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MoonLake Immunotherapeutics

Investor Day

June 22nd, 2026

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Welcome to our Investor Day

Date: June 22nd, 2026
Time: 8.00 am EST



Agenda

Topic	Sub-topics	Speaker	Timing
Introduction	Welcome MLTX & SLK summary	Jorge	10 mins
Final data from the VELA program in HS	Final Week 52 Phase 3 VELA data Update on VELA-TEEN data	Kristian	30 mins
BLA strategy	Proposed Label Update on BLA progress	Jorge	20 mins
Commercializing SLK in HS	Update on HS market view Why MLTX can win commercially in HS	Matthias	10 mins
Closing remarks	Summary & Guidance on H2 2026 Expectations for IZAR-1 readout	Jorge	5 mins

The presentation will be followed by a short Q&A session – please submit your questions via the dedicated Q&A function in the portal, in case of issues please e-mail ir@moonlaketx.com

Source: MoonLake Corporate Strategy

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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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Source: MoonLake Legal

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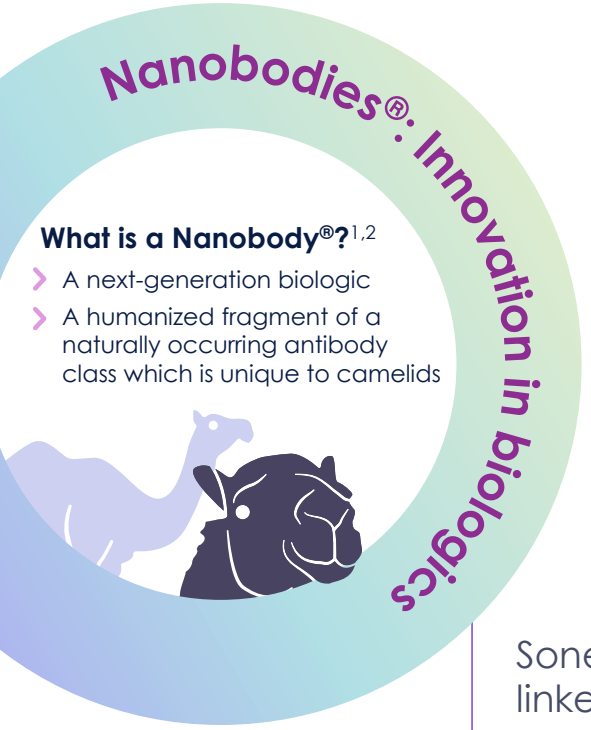
- **Founded in 2021** in Switzerland
- **Unique molecule with SLK**, tri-specific IL-17A & F Nanobody® to elevate treatment in inflammation in markets with **significant unmet needs** and **multi-bn $ potential**
- **Public on Nasdaq** since April 2022 with cash runway to end **of 2027 –** further access to up to $400 m in non-dilutive funds
- Driven by a top-tier team, aim is to unlock a **pipeline-in-a-product across indications**
- **Phase 3 studies completed in HS and PsA with data read-outs expected over coming months –** further Phase 2 studies completed in PPP, axSpA and PsO
- **First BLA submission** for SLK in HS expected in **Q3 2026 –** pre-commercial activities ramping up



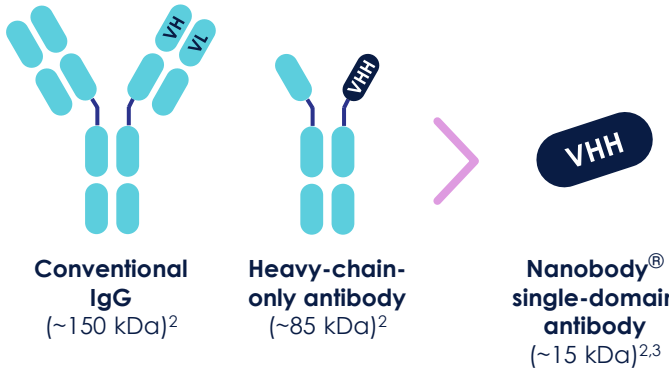
Source: MoonLake Corporate Strategy

A differentiated IL-17A and F molecule: Do you still Antibody?

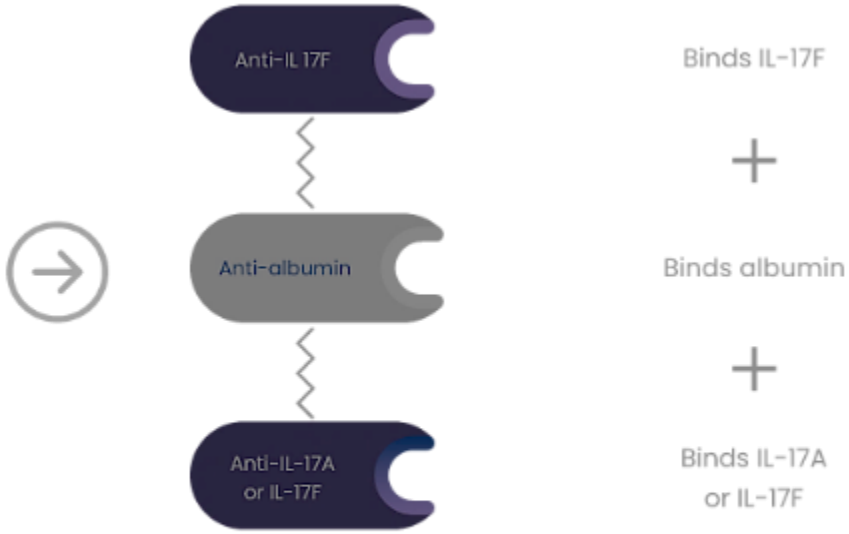
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Nanobodies® are much smaller than traditional antibodies



They can be designed to have multiple and different binding domains



Sonelokimab

Sonelokimab (SLK) is a ~40kDa humanized Nanobody® consisting of three VHH domains covalently linked by flexible spacers - around a **third/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**

SLK is the only asset that binds **all IL-17A and F dimers with leading and similar affinity** (shown in 2023)

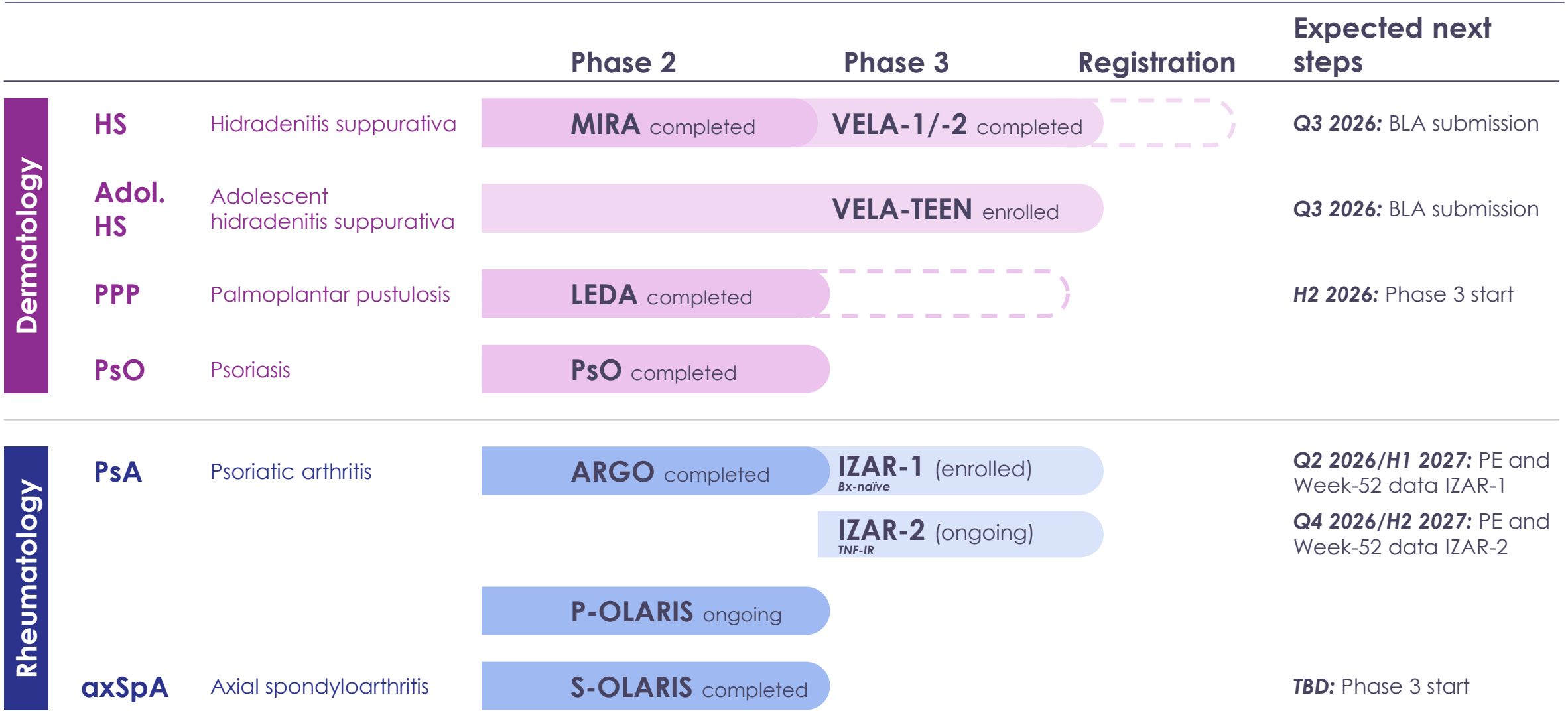
Ig, immunoglobulin; VH, heavy chain variable domain; VHH, variable heavy domain of heavy chain; VL, light chain variable domain; 1 Hamers-Casterman, C., et al. Nature. 1993; 363:446–448; 2 Jovčevska I, Muyldermans S. BioDrugs. 2020;34:11–26; 3 Tijink BM, et al. Mol Cancer Ther. 2008;7:2288–2297; For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

Source: MoonLake Medical Affairs & Research

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MLTX is **approaching registration** in Derm and Rheum indications

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PE, primary endpoint

Source: MoonLake Corporate Strategy

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SLK consistently shows **a leading profile** across multiple indications

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	Dermatology			Rheumatology	
	HS (incl. Adol)	**PPP**	**PsO**	**PsA**	**axSpA**
Estimated Market size ($, 2035)	**10-15bn** (14-18% p.a. growth from '26)	**3-4bn** (15-20% p.a. growth from '26)	**20-25bn** (6-8% p.a. growth from '26)	**10-15bn** (6-8% p.a. growth from '26)	**10-15bn** (7-9% p.a. growth from '26)
Key primary endpoint responses	*Phase 2 and 3* **34-43%** **HiSCR75** response at Week 12/16[1]	*Phase 2* *(Phase 3 to start soon)* **40%+** **PPPGA0/1** response at Week 16[2]	*Phase 2* **70%+** **PASI90** response at Week 12[3]	*Phase 2* *(Phase 3 ongoing)* **45%+** **ACR50** response at Week 12[4]	*Phase 2* **80%+** **ASAS40** response at Week 12[5]
Where MLTX elevates responses	**HiSCR75, HiSQOL**	**PPPGA0/1** and **PPPASI75**	**PASI90-100**	**ACR70 + PASI100, MDA**	**ASDAS-CRP, MRI/PET**

Robust benefit-risk profile – absence of signals of events of interest

Patient convenience – fewer injections, shorter injection time, lower volumes vs mAbs

Approximate responses; Selected data subject to change until final CSR is issued. 1 mNRI 120mg (VELA), ITT-NRI 120mg (MIRA): 34.4% for VELA-1 at Week 16, 34.1% for VELA-2 at Week 16, 43.3% for MIRA at Week 12; 2 mNRI 120mg; 3 ITT-NRI 120mg; 4 ITT-NRI, 60mg; 5 ITT-mNRI, 60mg

