Efficacy and safety of the IL-17A- and IL-17F-inhibiting Nanobody® sonelokimab in patients with active, moderate-to-severe hidradenitis suppurativa: Results from the global, randomized, double-blind, placebo-controlled Phase 2 MIRA trial

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Disclosures

ABK has received consulting fees from AbbVie, Alumis, Bayer, Boehringer Ingelheim, Eli Lilly, Evommune, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sonoma Bio, Sanofi, UCB, and Target RWE, and serves on the Board of Directors of Almirall. ABK's institution has received grants from AbbVie, Admirx, AnaptysBio, Aristea, Bristol-Myers Squibb, Eli Lilly, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, UCB, and Sonoma Bio, and fellowship funding from Janssen and AbbVie.

BK has received research support from/was a principal investigator (clinical trials) for AbbVie, Almirall, Janssen, Merck Sharpe Dohme, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; been a consultant for AbbVie, Almirall, Celgene, Janssen, Merck Sharpe Dohme, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; received honoraria from AbbVie, Almirall, Celgene, Janssen, Lilly, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB; and been on scientific advisory boards for AbbVie, Almirall, Celgene, GSK, Janssen, Lilly, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB.

FGB reports conflicts of interests relating to the following: AbbVie Inc., AbbVie Deutschland GmbH & Co. KG, Boehringer Ingelheim Pharma GmbH & Co. KG, Novartis Pharma GmbH, UCB Pharma, Incyte Corporation, Janssen-Cilag GmbH, MoonLake Immunotherapeutics, Dr. Wolff, Mölnlycke, and Celltrion.

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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.

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NB, **AG**, and **EC** are employees of, and may be stockholders of, MoonLake Immunotherapeutics.

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IL-17A and IL-17F are key mediators of inflammation in HS[1]

HS is an inflammatory disease characterized by difficult-to-reach sites of inflammation

HS lesions include:

- **Abscesses**
- **Nodules**
- Neo-epithelialized **tunnels** that form deep in the dermis and are associated with **purulent drainage**

Increasing evidence highlights IL-17A- and IL-17F-mediated inflammation in HS pathogenesis

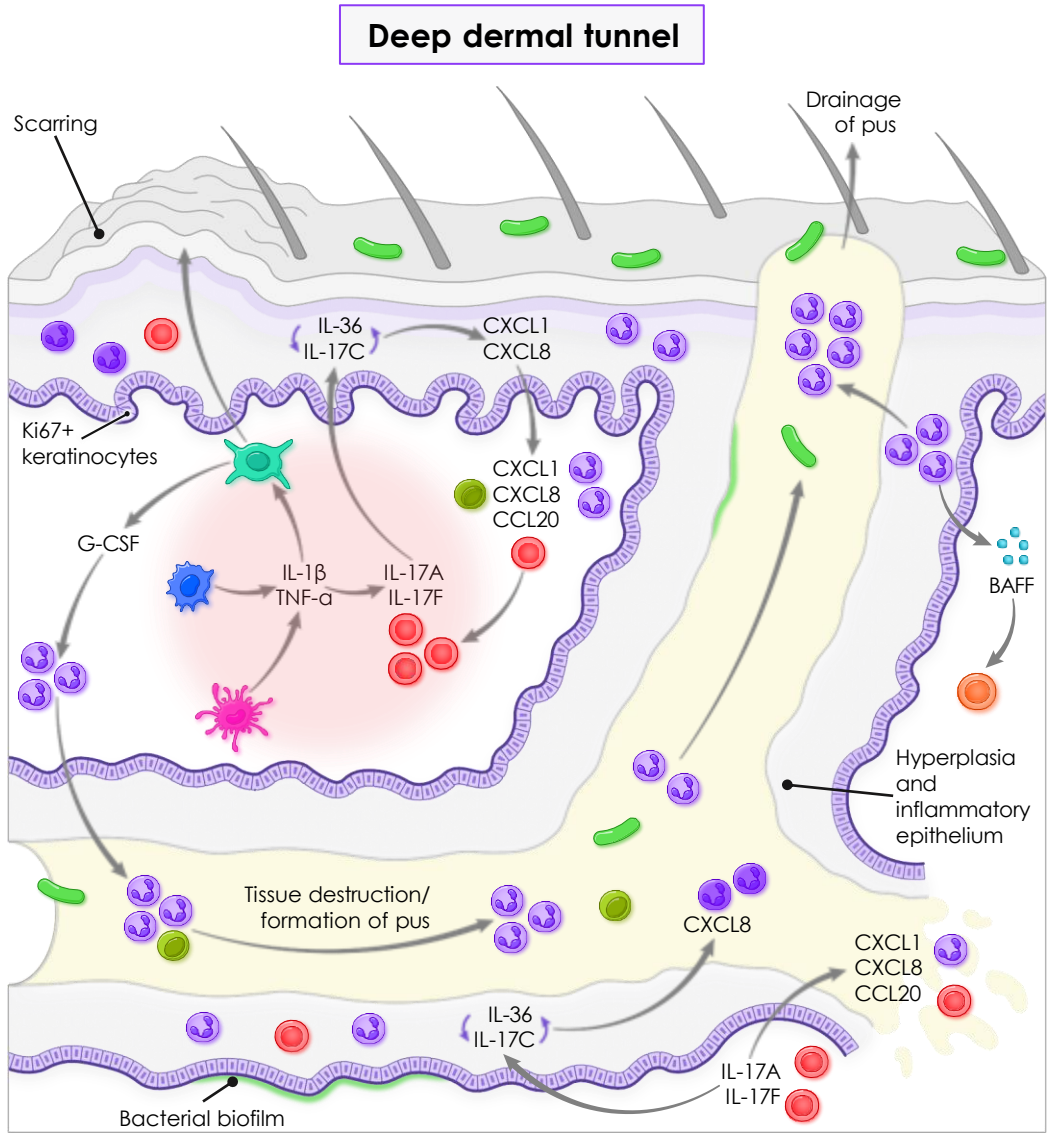


Figure adapted from Krueger JG, *et al. Br J Dermatol*. 2023; doi: 10.1093/bjd/ljad345. Licensed under the Creative Commons CC-BY license (https://creativecommons.org/licenses/by/4.0/).
BAFF, B-cell activating factor; CCL, CC chemokine ligand; CXCL, C-X-C motif chemokine ligand; G-CSF, granulocyte colony-stimulating factor; HS, hidradenitis suppurativa; IL, interleukin; TNF, tumor necrosis factor.

