Sonelokimab in moderate-to-severe HS: Efficacy and safety results from the Phase 3 VELA-1/-2 trials

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Disclosures

MLP has received consulting fees from AbbVie, Alumis, Arcutis, Avalo Therapeutics, Eli Lilly, FIDE, Incyte, Janssen, Merck, MoonLake Immunotherapeutics AG, Navigator Biosciences, Novartis, Pfizer, Sanofi, Sonoma Biotherapeutics, Trifecta Clinical/WCG, UCB, and ZuraBio; 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 the BIDMC training module. MLP's institution has received grants from AbbVie, AnaptysBio, Avalo Therapeutics, Bayer, BMS, Eli Lilly, Incyte, Janssen, MoonLake Immunotherapeutics AG, Novartis, Oasis Pharmaceuticals, Pfizer, Prometheus Laboratories, Regeneron, Sonoma Biotherapeutics, Sanofi, and UCB.

ABK's institution received grants from Abbvie, Admirx, AnaptysBio, Aristea, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, MoonLake Immunotherapeutics AG, Novartis, Pfizer, Prometheus, Sonoma Biotherapeutics and UCB; ABK received consulting fees from Abbvie, Alumis, Avalo, Bayer, Boehringer Ingelheim, Eli Lilly, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sanofi, Sonoma Biotherapeutics, Takeda, Target RWE, UCB, Union Therapeutics, and Ventyx; ABK serves on the board of directors of Almirall. **MJG** has been an investigator, speaker, and/or advisor for: AbbVie, Amgen, Akros, Arcutis, Aristea, AnaptysBio, Apogee, Bausch Health, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Dermira, Dermavant, Eli Lilly, Galderma, GSK, Incyte, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, MoonLake Immunotherapeutics AG, Nimbus, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Tarsus, Takeda, UCB, UNION Therapeutics, and Ventyx. **KBG** has received honoraria and/or research support from the following pharmaceutical companies: AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Boehringer Ingelheim, Dermavant, DICE Therapeutics, Incyte, Eli Lilly, Janssen, LEO Pharma, MoonLake Immunotherapeutics AG, Novartis, Pfizer, Protagonist, UCB, and Union Therapeutics. **ABG** receives research/educational grants from Bristol Myers Squibb, Janssen, MoonLake Immunotherapeutics AG, and UCB (all paid to Mount Sinai School of Medicine), and has received honoraria as an advisory board member and consultant for Amgen, Eli Lilly, Highlight Therapeutics, Janssen, Novartis, Sanofi, Sun Pharma, Takeda, Teva, UCB, and XBiotech (stock options for RA). **IHH** has received consulting fees from: AbbVie, Almirall, Boehringer Ingelheim, Chemocentryx, Galderma, Incyte, Janssen, MyDerm Portal, Novartis, Pfizer, Sonoma, UCB, UNION Therapeutics, and Vimela Therapeutics. 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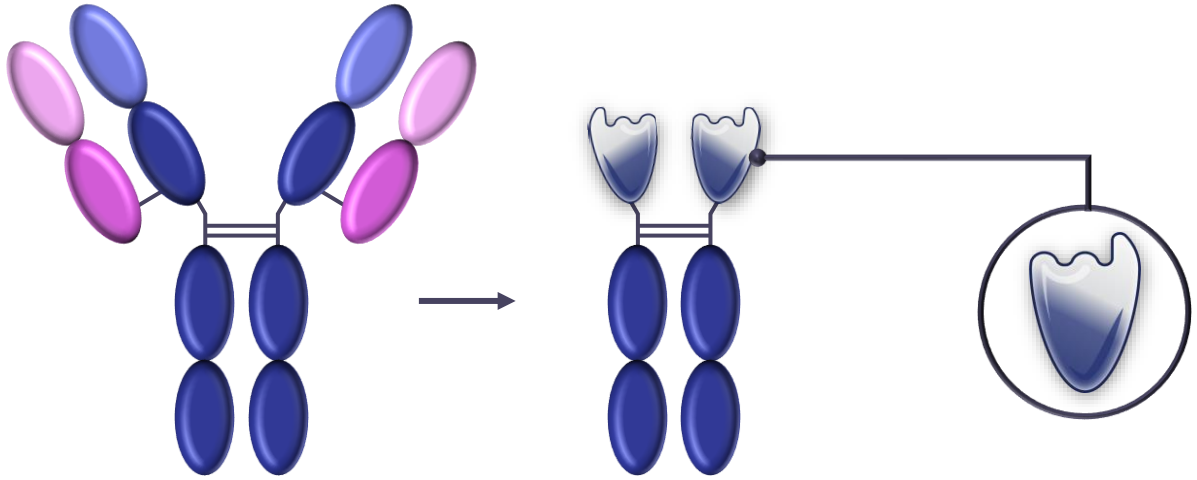
She has received fees for serving as a speaker or consultant for AbbVie, Bristol Myers Squibb, Janssen, Novartis, Sanofi Genzyme, and UCB. **CJS** has acted as a speaker for AbbVie and Novartis; received personal consulting fees from AbbVie, Novartis, Incyte, UCB, Sonoma Biotherapeutics, Alumis, AstraZeneca, and Sanofi; has been an investigator (fees to institution) in the last 24 months for Novartis, UCB, Incyte, and InflaRx; and has stock ownership for Eli Lilly. **VYS** is on the board of directors for the Hidradenitis Suppurativa Foundation (HSF), an advisor for the National Eczema Association, is a stock shareholder of Learn Health and has served as an advisory board member, investigator, speaker, and/or received research funding from Sanofi Genzyme, Regeneron, AbbVie, Genentech, Eli Lilly, Novartis, SUN Pharma, LEO Pharma, Pfizer, Incyte, Dermavant, Apogee, Boehringer Ingelheim, Almirall, Alumis, Aristea Therapeutics, Menlo Therapeutics, Dermira, Burt's Bees, Galderma, Kiniksa, UCB, Ceraclere, Bain Capital, Target-PharmaSolutions, Castle Bioscience, Altus Lab/cQuell, MYOR, Polyfins Technology, GpSkin, and Skin Actives Scientific. **HvdZ** has served as an advisor for AbbVie, Novartis, UCB, InflaRX, Insmed, and Incyte. **NA, NC, RS, NB, AG, and EC** are employees, and may be stockholders, of MoonLake Immunotherapeutics AG. **KR** has received consulting fees from Almirall S.A, Eli Lilly, Forward Therapeutics Inc, Janssen-Cilag, LEO Pharma, and Ocean Pharma; has received grants/research funding from AbbVie, Almirall S.A., Eli Lilly, LEO Pharma, and Janssen-Cilag; has received honoraria as a speaker for AbbVie, Almirall S.A., Eli Lilly, Janssen-Cilag, and LEO Pharma; has served on the board of directors for Dermagnostix GmbH and Derma2go; has participated an advisory board for Forward Therapeutics Inc.; has stock/stock options in Forward Pharma A/S, Forward Therapeutics Inc., MoonLake Immunotherapeutics AG, and Vidac Pharma; and is an employee of MoonLake Immunotherapeutics AG and the University Medical Centre Hamburg-Eppendorf. **JCS** participated in an advisory board for AbbVie, LEO Pharma, Novartis, Pfizer, Sanofi-Genzyme, Trevi, and Vifor, and as a speaker for AbbVie, Almirall, Janssen-Cilag, Eli Lilly, LEO Pharma, Novartis, Pfizer, and Sanofi-Genzyme.

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



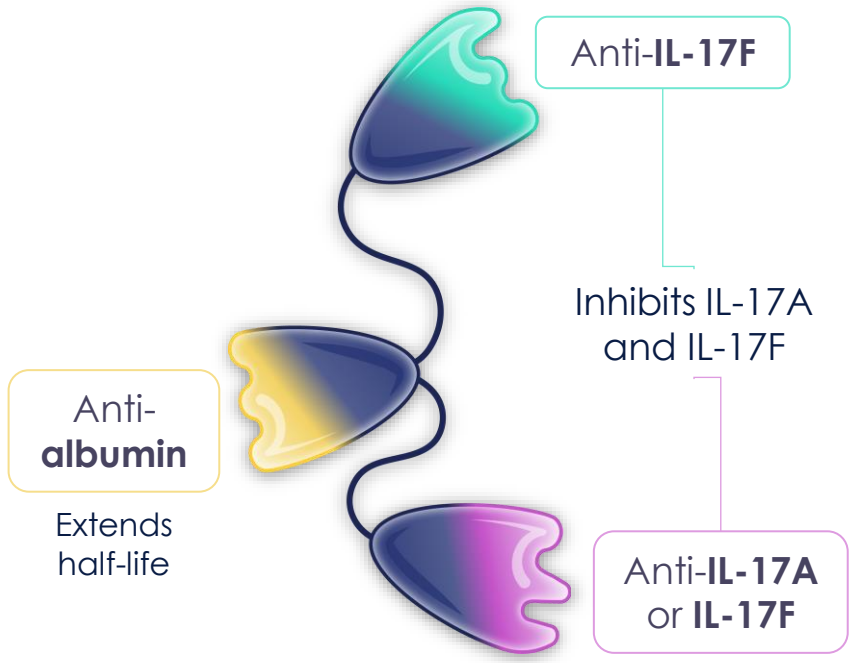
Conventional mAb (typical biologic)

Heavy-chain-only antibody (camelids)

Nanobody building block

- Small
- No Fc domain
- Humanized

Sonelokimab inhibits IL-17A and IL-17F



Sonelokimab has completed positive Phase 2 trials in **hidradenitis suppurativa**,[3] **psoriatic arthritis**,[4] and **plaque psoriasis**[1]

1. Papp KA, *et al*. *Lancet*. 2021;397:1564. 2. Svecova D, *et al*. *J Am Acad Dermatol*. 2019;81:196. 3. Kimball AB, *et al*. EADV 2023. 4. McInnes IB, *et al*. *Nature Med*. 2025;doi:10.1038/s41591-025-03971-6.

