Sonelokimab in Moderate-to-Severe HS: Long-Term Results through Week 40 of Two Phase 3 Trials

Alexa B. Kimball,[1] Martina L. Porter,[1] Melinda J. Gooderham,[2] Iltefat H. Hamzavi,[3] Jennifer L. Hsiao,[4] Brian Kirby,[5] Hadar Lev-Tov,[6] Christopher J. Sayed,[7] Vivian Y. Shi,[8] Nancy Carpenter,[9] Nuala Brennan,[9] Eva Cullen,[10] Kristian Reich,[10,11] Jacek C. Szepietowski[12]

[1]Department of Dermatology, Harvard Medical School and Beth Israel Deaconess Medical Center, Boston, MA, USA; [2]SKiN Centre for Dermatology, Probity Medical Research and Queen's University, Peterborough, ON, Canada; [3]Department of Dermatology, Henry Ford Hospital, Detroit, MI, USA; [4]Department of Dermatology, University of Southern California, Los Angeles, CA, USA; [5]Charles Department of Dermatology, St Vincent's University Hospital and Charles Institute of Dermatology, University College Dublin, Dublin, Ireland; [6]Dr Phillip Frost Department of Dermatology and Cutaneous Surgery, Miller School of Medicine, University of Miami, Miami, FL, USA; [7]Department of Dermatology, School of Medicine, University of North Carolina, Chapel Hill, NC, USA; [8]Department of Dermatology, University of Washington, Seattle, WA, USA; [9]MoonLake Immunotherapeutics AG, Cambridge, United Kingdom; [10]MoonLake Immunotherapeutics AG, Zug, Switzerland; [11]Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Hamburg, Germany; [12]Division of Dermatology, Venereology and Clinical Immunology, Faculty of Medicine, Wrocław University of Science and Technology, Wrocław, Poland

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Disclosures

ABK reports their institution has received grants from AbbVie, AnaptysBio, BMS, Eli Lilly, Incyte, Janssen, MoonLake Immunotherapeutics AG, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; has received consulting fees from AbbVie, Alumis, Avalo Therapeutics, Boehringer Ingelheim, Eli Lilly, Janssen, MSD, MoonLake Immunotherapeutics AG, Novartis, Pfizer, Priovant Therapeutics, Sanofi, Sonoma Biotherapeutics, Takeda, Target RWE, UCB, UNION Therapeutics, Ventyx Biosciences, and Zura Bio; and serves on the Board of Directors for Almirall. **MLP** has received consultation fees from AbbVie, Almirall, Arcutis Biotherapeutics, Avalo Therapeutics, Eli Lilly, FIDE, Incyte, Janssen, MSD, MoonLake Immunotherapeutics AG, NavigatorBIO, Novartis, Propeller, Pfizer, Sanofi, Sonoma Biotherapeutics, Trifecta Clinical/WCG, UCB, and Zura Bio; serves as Chair for the American Academy of Dermatology (AAD) Patient Safety and Quality Committee and the Symposium on Hidradenitis Suppurativa Advances Planning Committee; is a member of the AAD Science and Research Council; and has received royalties for a Beth Israel Deaconess Medical Center training module. 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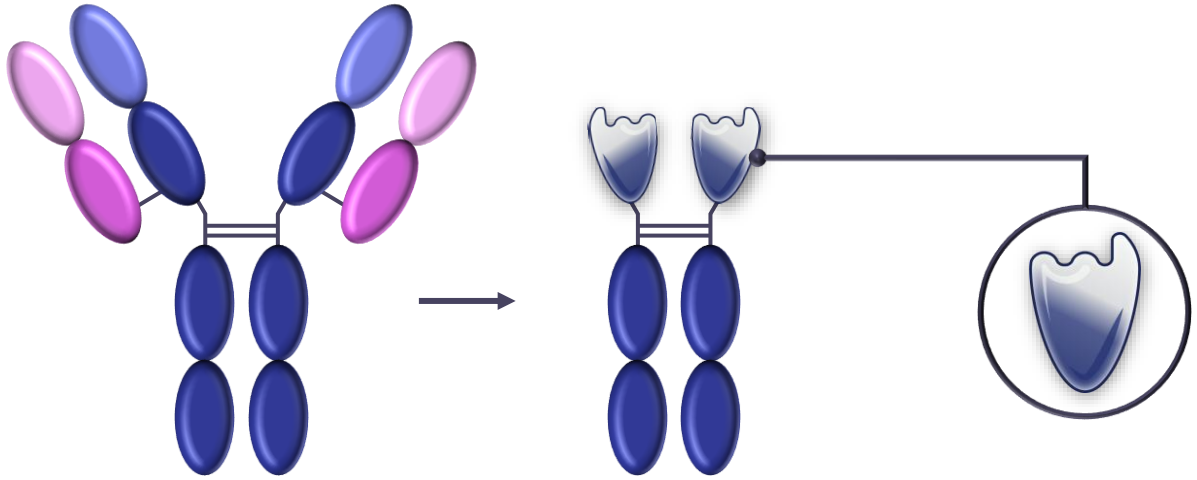
Sonelokimab is not currently approved by the FDA for any indication.

The VELA program trials are funded by MoonLake Immunotherapeutics AG, Zug, Switzerland.

Sonelokimab is a novel IL-17A- and IL-17F-inhibiting nanobody[1,2]

Sonelokimab is a nanobody, a novel biologic class[3]



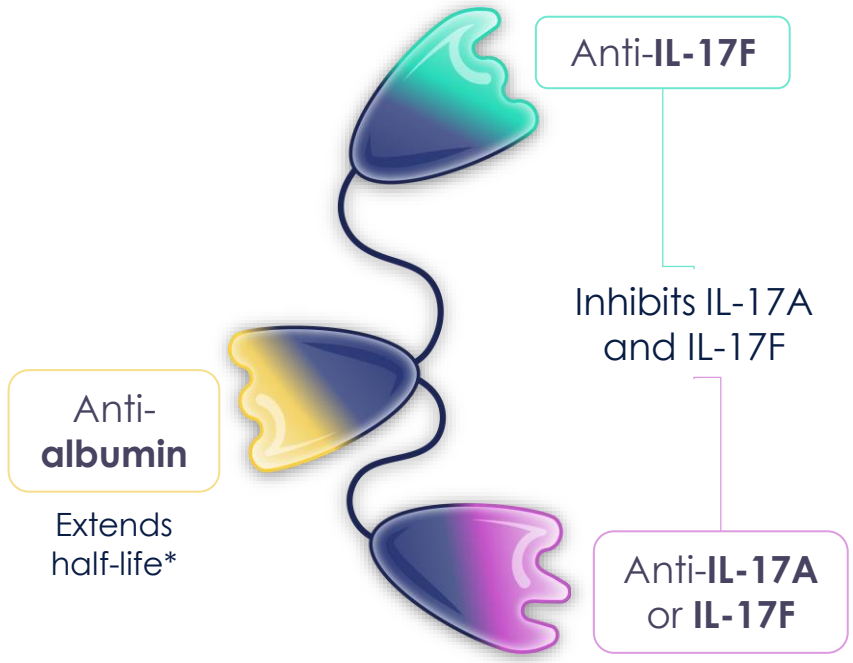
Conventional mAb (typical biologic)

Heavy-chain-only antibody (camelids)

Nanobody building block

- Small
- No Fc domain
- Humanized

Sonelokimab inhibits IL-17A and IL-17F[1,2]



Positive Phase 2 trials have been completed with sonelokimab in **hidradenitis suppurativa**,[4] **psoriatic arthritis**,[2] and **plaque psoriasis**[1]

*Albumin binding extends the half-life to the range of larger mAb biologic therapies. Figure adapted from Ref. 2, under the CC-BY 4.0 license (https://creativecommons.org/licenses/by/4.0/).

