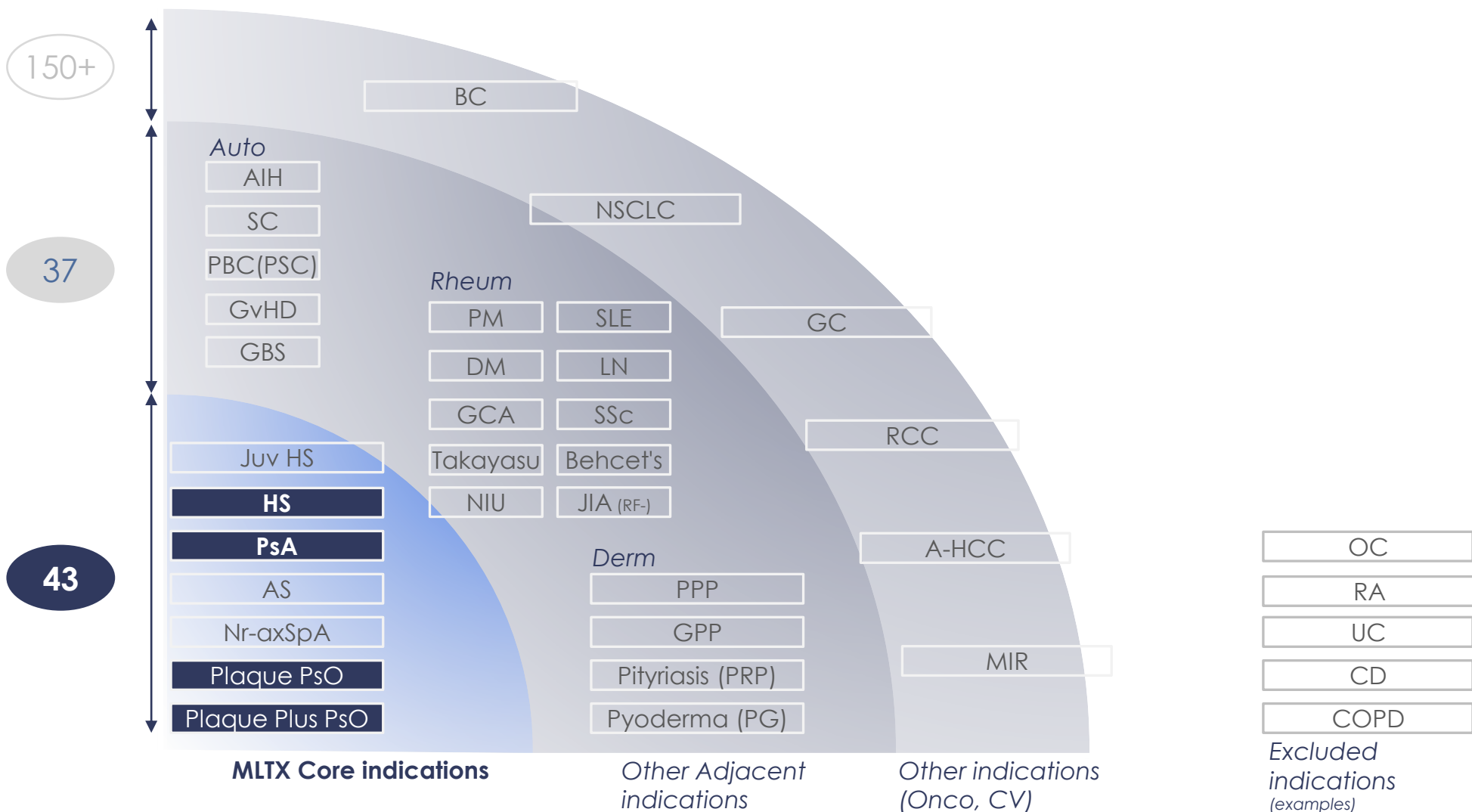
IL-17A and F induce multiple pro-inflammatory effectors, e.g. activation of keratinocytes