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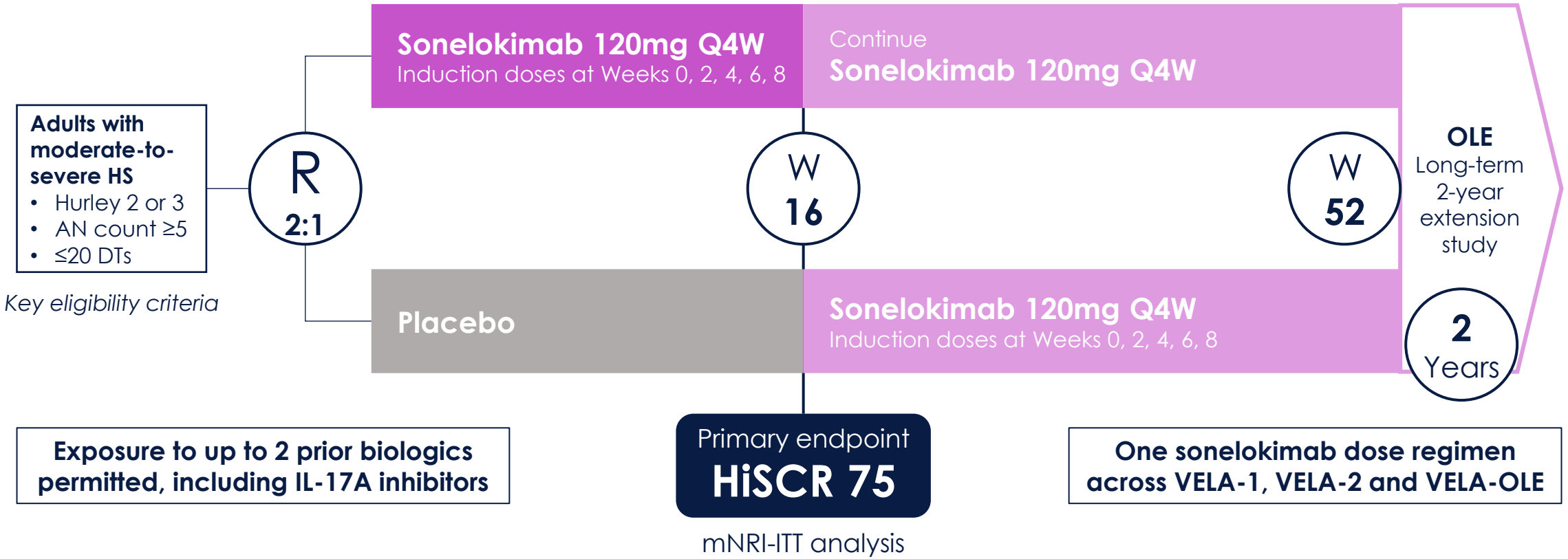
VELA-1 and VELA-2 are identically designed Phase 3 trials

Two global, randomized, double-blind, placebo-controlled **52-week trials** to evaluate the efficacy and safety of **subcutaneous sonelokimab** in **adults with moderate-to-severe HS**



A safety follow-up period follows the end-of-trial visit for patients who do not enter the open-label extension study. VELA-1: NCT06411899. VELA-2: NCT06411379.

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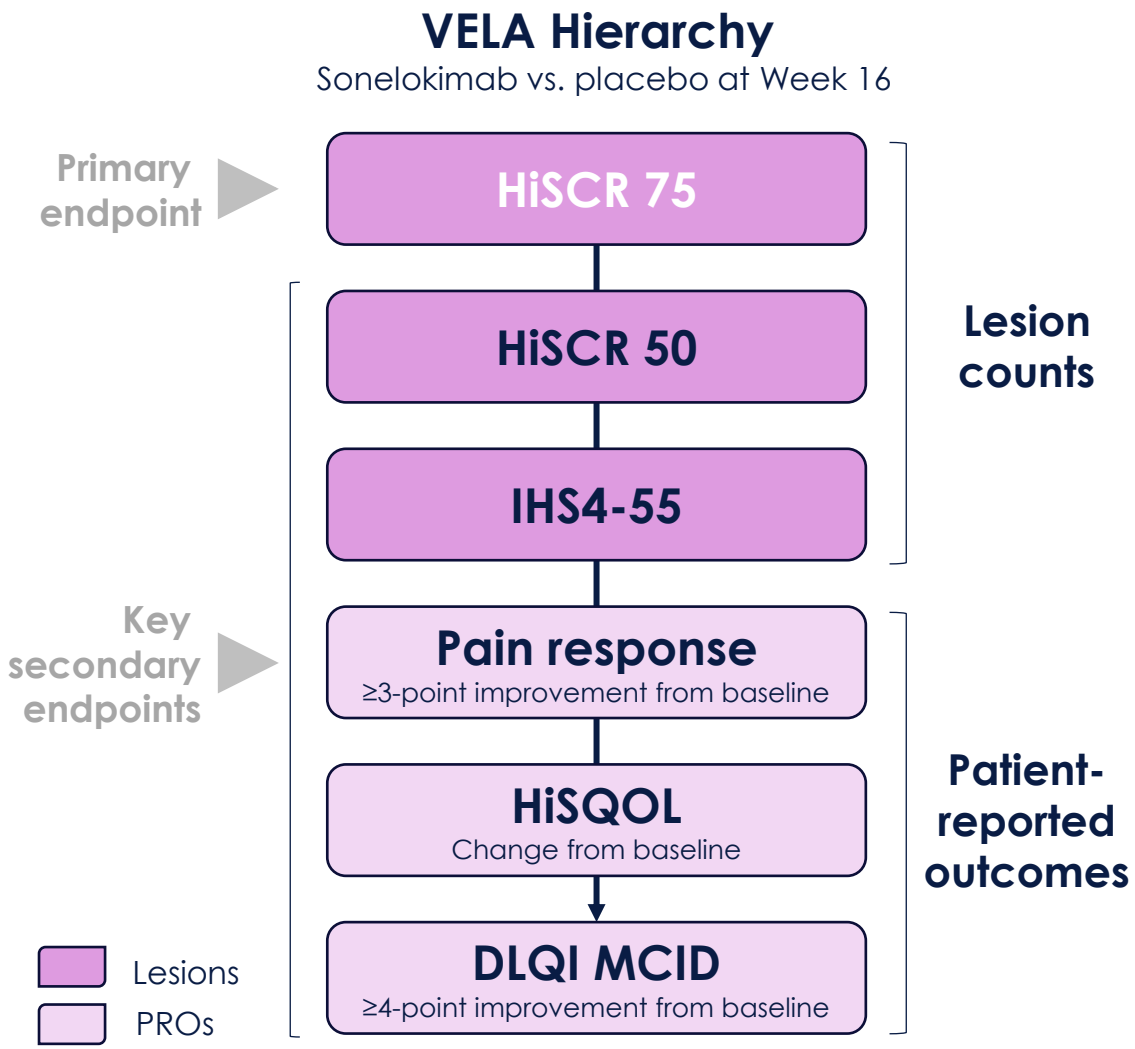
Key endpoints in VELA-1 and VELA-2 include both lesion scores and PROs



Composite strategy for intercurrent events

Prespecified primary analysis

Treatment Policy strategy for intercurrent events

Prespecified supplemental analysis

Threshold for meeting each endpoint: *P*<0.05 (multiplicity controlled), analyzed in the ITT population using logistic regression, except for HiSQOL (analysis of covariance model). Covariates were stratification factors (Hurley Stage, prior biologic exposure, and geographic region) and treatment group, plus baseline values for HiSQOL. The composite and treatment policy strategy used alternative approaches to handle intercurrent events: in the composite strategy (primary analysis), participants were imputed as non-responders for the remainder of the trial if they discontinued due to lack of efficacy or due to adverse events, if they received certain prohibited medications, or if they initiated or intensified systemic antibiotics as rescue therapy for HS; other missing data points were imputed by multiple imputation. In the treatment policy strategy, available data was used regardless of treatment discontinuation or use of rescue or prohibited medication, and any missing data were imputed by multiple imputation. HiSCR 75/50: ≥75/50% reduction from baseline in AN count with no increase in As or DTs. IHS4-55: ≥55% reduction from baseline in IHS4 (a weighted lesion score where N=1, A=2, and DT=4). Pain response: weekly average of worst daily skin pain on the Patient Global Assessment of Skin Pain 0–10 numerical rating scale. HiSQoL: a validated, HS-specific patient-reported quality of life measure. DLQI MCID: minimal clinically important difference (≥4-point improvement from baseline) in Dermatology Life Quality Index. A, abscess; DT, draining tunnel; ITT, intention-to-treat; N, inflammatory nodule.