1. Papp et al. Lancet. 2021;397:1564. 2. McInnes et al. Nat Med. 2025;31:4160. 3. Jovčevska, Muyldermans. BioDrugs. 2020;34:11. 4. Kimball et al. AAD 2024.

Week 40 interim results from the VELA-1 and VELA-2 Phase 3 HS trials

VELA-1 and **VELA-2** are identically designed, global, randomized, double-blind, placebo-controlled **52-week trials** to evaluate the efficacy and safety of **sonelokimab** in **adults with moderate-to-severe HS**

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

participants randomized at baseline

Key inclusion criteria

- **Hurley II** or **III**
- **≥5 AN** count
- **Up to 2** prior **biologics**

Dosing regimen

Sonelokimab **120mg SC Q4W**
Induction doses at Weeks 0, 2, 4, 6 & 8

HiSCR75 (primary endpoint) and other Week 16 results were previously reported;[1] here, we present **longer-term efficacy and QoL results with sonelokimab to Week 40**

Week 40 data are preliminary, subject to Week 52/end-of-trial database lock. 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. AN, abscess and inflammatory nodule; QoL, Quality of Life. 1. Porter et al. SHSA 2025.

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Baseline characteristics were balanced across treatment arms

	VELA-1		VELA-2	
	Placebo n=138	**Sonelokimab** n=283	**Placebo** n=141	**Sonelokimab** n=276
Age [years], mean	36.1	37.2	38.0	37.2
Female, %	62.3	61.5	49.6	53.6
Race, % White Black or African American	 76.1 15.2	 77.7 12.0	 85.1 10.6	 81.5 9.4
BMI [kg/m^2], mean	33.6	33.5	32.7	33.0
Current smoker, %	41.3	43.8	56.0	51.8
Hurley Stage II/III, %	63.8/36.2	64.0/36.0	67.4/32.6	63.0/37.0
Years since diagnosis, mean	8.4	8.1	7.7	7.5
AN count, mean	13.3	13.5	13.8	14.5
Draining tunnels, mean	2.8	3.2	3.5	3.9
DLQI Total, mean	11.8	11.7	11.3	12.6
HiSQOL Total, mean	27.6	26.5	23.8	28.0
Worst skin pain NRS, mean	4.9	4.7	5.0	4.9
Prior biologic use, %	15.9	15.5	22.0	19.6
Concomitant antibiotics, %	8.7	6.7	7.8	10.5

Stratification factors shown **in bold**. Geographic region was an additional stratification factor.
AN, abscess and inflammatory nodule; DLQI, Dermatology Life Quality Index; HiSQOL, HS Quality of Life; NRS, numerical rating scale.