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

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

Addressable Market Size  
USD bn



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

- **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**



**Palmo-Plantar  
pustulosis**

*(Phase 2)*



**Juvenile HS**

*(Phase 3)*



**Rheum**



**axSpA**

*(Phase 2)*



**PsA**

*(Phase 2)*

New  
indication



**PPP**  
(Phase 2)

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

**Derm**

**Rheum**

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



## SLK can be highly differentiated...

## ... in a severe disease without effective treatments...

## ...by breaking new ground where others have given up

IL-17 A&F is **most promising MoA** considering BKZ cases<sup>1</sup> and previously shown relative performance of SLK vs BKZ

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

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



**Chronic inflammation:** Crops of pustules causing pain & bleeding<sup>2</sup>

**No approved therapy**

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

**ppPASI** as primary endpoint to elevate the bar vs previous attempts

**Objective inflammation endpoints** as additional scores to establish broader treatment goals

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

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

### Market size

**0.3%** Global prevalence

**4+** USD bn sales beyond 2037

### Unmet Needs

**~10-15%** Of PsO patients with palmoplantar involvement<sup>3</sup>

**0** Approved or effective treatment options

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

**Derm**



**PPP**

(Phase 2)



**Juv HS**

(Phase 3)

- **“HS-like” disease**, key priority for Derms, large unmet need
- **Up to ~10-15% of PsO patients have palmoplantar involvement<sup>1</sup>**
- **IL17 A&F** relevance shown through BKZ case series<sup>2</sup>
- **First clinical trial in juvenile HS**, addressing critical gap for derms
- **Opportunity** to control progressive disease pre-irreversible damage
- **Parallel to adult HS Ph 3**, allowing further differentiation as “HS leader”

New indication

Strengthen indication

**Rheum**

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



## Derm



**PPP**

(Phase 2)



**Juv HS**

(Phase 3)



**axSpA**

(Phase 2)

## Rheum

- **“HS-like” disease**, key priority for Derms, large unmet need
  - **Up to ~10-15% of PsO patients have palmoplantar involvement<sup>1</sup>**
  - **IL17 A&F** relevance shown through BKZ case series<sup>2</sup>
- New indication**
- **First clinical trial in juvenile HS**, addressing critical gap for derms
  - **Opportunity** to control progressive disease pre-irreversible damage
  - **Parallel to adult HS Ph 3**, allowing further differentiation as “HS leader”
- Strengthen indication**
- **Multi-bn markets** (r/nr-axSpA) with limited efficacy of current SoC<sup>3</sup>
  - With PsA allows MLTX to further **lead in seronegative Spondylarthritis**
  - **IL17 A&F** relevance shown through BKZ cases<sup>4</sup>, small size an advantage
- New indication**

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

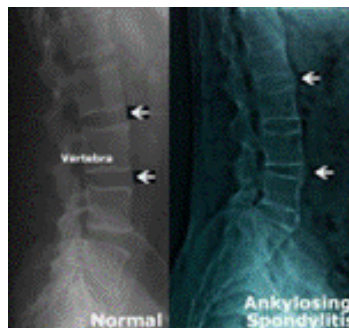
## SLK to elevate care to new efficacy levels...

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

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

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

## ... in a disease with high unmet need...

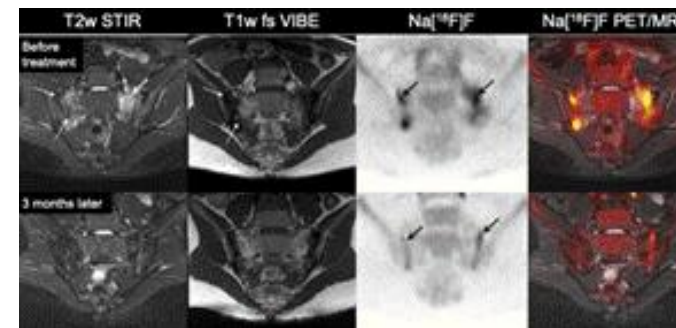


**Chronic inflammation** of axial skeleton

Large **unmet needs**, at least 1.5M US patients diagnosed & treated in 2015-2023<sup>2</sup>