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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	76.1	77.7	85.1	81.5
Black or African American	15.2	12.0	10.6	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

Discontinuation rates were low, and highly similar between treatment arms, as well as between the two trials

AN, abscess or inflammatory nodule; DLQI, Dermatology Life Quality Index; HiSQOL, HS Quality of Life; NRS, numerical rating scale.

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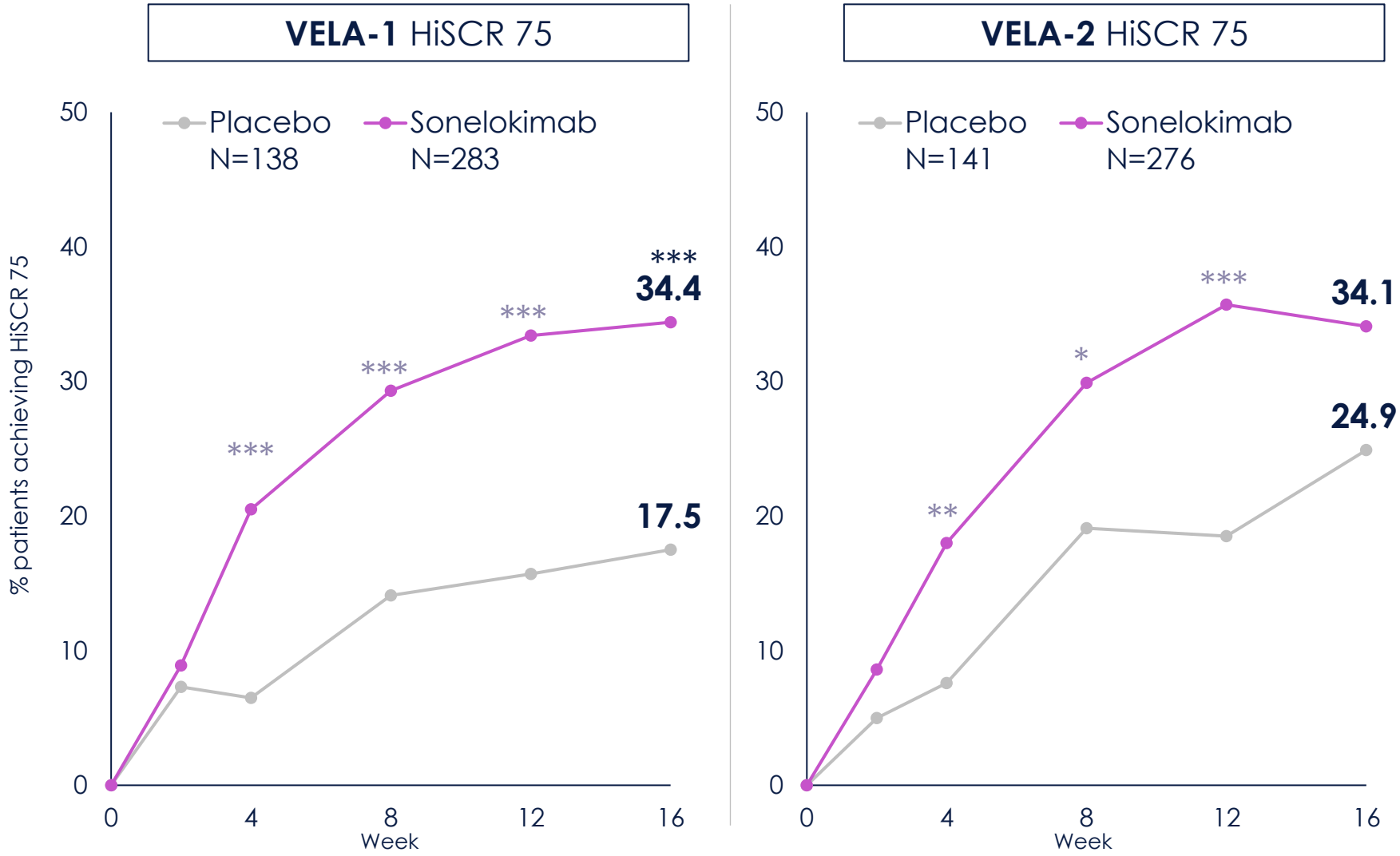
Sonelokimab treatment led to strong and reproducible HiSCR 75 responses

ITT, mNRI

Composite strategy
for intercurrent events
Primary analysis

****P*<0.001
***P*<0.01
**P*<0.05



P values multiplicity controlled at Week 16, otherwise nominal; logistic regression stratified by Hurley, prior biologics, geography. HiSCR 75: ≥75% reduction from baseline in AN count with no increase in As or draining tunnels. A, abscess; ITT, intention-to-treat; mNRI, modified nonresponder imputation; N, inflammatory nodule.

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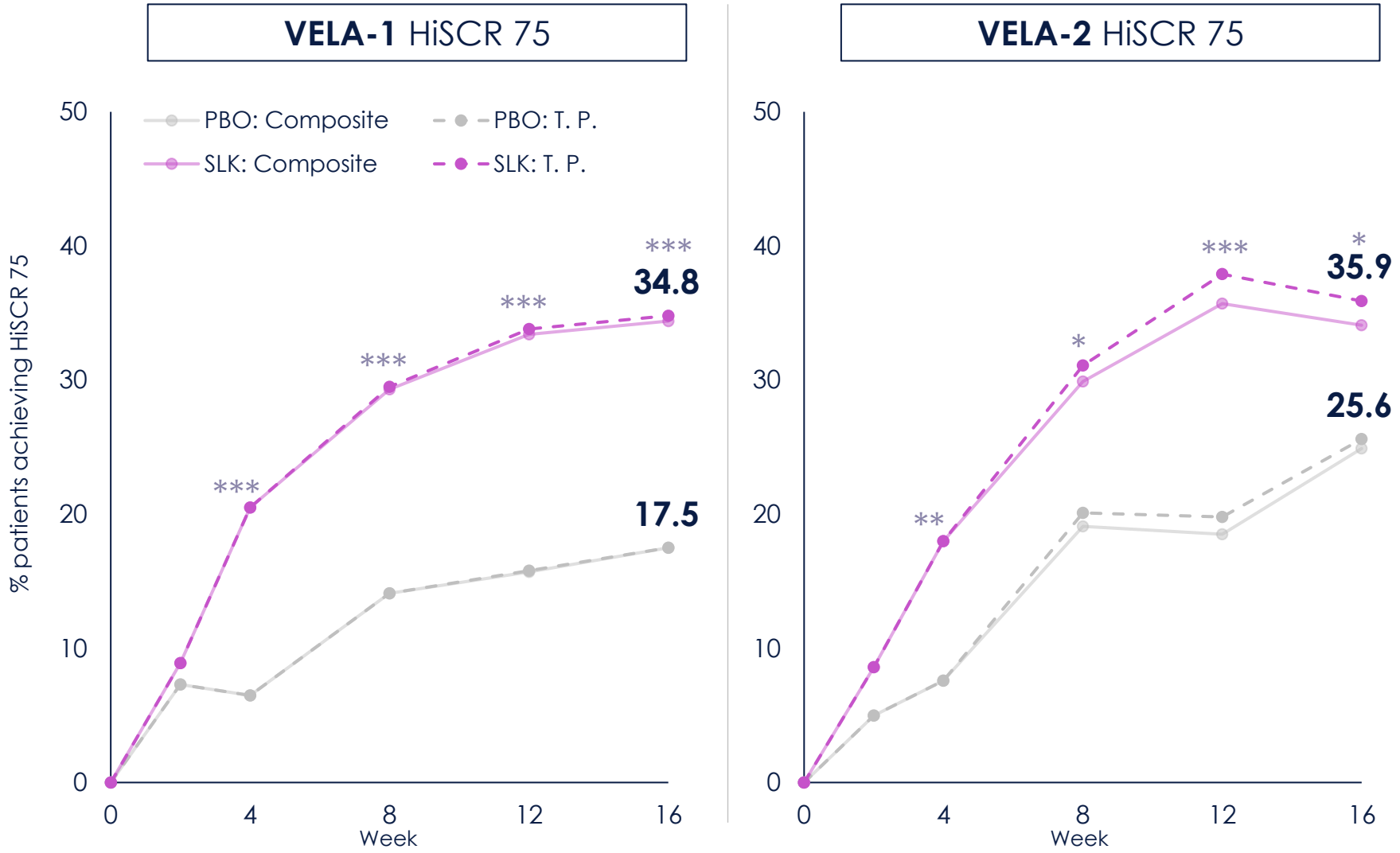
HiSCR 75 responses were similar across both prespecified analysis strategies

ITT, MI

Treatment policy (T. P.) strategy for intercurrent events

****P*<0.001
***P*<0.01
**P*<0.05



P values for T.P. strategy are nominal; logistic regression stratified by Hurley, prior biologics, geography. HiSCR 75: ≥75% reduction from baseline in AN count with no increase in As or draining tunnels. A, abscess; ITT, intention-to-treat; MI, multiple imputation; N, inflammatory nodule.