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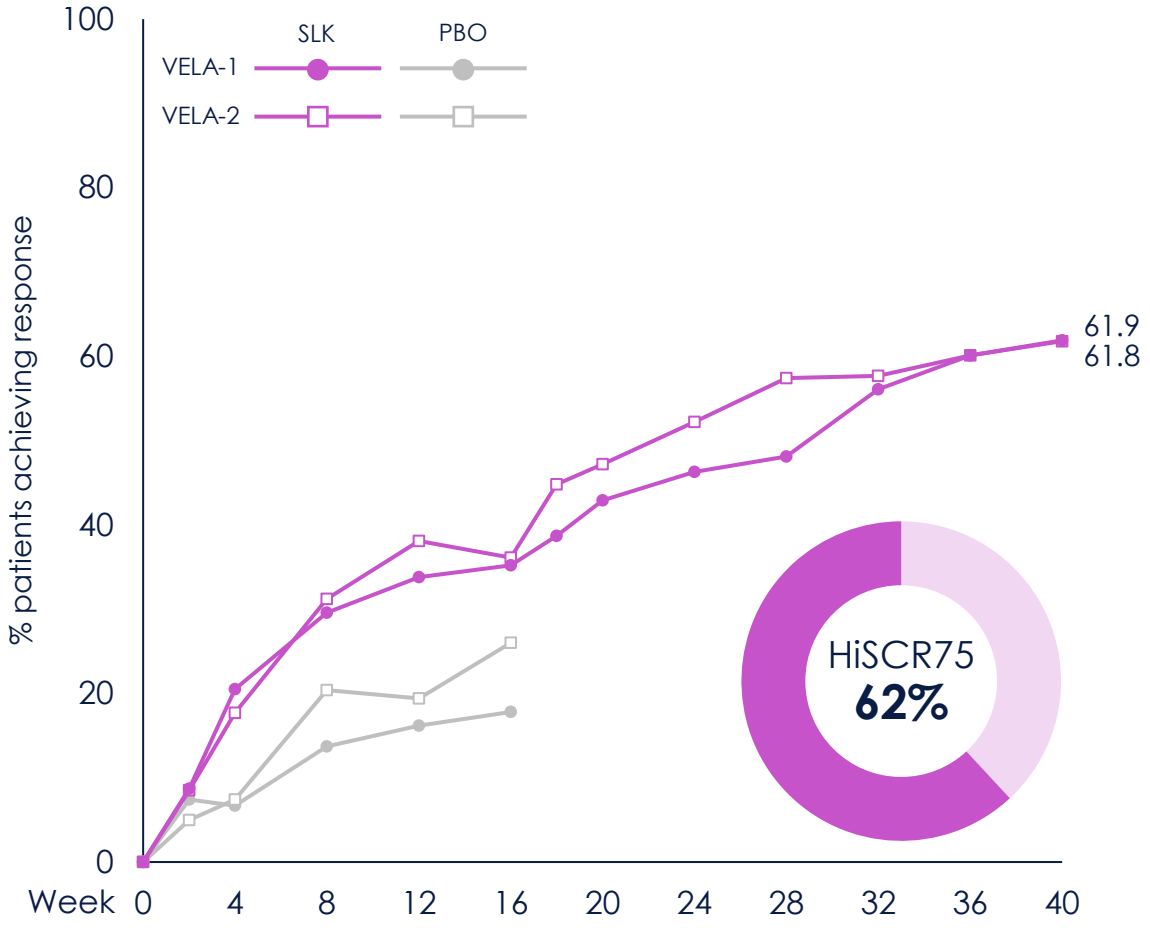
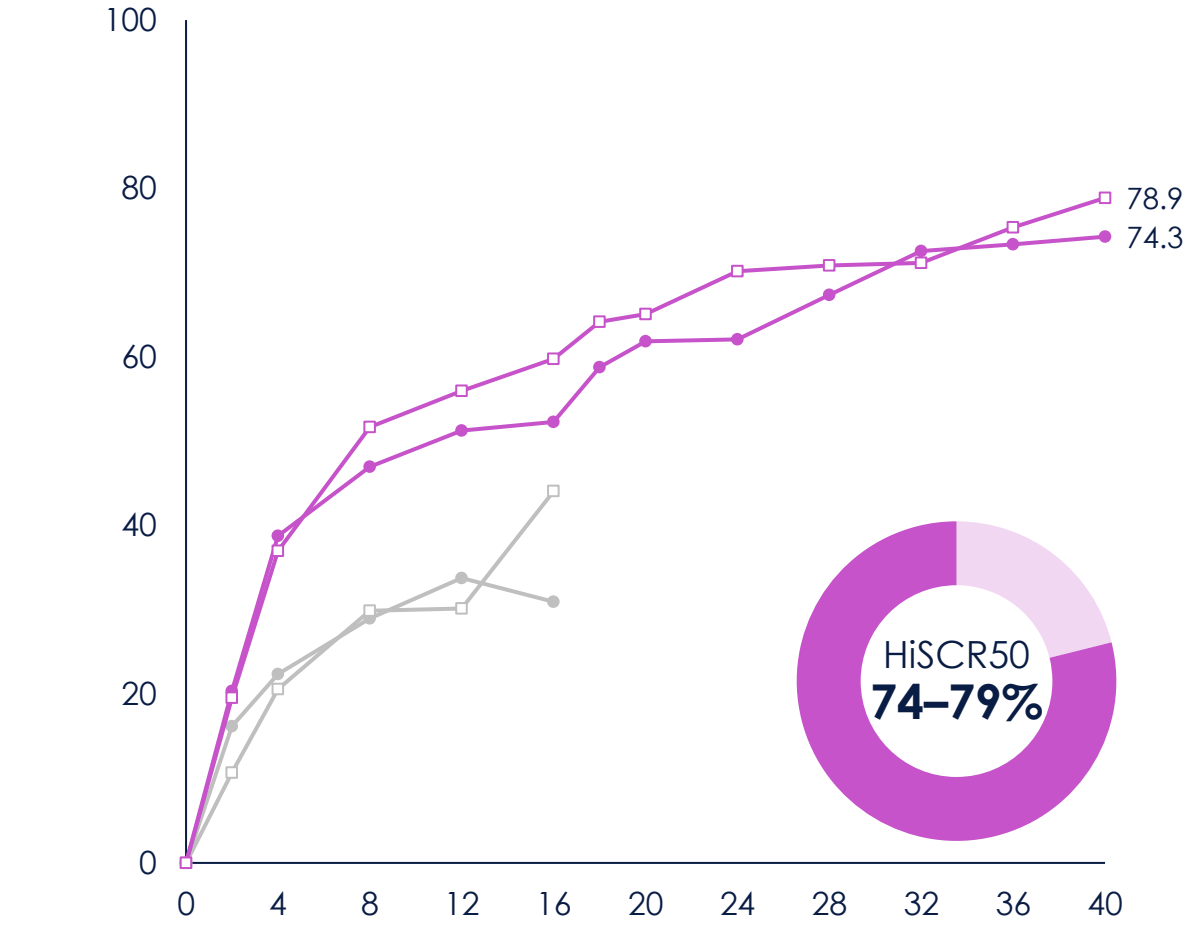
Longer term HiSCR75/50 outcomes continue to improve through Week 40

HiSCR75 to Week 40 in VELA-1/-2



HiSCR50 to Week 40 in VELA-1/-2



Data reported as observed. Week 40 data are preliminary, subject to Week 52/end-of-trial database lock.
HiSCR50/75: ≥50/75% reduction from baseline in AN count with no increase in abscesses or draining tunnels; PBO, placebo; SLK, sonelokimab.