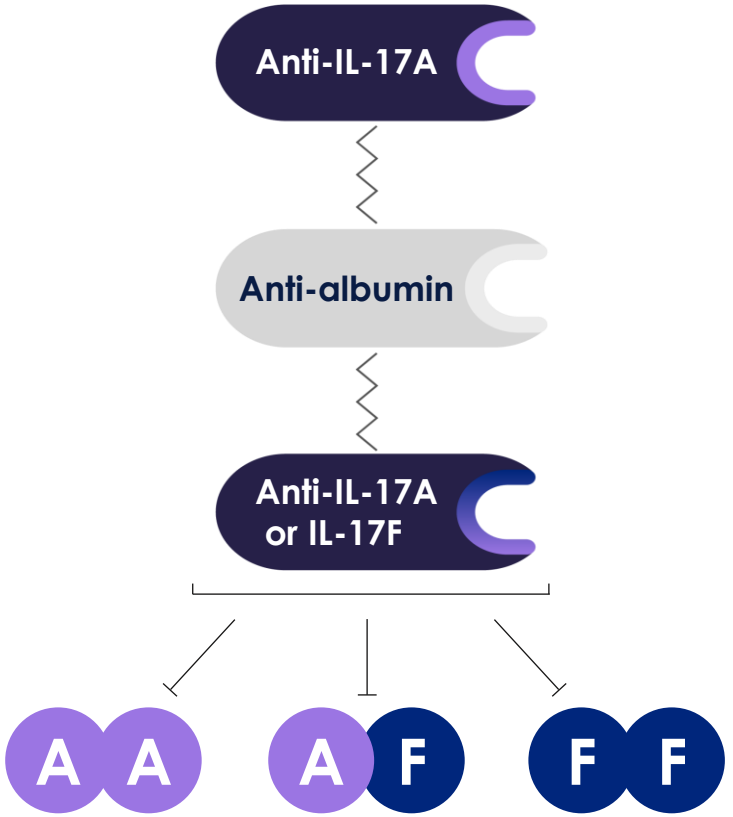
1. Krueger JG, *et al*. *Br J Dermatol*. 2023; doi: 10.1093/bjd/ljad345.

Sonelokimab is a novel humanized Nanobody that selectively binds with high affinity to IL-17A and IL-17F[1,2]

We present the Week 12 results of the MIRA trial evaluating the clinical efficacy and safety of the Nanobody sonelokimab in patients with active, moderate-to-severe HS

- Nanobodies represent a new generation of antibody-derived therapies
- **Sonelokimab** is designed to penetrate difficult-to-reach tissues and directly target sites of inflammation:
  - **IL-17A and IL-17F targeting**
  - **Small size** (~40 kDa vs. ~150 kDa for a conventional mAb)
  - **Albumin-binding domain**