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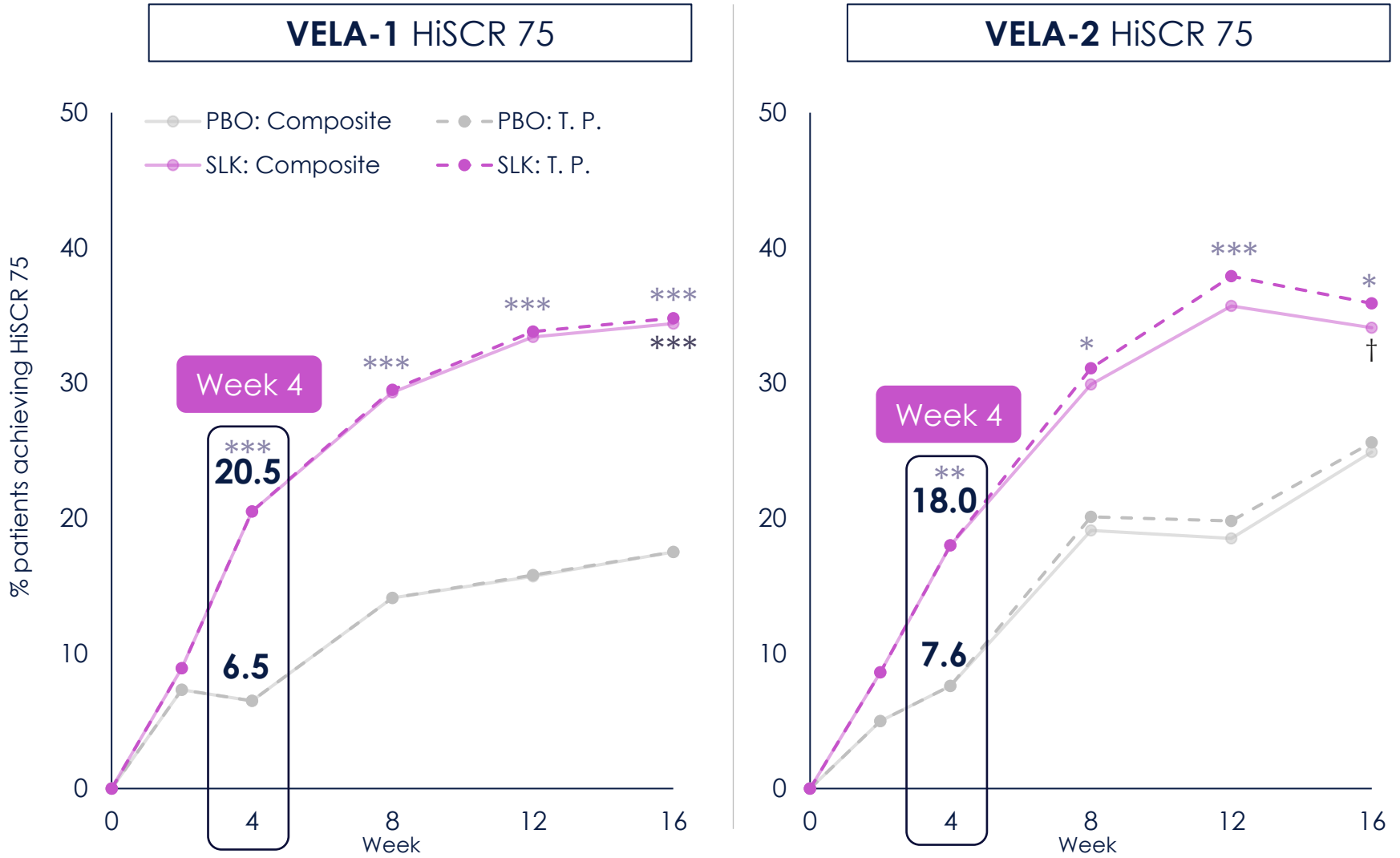
HiSCR 75 responses were significant with sonelokimab as early as Week 4

ITT, mNRI/MI

HiSCR 75 at Week 4
Both prespecified strategies

****P*<0.001
***P*<0.01
**P*<0.05



†*P*=0.053 (not significant) using composite strategy in VELA-2 at Week 16. *P* values multiplicity controlled for composite strategy at Week 16, otherwise nominal; logistic regression stratified by Hurley, prior biologics, geography. ITT, intention-to-treat; MI, multiple imputation; mNRI, modified nonresponder imputation.

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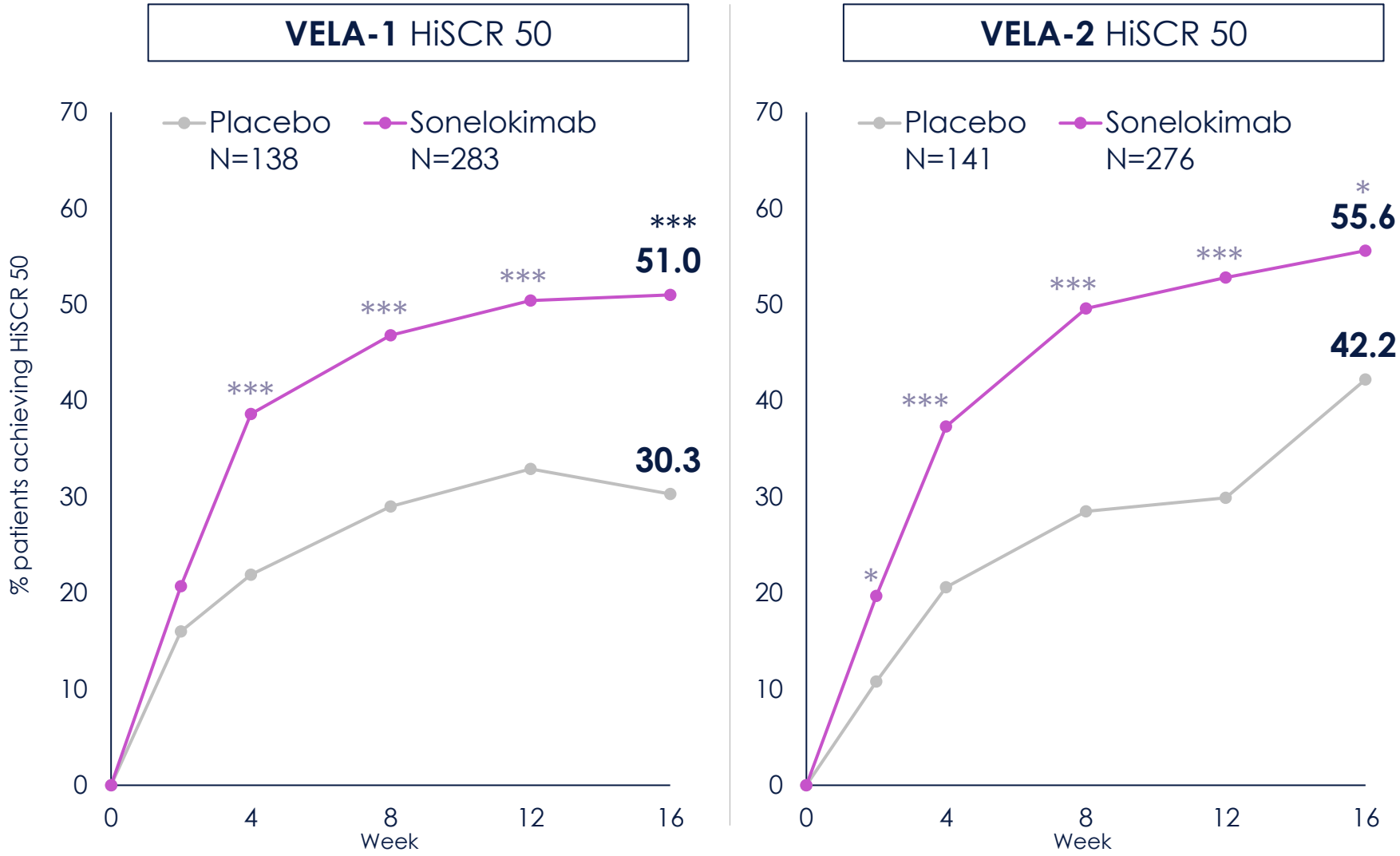
Sonelokimab led to strong, rapid and reproducible HiSCR 50 responses

ITT, mNRI

Composite strategy

HiSCR 50
Key secondary endpoint

****P*<0.001
**P*<0.05



P values multiplicity controlled at Week 16 in VELA-1, otherwise nominal; logistic regression stratified by Hurley, prior biologics, geography. HiSCR 50: ≥50% reduction from baseline in AN count with no increase in As or draining tunnels. ITT, intention-to-treat; mNRI, modified nonresponder imputation.