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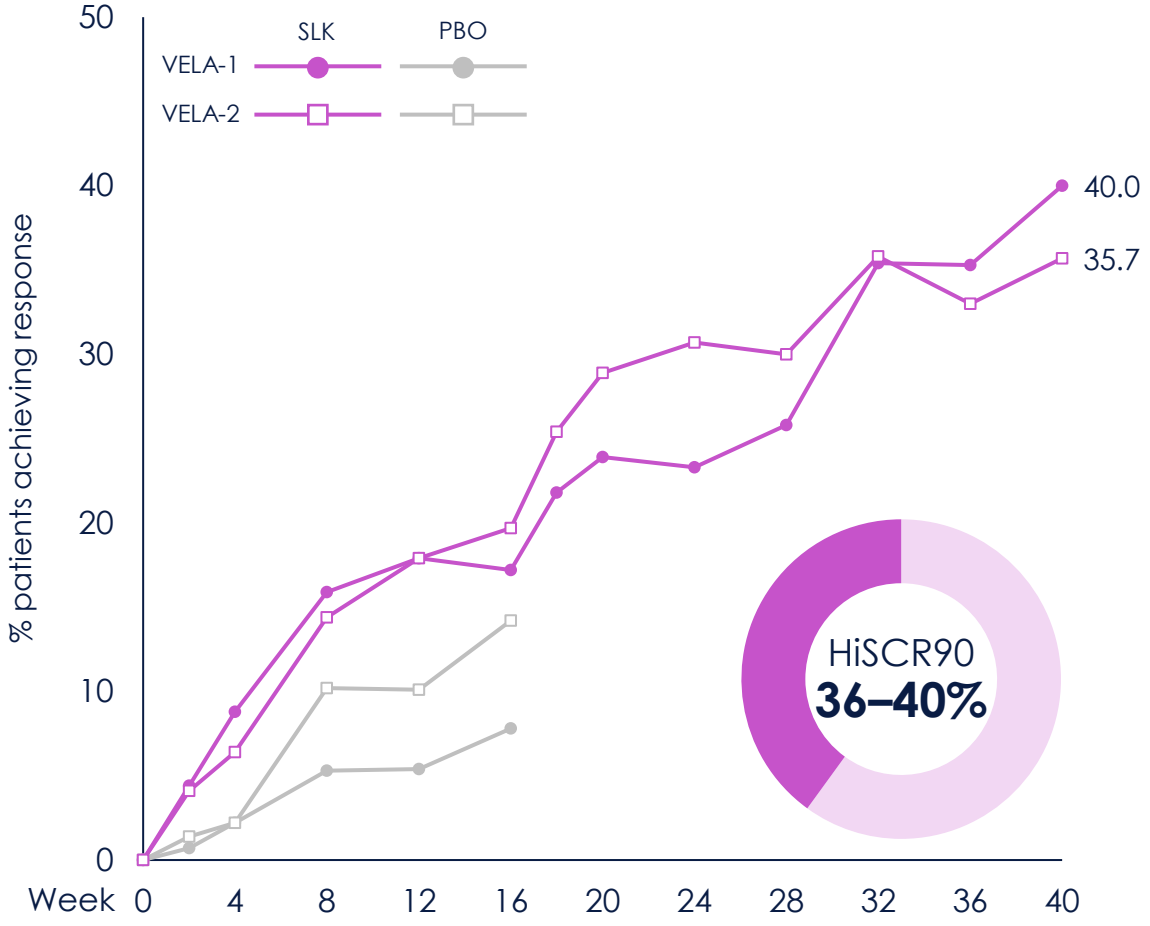
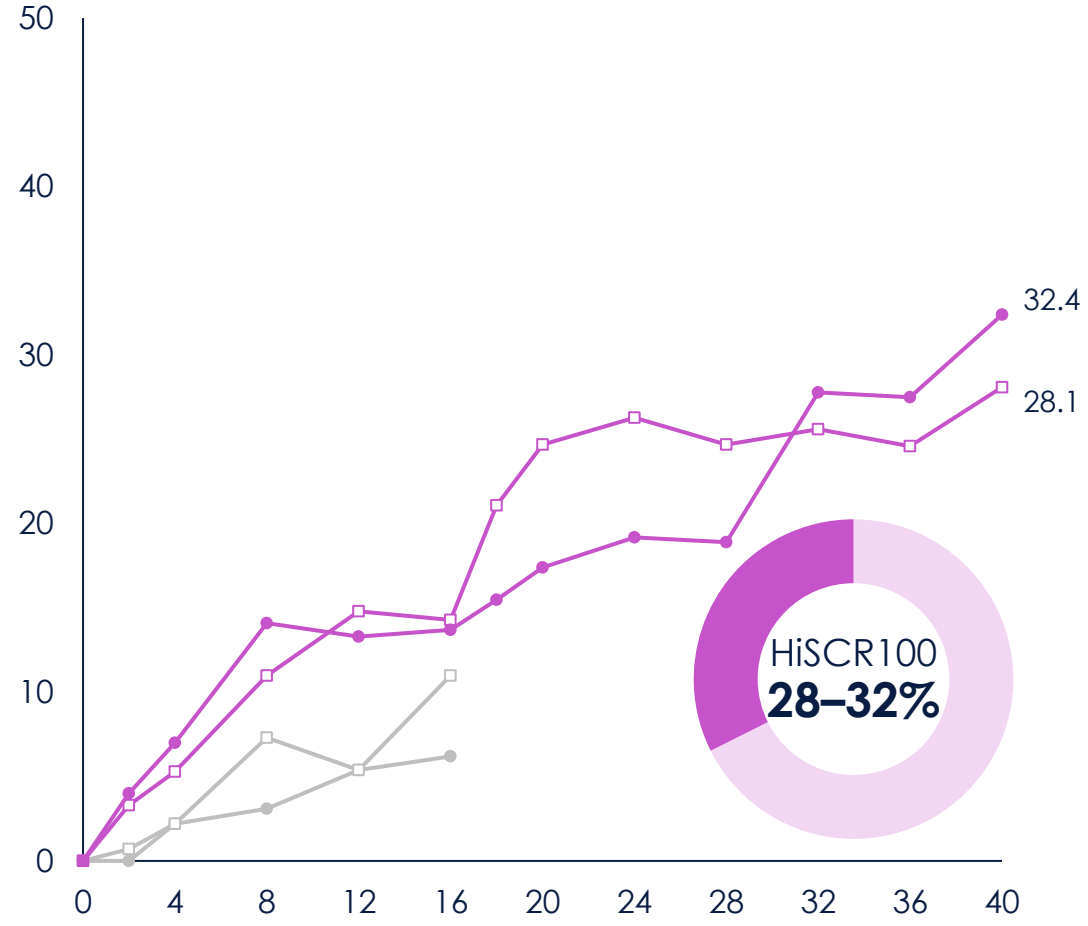
HiSCR90/100 response rates also continue to increase through Week 40

HiSCR90 to Week 40 in VELA-1/-2



Week	0	4	8	12	16	20	24	28	32	36	40
SLK VELA-1 n, 283	273	270	263	256	247	240	233	223	218	210	
SLK VELA-2 n, 276	265	263	257	244	235	228	223	215	203	199	

HiSCR100 to Week 40 in VELA-1/-2



	0	4	8	12	16	20	24	28	32	36	40
SLK VELA-1 n, 283	273	270	263	256	247	240	233	223	218	210	
SLK VELA-2 n, 276	265	263	257	244	235	228	223	215	203	199	

Data reported as observed. Week 40 data are preliminary, subject to Week 52/end-of-trial database lock.
HiSCR90/100: ≥90/100% reduction from baseline in AN count with no increase in abscesses or draining tunnels.