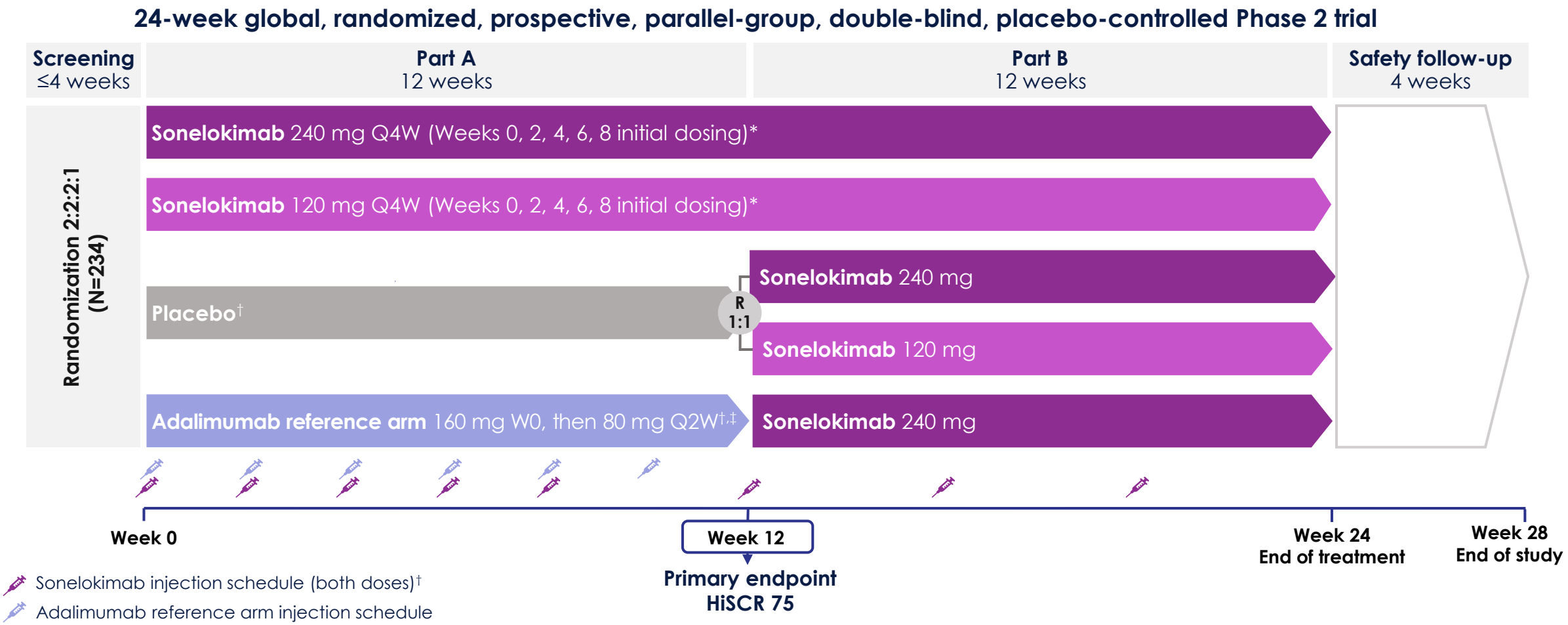
Sonelokimab Nanobody ~40 kDa



Inhibits IL-17A/A, IL-17A/F, and IL-17F/F dimers

HS, hidradenitis suppurativa; IL, interleukin; mAb, monoclonal antibody.
1. Papp KA, *et al*. *Lancet*. 2021; 397:1564–1575. 2. Svecova D, *et al*. *J Am Acad Dermatol*. 2019; 81:196–203.

MIRA trial design: Primary endpoint of HiSCR 75 at Week 12



MIRA is the **first registered trial** to use the high threshold of clinical response **HiSCR 75 as its primary endpoint**

*At Weeks 10, 14, and 18, participants received placebo injections to maintain the blind. †Dosing for crossover arms at Weeks 12, 14, 16, 18, and 20.
‡Adalimumab reference arm included was not powered for statistical comparisons.
HiSCR, Hidradenitis Suppurativa Clinical Response; Q2W, every 2 weeks; Q4W, every 4 weeks; W, week.

Key eligibility criteria, stratification factors, and primary analysis methods

Key inclusion criteria

- Adults with **moderate-to-severe HS**
- **Hurley Stage II or III**
- **Total AN count ≥5 lesions**
- HS lesions in **≥2 anatomical areas**
- Patients in the antibiotic stratum permitted to enter on stable dose of doxycycline, minocycline, or an equivalent systemic tetracycline

Key exclusion criteria

- **Prior exposure to >2 biologics**
- Prior exposure to IL-17A+IL-17F or IL-17RA therapy
- Primary non-responder to IL-17A or TNF therapy
- Any other active skin condition that may interfere with the assessment of HS
- Diagnosis of ulcerative colitis or Crohn's disease
- ≥20 draining tunnels

Analysis methods

Stratification factors

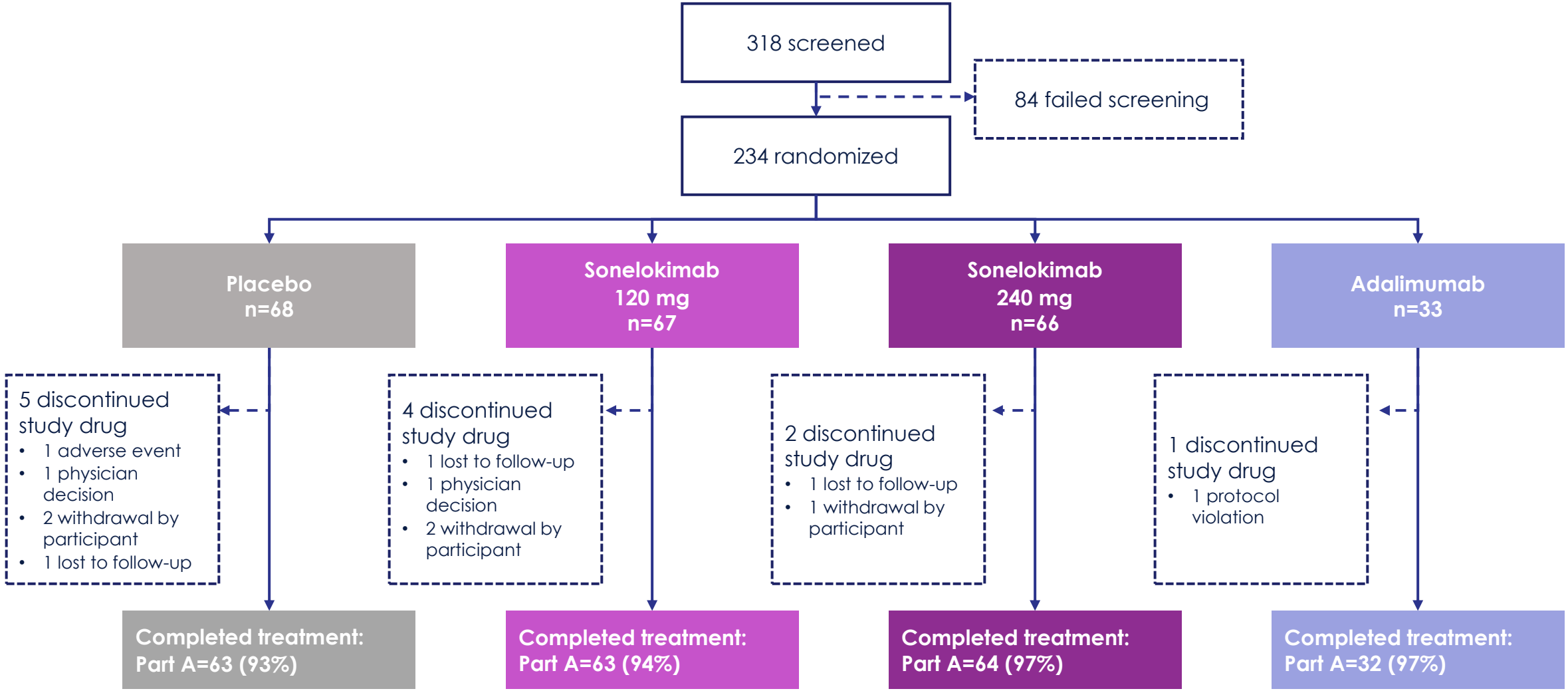
- Hurley Stage (II/III)
- Previous biologic use (Yes/No)

Primary endpoint and analysis

- The proportion of patients achieving **HiSCR 75** (≥75% reduction from baseline in total AN count, with no increase in abscess or draining tunnel count) in the sonelokimab 120 mg and sonelokimab 240 mg treatment arms vs. placebo at **Week 12**
- Based on the **ITT population**, with **missing data imputed as non-responders (ITT-NRI)**
- **Multiplicity control for primary and key secondary endpoints for the sonelokimab doses**
- **New antibiotic use for HS** was imputed as a non-responder

AN, abscess or inflammatory nodule; HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; IL, interleukin; ITT, intention-to-treat; NRI, non-responder imputation; TNF, tumor necrosis factor.