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Patients reported meaningful improvements in skin pain as early as Week 1

ITT, mNRI

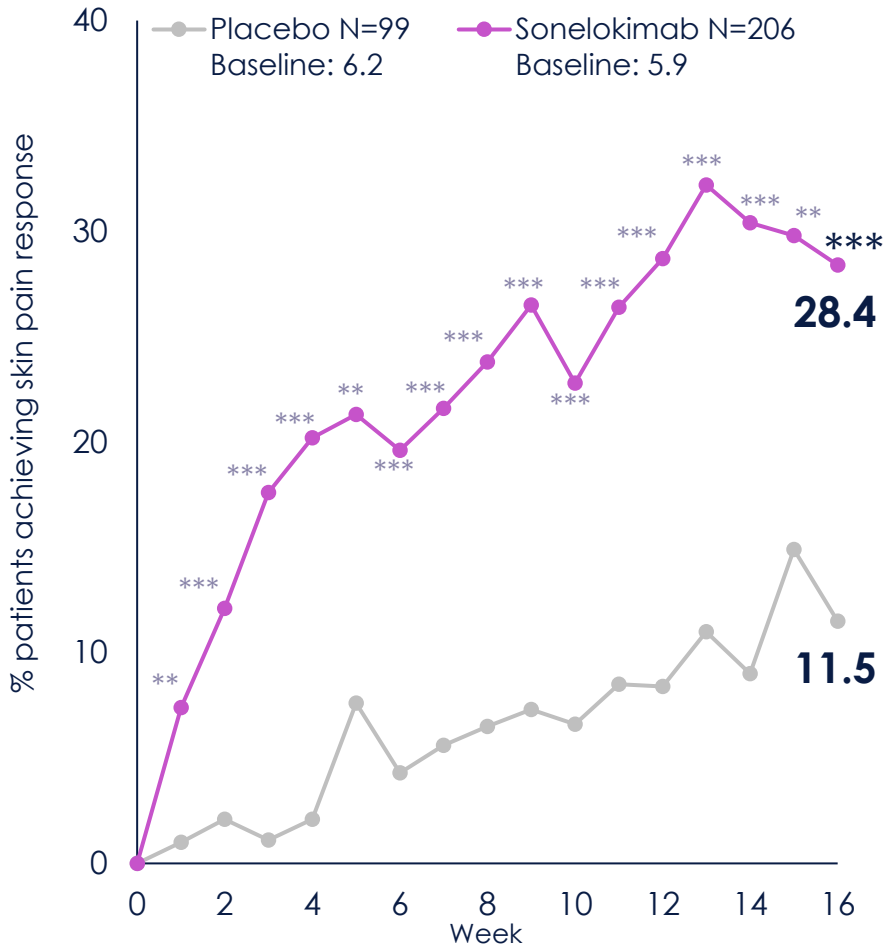
Composite strategy

Skin pain response
Key secondary endpoint

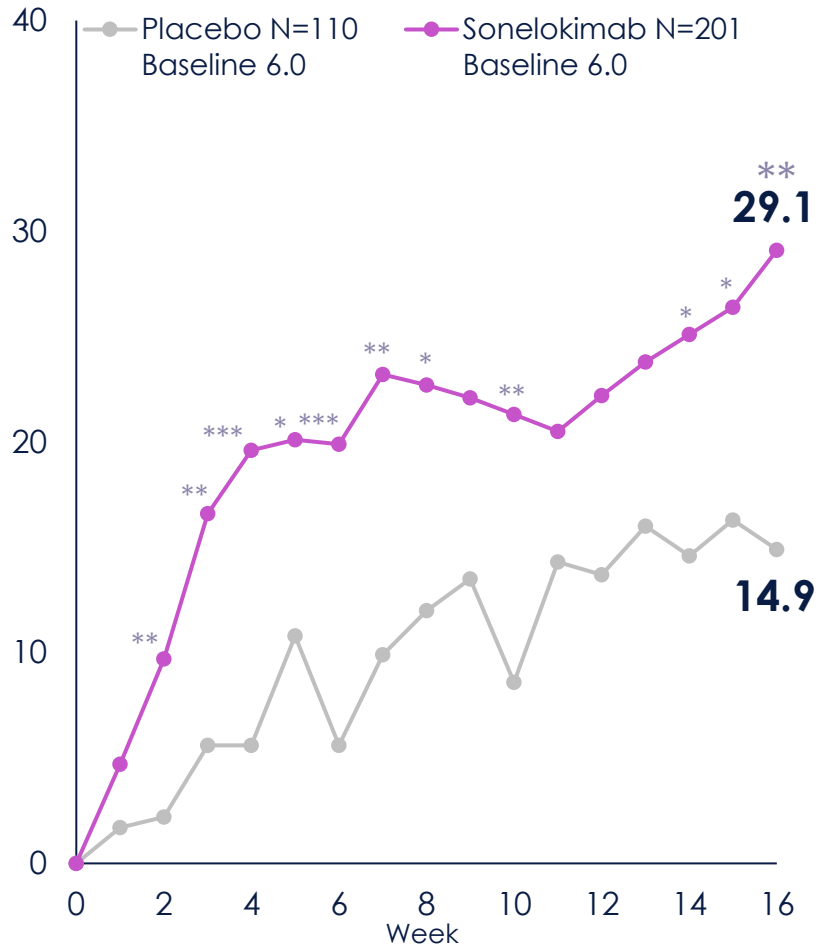
≥3-point improvement from baseline in worst skin pain, in patients with baseline NRS ≥3

****P*<0.001
***P*<0.01
**P*<0.05

VELA-1 Skin pain response



VELA-2 Skin pain response



P values multiplicity controlled at Week 16 in VELA-1, otherwise nominal; logistic regression stratified by Hurley, prior biologics, geography. Worst skin pain in the past 24 hours, averaged over a week, on the Patient Global Assessment of Skin Pain NRS. ITT, intention-to-treat; mNRI, modified non-responder imputation.

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Sonelokimab substantially improved the impact of HS on quality of life