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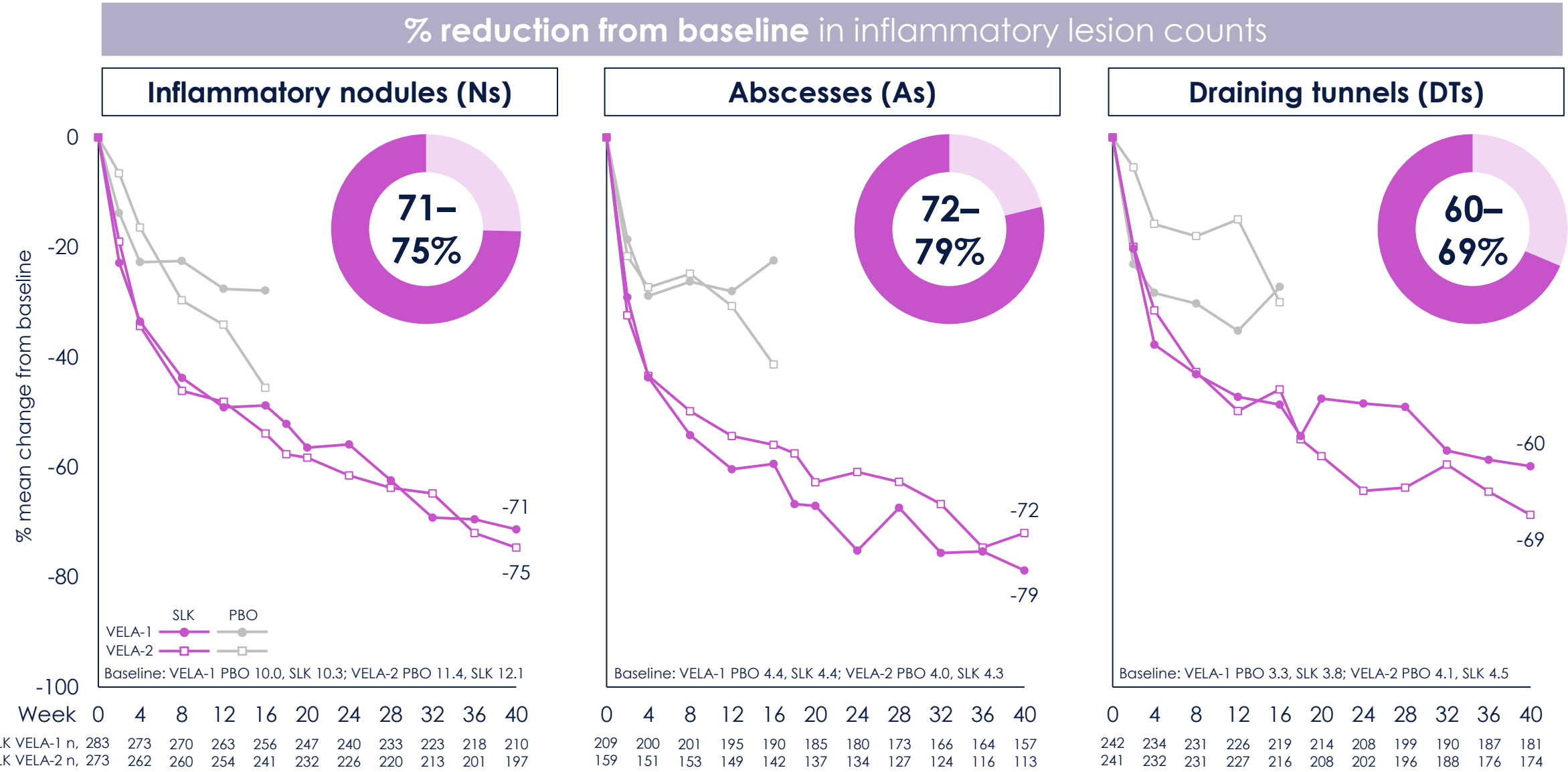
Improvements are consistent across lesion types



Data reported as observed, for patients with baseline count >0. Week 40 data are preliminary, subject to Week 52/end-of-trial database lock.

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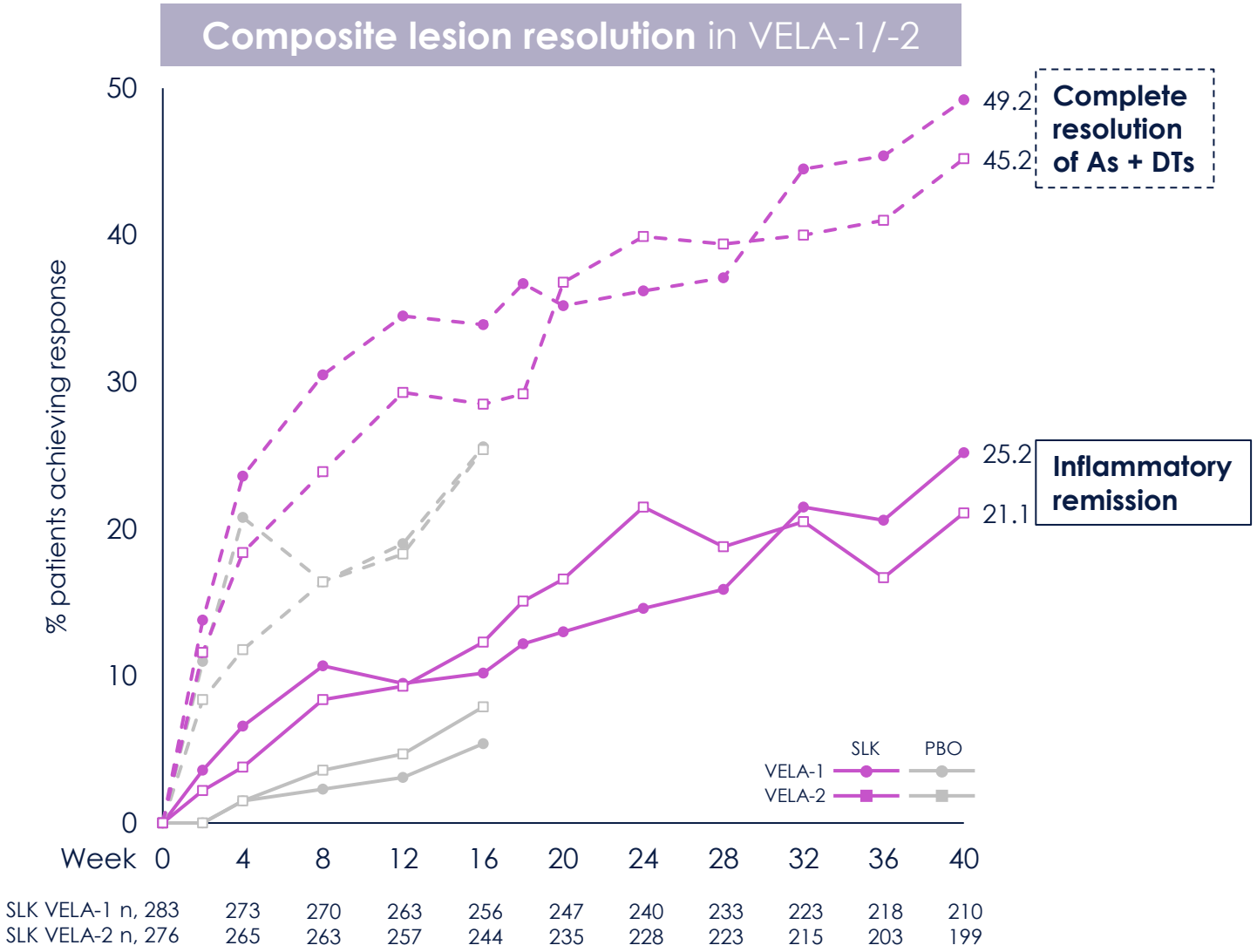
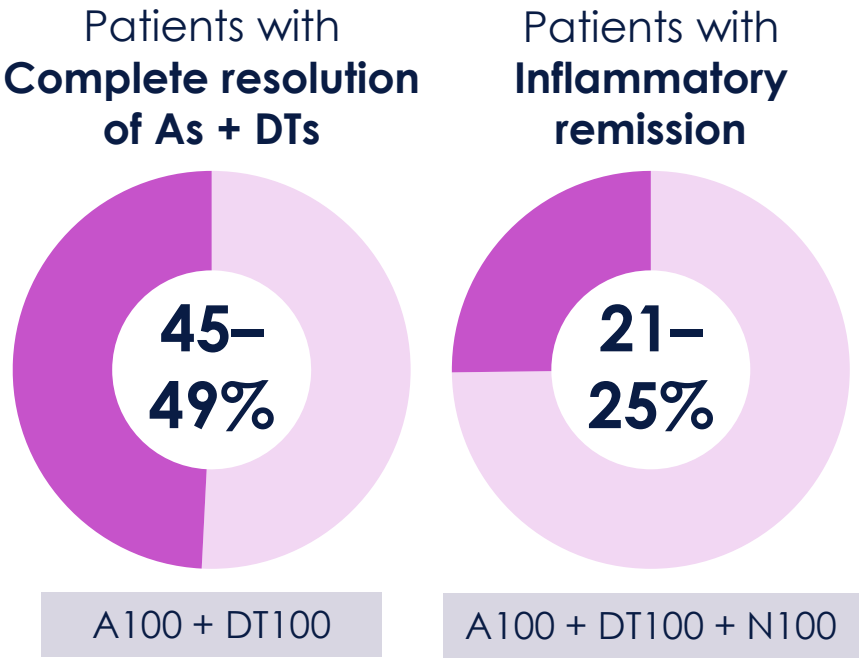
High rates of composite lesion resolution at Week 40