Source: MoonLake Corporate Strategy

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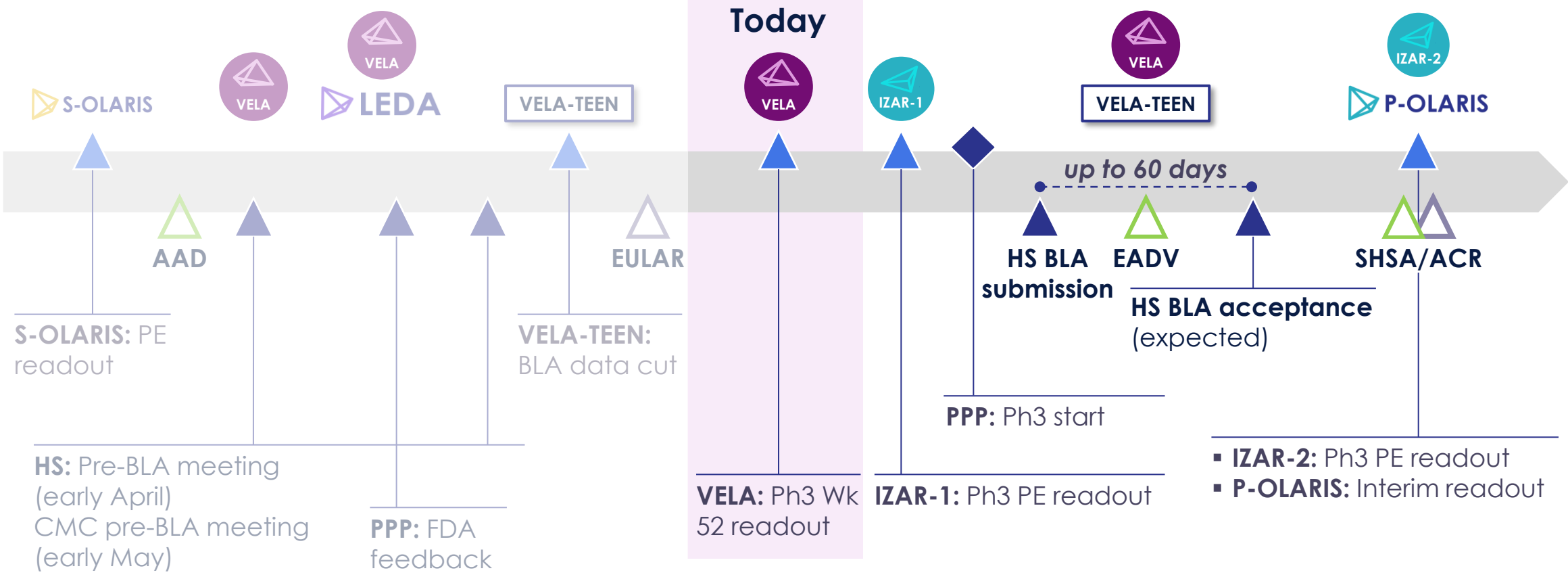
2026 is a **catalyst-rich year** for MLTX

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FDA interaction | Trial data | Derm event | Rheum event

2026

Q1 | Mid-year | Q4



Timeline not scaled, non-exhaustive; All future milestones are anticipated dates

Source: MoonLake Corporate Strategy

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We believe **SLK is on schedule** to be a **potential best-in-class in HS**

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Broader Label

First molecule clinically tested in adolescent HS allowing earlier therapy to avoid irreversible damage

~1 in 2 patients reach HiSCR100

No new safety signals in adolescents

Leading Efficacy

Leading performance across elevated treatment goals & time points incl. lesion counts, quality of life & pain scores

67% HiSCR75 at 1 year

~1 in 3 reach HiSCR100 & ~1 in 4 remission at 1 yr

Expected 22-23 pp delta-to-placebo on label

Advantageous Benefit Ratio

Rapid onset, durable response Nanobody® with safety profile of traditional IL-17s & differentiation to other IL-17F inhibitors

No SIB, Liver, IBD and other signals versus placebo

Consistent long-term safety profile

Improved convenience

Faster, lower volume, monthly Nanobody® injections vs. bi-weekly or high volume

Two-month induction only with 5 fast 1 ml injections

Monthly single fast 1ml injection

Unique mode of action

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

Source: MoonLake Corporate Strategy

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Final data from the VELA program in HS



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HS is a **major I&I challenge** with very significant unmet needs

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

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

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

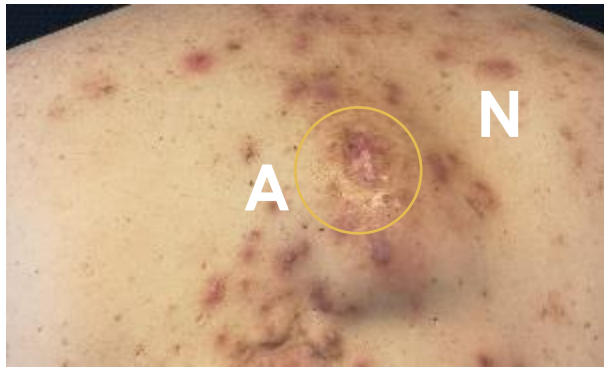
…we need HS therapies that provide **sustained and significant improvements** to patients' lives

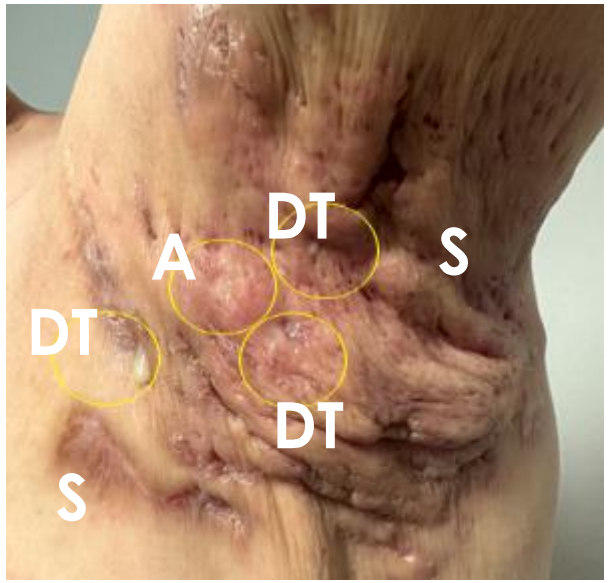
2% Est. global prevalence

Delayed and **underdiagnosis** drive conservative prevalence estimates…[2,3]

…we need HS therapies that are **developed with all (many millions) patients in mind**

Advanced disease stages with nodules (N), deep dermal abscesses (A), draining tunnels (DT) and scarring (S)





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

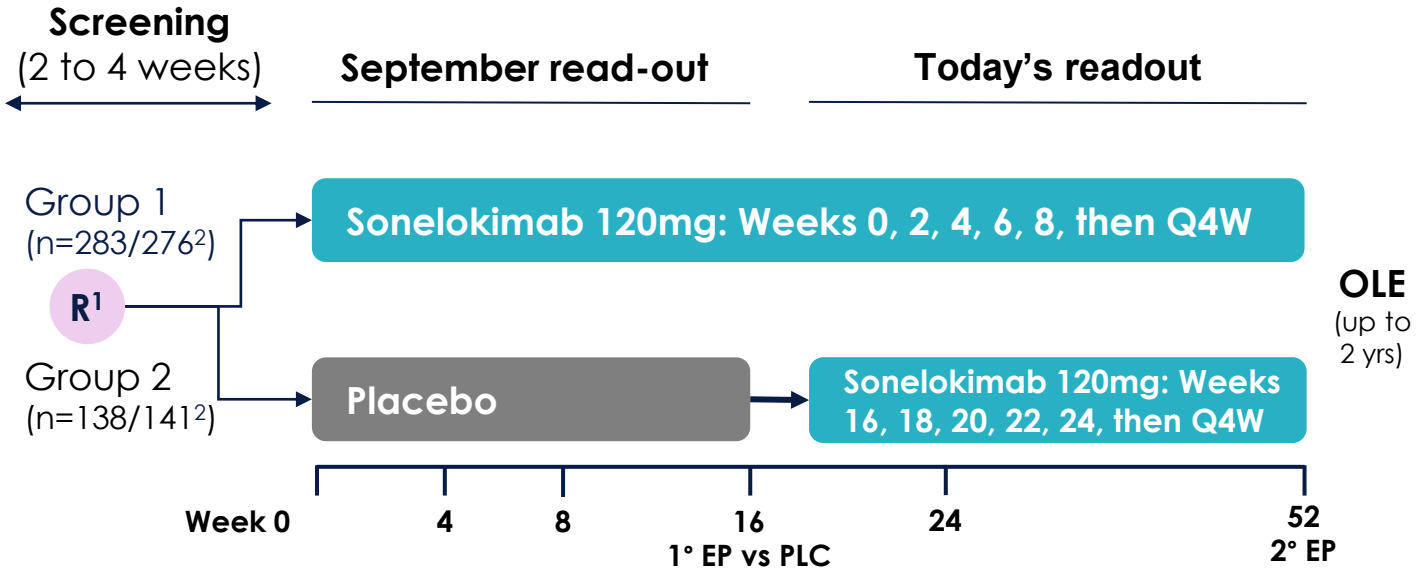
Source: MoonLake Medical Affairs & Research

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Recap: Phase 3 design and endpoints of VELA trials

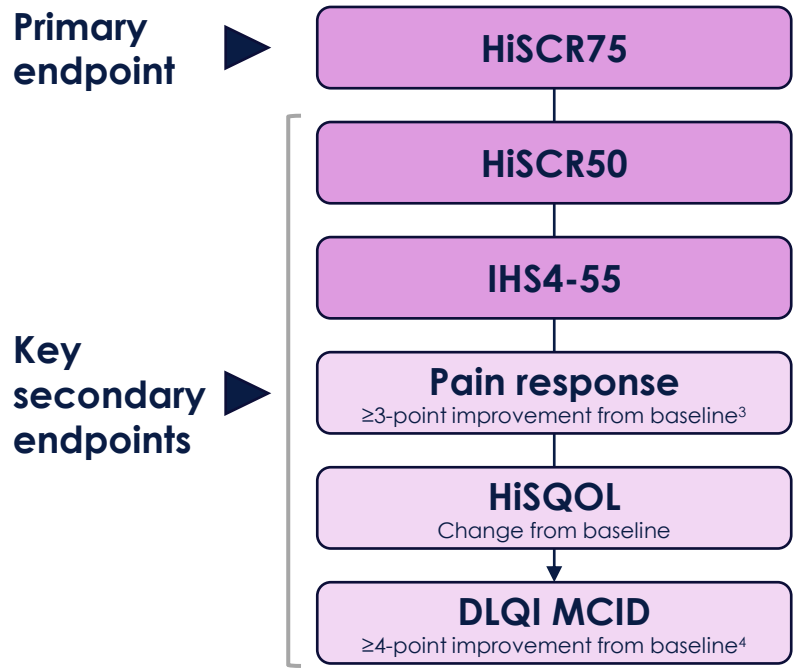
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Phase 3 study design for VELA-1 and VELA-2 – identical, global, randomized, double-blind, placebo-controlled 52-week trials



VELA-1 and VELA-2 (n=838 patients) both used the same protocol

Endpoints – SLK vs Placebo W16



High-bar primary endpoint (i.e., HiSCR75 vs. historical HiSCR50), a **clinically relevant patient population,** and a **convenient, consistent dosing** regimen