HiSQOL HS-specific QOL score

17 items, including those specific to HS such as **drainage**, and **odor**

ITT, mNRI

\+ Composite strategy

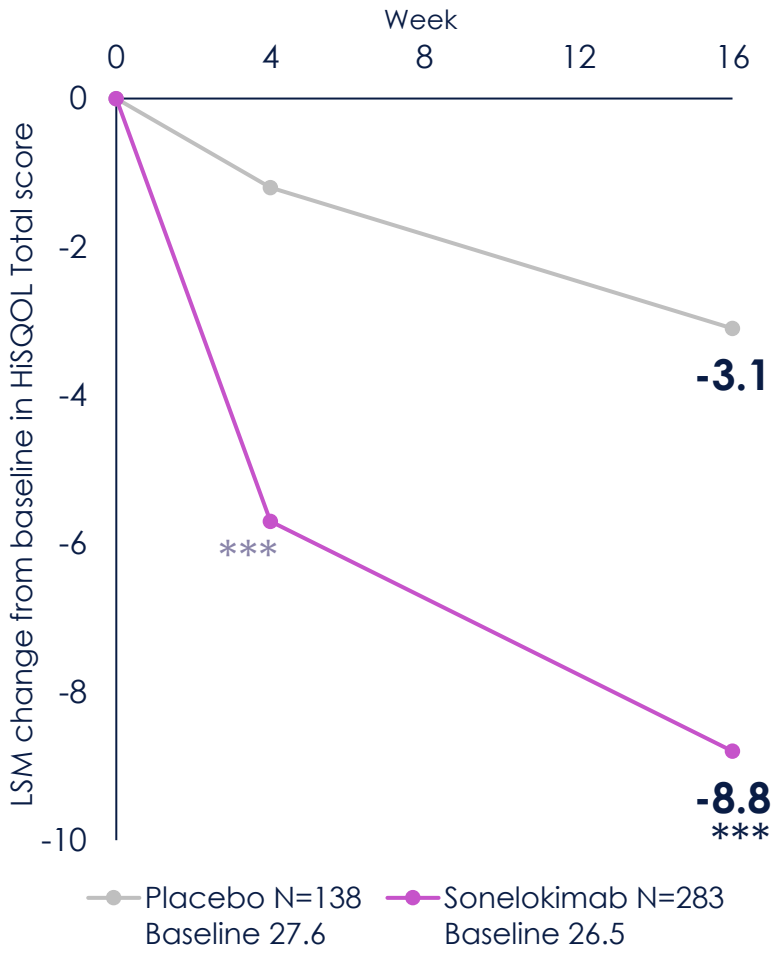
HiSQOL
Key secondary endpoint

LSM change from baseline in HiSQOL Total score

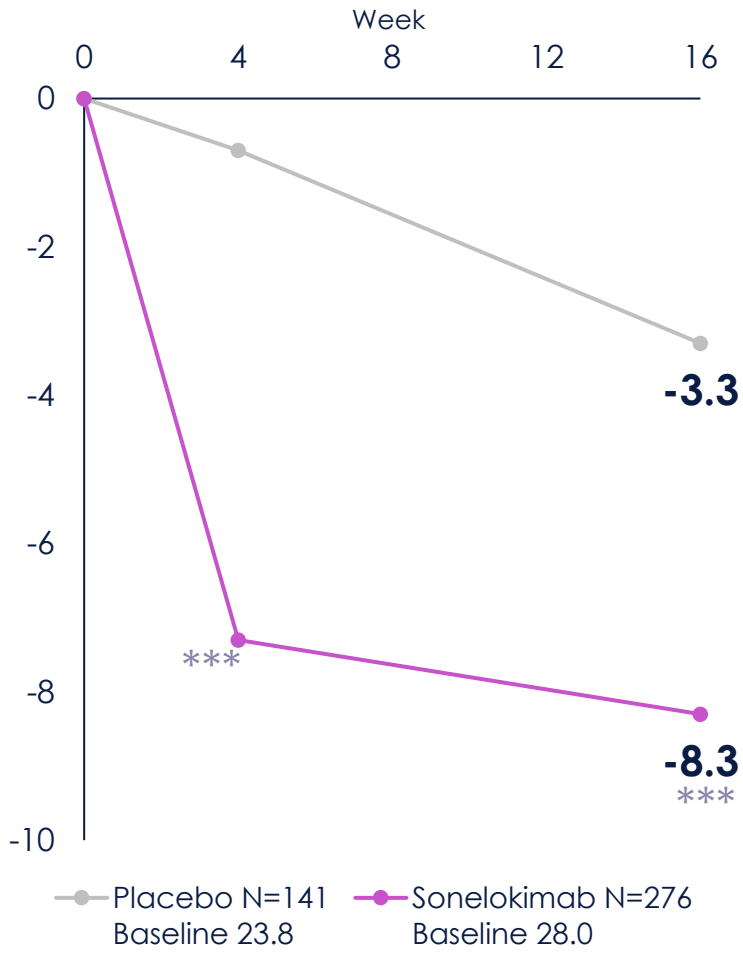
***$P<0.001$

1st trials with HiSQOL as a key endpoint

VELA-1 HiSQOL improvement



VELA-2 HiSQOL improvement



The maximum possible HiSQOL Total is 68 (each item is scored 0–4). *P* values multiplicity controlled at Week 16 in VELA-1, otherwise nominal; ANCOVA model stratified by Hurley, prior biologics, geography, and with baseline HiSQOL values also included as co-variate. Worst observation carried forward used to impute intercurrent events considered as non-response.
HiSQOL, HS quality of life; ITT, intention-to-treat; LSM, least squares mean; mNRI, modified nonresponder imputation; QOL, quality of life.

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Patients reported meaningful improvements in quality of life with sonelokimab

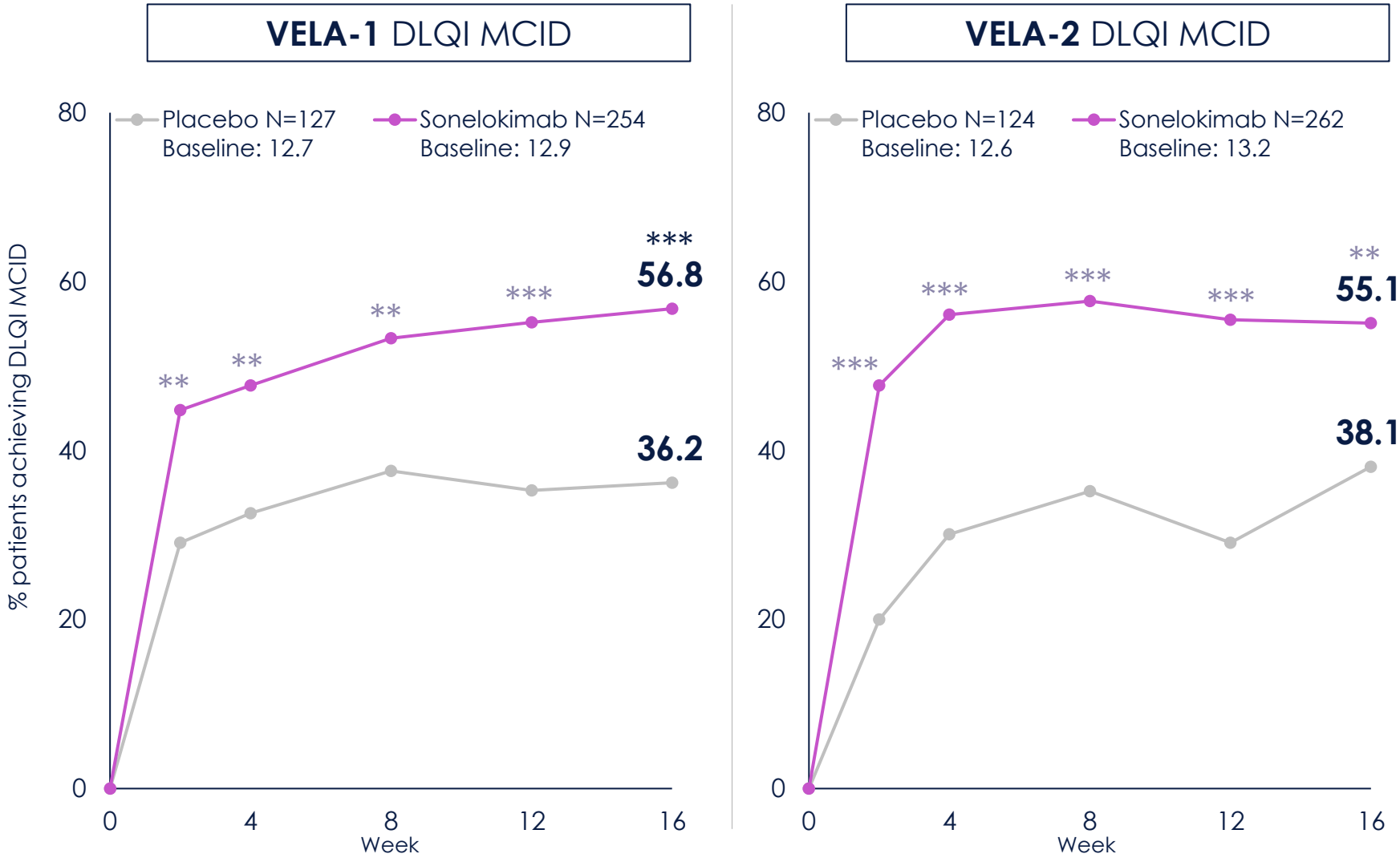
ITT, mNRI

Composite strategy

DLQI MCID
Key secondary endpoint

≥4-point improvement from baseline in patients with baseline DLQI of ≥4 points

***P<0.001
**P<0.01



P values multiplicity controlled at Week 16 in VELA-1, otherwise nominal; logistic regression stratified by Hurley, prior biologics, geography. DLQI MCID: Minimal Clinically Important Difference (≥4-point improvement) in Dermatology Life Quality Index; ITT, intention-to-treat; mNRI, modified non-responder imputation.

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Efficacy with sonelokimab was consistent across trials and analysis strategies

	VELA-1				VELA-2				VELA-1 and VELA-2 Combined			
	Placebo N=138	SLK 120mg N=283	Delta	*P* value	Placebo N=141	SLK 120mg N=276	Delta	*P* value	Placebo N=279	SLK 120mg N=559	Delta	*P* value
Composite Strategy (Primary Estimand)												
HiSCR 75 (%)	**17.5**	**34.4**	**16.9**	<0.001	**24.9**	**34.1**	**9.2**	0.053	**21.2**	**34.3**	**13.1**	<0.001
HiSCR 50 (%)	30.3	51.0	20.7	<0.001	42.2	55.6	13.4	0.011	36.3	53.3	17.0	<0.001
IHS4-55 (%)	33.9	53.2	19.3	<0.001	43.0	54.9	11.9	0.024	38.4	54.1	15.6	<0.001
Pain response (%)	11.5	28.4	16.9	<0.001	14.9	29.1	14.1	0.003	13.3	28.7	15.4	<0.001
HiSQOL LSM CfB	-3.1	-8.8	-5.7	<0.001	-3.3	-8.3	-5.0	<0.001	-3.2	-8.5	-5.3	<0.001
DLQI MCID(%)	36.2	56.8	20.6	<0.001	38.1	55.1	16.9	0.002	37.1	55.9	18.9	<0.001
Treatment Policy												
HiSCR 75 (%)	**17.5**	**34.8**	**17.3**	<0.001	**25.6**	**35.9**	**10.3**	0.033	**21.6**	**35.4**	**13.8**	<0.001
HiSCR 50 (%)	30.3	51.6	21.3	<0.001	43.0	58.7	15.6	0.003	36.7	55.1	18.4	<0.001
IHS4-55 (%)	34.2	54.4	20.3	<0.001	44.7	56.9	12.3	0.021	39.4	55.7	16.3	<0.001
Pain response (%)	12.7	28.4	15.8	0.001	14.9	29.8	14.9	0.002	13.9	29.1	15.2	<0.001
HiSQOL LSM CfB	-3.8	-9.4	-5.6	<0.001	-3.5	-9.0	-5.6	<0.001	-3.5	-9.1	-5.6	<0.001
DLQI MCID (%)	37.8	59.0	21.2	<0.001	39.0	58.1	19.0	0.001	38.3	58.6	20.3	<0.001

P values for VELA-1 (composite strategy, all endpoints) and VELA-2 (composite strategy, HiSCR 75) are multiplicity controlled; all other *P* values are nominal.
DLQI MCID, Minimal Clinically Important Difference (≥4-pt improvement) in Dermatology Quality of Life Index; HiSQOL LSM CfB, least mean squares change from baseline in HS Quality of Life; Pain response, ≥3-pt improvement from baseline in worst skin pain on the Patient Global Assessment of Skin Pain 0–10 NRS.