Data reported as observed. Week 40 data are preliminary, subject to Week 52/end-of-trial database lock. ns are for inflammatory remission analysis; 93% of these patients had baseline A+DT count >0 and were analyzed for A+DT100. A/DT/N100: 100% reduction from baseline in abscess/draining tunnel/inflammatory nodule count.

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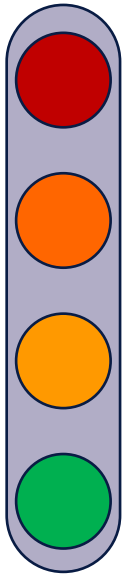
>60% of patients achieve ‘Mild/None’ in HiSQOL severity at Week 40

HiSQOL severity scale[1]
Impact of HS on QoL



Very Severe
≥24

Severe
22–23

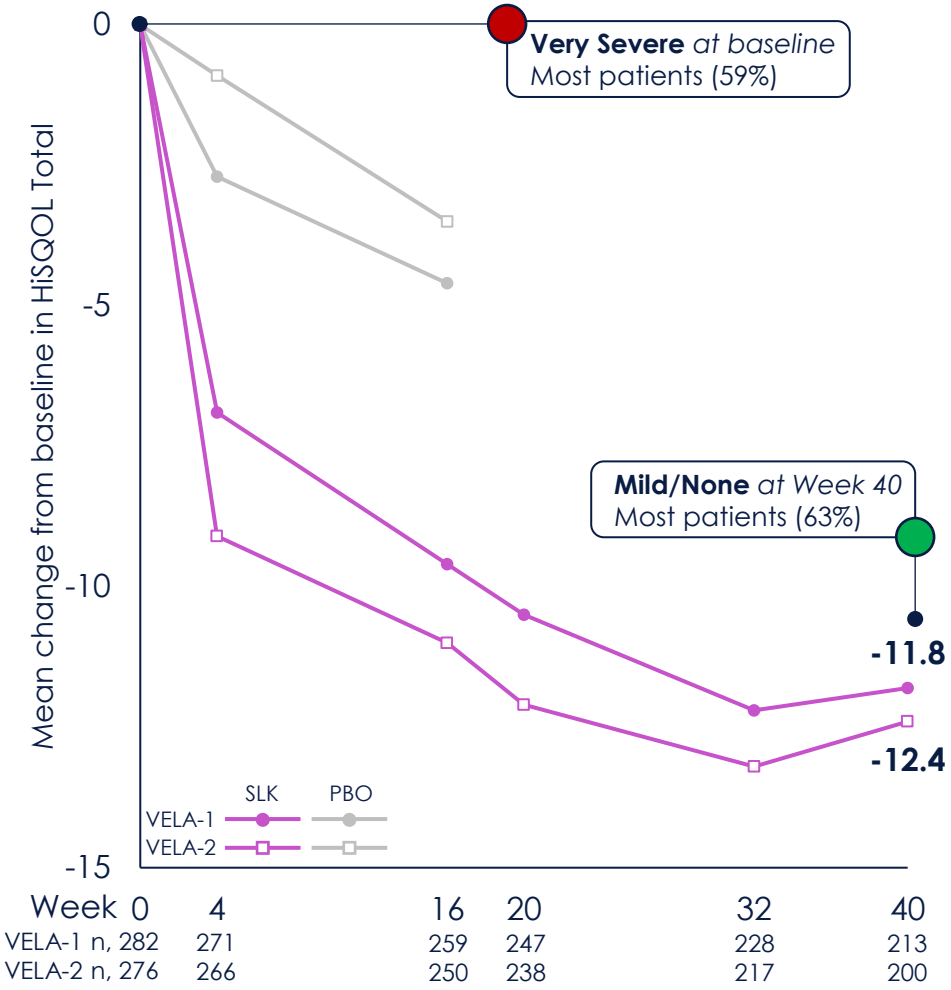
Moderate
15–21

Mild/None
≤14

Mean HiSQOL at Baseline

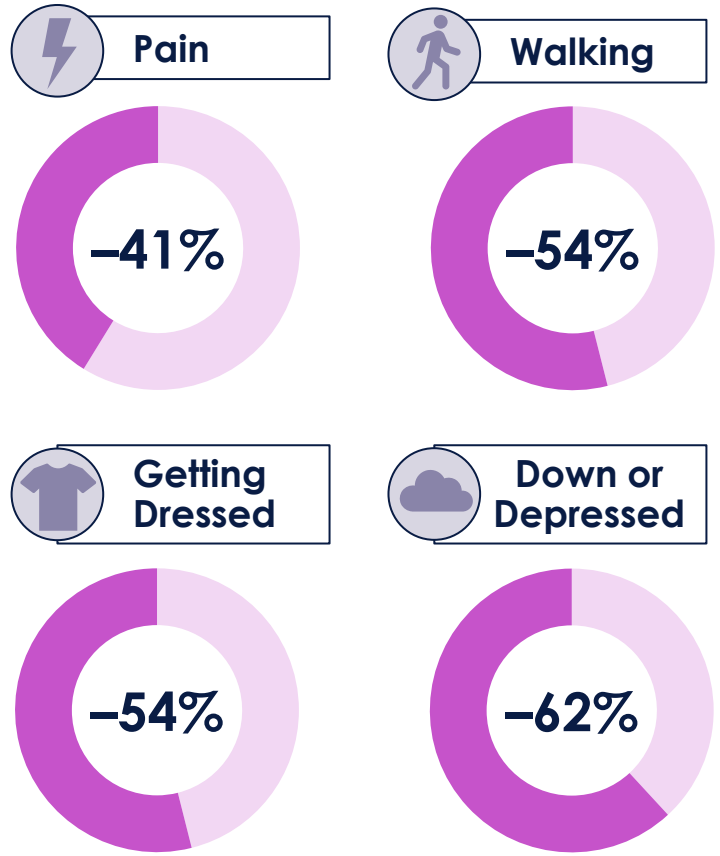
VELA-1: PBO, 27.6; SLK, 26.5
VELA-2: PBO, 23.8; SLK, 28.0