A safety follow-up period follows the end-of-trial visit for patients who do not enter the long-term extension; VELA-1: NCT06411899. VELA-2: NCT06411379; 1 Randomization stratified by Hurley stage status (II vs. III), prior biologic use (Y/N) and geographic region (NA/EU). Patients in Hurley stage III limited to ~40% EoPh2, End of Phase 2; 2 n for VELA-1 and VELA-2 respectively; 3 Baseline worst skin pain score of ≥3; 4 Baseline DLQI of ≥4

Source: MoonLake Clinical

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SLK pivotal trials: Consistent & high HiSCR75 response in pivotal trials

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	SLK HS Pivotal trials		
	MIRA	**VELA-1**	**VELA-2**
HiSCR75 response in SLK treated patients (%)	**43.3** (week 12)	**34.4** (week 16)	**34.1** (week 16)
HiSCR75 response in PBO treated patients (%)	**14.7** (week 12)	**17.5** (week 16)	**24.9** (week 16)
p-value (pre-specified analyses)	p<0.001 (NRI analysis)	p<0.001 (composite strategy) p<0.001 (treatment policy)	p=0.053 (composite strategy) p=0.033 (treatment policy))

Trials selected for demonstration of Substantial Evidence of Effectiveness (SEE)

Week 16 data showed **consistent HiSCR75 response with SLK** across both VELA trials and early onset of response
VELA-2 experienced a **spike in placebo response at Week 16 –** no stat sig on composite strategy pre-specified analysis
In both VELA-1 and VELA-2, patient-reported outcomes differences to placebo were **highly statistically significant** (p<0.01)[1]

HiSCR75 responders, MIRA ITT-NRI: SLK 120mg arm (n=67), PBO arm (n=68), VELA-1 mNRI: SLK 120mg arm (n=283), PBO arm (n=138), VELA-2 mNRI: SLK 120mg arm (n=276), PBO arm (n=141); Data subject to change until final CSR is issued; 1 VELA-1 achieved statistical significance multiplicity-controlled, VELA-2 achieved nominal statistical significance

Source: MoonLake Corporate Strategy

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VELA is a **landmark HS program** with **high patient retention rate**

Largest treatment arms in a Phase 3 for HS

VELA-1	VELA-2
283 sonelokimab	**276** sonelokimab
138 placebo	**141** placebo

Participants randomized at baseline and treated

High retention rates in the VELA trials

Low drop-out rate – through the end of parental VELA trials[1] ~26%

High roll-over to VELA-OLE (2 years) ~88%

Two **identical, global Phase 3 trials** with a **higher-bar primary endpoint** (HiSCR75 vs. historical HiSCR50), and **clinically relevant patient population**

Convenient dosing
High VELA-OLE acceptance reflects confidence in strength of 120mg in Q4W maintenance dosing

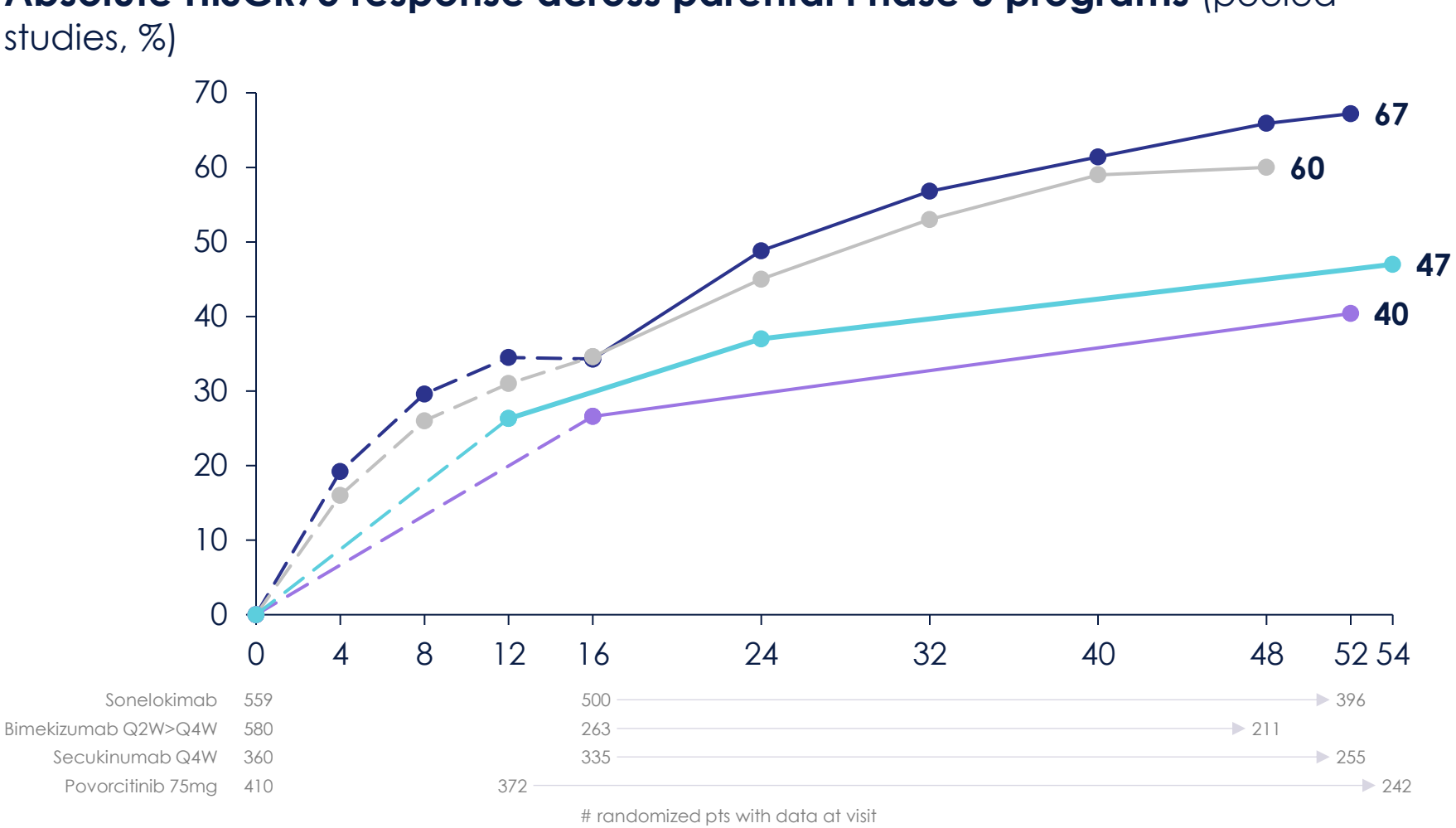
1 Trial end at Week 52; Data subject to change until final CSR is issued

Source: MoonLake Clinical

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VELA program demonstrates **leading SLK long-term HiSCR75 efficacy**

Absolute HiSCR75 response across parental Phase 3 programs (pooled studies, %)



SLK shows **highest long-term HiSCR75 response** across HS therapies to-date, with ~70% of patients reaching HiSCR75

Long-term (1yr) responses **key for prescription decisions**

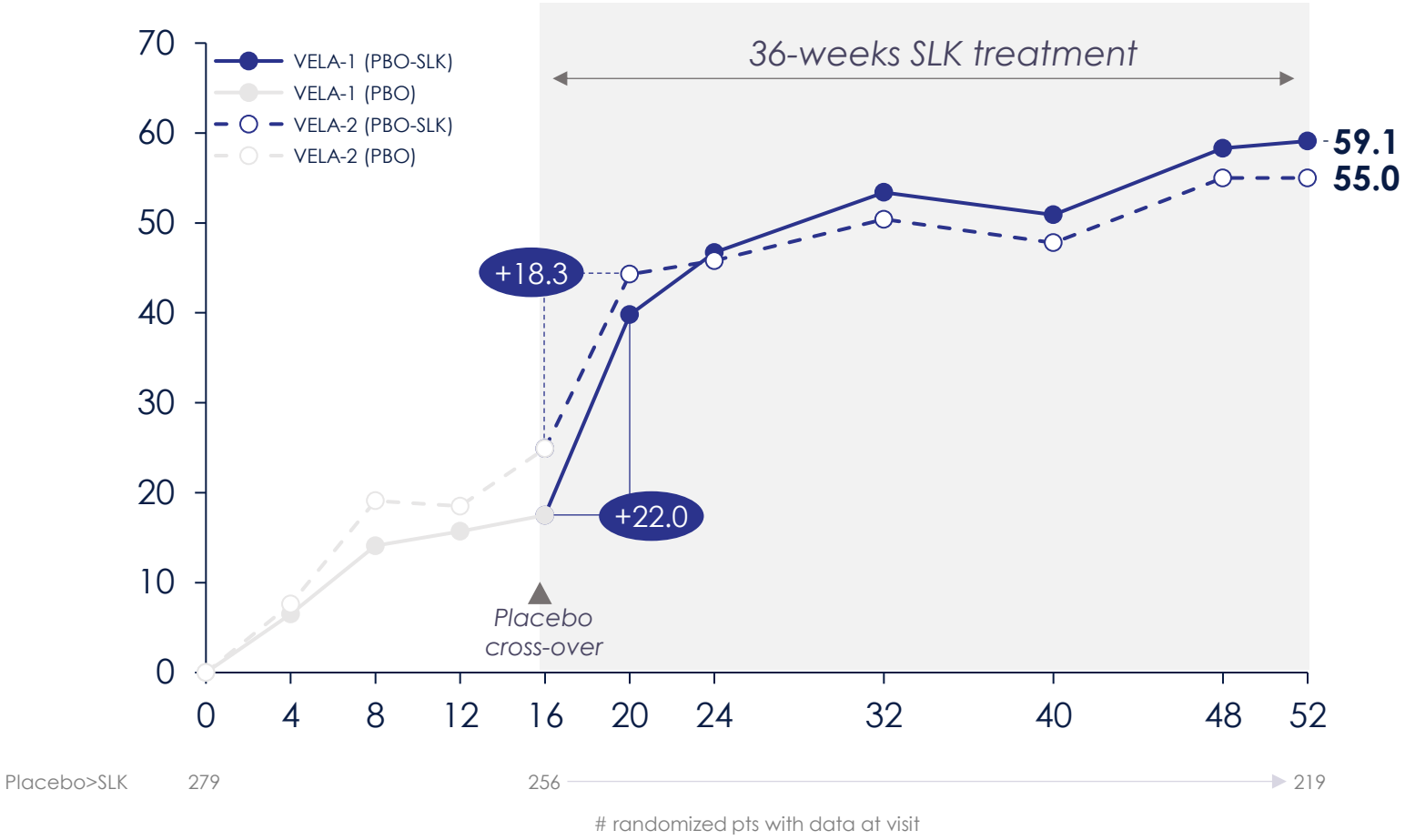
Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Data shown as per length of parental trials: SLK and SEC 52-wk, BKZ 48-wk, POVO 54-wk; Data only from patients on continuous active treatment with (m)NRI until primary endpoint (dashed lines), then as observed (solid lines); Patient counts shown: Wk 0 counts were used for (m)NRI analyses, Week 12/16 and 48/52/54 counts are the respective number of patients at the beginning and end of the presented as observed analyses; Doses shown: SLK 120mg (ITT-mNRI until Week 16), BKZ 320mg Q2W until Wk 16 (ITT-mNRI, all-ABX) and Q4W thereafter, SEC 300mg Q4W (ITT-mNRI until Wk 16), POVO 75mg (NRI until Wk 12); ADA HiSCR75 AO data not available; BKZ data for Wks other than 16 and 48 estimated from a graph; BKZ data until Wk 16 refers to all patients with 320mg Q2W, as of Wk 16 refers to patients switching from Q2W to Q4W; Data subject to change until final CSR is issued; Sources: Kimball et al. EADV 2023, Porter et al. SHSA 2025; Porter et al. AAD 2026; Kimball A et al. Lancet 2024; 403:2504-2519; Zouboulis et al. EHSF 2026