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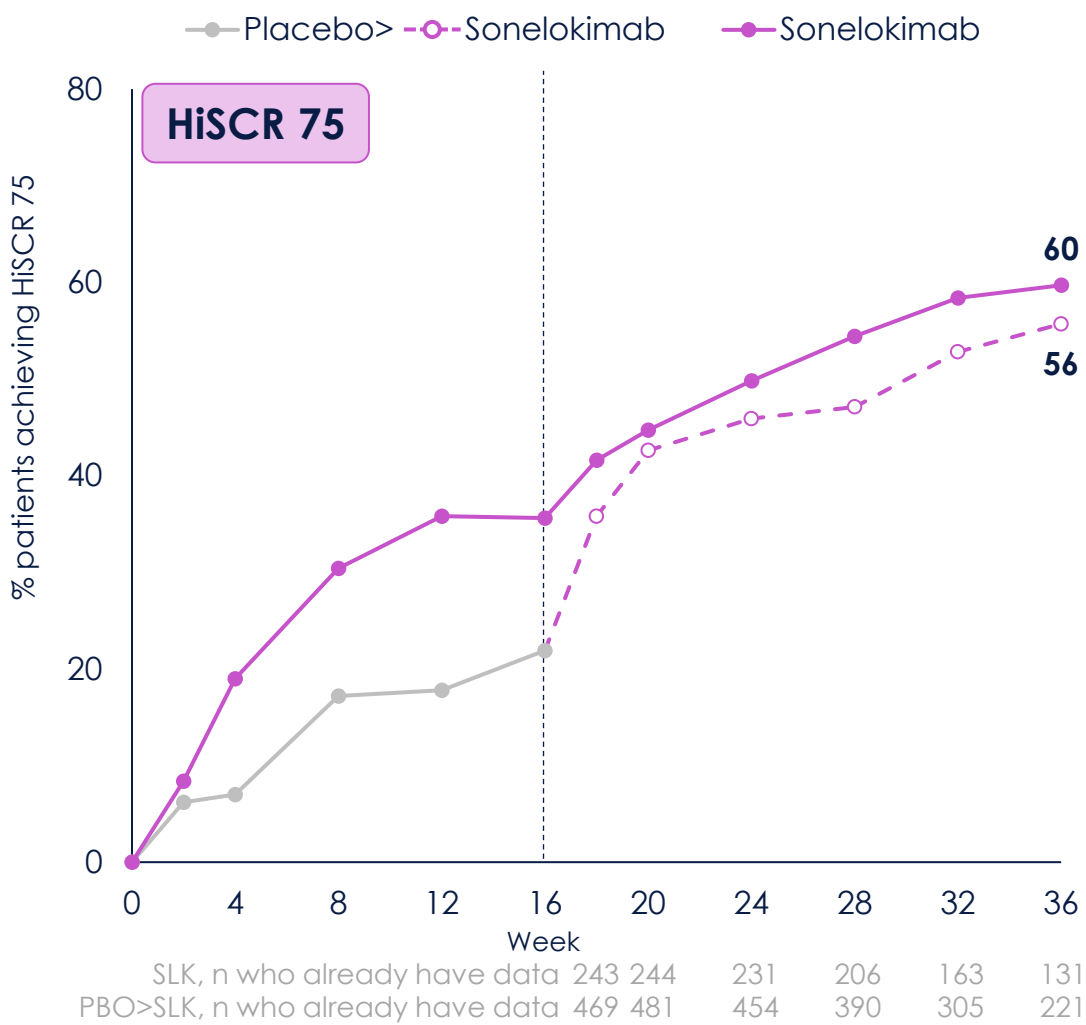
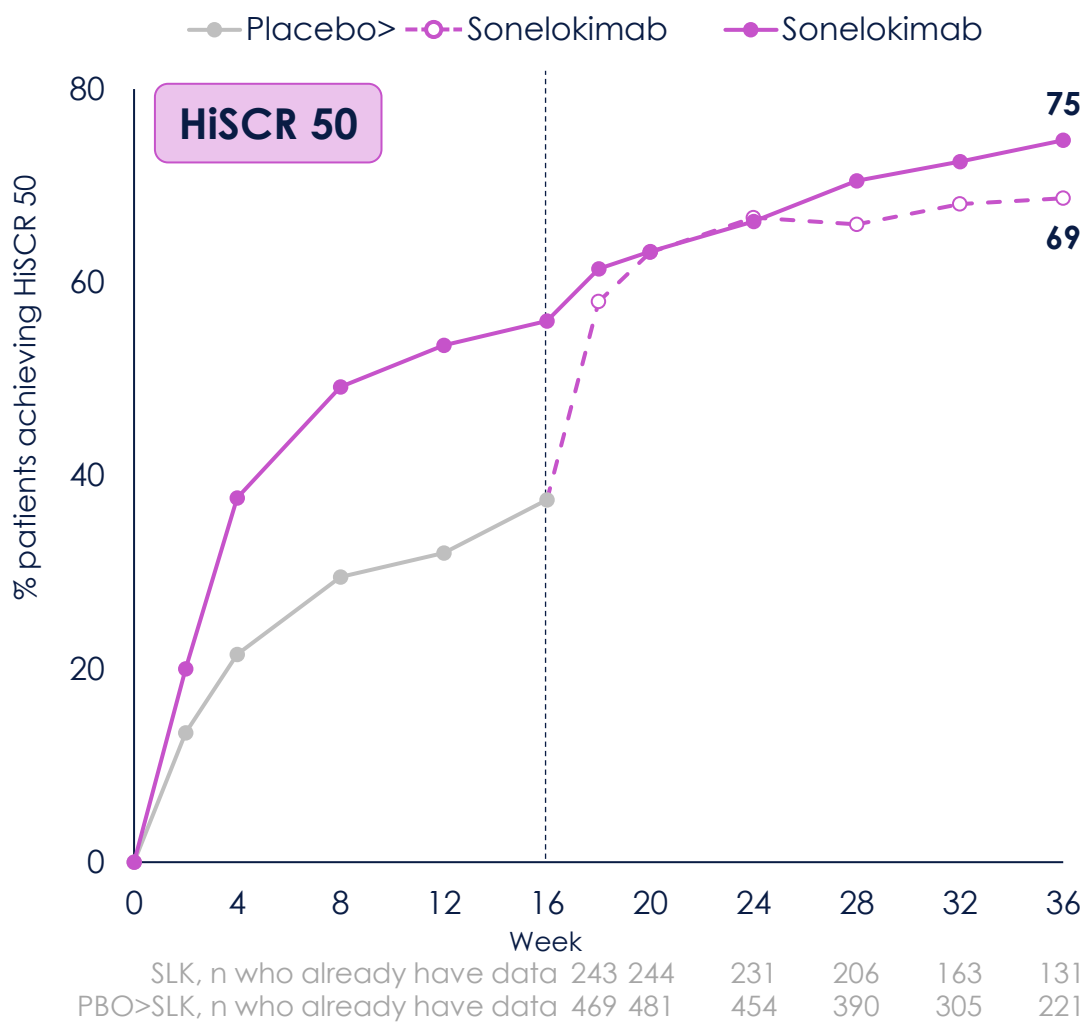
Interim analysis shows continued HiSCR 75 / 50 improvement to Week 36

VELA-1 and VELA-2 Combined As observed



VELA-1 and VELA-2 Combined As observed



Preliminary data for subjects who have already reached post-16 visits, subject to Week 52 database lock. Data are descriptive. Preliminary, pre-specified analysis suggests continued improvement beyond Week 16, subject to Week 52 database lock. Post-Week 16 ns reflect incomplete data due to patients not yet reaching these visits at data cut-off on Oct 20 2025, but who may do so in the future in these ongoing trials. Individual trials had similar results consistent with these combined data.