**Limited disease control for SoC** – even at lower levels<sup>3</sup>

## ...with innovative imaging to redefine outcome measurements



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

**Accelerated path** to Phase 3  
Competitive **number of patients** in trial, with **attractive design** for the **specialized sites**

### Market size

**1.5%**

As current upper level of global prevalence

**10+**

USD bn market potential in next 10 yrs

### Unmet Needs

**40%**

Of pts do not reach relevant improvements with current therapies<sup>3</sup>

**30%**

As current upper limit of nr-axSpA patients that progress to r-axSpA<sup>4</sup>

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

## Derm



**PPP**

(Phase 2)



**Juv HS**

(Phase 3)



**axSpA**

(Phase 2)







**PsA**

(Phase 2)

## Rheum

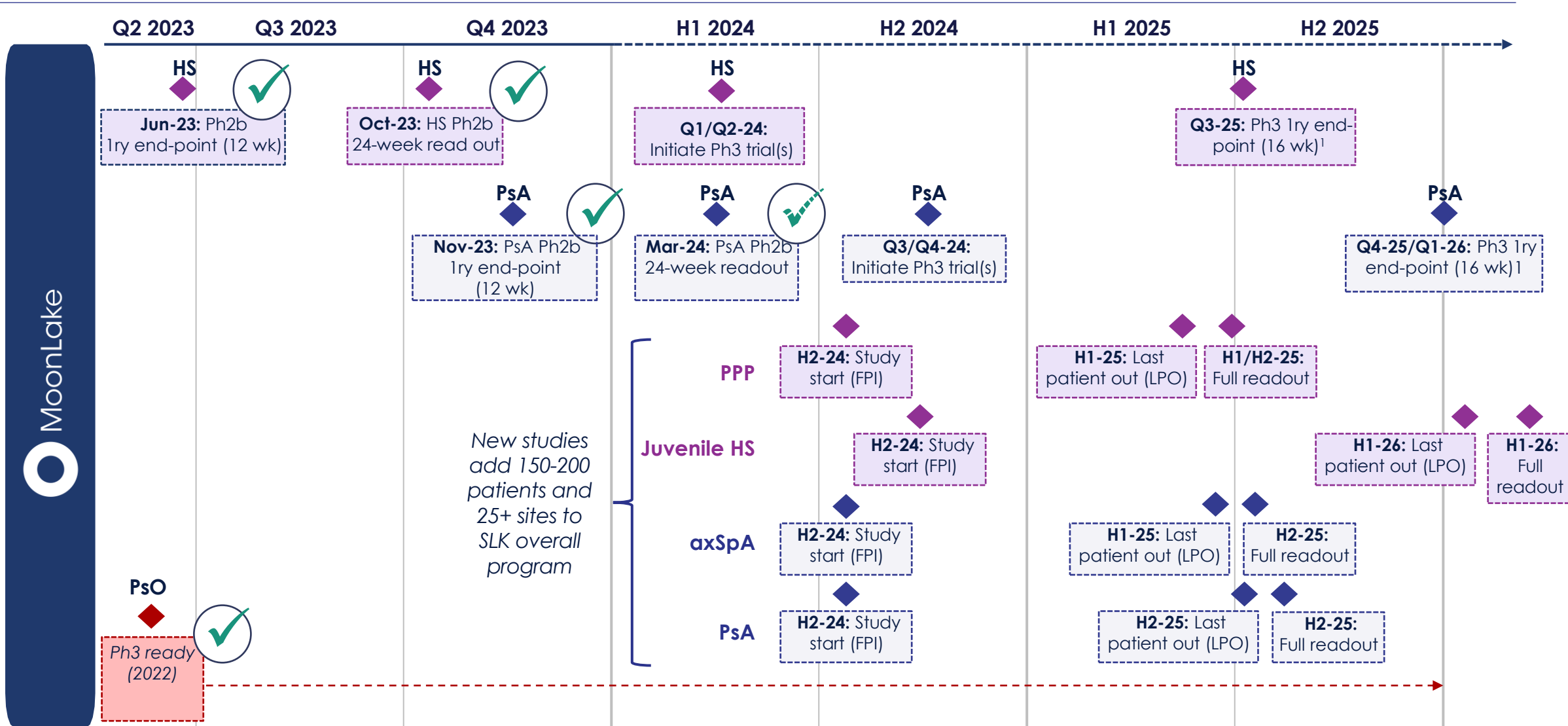
- **“HS-like” disease**, key priority for Derms, large unmet need
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- **Multi-bn markets** (r/nr-axSpA) with limited efficacy of current SoC<sup>3</sup>
  - With PsA allows MLTX to further **lead in seronegative Spondylarthritis**
  - **IL17 A&F** relevance shown through BKZ cases<sup>4</sup>, small size an advantage
- New indication**
- **Double down on PsA** (and spondyloarthritis) by elevating bar on outcomes
  - **Innovation to measure disease-modification** in joints, enthesitis, dactylitis
  - **Parallel to current Ph 3**, further enabling commercial success
- Strengthen indication**