Source: MoonLake Clinical

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Crossover arms in VELA show **consistently high responses**

Absolute HiSCR75 response across parental VELA program (cross-over arms, %)



SLK responds **consistently across trials and arms** (including placebo to SLK cross-overs)

After 36 weeks of SLK treatment, patients who crossed over from **placebo achieved a response similar to that observed during the first 36 weeks** in patients treated with SLK from baseline (~60% HiSCR75)

SLK treatment **shows consistent responses** post cross-over, despite high placebo rate in VELA-2 at week 16

Data subject to change until final CSR is issued; Data shown: (m)NRI until primary endpoint (grey), then as observed (blue); Cross-over percentage point increase shown for "AO to AO"; Patient counts shown: Week 0 counts were used for (m)NRI analyses, Week 16 and 52 counts are the respective number of patients at the beginning and end of the presented as observed analyses

Source: MoonLake Clinical

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SLK shows the scorecard of a **potential best-in-class drug in HS**

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Parental trial responses (as observed)

SLK with highest HS data to-date

		VELA (pooled, active arms) n=396	**BE HEARD** (pooled, active arms) n=211	**Relative SLK advantage** in % increase in response
PE VELA[3]	HiSCR75, in %	67.2	60.2	11.6
HiSCR	HiSCR50, in %	78.0	80.6	-3.2
	HiSCR100, in %	33.1	28.9	14.5
IHS4	IHS4-55, in %	77.5	75.8	2.2
	IHS4-75, in %	62.9	59.2	6.3
	IHS4-100, in %	26.0	23.7	9.7
HiSQOL	Mean score difference between end of trial and baseline, absolute	-15.0[4]	-13.1[5]	14.5
DLQI	≥4-point improvement from baseline, in %[8]	72.2[6]	63.5[2]	13.7
Pain	≥3-point improvement from baseline, in %[1]	46.5[7]	NR	N/A

Across the scorecard, SLK achieves highest HS responses to-date

This is observed across **lesion efficacy scores and patient reported outcome efficacy** endpoints

1 in 3 patients reach HiSCR100 and **1 in 4** reach IHS4-100 (10%+ more than the competitor)

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Data subject to change until final CSR is issued; The VELA parental trials were 52-week while the Bimekizumab parental trials were 48-week studies; Doses shown: SLK-SLK 120mg, BKZ-BKZ 320mg (Q2W>Q4W); 1 Baseline worst skin pain score of ≥3; 2 n=178; 3 HiSCR75 was PE for VELA trials at Week 16; 4 Baseline HiSQOL of 27.2, n=558 for HiSQOL at baseline, n=395 for HiSQOL at Week 52; 5 Baseline HiSQOL of 24.5, n=292 at baseline (numbers with non-missing HiSQOL data not available); 6 n=363; 7 n=241; 8 Baseline DLQI of ≥4; PE, primary endpoint; Sources: HiSCR 50/75/100: Zouboulis EADV 2023; IHS4: Tzellos T et al. J Eur Acad Dermatol Venereol. 2026;doi:10.1111/jdv.70356; HiSQOL and DLQI: Shi V et al. Dermatol Ther. 2025;15:2553; Mayo SHSA 2023

Source: MoonLake Clinical

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SLK demonstrates a **favorable safety profile at Week 16**

SLK advantageous versus IL-17A & F mAb

Treatment-emergent adverse events (TEAE), %	Week 16		
	VELA-1/-2 to Week 16		BE HEARD I/II to Week 16[1]
	Placebo patients N=279	Sonelokimab patients N=559	Bimekizumab 320 mg Q2W N=576[2]
Any TEAE	55.9%	67.6%	65.8%
Any Serious TEAE	1.8%	2.7%	2.6%
Any TEAE leading to treatment discontinuation	1.8%	3.4%	3.8%
Common TEAE[D]			
Hidradenitis	2.9%	2.3%	7.6%
Oral candidiasis	0.4%	7.3%	7.1%
Headache	5.0%	5.0%	6.9%
Diarrhea[A]	0.7%	2.9%	6.3%
TEAEs of interest SLK			
Serious infection	0.7%	0.7%	0.2%
Hepatic event[B]	0.7%	0.9%	2.4%
Definite or probable adjudicated inflammatory bowel disease (IBD)	0%	0%	0.2%
Adjudicated suicidal ideation and behavior (SIB)	0%	0%	0.2%
Serious hypersensitivity reaction[C]	0%	0%	0%
Adjudicated major adverse cardiovascular event (MACE)	0%	0%	0%

No IBD or SIB – hepatic events similar to placebo

SLK is observed to have a favorable safety profile without imbalances at Week 16 – enabling potentially a label without warnings of inflammatory bowel disease and suicidal ideation and behavior

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; SLK and BKZ comparison based on numerical incidence rates; Methods to describe safety events may differ (e.g., diarrhea); Data subject to change until final CSR is issued; 1 Kimball A et al. Lancet 2024; 403:2504-2519; 2 Pooled data from BKZ BE HEARD I/II Q2W dose arms until Week 16; A For SLK: Includes infectious (diarrhea infectious, viral diarrhea, bacterial diarrhea) and non-infectious diarrhea; B For SLK: SMQ Drug related hepatic disorders – comprehensive search (Narrow); C SMQ Hypersensitivity (Narrow); D Common TEAEs based on the most commonly reported in BE HEARD studies (excluding COVID-19)

Source: MoonLake Medical & Safety

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No new signals emerged post Week-16

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SLK advantageous versus IL-17A & F mAb

Treatment-emergent adverse events (TEAE), %	Week 52 / 48	
	VELA-1/-2 to Week 52	BE HEARD I/II to Week 48[1]
	All patients (SLK; Part A and B) N=816	BKZ Q4W maintenance (BKZ; Part A and B) N=576[2]
Any TEAE	80.5%	84.5%
Any Serious TEAE	6.5%	5.7%
Any TEAE leading to treatment discontinuation	4.4%	7.1%
Common TEAE[D]		
Hidradenitis	5.5%	20.8%
Oral candidiasis	12.4%	11.8%
Headache	6.3%	9.2%
Diarrhea[A]	3.9%	9.4%
TEAEs of interest SLK		
Serious infection	1.6%	1.2%
Hepatic event[B]	2.0%	4.0%
Definite or probable adjudicated inflammatory bowel disease (IBD)	0.1%	0.9%
Adjudicated suicidal ideation and behavior (SIB)	0.2%[E]	0.7%
Serious hypersensitivity reaction[C]	0%	0%
Adjudicated major adverse cardiovascular event (MACE)	0.2%	0.2%

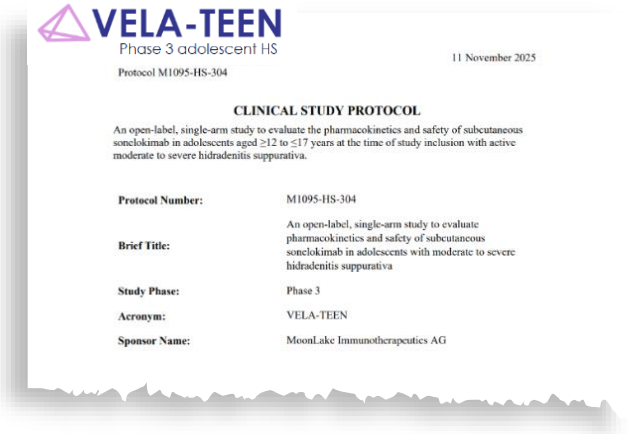
SLK shows an advantageous long-term benefit-risk ratio, with **no new safety signals and low rates of SIB, IBD and Hepatic events**

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; SLK and BKZ comparison based on numerical incidence rates; Methods to describe safety events may differ (e.g., diarrhea); Data subject to change until final CSR is issued; 1 Kimball A et al. Lancet 2024; 403:2504-2519; 2 Pooled data from BKZ BE HEARD I/II Q2W/Q4W and Q4W/Q4W dose arms; A For SLK: Includes infectious (diarrhea infectious, viral diarrhea, bacterial diarrhea) and non-infectious diarrhea; B For SLK: SMQ Drug related hepatic disorders – comprehensive search (Narrow); C SMQ Hypersensitivity (Narrow); D Common TEAEs based on the most commonly reported in BE HEARD studies (excluding COVID-19); E Adjudicated as not-related

Source: MoonLake Medical & Safety

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VELA-TEEN **met** its endpoint


VELA-TEEN
Phase 3 adolescent HS
11 November 2025
Protocol M1095-HS-304

CLINICAL STUDY PROTOCOL

An open-label, single-arm study to evaluate the pharmacokinetics and safety of subcutaneous sonelokimab in adolescents aged ≥12 to ≤17 years at the time of study inclusion with active moderate to severe hidradenitis suppurativa.

Protocol Number:	M1095-HS-304
Brief Title:	An open-label, single-arm study to evaluate pharmacokinetics and safety of subcutaneous sonelokimab in adolescents with moderate to severe hidradenitis suppurativa
Study Phase:	Phase 3
Acronym:	VELA-TEEN
Sponsor Name:	MoonLake Immunotherapeutics AG

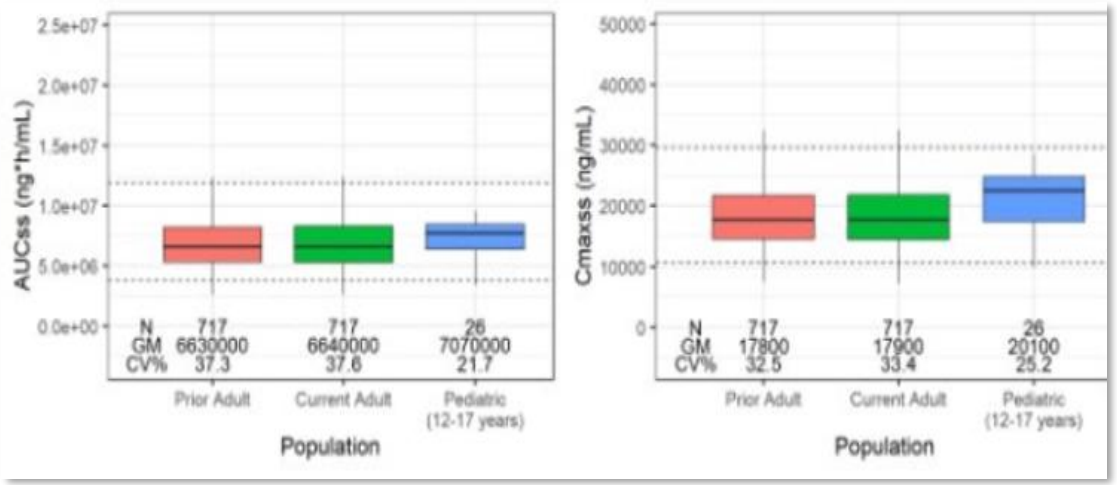
Co-primary endpoints:

- **PK**
- **Safety** (signal detection)

Study enrollment completed (n=35)

PK analysis of VELA-TEEN – results

- Results indicate that **adolescent estimates are within the range of adult exposures** and are **supportive of exposure matching**
- Adolescent data show **less variability than the adult dataset**
- Given adolescent exposures are likely to be within the adult 90% CI **no new dose-limiting toxicities were anticipated**



C_{max} and AUC_{ss} at steady state from analysis of adolescent (blue bar) compared to adult (green and red bar) PK data