HiSQOL Total improvement



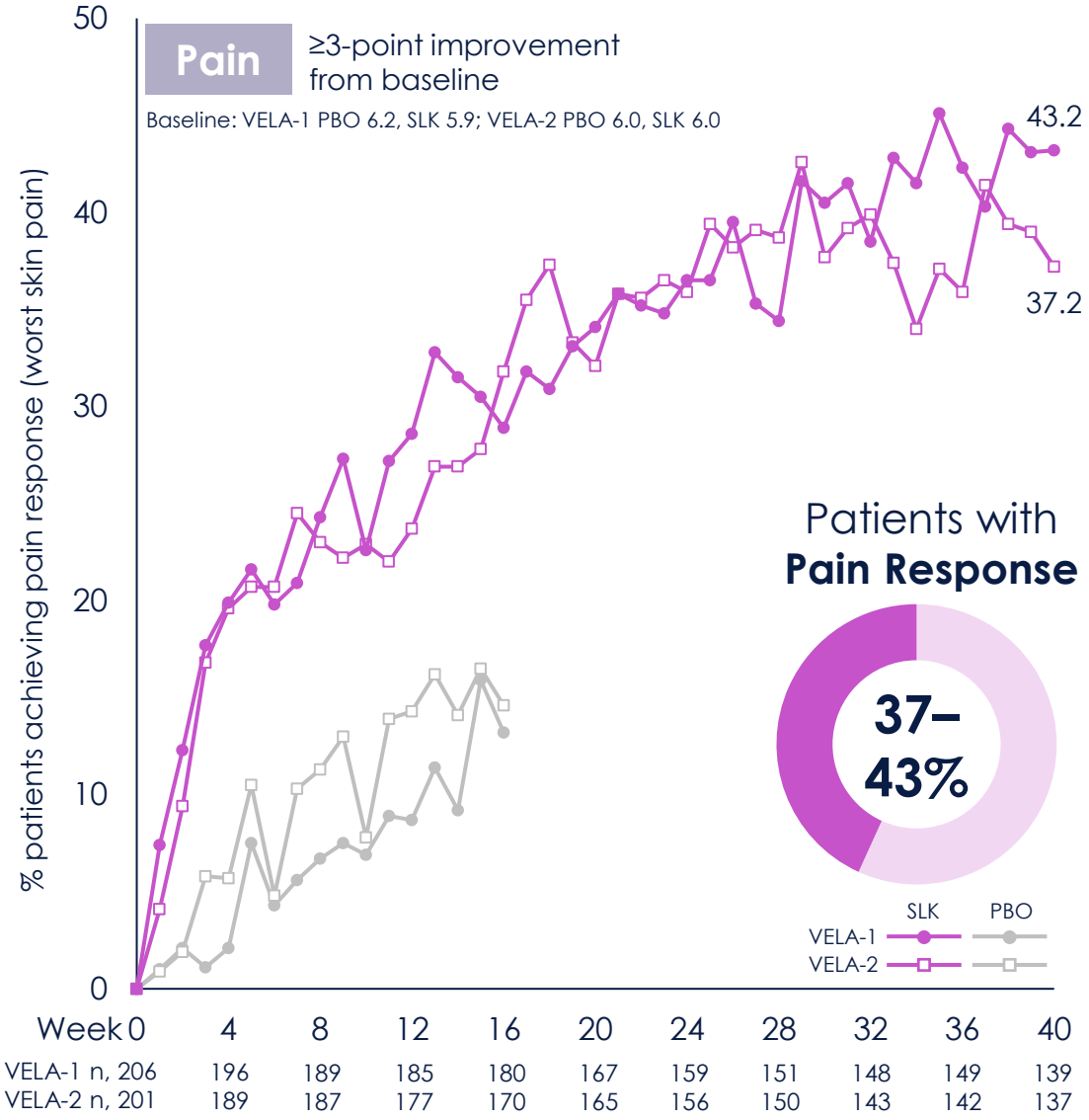
% improvement in HiSQOL items

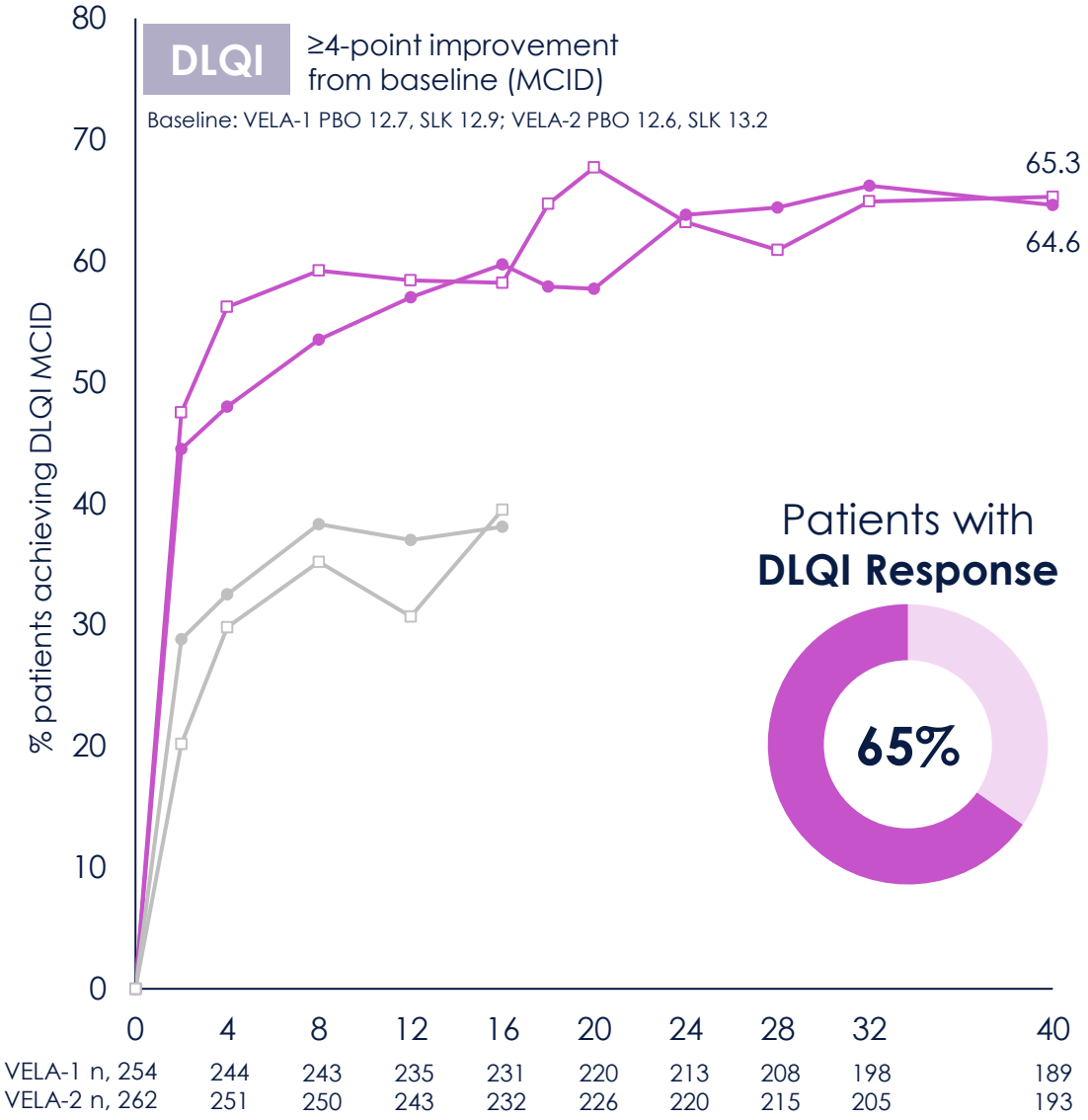
Mean % change from baseline in HiSQOL-Mini[2] items at Week 40