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

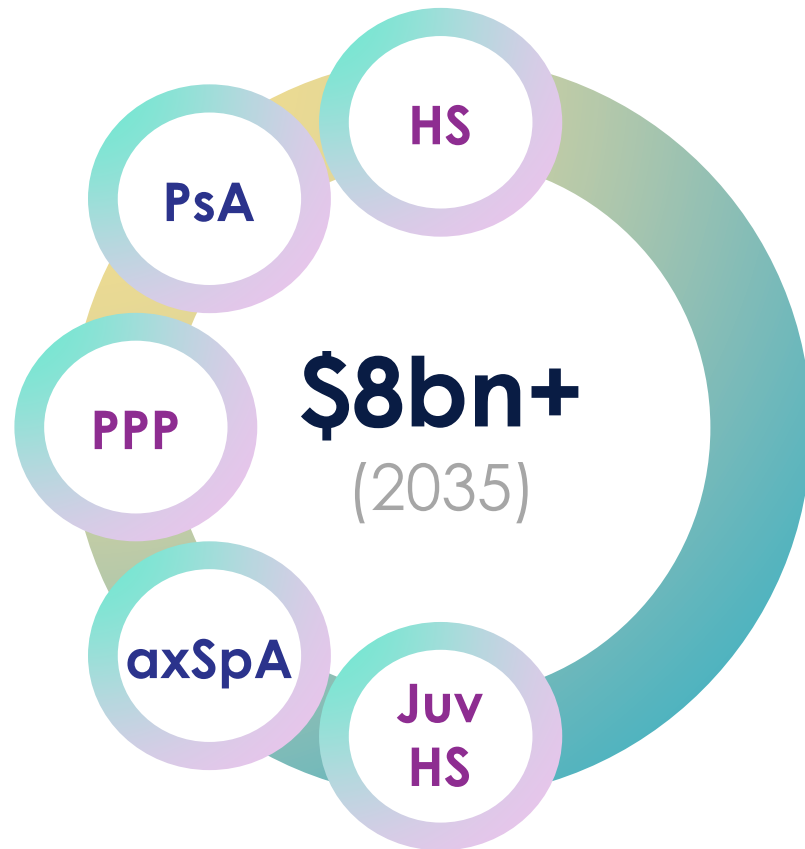
		Leading MoA	Prevalence (%)	Mkt size (\$, 2035)	Key challenge
Derm	 <b>PPP</b> (Phase 2)	IL-17A&F <sup>1</sup>	0.3%	3.5-4bn (12% growth from '22)	No approved or effective therapy
	 <b>Juv HS</b> (Phase 3)	IL-17A&F TNF (no trial)	1%	USD 1-2bn (9% growth from '22)	No clinically studied product <sup>4</sup>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