MIRA patient disposition: Discontinuation rates were low and similar between treatment arms

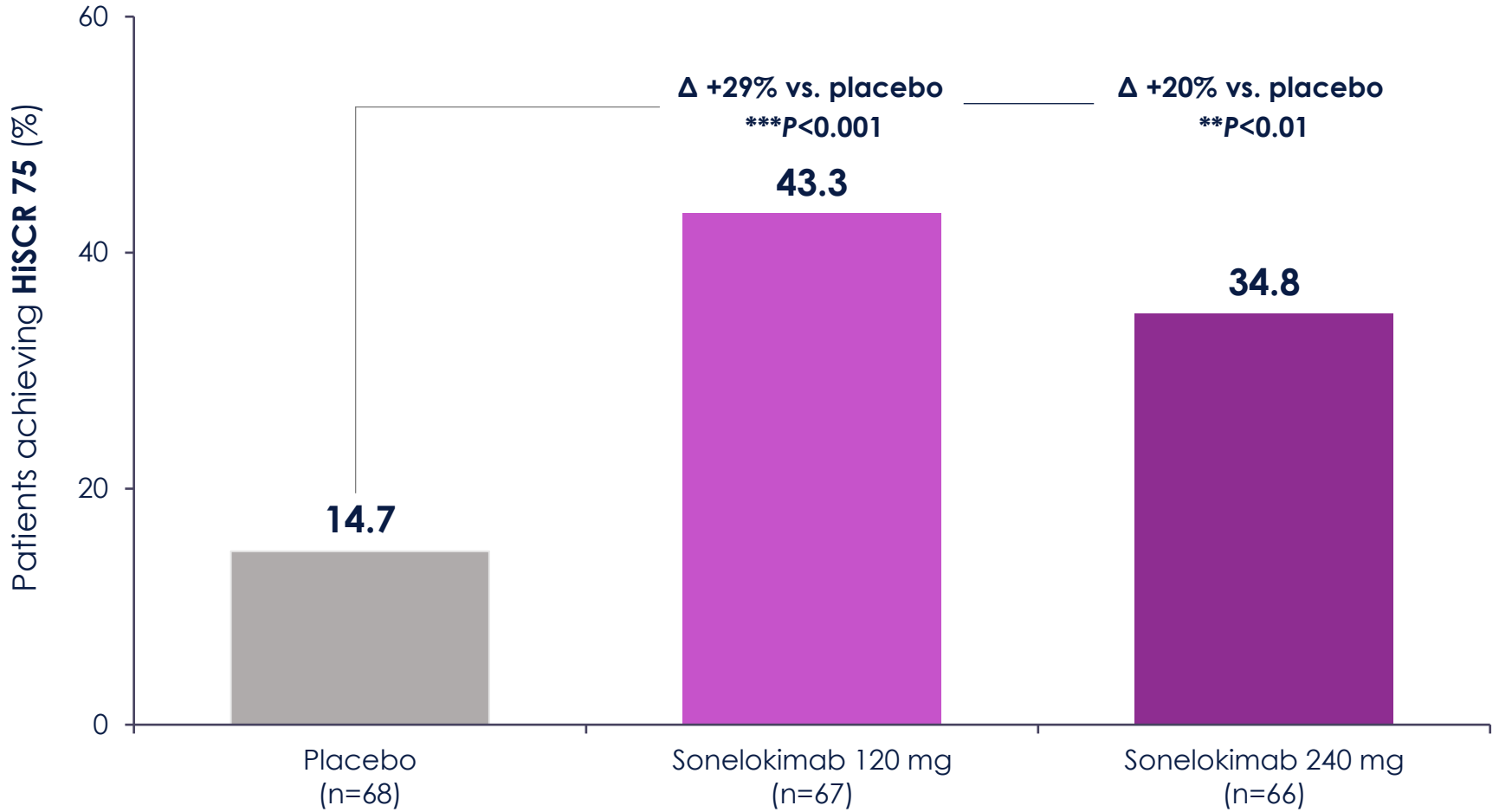


Baseline characteristics were balanced across treatment arms

Characteristic	Placebo n=68	Sonelokimab 120 mg n=67	Sonelokimab 240 mg n=66	Adalimumab reference arm n=33
Age [years], mean (SD)	39.3 (13.1)	37.6 (10.5)	36.2 (11.7)	37.1 (10.6)
Female, n (%)	36 (52.9)	42 (62.7)	42 (63.6)	20 (60.6)
White, n (%)	59 (86.8)	57 (85.1)	54 (81.8)	29 (87.9)
BMI [kg/m^2], mean (SD)	32.7 (7.2)	35.0 (7.9)	33.5 (6.8)	33.9 (8.4)
Current smoker, n (%)	37 (54.4)	26 (38.8)	29 (43.9)	17 (51.5)
Hurley stage				
II, n (%)	42 (61.8)	44 (65.7)	42 (63.6)	21 (63.6)
III, n (%)	26 (38.2)	23 (34.3)	24 (36.4)	12 (36.4)
Time since diagnosis [years], mean (SD)	8.3 (8.5)	8.8 (8.7)	8.4 (8.3)	8.3 (8.4)
AN count, mean (SD)	14.6 (11.6)	14.5 (11.9)	12.3 (8.8)	15.2 (13.4)
Draining tunnel count, mean (SD)	3.7 (3.4)	3.7 (4.4)	2.9 (3.4)	3.6 (3.9)
DLQI total, mean (SD)	10.8 (6.4)	12.3 (6.7)	12.7 (6.9)	12.8 (7.1)
PGA skin pain NRS, mean (SD)	4.2 (2.6)	4.6 (2.3)	4.6 (2.4)	4.1 (2.3)
Prior biologic use, n (%)	12 (17.6)	13 (19.4)	12 (18.2)	4 (12.1)
Concomitant antibiotics, n (%)	5 (7.4)	9 (13.4)	8 (12.1)	3 (9.1)

Baseline characteristics reflect actual assessments per CRF. Stratification factors are shown in bold.
AN, abscess and inflammatory nodule; BMI, body mass index; CRF, case report form; DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; NRS, numerical rating scale; PGA, Patient Global Assessment; SD, standard deviation.