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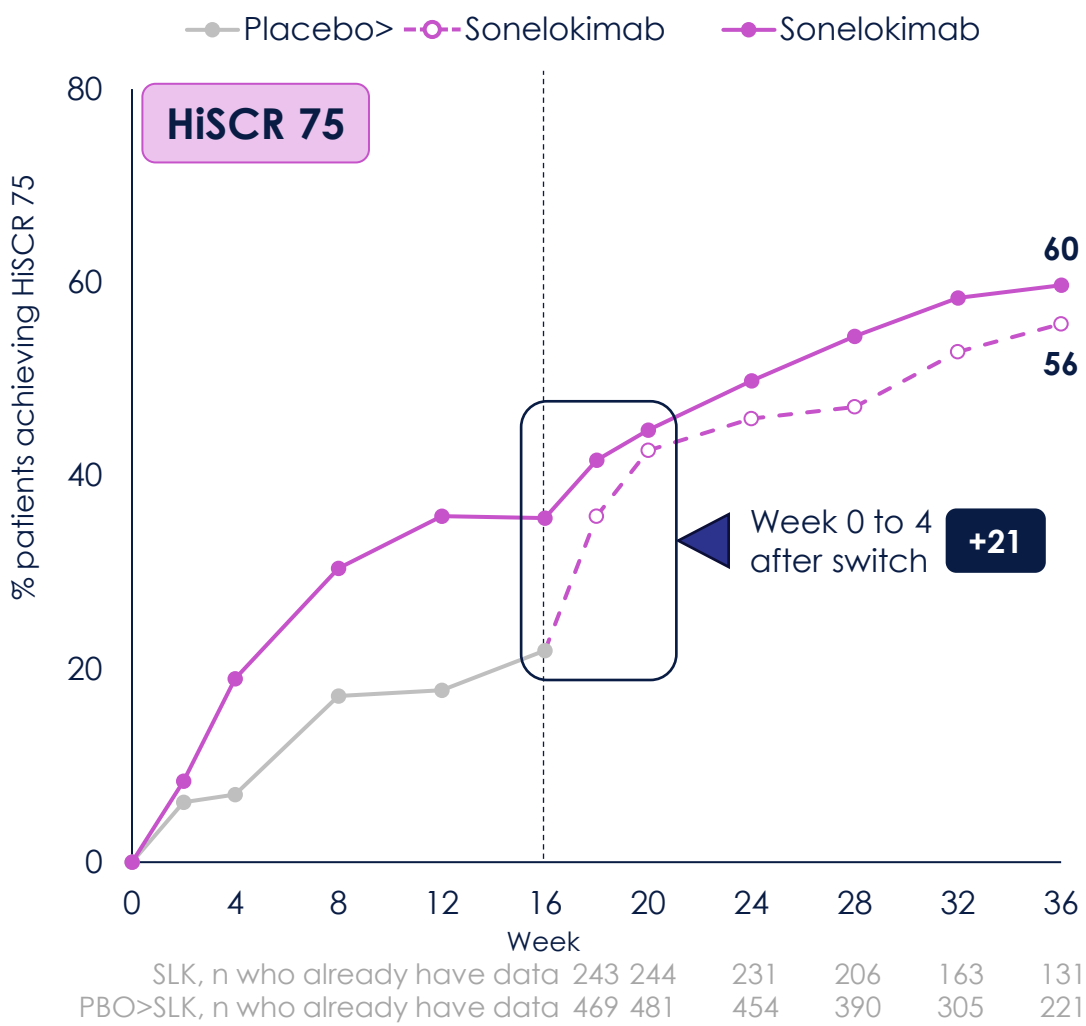
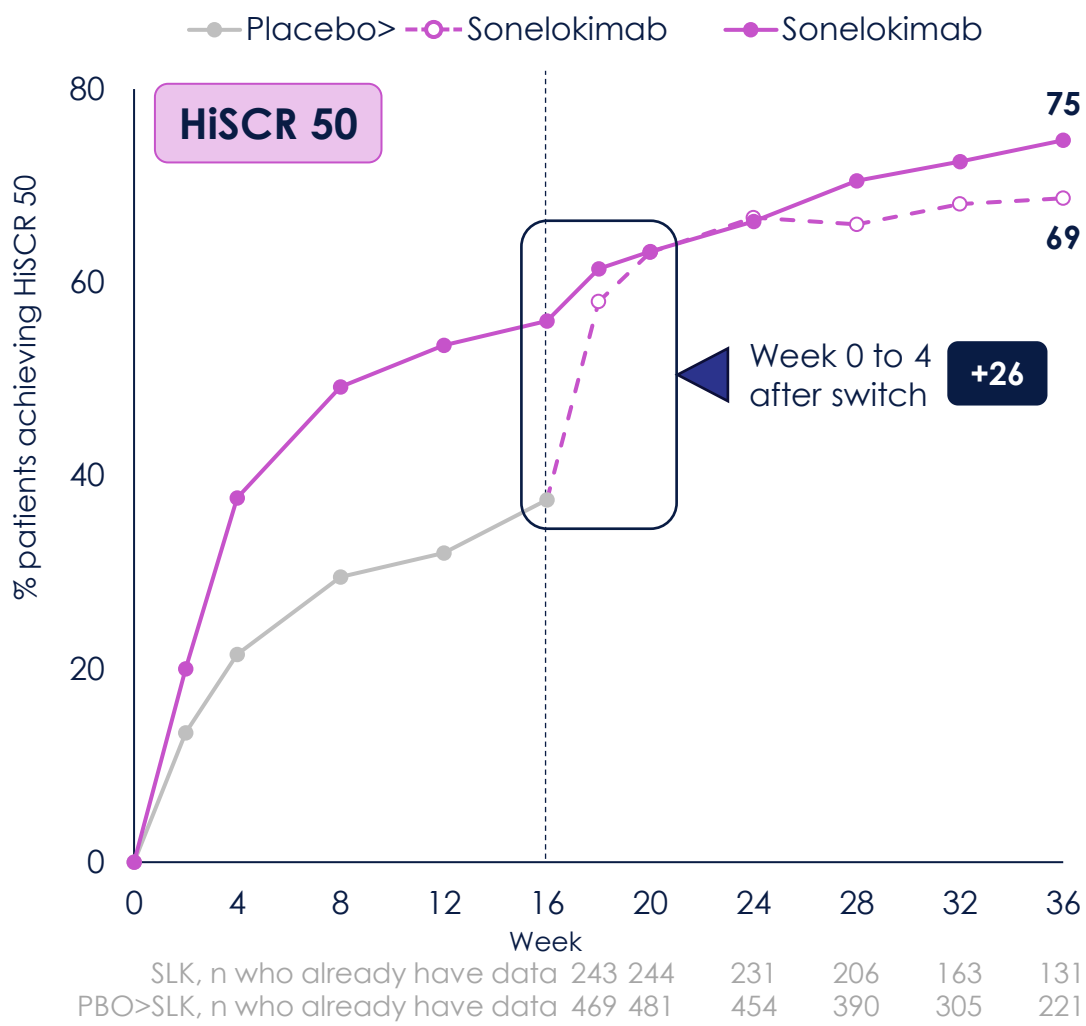
Interim analysis shows rapid responses after crossover from placebo

VELA-1 and VELA-2 Combined As observed



VELA-1 and VELA-2 Combined As observed



Preliminary data for subjects who have already reached post-16 visits, subject to Week 52 database lock. Data are descriptive. Preliminary, pre-specified analysis suggests continued improvement beyond Week 16, subject to Week 52 database lock. Post-Week 16 ns reflect incomplete data due to patients not yet reaching these visits at data cut-off on Oct 20 2025, but who may do so in the future in these ongoing trials. Individual trials had similar results consistent with these combined data.

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Sonelokimab was well tolerated to Week 16, with no new safety signals

Treatment-emergent adverse events (TEAE), 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	1 (0.4)	41 (7.3)
TEAEs of interest		
Oral candidiasis[a]	**1 (0.4)**	**41 (7.3)**
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

All cases of **candidiasis** were **mild-to-moderate**

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; 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, with 3 (1.1%) in the placebo group and 1 (0.2%) in the sonelokimab group adjudicated as 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).

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Conclusions

Sonelokimab: Key Findings from VELA-1 and VELA-2

- **Efficacy:** High and sustained HiSCR 75 (primary endpoint) and other clinical responses across both trials, including after switching from placebo
- **Symptoms and quality of life:** Meaningful, consistent improvements in pain, HiSQOL, and DLQI
- **Onset:** Rapid clinical response—HiSCR 75 by Week 4; pain reduction as early as Week 1
- **Safety:** Well tolerated with no new safety signals, and no IBD, SIB, or MACE adverse events; hepatic adverse 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:* trials are ongoing, with further results to be reported upon completion
- *Other ongoing sonelokimab HS trials:* VELA-OLE—long-term treatment, VELA-TEEN—adolescents

VELA-OLE, NCT07007637. VELA-TEEN, NCT06768671.

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