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

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



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

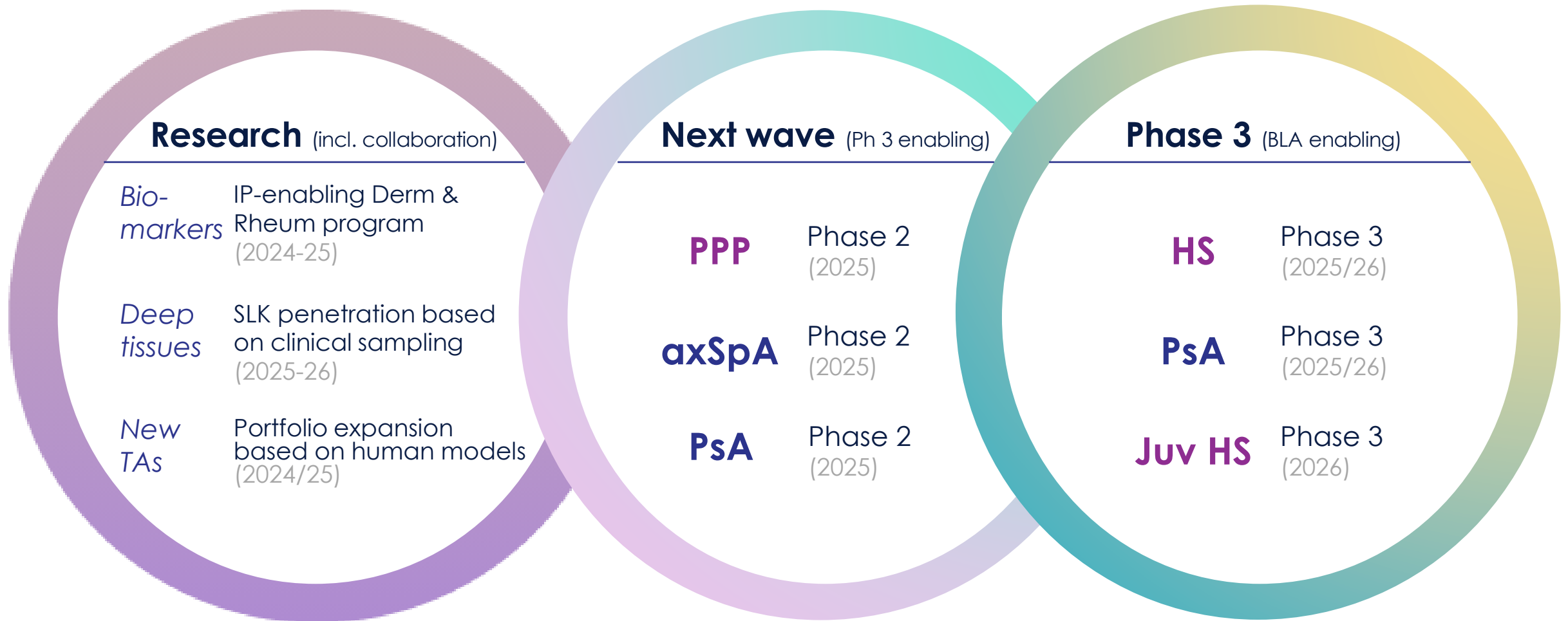


MoonLake continues to address the **most pressing unmet needs** in inflammatory diseases

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

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

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





# Moving Forward



## A promising MoA...

- **Highest responses**

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

- **Favorable safety profile**

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

- **Leading potential**

*Top 2 typically get 2/3 of indication bio sales (avg. \$4bn+)<sup>1</sup>*

## ... and a differentiated molecule

- **Elevated Performance**

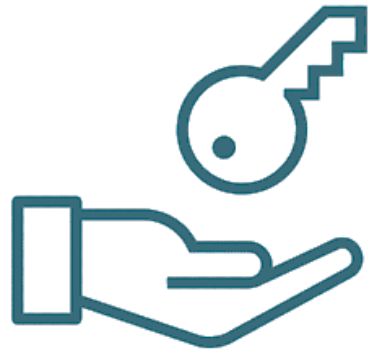
*SLK shows highest responses at high treatment goals, HiSCR75, IHS4-100, PsO PASI100, PsA MDA, ACR50/70+PASI90/100 and key patient outcomes*