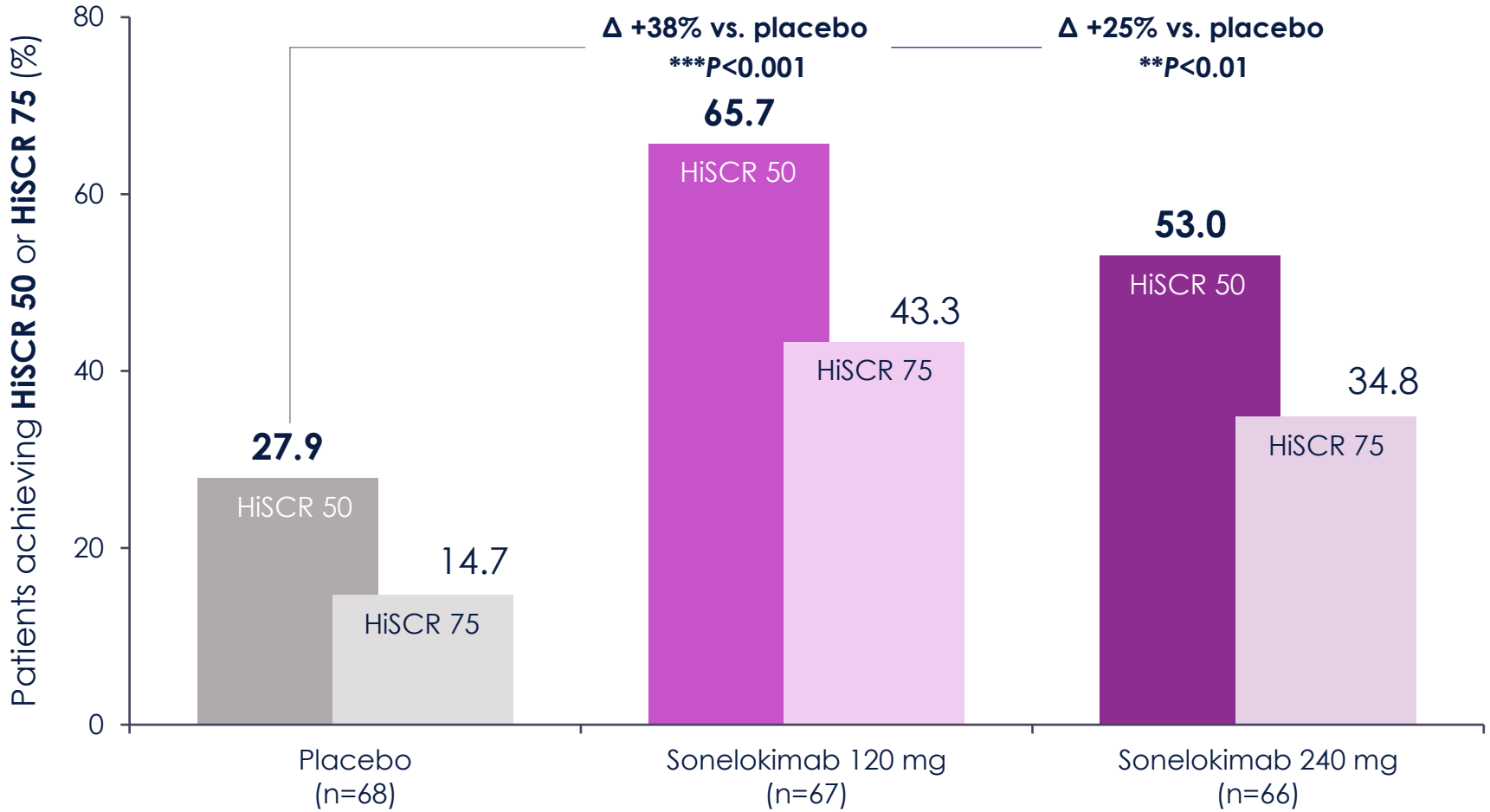
Sonelokimab met the primary endpoint of HiSCR 75 at Week 12 (ITT-NRI)



A significantly higher proportion of patients on sonelokimab achieved the primary endpoint of HiSCR 75 vs. placebo at Week 12

P-values (multiplicity controlled) estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use. HiSCR 75 responder is a participant who has a ≥75% reduction from baseline in abscess and inflammatory nodule count with no increase in abscesses or draining tunnels. Missing data are imputed as a non-response.
HiSCR, Hidradenitis Suppurativa Clinical Response; ITT, intention-to-treat; n, number of participants; NRI, non-responder imputation.