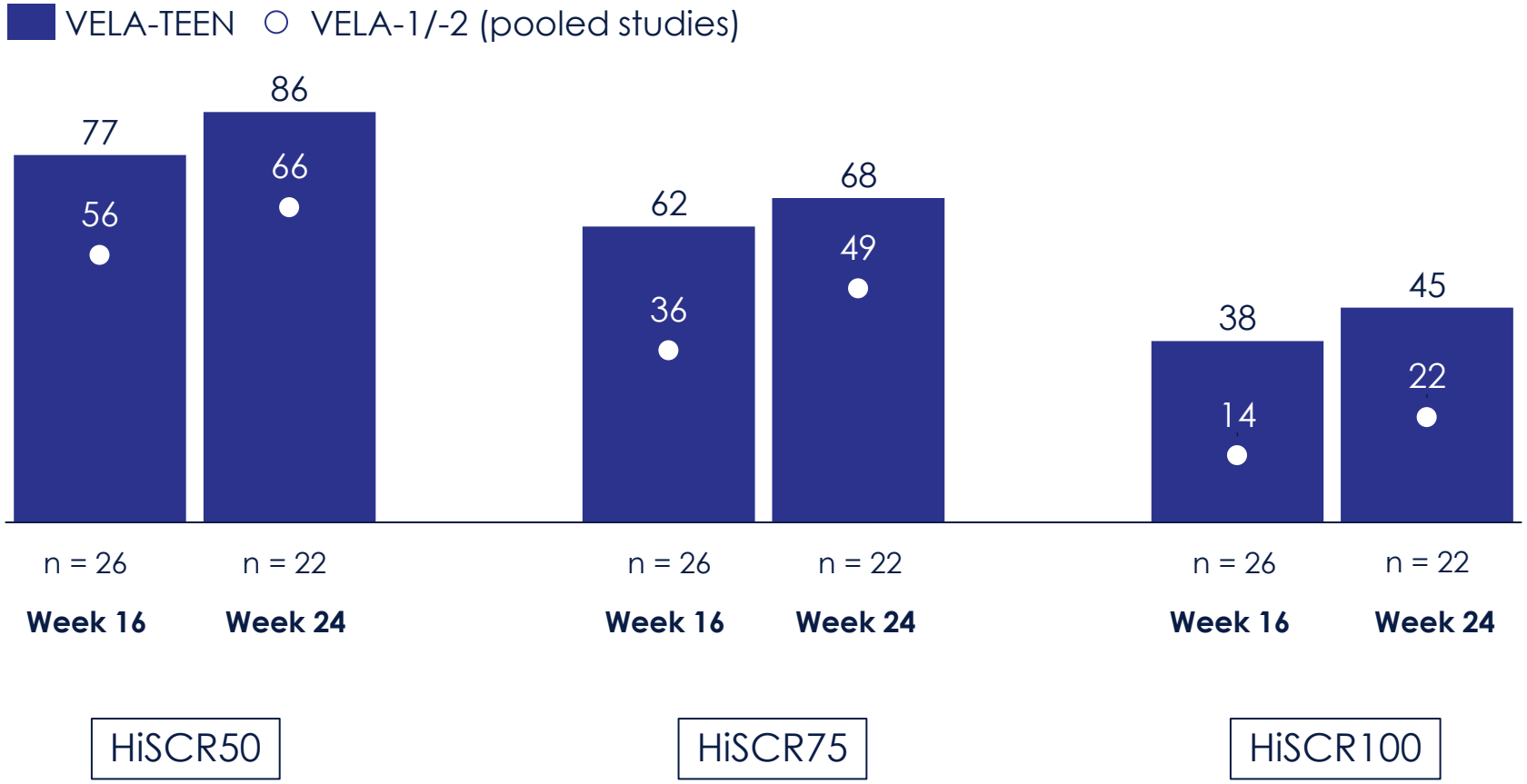
Prior Adult model: based on all Phase I and Phase II data, including MIRA. Current Adult model: updated model including VELA Week 16 data.

Source: MoonLake Regulatory

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SLK shows **rapid onset and high response rates** in adolescents

HiSCR response rates over time (in % of patients, as observed)



VELA-TEEN is the **only dedicated study in adolescent HS** to date and demonstrates **breakthrough efficacy with SLK** – almost 70% of adolescents achieve HiSCR75 at Week 24, 45% reach HiSCR100

Total participants at each timepoint; VELA-TEEN trial is ongoing with the number of participants reaching W16 and W24 expected to increase over time; VELA-TEEN and VELA-1/-2 as observed data at Week 16 and Week 24; Data subject to change until final CSR is issued

Source: MoonLake Clinical

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VELA-TEEN data shows **favorable safety profile with no new signals**

Treatment-emergent adverse events (TEAE), n (%)	VELA-TEEN to Week 28
	Sonelokimab 120 mg N=35[1]
Any TEAE	17 (48.6)
Any Serious TEAE	0
Any TEAE leading to discontinuation	1 (2.9)
Most frequent TEAEs of SLK (≥5% with active treatment)	
Oropharyngeal pain	4 (11.4)
Nasopharyngitis	3 (8.6)
Injection site reaction	3 (8.6)
Acne	2 (5.7)
Oral candidiasis	2 (5.7)
Vulvovaginal candidiasis	2 (5.7)
Pruritus	2 (5.7)
TEAEs of interest	
Dermatitis	1 (2.9)
Eczema	0
Serious infection	0
Diarrhea (non-infectious)	1 (2.9)
Hepatic event	0
Inflammatory bowel disease (IBD)	0
Suicidal ideation and behavior (SIB)	0
Serious hypersensitivity	0
Major adverse cardiovascular event (MACE)	0

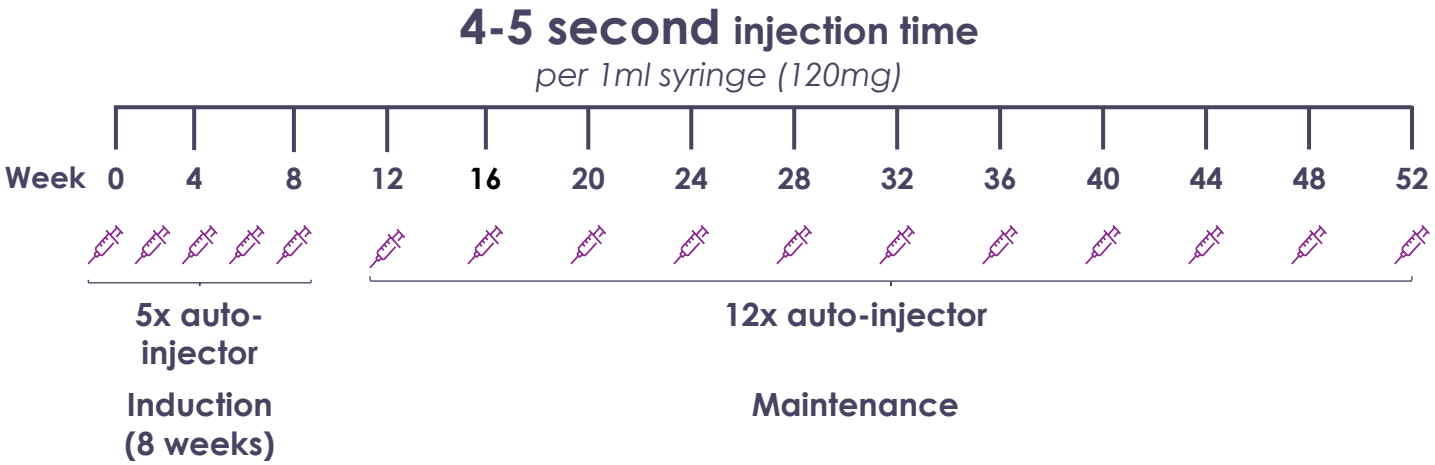
Data subject to change until final CSR is issued; 1 VELA-TEEN trial is ongoing – not all patients reached Week 28 yet

Source: MoonLake Medical & Safety

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Convenience: SLK offers convenience in induction and maintenance

Sonelokimab dosing regimen is advantageous



Available treatment options with **up to 18 syringes in induction phase, longer induction phase (4 months)** and **longer injection time (up to 25 seconds)**

These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations.

Source: MoonLake Medical, BKZ Instructions for Use and FDA label

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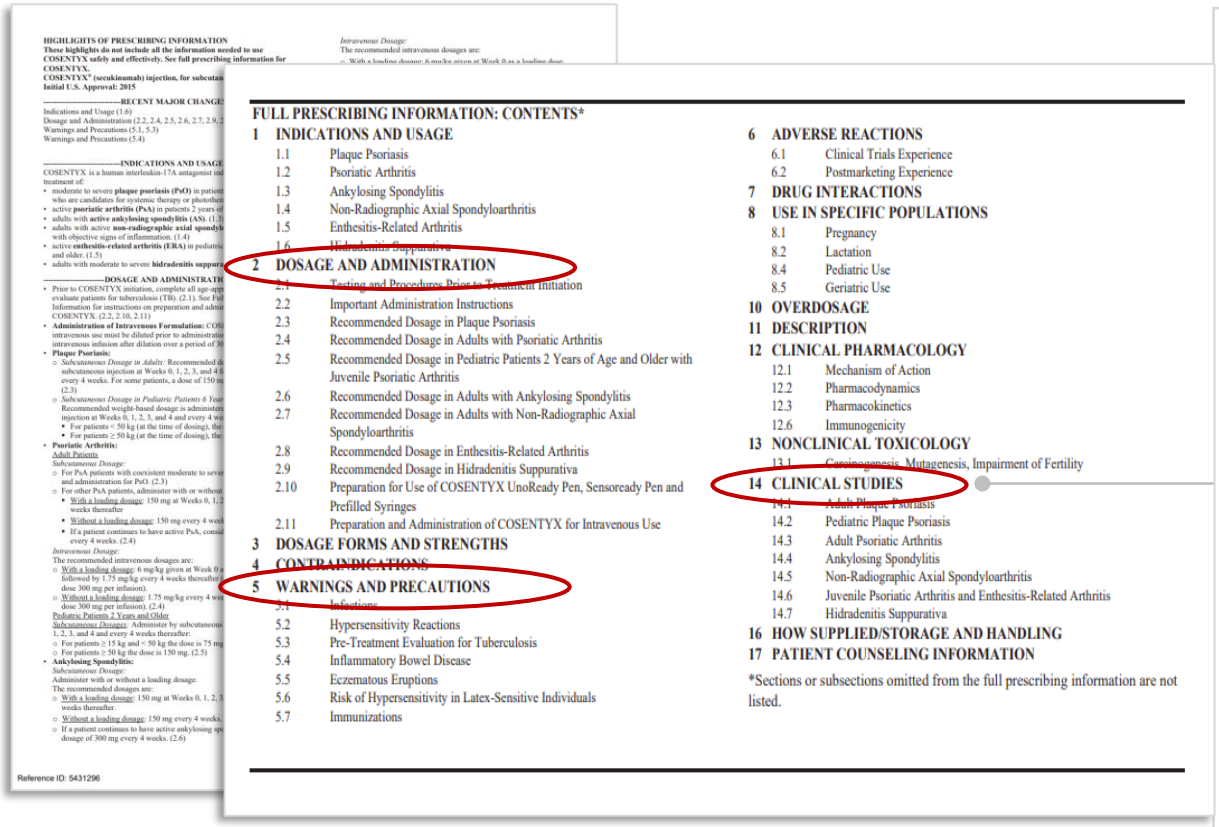
BLA strategy



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What matters in a label: Sections 14, 5 and 2

FDA label example, *secukinumab example*



FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
- 1.1 Plaque Psoriasis
- 1.2 Psoriatic Arthritis
- 1.3 Ankylosing Spondylitis
- 1.4 Non-Radiographic Axial Spondyloarthritis
- 1.5 Enthesitis-Related Arthritis
- 1.6 Hidradenitis Suppurativa