Data reported as observed. Week 40 data are preliminary, subject to Week 52/end-of-trial database lock. HiSQOL: HS-specific QoL score (17 items scored 0–4). HiSQOL-Mini (4 items) and % severity: post hoc analyses (pooled sonelokimab arms in VELA-1/-2). HiSQOL-Mini analyzed in patients with baseline >0. 1. Kirby et al. Br J Dermatol. 2025;193:93. 2. Hasan et al. EHSF 2023. Kimball AB, *et al*. AAD 2026. Presentation 79289.

Patients report clinically meaningful responses in pain and DLQI





Data reported as observed. Week 40 data are preliminary, subject to database lock. Pain response analyzed for worst skin pain in patients with a baseline worst skin pain score of ≥3. DLQI MCID (minimal clinically important difference) analyzed in patients with a baseline DLQI score of ≥4.

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Week 16 Safety: Sonelokimab was well tolerated, with no new safety signals[1]

Treatment-emergent adverse events (TEAEs), n (%)	VELA-1 and VELA-2 combined to Week 16	
	Placebo n=279	Sonelokimab n=559
Any TEAE	155 (55.6)	376 (67.3)
Any serious TEAE	5 (1.8)	14 (2.5)
Any TEAE leading to discontinuation	4 (1.4)	16 (2.9)
Most frequent TEAEs (≥5% with active treatment)		
Nasopharyngitis	28 (10.0)	48 (8.6)
Oral candidiasis[a]	**1 (0.4)**	**41 (7.3)**
Other TEAEs of interest		
Dermatitis and eczema[b]	**7 (2.5)**	**20 (3.6)**
Serious infection	2 (0.7)	4 (0.7)
Diarrhea (non-infectious)	1 (0.4)	2 (0.4)
Hepatic event[c]	3 (1.1)	1 (0.2)
Inflammatory bowel disease (IBD)[d]	**0**	**0**
Suicidal ideation and behavior (SIB)	0	0
Serious hypersensitivity	0	0
Major adverse cardiovascular event (MACE)[e]	0	0

Longer-term safety outcomes after Week 16 will be presented following trial completion

- VELA-1 and VELA-2 are ongoing trials; an unblinded safety analysis will be available after trial completion
- Ongoing medical monitoring by the sponsor and an independent DSMB has not thus far identified any new or unexpected safety findings beyond Week 16

All cases of **candidiasis** were **mild to moderate**, and most were oral

No **IBD**, **SIB**, or **MACE** adverse events were observed with sonelokimab[d,e]

Trials are still ongoing, and treatment assignment remains blinded to patients and trial site staff; the table only includes events where blinding can still be maintained. Adjudication is preliminary and ongoing. **a** 3 events of esophageal and 2 of oropharyngeal candidiasis were reported in the sonelokimab group. **b** Patients with events assigned to either of the preferred terms 'dermatitis' or 'eczema.' **c** Adjudicated adverse events or hepatic enzyme elevations; 8 (2.9%) patients in the placebo group and 9 (1.6%) in the sonelokimab group had adverse events and/or laboratory elevations of liver function tests sent for adjudication as possible drug-induced liver injury (DILI), with 3 (1.1%) in the placebo group and 1 (0.2%) in the sonelokimab group adjudicated as possible DILI (no Hy's law events were observed), and 3 (1.1%) in the placebo group and 1 (0.2%) in the sonelokimab group adjudicated as non-DILI hepatic elevations. **d** 1 event recorded as Crohn's disease in the placebo group was adjudicated as not IBD. **e** Adjudicated MACE (defined as cardiovascular death, stroke, myocardial infarction, resuscitated cardiac arrest, or hospitalization for heart failure or for unstable angina). 1. Porter et al. SHSA 2025. Kimball AB, *et al*. AAD 2026. Presentation 79289.

Conclusions

Sonelokimab: Key findings from VELA-1 and VELA-2 at Week 40

- *Efficacy:* **High, sustained and improving HiSCR75** (primary endpoint) and other clinical responses to Week 40 across both trials
- *Symptoms and quality of life:* **'Mild/None'** impact of HS (**HiSQOL**) in most patients at Week 40, and high, sustained rates of **clinically meaningful pain** and **DLQI** responses

Safety at Week 16 (Week 52 pending): Well tolerated, with no new safety signals, and no IBD, SIB, or MACE adverse events; hepatic events more frequent in placebo group than sonelokimab group

Dosing: Convenient 1 mL monthly maintenance from Week 8 onward

Future directions: VELA-1 and VELA-2 are ongoing 52-week trials

- *Full VELA-1 and VELA-2 results:* Further results to be reported upon completion
- *Other ongoing sonelokimab HS trials:* VELA-OLE—long-term treatment; VELA-TEEN—adolescents
- *Regulatory:* The sponsor intends to file a Biologics License Application later this year

SIB, suicidal ideation and behavior. Week 40 data are preliminary, subject to database lock. VELA-OLE: NCT07007637. VELA-TEEN: NCT06768671.

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