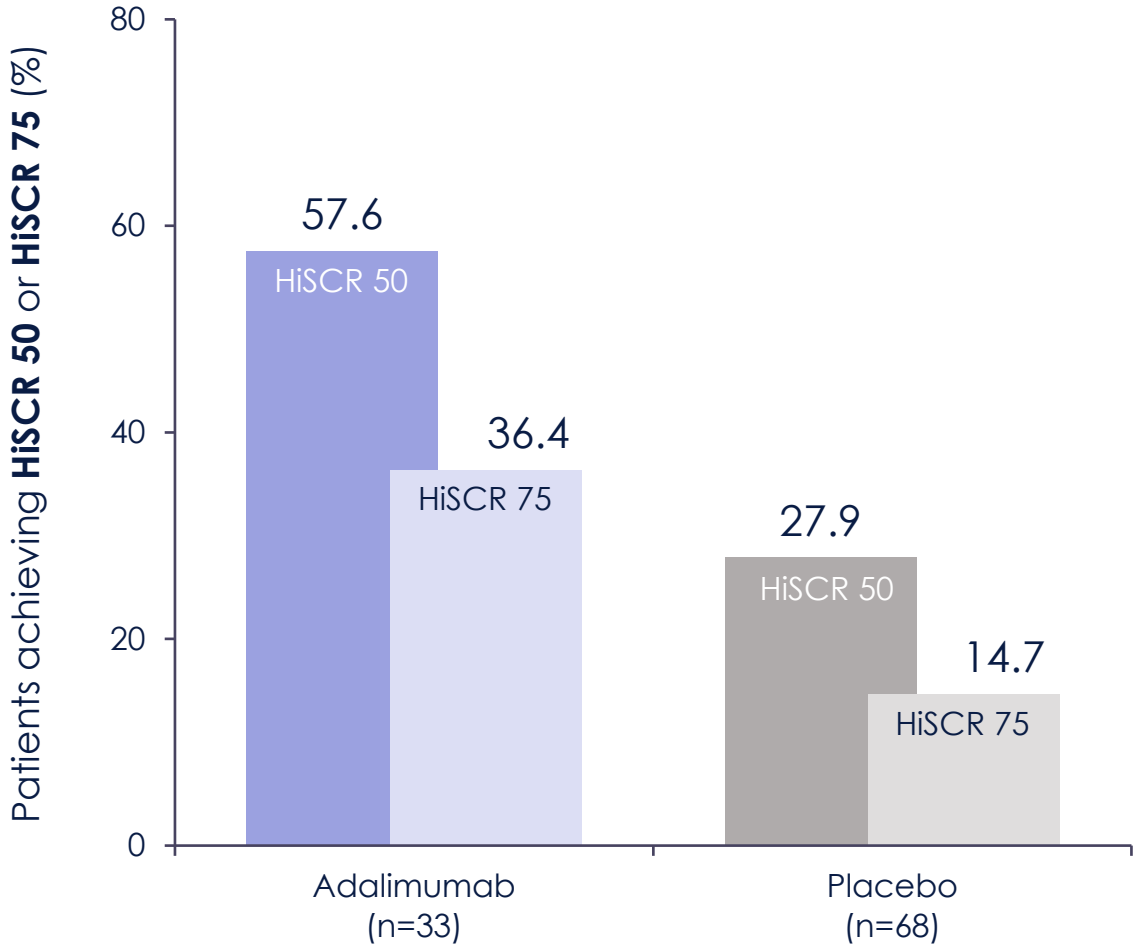
Sonelokimab met the key secondary endpoint of HiSCR 50 at Week 12 (ITT-NRI)



Significantly more sonelokimab-treated patients achieved the key secondary endpoint of HiSCR 50 compared with placebo at Week 12 (ITT-NRI)

P-values (multiplicity controlled) estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use. HiSCR 50/75 responder is a participant who has a ≥50/75% reduction from baseline in abscess and inflammatory nodule count with no increase in abscesses or draining tunnels. Missing data are imputed as a non-response.
HiSCR, Hidradenitis Suppurativa Clinical Response; ITT, intention-to-treat; n, number of participants; NRI, non-responder imputation.

HiSCR 75/50 responses at Week 12 in the reference arm were highly consistent with previous Phase 3 results (ITT-NRI)