2 DOSAGE AND ADMINISTRATION
- 2.1 Testing and Procedures Prior to Treatment Initiation
- 2.2 Important Administration Instructions
- 2.3 Recommended Dosage in Plaque Psoriasis
- 2.4 Recommended Dosage in Adults with Psoriatic Arthritis
- 2.5 Recommended Dosage in Pediatric Patients 2 Years of Age and Older with Juvenile Psoriatic Arthritis
- 2.6 Recommended Dosage in Adults with Ankylosing Spondylitis
- 2.7 Recommended Dosage in Adults with Non-Radiographic Axial Spondyloarthritis
- 2.8 Recommended Dosage in Enthesitis-Related Arthritis
- 2.9 Recommended Dosage in Hidradenitis Suppurativa
- 2.10 Preparation for Use of COSENTYX UnoReady Pen, Sensoready Pen and Prefilled Syringes
- 2.11 Preparation and Administration of COSENTYX for Intravenous Use

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS
- 5.1 Infections
- 5.2 Hypersensitivity Reactions
- 5.3 Pre-Treatment Evaluation for Tuberculosis
- 5.4 Inflammatory Bowel Disease
- 5.5 Eczematous Eruptions
- 5.6 Risk of Hypersensitivity in Latex-Sensitive Individuals
- 5.7 Immunizations

6 ADVERSE REACTIONS
- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS
- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY
- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics
- 12.6 Immunogenicity

13 NONCLINICAL TOXICOLOGY
- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES
- 14.1 Adult Plaque Psoriasis
- 14.2 Pediatric Plaque Psoriasis
- 14.3 Adult Psoriatic Arthritis
- 14.4 Ankylosing Spondylitis
- 14.5 Non-Radiographic Axial Spondyloarthritis
- 14.6 Juvenile Psoriatic Arthritis and Enthesitis-Related Arthritis
- 14.7 Hidradenitis Suppurativa

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

Potential areas of differentiation

Section 14 **Clinical response of trials incl. supplementary text, figures and additional clinical data –** enabling potential differentiation on efficacy and PROs (where SEE is primarily reflected), competitors only with HiSCR

Section 5 **Warnings and precautions –** enabling potential differentiation of safety-benefit ratio

Section 2 **Required dosing scheme –** enabling potential differentiation in number, time and volume of injections

Source: MoonLake Regulatory

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Competitor data leaves **space for SLK to compete** as the leading drug

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Section 14

p-values are not included in respective labels

Delta-to-placebo not shown in SEC label

…nse at Week 16 (Trials HS-1 and HS-2)

…trials, a higher proportion of BIMZELX-treated subjects achieved HiSCR50 and HiSCR75 compared to placebo (see Table 11).

Table 11: Efficacy Results in Adults with HS in Trials HS-1 and HS-2 at Week 16 [a]

	Trial HS-1		Trial HS-2	
	BIMZELX 320mg Q2W (N=289)	Placebo (N=72)	BIMZELX 320 mg Q2W (N=291)	Placebo (N=74)
HiSCR50	48%	29%	52%	32%
Difference (95% CI)	18% (6%, 30%)		20% (8%, 32%)	
HiSCR75	33%	18%	36%	16%
Difference (95% CI)	15% (4%, 27%)		20% (10%, 31%)	

[a] Subjects who initiated systemic antibiotics (new antibiotic or change in the dose/type of current antibiotic) for any reason or who discontinued due to adverse event or lack of efficacy are treated as non-responders at all subsequent visits. Other missing data were imputed via multiple imputation.

Bimzelx® (bimekizumab)

…. Clinical Response at Week 16 in Adults with Hidradenitis Suppurativa in HS Trial 1 and HS Trial 2[1]

	HS Trial 1			HS Trial 2		
	Placebo (n = 180)	COSENTYX 300 mg every 4 weeks[2] (n = 180)	COSENTYX 300 mg every 2 weeks[2] (n = 181)	Placebo (n = 183)	COSENTYX 300 mg every 4 weeks[2] (n = 180)	COSENTYX 300 mg every 2 weeks[2] (n = 180)
HiSCR50	29.4%	41.3%	44.5%*	26.1%	42.5%*	38.3%*

[1]Multiple imputation was implemented for missing data.
[2]Subjects received COSENTYX 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks (Q4W) or every 2 weeks (Q2W).
*Statistically significant versus placebo based on the pre-de… with overall alpha = 0.05 (two-sided)

Cosentyx® (secukinumab)

SEC does **not demonstrate statistical significance** for the 300 mg Q4W dose arm in its label

Section 5

5 WARNINGS AND PRECAUTIONS
5.1 Suicidal Ideation and Behavior
An increased incidence of new onset or worsening suicidal ideation and behavior was observed in subjects treated with BIMZELX. A causal association between treatment with BIMZELX and increased risk of suicidal ideation and behavior has not been definitively established.

Suicidal ideation and behavior were prospectively monitored using the Columbia Suicide Severity Rating Scale (C-SSRS) in clinical trials. The C-SSRS is an interview-based instrument used to monitor for the presence and severity of suicidal ideation (ranging from "none" to "active suicidal ideation with specific plan and intent") and behaviors (rating the injury and potential lethalit…

5 WARNINGS AND PRECAUTIONS
5.1 Infections
COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe PsO, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed in subjects treated with COSENTYX compared to placebo-treated subjects. A similar increase in risk of infection in subjects treated with COSENTYX was seen in placebo-controlled trials in subjects with PsA, AS and nr-axSpA. The incidence of some types of infections, including fungal infections, appeared to be dose-dependent in clinical trials *[see Adverse Reactions (6.1)]*.

Warnings and precautions related to SIB, IBD, Liver and others

Section 2

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Evaluations and Immunization Prior to Treatment Initiation
- Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX *[see Warnings and Precautions (5.3)]*.
- Test liver enzymes, alkaline phosphatase and bilirubin prior to initiating treatment with BIMZELX *[see Warnings and Precautions (5.4)]*.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines *[see Warning and Precautions (5.6)]*.

2.2 Recommended Dosage for Plaque Psoriasis
The recommended dosage is 320 mg by subcutaneous in…

2 DOSAGE AND ADMINISTRATION
2.1 Testing and Procedures Prior to Treatment Initiation
Perform the following evaluations prior to COSENTYX initiation:
- Evaluate for active or latent tuberculosis (TB). COSENTYX initiation is not recommended in patients with active TB infection. Initiate treatment of latent TB prior to initiation of COSENTYX *[see Warnings and Precautions (5.3)]*.
- Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with COSENTYX *[see Warnings and Precautions (5.7)]*.

2.2 Important Administration Instructions
- COSENTYX is for use under the guidance and supervi…

Source: MoonLake Regulatory

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Building on feedback, this is our **base scenario for Sec. 14 table**

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SLK proposed table for Sec. 14

Efficacy data relevant for potential label *(in brackets delta to placebo)*	**HS trial 1** *(Corresponds to VELA-1)*	**HS trial 2** (Corresponds to MIRA)
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)
Pain NRS-3, %	*These endpoints likely as narrative points of Section 14*	
HiSQOL, CfB[1]		
IHS4-55, %		

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 pp**)*

IL-17A and F mAb

HS trial 1	HS trial 2
33 (15)	**36** (20)
48 (18)	**52** (20)

Note on improvement in patient-reported worst skin pain (lesion pain) compared to placebo at Week 16 (despite not meeting stat sig in BH1 and for one dose in BH2)

No HiSQOL, no IHS4 notes

For illustrative purposes only; Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Potential label options for sonelokimab reflecting MLTX's current views based on data and prior regulatory correspondence; Absolute responses shown, delta to placebo in brackets; Data reflects composite strategy (ITT-mNRI) for VELA and ITT-NRI for MIRA; VELA-1 and VELA-2 results for Week 16, MIRA results for Week 12; IHS4-55, Pain NRS-3, HiSQOL were not ranked endpoints in MIRA; Bimekizumab data as per FDA label for HS (Section 14); Data subject to change until final CSR is issued; 1 Baseline numbers would be included

Source: MoonLake Regulatory

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"Upside case" also includes other HS responses in Sec. 14 table

MoonLake

SLK proposed table for Sec. 14

Efficacy data relevant for potential label *(in brackets delta to placebo)*	**HS trial 1** *(Corresponds to VELA-1)*	**HS trial 2** *(Corresponds to MIRA)*
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)
Pain NRS-3, %	**28.3** (16.8)	**22.0** (19.9)
HiSQOL, CfB[1]	**-8.7** (-5.7)	**-9.4** (-4.4)
IHS4-55, %	**53.3** (19.4)	**62.7** (33.3)

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 ppt**)*
"Upside case" would feature specific PRO results for **first time in an HS label**

IL-17A and F mAb

HS trial 1	HS trial 2
33 (15)	**36** (20)
48 (18)	**52** (20)

Note on improvement in patient-reported worst skin pain (lesion pain) compared to placebo at Week 16 (despite not meeting stat sig in BH1 and for one dose in BH2)

No HiSQOL, no IHS4 notes

For illustrative purposes only; Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; Potential label options for sonelokimab reflecting MLTX's current views based on data and prior regulatory correspondence; Absolute responses shown, delta to placebo in brackets; Data reflects composite strategy (ITT-mNRI) for VELA and ITT-NRI for MIRA; VELA-1 and VELA-2 results for Week 16, MIRA results for Week 12; IHS4-55, Pain NRS-3, HiSQOL were not ranked endpoints in MIRA; Bimekizumab data as per FDA label for HS (Section 14); Data subject to change until final CSR is issued; 1 Baseline numbers would be included

Source: MoonLake Regulatory

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SLK has **further differentiation potential** in Sec. 5 and Sec. 2

	Bimzelx® (bimekizumab)	Cosentyx® (secukinumab)	SLK differentiation potential
Section 5 Warnings and Precautions	▪ *Suicidal Ideation and Behavior* ▪ *Infections* ▪ *Tuberculosis* ▪ *Liver Biochemical Abnormalities* ▪ *Inflammatory Bowel Disease* ▪ *Immunization*	▪ *Infections* ▪ *Hypersensitivity Reactions* ▪ *Pre-Treatment Evaluation for Tuberculosis* ▪ *Inflammatory Bowel Disease* ▪ *Eczematous Eruptions* ▪ *Risk of Hypersensitivity in Latex-Sensitive Individuals* ▪ *Immunization*	✓ No TEAEs of SIB reported in controlled part of trial[1]. C-SSRS validated for risk identification/monitoring responses ✓ No signal for hepatic events including elevated transaminases in SLK clinical trials ✓ No signal for IBD in SLK trials ✓ No evidence of association between IL-17 inhibition and TB reactivation. Clinical trials and post-marketing data show no increased TB risk
Section 2 Dosage and Administration	▪ *320 mg by subcutaneous injection* ▪ *Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter*	▪ *300 mg by subcutaneous injection* ▪ *Weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter* ▪ *If patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks*	✓ Low injection volume: 120mg subcutaneous injection ✓ Few induction injections: 5 injections for induction period ✓ Short induction duration: 8 weeks induction period
Additional potential differentiation points			✓ *Low eczema and dermatitis signals long-term* ✓ *Lower diarrhea rates*

Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; 1 Two TEAEs of SIB reported after controlled part of the trial (post Week 16) – both adjudicated as not-related

Source: MoonLake Regulatory

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VELA-TEEN provides **potential for Priority Review** of the HS BLA

FDA Priority Review



Priority Review

Prior to approval, each drug marketed in the United States must go through a detailed FDA review process. In 1992, under the Prescription Drug User Act (PDUFA), FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – *Standard Review* and *Priority Review*. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

A *Priority Review* designation will direct over

Eligibility criteria:

1. "Evidence of **increased effectiveness** in treatment, prevention, or diagnosis of condition"
2. "Elimination or substantial **reduction of a treatment-limiting drug reaction"**
3. **"Documented enhancement of patient compliance** that is expected to lead to an **improvement in serious outcomes**"
4. **"Evidence of safety and effectiveness in a new subpopulation**"

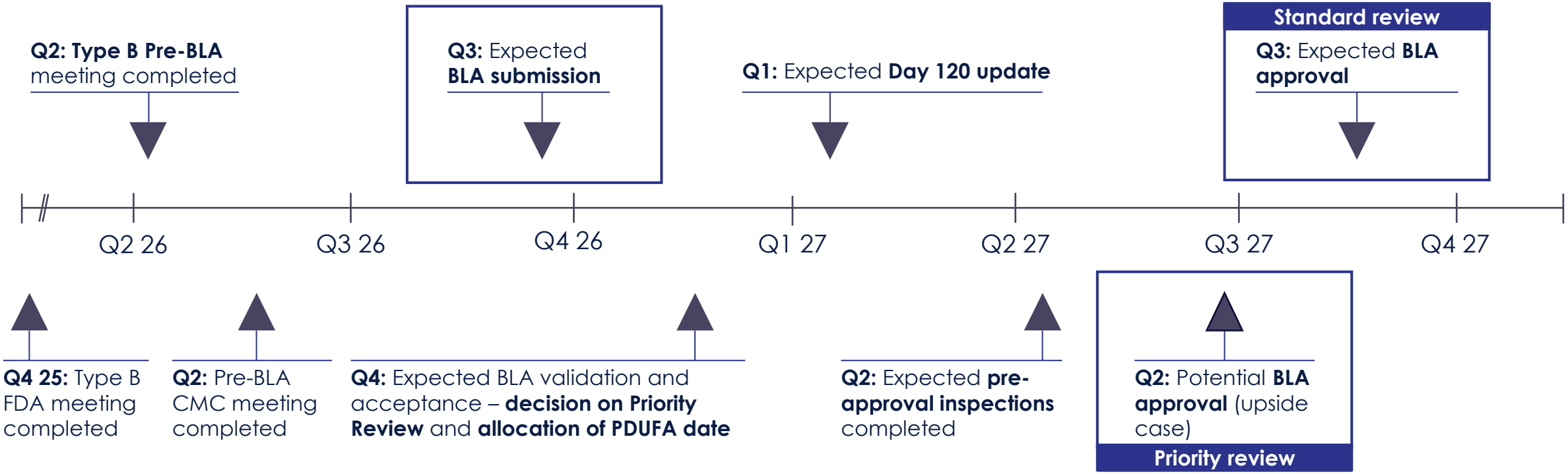
- High unmet need exists across adolescent HS population with **limited approved treatment options for adolescent patients**[1]
- **VELA-TEEN is the first dedicated study** in adolescent HS patients (no extrapolation)
- **Designation of Priority Review is not guaranteed –** potential FDA capacity constraints
- MLTX therefore sees granting of a Priority Review for the HS BLA as **an "upside case"**

1 Secukinumab received FDA approval for adolescent HS population in March 2026

Source: MoonLake Regulatory

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HS BLA timeline: BLA acceptance expected by end of November 2026



FDA pre-BLA process expected to be fully completed with submission at **end of Sep 2026**
Granting of PDUFA date as well as decision on Priority Review expected at **end of Nov 2026** – potentially accelerating SLK launch by **~4 months**

Timeline not scaled; All future milestones are anticipated dates; PDUFA, Prescription Drug User Fee Act

Source: MoonLake Regulatory

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Commercializing SLK in HS



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Continued growth in real-world data confirms **market potential at $10bn+**

Market trends continue to show strong growth & large potential

Large existing prevalence:
Unique diagnosed & treated patients[1]

~2.9m in Q1 2026
(+25% vs Q4 2015)

Strong growth in new patients:
New diagnosed and treated pts. (previously undiagnosed)[2]

~310k
(LTM Q1 2026)

Higher prices in HS:
List price of approved HS dose of Bimekizumab

$217k
(2026)

Penetration still low
Share of biologics in treated patients in Q1'26 vs Q4'23

Still 3%
(growing as fast diagnosis)

Market potential now consistently understood to be $10bn+

MoonLake

2035 $10-15bn

US HS Biologics Market

- Prevalence at 2% in 2035
- Biologics use increasing (30% YoY)
- HS with 2x price level vs. PsO

UCB

2035 $10bn+

HS Biologics Market

Estimated to be $5B by 2029

avalo THERAPEUTICS

2035 $10bn+

US HS Biologics Market

- >200k treated with biologics 2035
- Prevalence 2026 3.4m patients

LEERINK COWEN
OPPENHEIMER
CANTOR Fitzgerald

2035 $10bn+

US HS Biologics Market

"…potential for a commercial opportunity in excess of $10bn+, and capable of supporting multiple blockbuster therapies"

Diagnosed & treated patients with HS diagnosis (ICD-10 L73.2); Applied ~75% coverage rate of U.S. claims; Applied claims collection lag extrapolation for last 12 months; 1 Patients ≥18 years with a HS diagnosis; 2 Net new diagnosed HS patients

Source: Company information. Analyst research. MoonLake IR, Unique U.S. patients from prescription data, MoonLake Commercial, © 2026 Komodo Health, Inc. All rights reserved

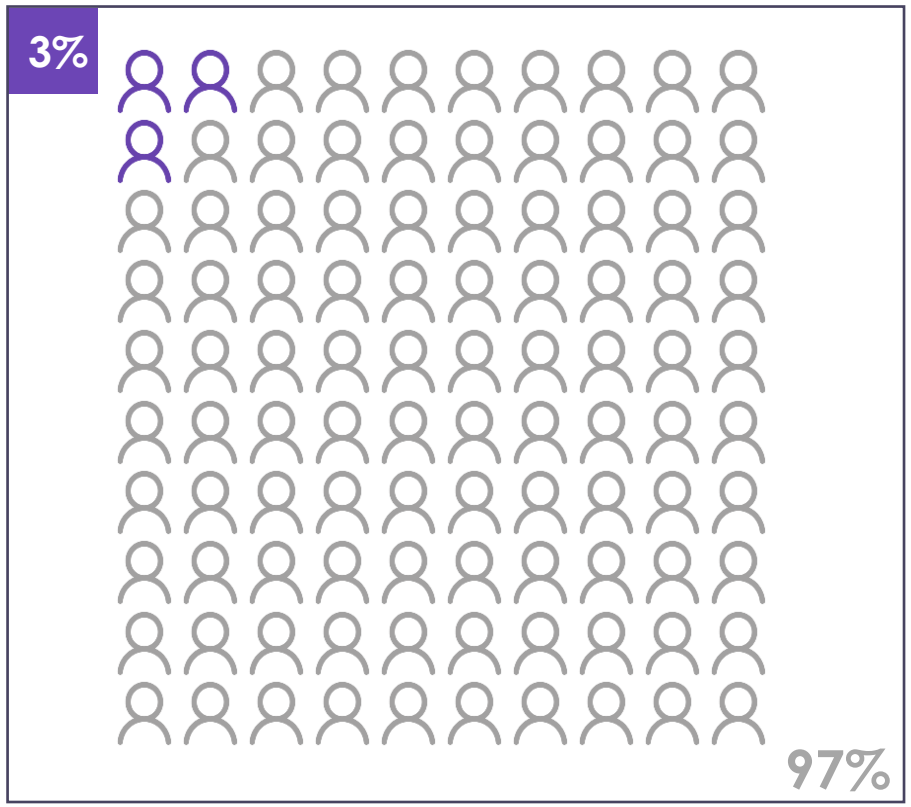
HS is a naïve market with **great conditions for a biotech launch**

HS is a naïve market where the leading drug is not defined

Only 3% of HS patients treated with biologics today: *players not going to fight over the same treated patients (not a "switch market" any time soon)*

The jury is still out for the leading drug: *research shows that prescribers look for a balanced profile with strong efficacy and safety*

+2.9m *patients diagnosed with HS* *in the US*



HS is an attractive market for Biotech

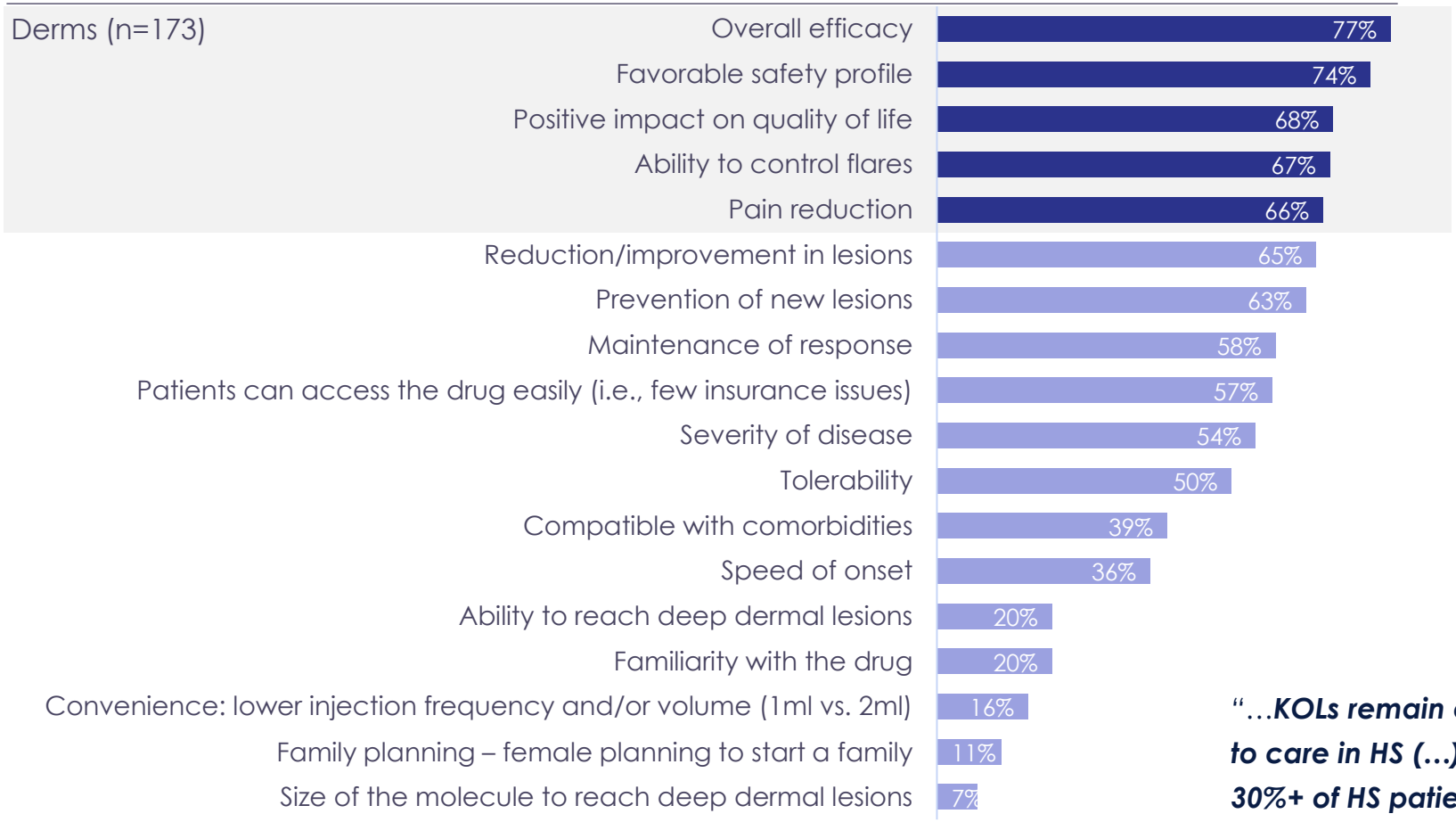
- In contrast to other major I&I markets, HS with **limited number of drugs available**
- Due to limited treatment options and irreversible tissue damage, **HS less closely managed by payors** and with high medical exception rates
- **1L drugs with limited efficacy or limited durability** (e.g., Humira median time on therapy: 11 months)
- **Highly concentrated prescriber base** enabling focused GTM approach
- **1/3 of launches** now done by Biotechs (not Pharma) in last 5 years[1]
- **75% of Biotech launches** above expectations in last 5 years[2,3]