- **Higher goals**

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

- **Improved convenience**

*Monthly 1ml maintenance injections and leading benefit-risk profile*

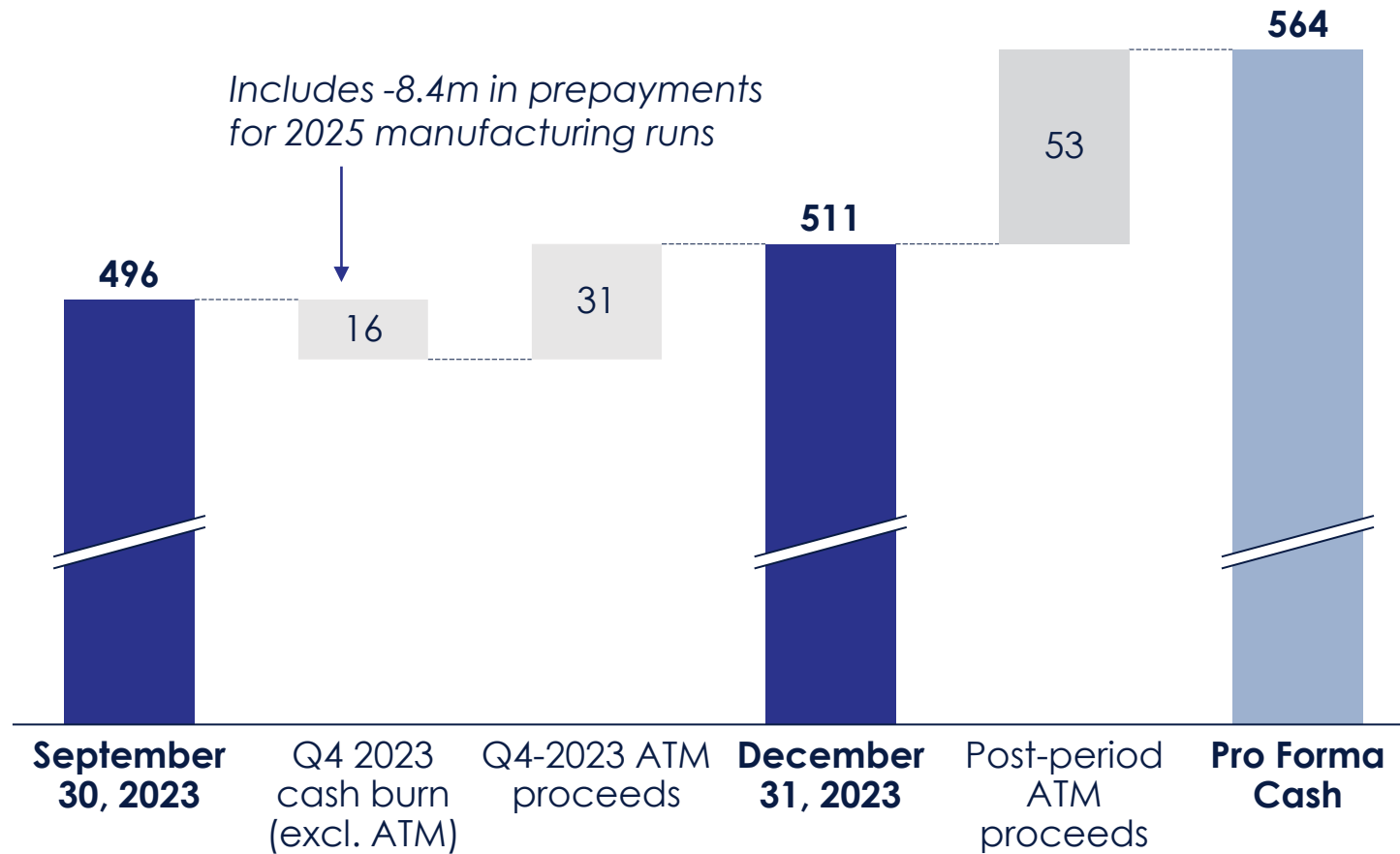


**Current  
owner**



**Better  
owner**

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



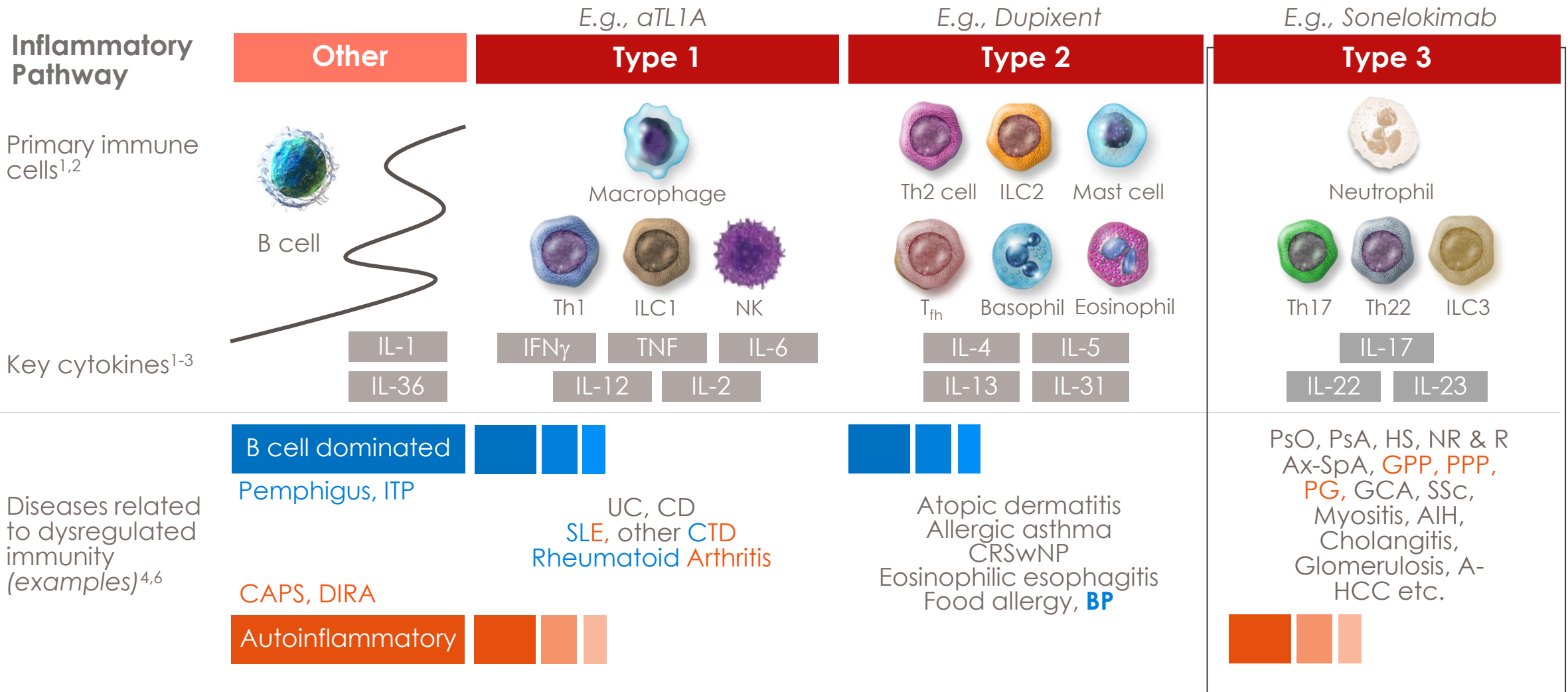
**Expected sufficient cash runway until the end of 2026**, covering

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

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

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

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



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

1 Kaiko GE, et al. *Immunology*. 2008;123:326-338  
2017;35:53-84

5 Coates LC, et al. *Semin Arthritis Rheum*. 2016;46:291-304

2 Eyerich K, Eyerich S. *J Eur Acad Dermatol Venereol*. 2018;32:692-703

6 Gandhi NA, et al. *Expert Rev Clin Immunol*. 2017;13(5):425-437.

3 Raphael I, et al. *Cytokine*. 2015;74:5-17

4 Nakayama T, et al. *Annu Rev Immunol*.



# Q & A



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