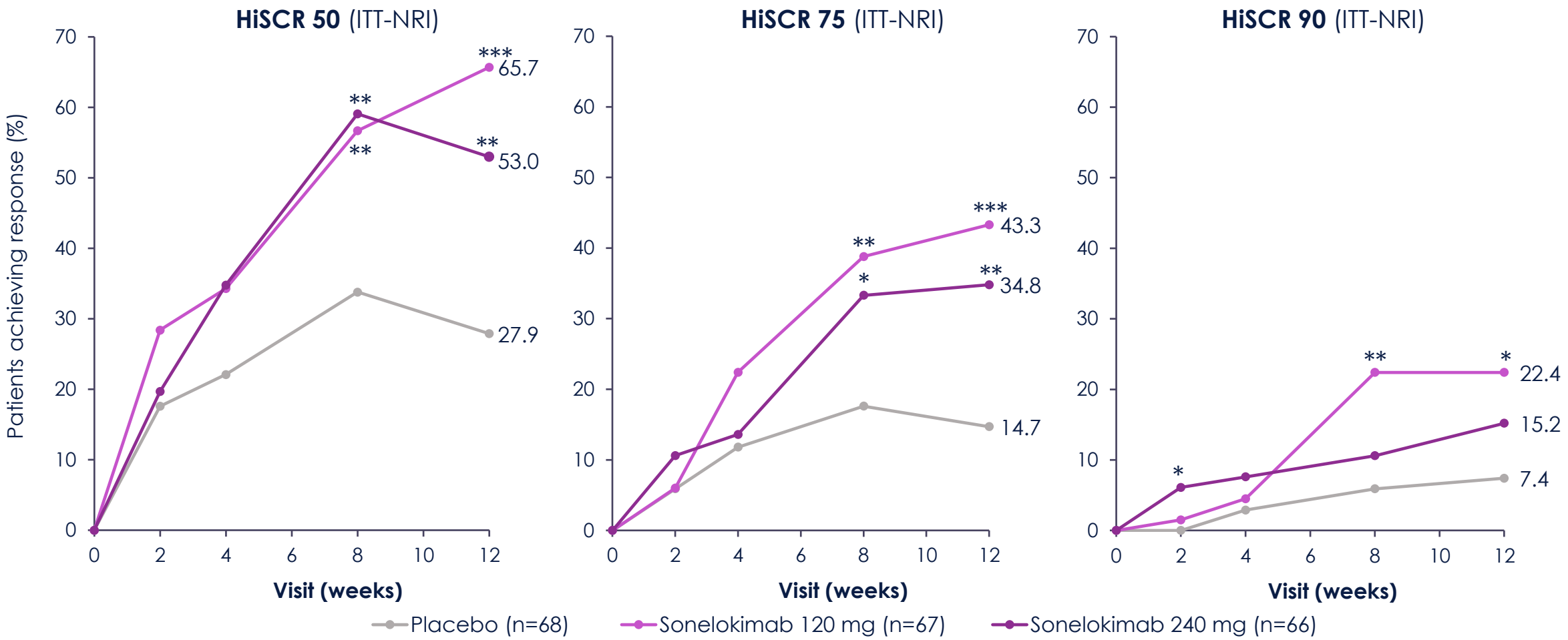


The adalimumab reference arm:

- Represented 14% (n=33/234) of the total randomized patients in the MIRA trial
- Was included to validate clinical findings in MIRA
- Was not powered for any statistical comparisons with sonelokimab or placebo
- Responses were highly consistent with the results of the PIONEER II Phase 3 trial of adalimumab[1,2]

HiSCR 75/50 responder is a participant who has a ≥75/50% reduction from baseline in abscess and inflammatory nodule count with no increase in abscesses or draining tunnels. Missing data are imputed as a non-response.
PIONEER II Week 12 HiSCR 50 response rates (primary analysis): 58.9% for adalimumab, 27.6% for placebo; HiSCR 75 (*post hoc* analysis) 35.0% adalimumab, 14.1% placebo.[1,2] Similarly to MIRA, in PIONEER II concomitant antibiotics were permitted at baseline.
HiSCR, Hidradenitis Suppurativa Clinical Response; ITT, intention-to-treat; n, number of participants; NRI, non-responder imputation.
1. Kimball AB, *et al. N Engl J Med*. 2016; 375:422–434. 2. Porter ML, *et al*. SHSA 2022 (Poster 3814).

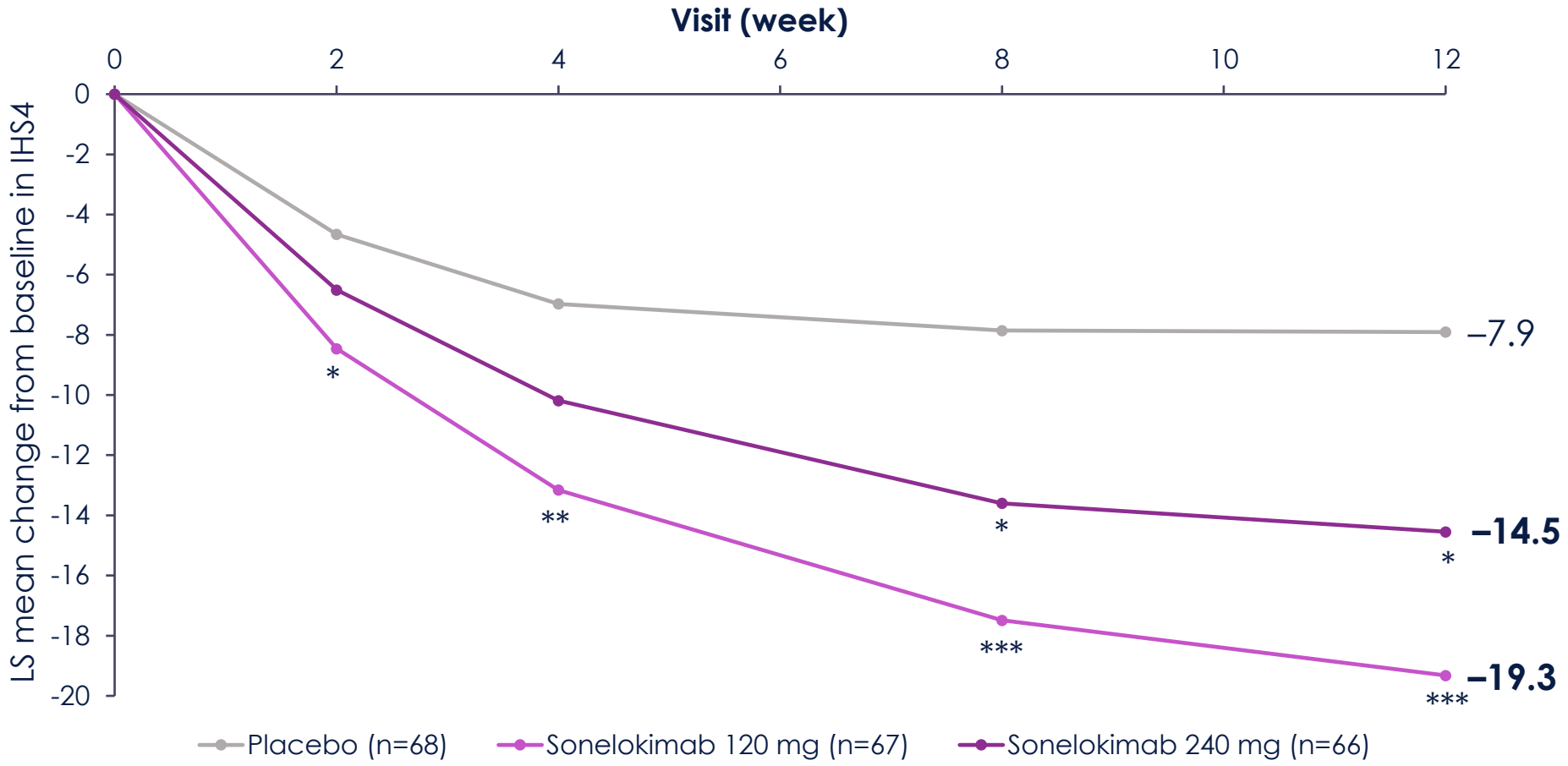
Sonelokimab rapidly achieved high levels of response across HiSCR thresholds, including HiSCR 90 (ITT-NRI)