1 Based on McKinsey report published November 2024; and additional MLTX analyses for the 2024-26 period; 2 First-time launches since 2016 based on Evaluate Pharma database analysis as of May 2026 – with minimum peak based on latest actuals/estimates of at least $1000m in the US; 3 Based on expectations at launch vs. actuals of first 3 calendar years (incl. first partial year)

Source: MoonLake Commercial, Cantor, Evaluate Pharma, Unique U.S. patients from prescription data; MoonLake Commercial, © 2026 Komodo Health, Inc. All rights reserved. MMIT 2026

US prescribers look for a **balanced profile** to treat HS patients

US Derm market research ranked important attributes for Bx selection in HS



Dermatologists report **significant remaining unmet medical need**

Dermatologists look for a **balance between high efficacy** (focus on absolute response rates, quality of life, pain) **and a favorable safety profile** (Cosentyx considered "safest option" among approved drugs)

A **conjoint analysis** (n=250)

- ~25% of physicians intend to prescribe SLK based on current data (Week 16 and full-year data)
- Advantages "re": Liver monitoring, inclusion of pain or HiSQoL data or "lighter" warnings will make SLK the leading prescribed drug

"…KOLs remain enthusiastic about SLK's potential to contribute to care in HS (…) surveyed physicians expect to use SLK in 30%+ of HS patients."

TD Cowen
a division of TD Securities

Survey results were derived from the question "Which of the following attributes are important in your decision when selecting a biologic treatment for moderate to severe HS? Select ten factors"

Source: US Dermatology Survey Fielded August 2025 (n=173); US Dermatology Conjoint Study Fielded between December 2025 and February 2026 (n=250); TD Cowen research (May 11, 2026)

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We are **on track** to seize the opportunity in HS in the US

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Groundwork for commercialization is established

- ✓ **US entity incorporated**
- ✓ **Distribution operation setup** (state licenses, 3PL / SP setup, serialization, 1st commercial batches ready)
- ✓ **Strategic positioning and GTM model** with focus on access pull through, incl. pricing model
- ✓ **Collaboration network** with top decile KOLs, patient advocacy groups and HS Foundation
- ✓ **Market access partnership planning** with key decision makers at payors and PBMs
- ✓ **Creation of brand identity** (name and visuals)

Expected milestones ahead

- **US headquarters** location announcement
- **US leadership** appointment
- **Commercial team expansion** including setup of a pre-launch field team
- **Expansion of full US team** including access, medical & marketing (to total of ~150 FTE)
- **Lock unique MLTX partnerships** with key stakeholders such as PBMs, payors
- **Pre-launch campaign** ramp-up
- More commercial **batch manufacturing**

Balance sheet provides runway to the end of 2027 + access to up to $400m from facility with Hercules Capital

Source: MoonLake Commercial

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Closing remarks



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MLTX has gathered the data to propose **a leading label**

Key label sections	SLK potential competitive position
Section 14 *Clinical studies*	Strongest HiSCR75 absolute response on label and inclusion of adolescent patients (as of 12 years of age) – expected SLK delta-to-placebo of 22-23 pp
Section 5 *Warnings & precautions*	No signal observed for SIB, hepatic events or TB reactivation – possible advantages also in other dimensions, e.g., diarrhea, IBD
Section 2 *Dosage & administration*	Convenient dosing and administration versus competitor mAb – fewer injections, shorter induction vs currently available therapies to make it easier for patients and physicians

Source: MoonLake Corporate Strategy

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Overall SLK data in HS supports **strong payor value story**

SLK demonstrates potential for leadership in HS

Relative advantage vs. IL-17A/F competitor – in % increase in response, as observed end of parental trial data

Efficacy	HiSCR75	12
	HiSCR100	15
	IHS4-100	10
PROs	HiSQOL	15
	DLQI	14
	Pain	*No equivalent data*

Clear potential for a leading HS label

SLK proposed table for Sec. 14

Efficacy data relevant for potential label *(in brackets delta to placebo)*	**HS trial 1** *(Corresponds to VELA-1)*	**HS trial 2** *(Corresponds to MIRA)*
HiSCR75, %	**34.4** (16.9)	**43.3** (28.6)
HiSCR50, %	**51.1** (20.8)	**65.7** (37.8)
Pain NRS-3, %	**28.3** (16.8)	**22.0** (19.9)
HiSQOL, CfB[1]	**-8.7** (-5.7)	**-9.4** (-4.4)
IHS4-55, %	**53.3** (19.4)	**62.7** (33.3)

VELA-2, if included, likely as narrative points of Section 14 (alternatively, as additional HS trial)

Proposed FDA label expected to show **highest response levels** across approved drug labels *(for investors: delta-to-placebo around **22-23 ppt**)*
"Upside case" would feature specific PRO results for **first time in an HS label**

Proposed label – subject to FDA review

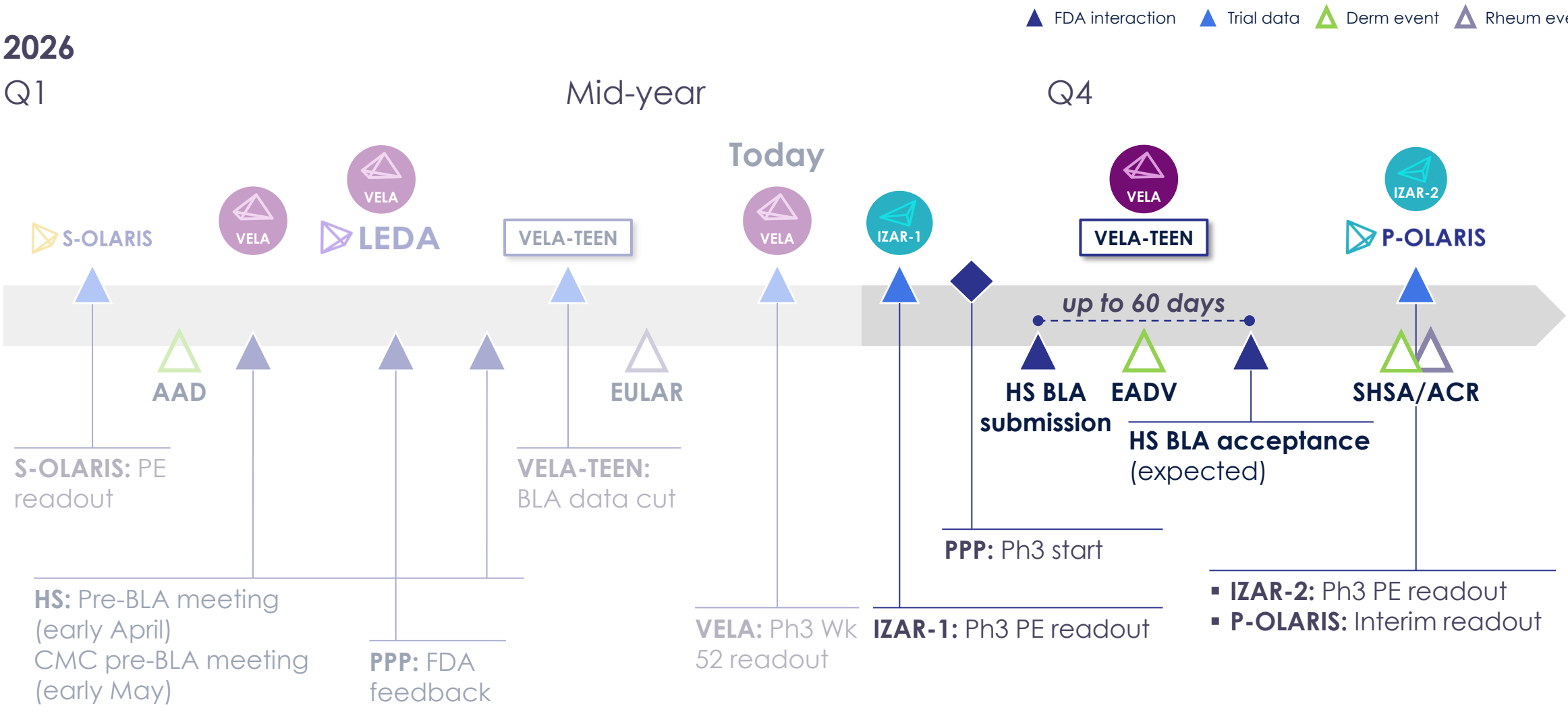
Comparisons across trials are subject to inherent limitations, as no head-to-head clinical trials have been conducted; The VELA parental trials were 52-week while the Bimekizumab parental trials were 48-week studies; Doses shown: SLK-SLK 120mg, pooled, as observed, n=396 (Baseline HiSQOL of 27.2, n=558 for HiSQOL at baseline, n=395 for HiSQOL at Week 52; n=363 for DLQI; n=241 for pain), BKZ-BKZ 320mg, pooled, as observed, n=211, Q2W>Q4W (HiSQOL: Baseline HiSQOL of 24.5, n=292 at baseline (numbers with non-missing HiSQOL data not available); DLQI: n=178); HiSQOL: Mean score difference between end of trial and baseline; DLQI definition: ≥4-point improvement from baseline, baseline DLQI of ≥4; Pain: ≥3-point improvement from baseline, baseline worst skin pain score of ≥3; Data subject to change until final CSR is issued; Sources: HiSCR 75/100: Zouboulis EADV 2023; IHS4: Tzellos T et al. J Eur Acad Dermatol Venereol. 2026;doi:10.1111/jdv.70356; HiSQOL and DLQI: Shi V et al. Dermatol Ther. 2025;15:2553; Mayo SHSA 2023

Source: MoonLake Corporate Strategy

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Catalyst-rich year: Rheumatology (PsA) starts reading pivotal data soon

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Timeline not scaled, non-exhaustive; All future milestones are anticipated dates

Source: MoonLake Corporate Strategy

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What to expect from the **IZAR-1 readout in PsA**

General disclosures in PsA

- **Recent disclosures of PsA data, e.g., bimekizumab showed only limited information –** mainly focusing on "stat sig" descriptions without disclosing absolute results of active or placebo arm
- This is usual, to **avoid unduly unblinding** the studies and is a prerogative of the FDA
- Specific guidance from **FDA is to not disclose any comparative data –** protecting integrity of data collected after read-out

Expected disclosures on IZAR-1

- Disclosures expected in a **Q3 2026 press release**, incl. "met" vs. "did not meet" endpoint reference, in line with prior competitor disclosures
- Disclosure of **absolute responses across key endpoints** (incl. ACR50, MDA, PASI90) is expected for SLK 60mg (with induction), ensuring deeper understanding of data vs. usual disclosure of peers
- **Aligned approach to keep blinding** across the various 52-week arms – IZAR-1 (3 arms) and IZAR-2 (4 arms)
- Responses across different endpoints, in the IZAR-1 bio-naïve population, in line with ARGO are a **clear success for SLK**
- In PsA, **absolute response levels are key** as the placebo is heavily influenced by concomitant medications (e.g., methotrexate)

Source: MoonLake Corporate Strategy

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Q & A

Please submit your questions via the dedicated Q&A function in the portal

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