As early as Week 8, a significant difference in response between sonelokimab and placebo was observed across HiSCR thresholds

***P<0.001, **P<0.01, *P<0.05, estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use; P-values for HiSCR 50 and HiSCR 75 at Week 12 are multiplicity controlled, while P-values for HiSCR 90 at all time points, and for HiSCR 50 and HiSCR 75 prior to Week 12, are nominal. Missing data are imputed as a non-response (NRI). HiSCR 50/75/90 responder is a participant who has a ≥50/75/90% reduction from baseline in abscess and inflammatory nodule count with no increase in abscesses or draining tunnels.
HiSCR, Hidradenitis Suppurativa Clinical Response; ITT, intention-to-treat; n, number of participants; NRI, non-responder imputation.

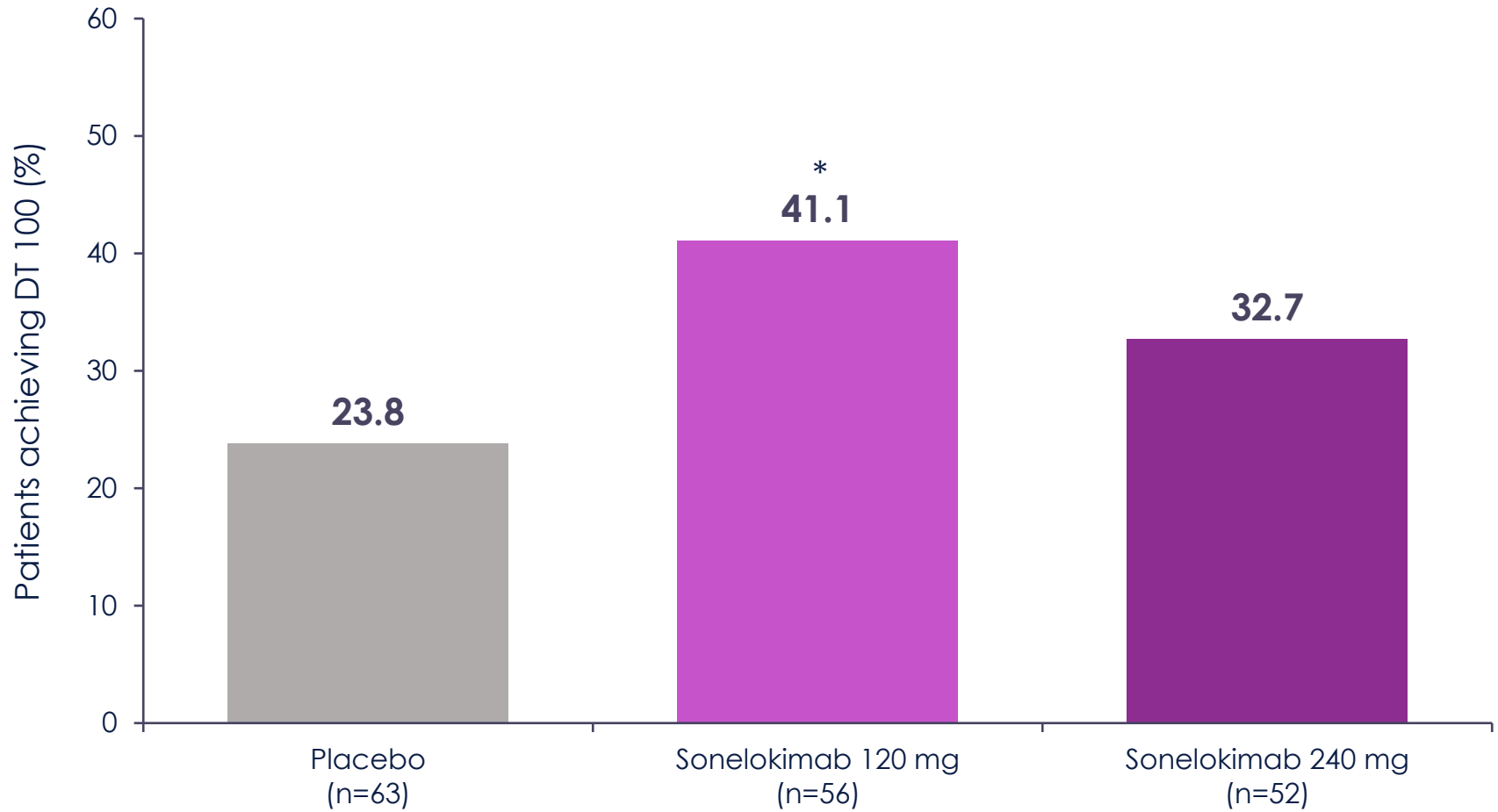
Significant decreases from baseline in IHS4 were seen with sonelokimab vs. placebo



Compared with placebo, treatment with sonelokimab resulted in a rapid and significant reduction from baseline (i.e. improvement) in IHS4, a validated tool that evaluates nodules, abscesses, and draining tunnels

***P<0.001, **P<0.01, *P<0.05; P-values for Week 12 are multiplicity controlled, while P-values prior to Week 12 are nominal. LS mean change from baseline and associated P-values are analyzed using MMRM with treatment group, visit, Hurley stage status, prior biologic use, associated baseline measurements, and visit by treatment as fixed effects and participant as a random effect.
Baseline mean IHS4: 32.1 (placebo); 33.1 (sonelokimab 120 mg); 26.2 (sonelokimab 240 mg).
IHS4, International Hidradenitis Suppurativa Severity Score System; LS, least squares; MMRM, mixed model for repeated measures; n, number of participants.

A greater proportion of patients receiving sonelokimab achieved complete resolution of draining tunnels (DT 100) vs. placebo at Week 12 (NRI)

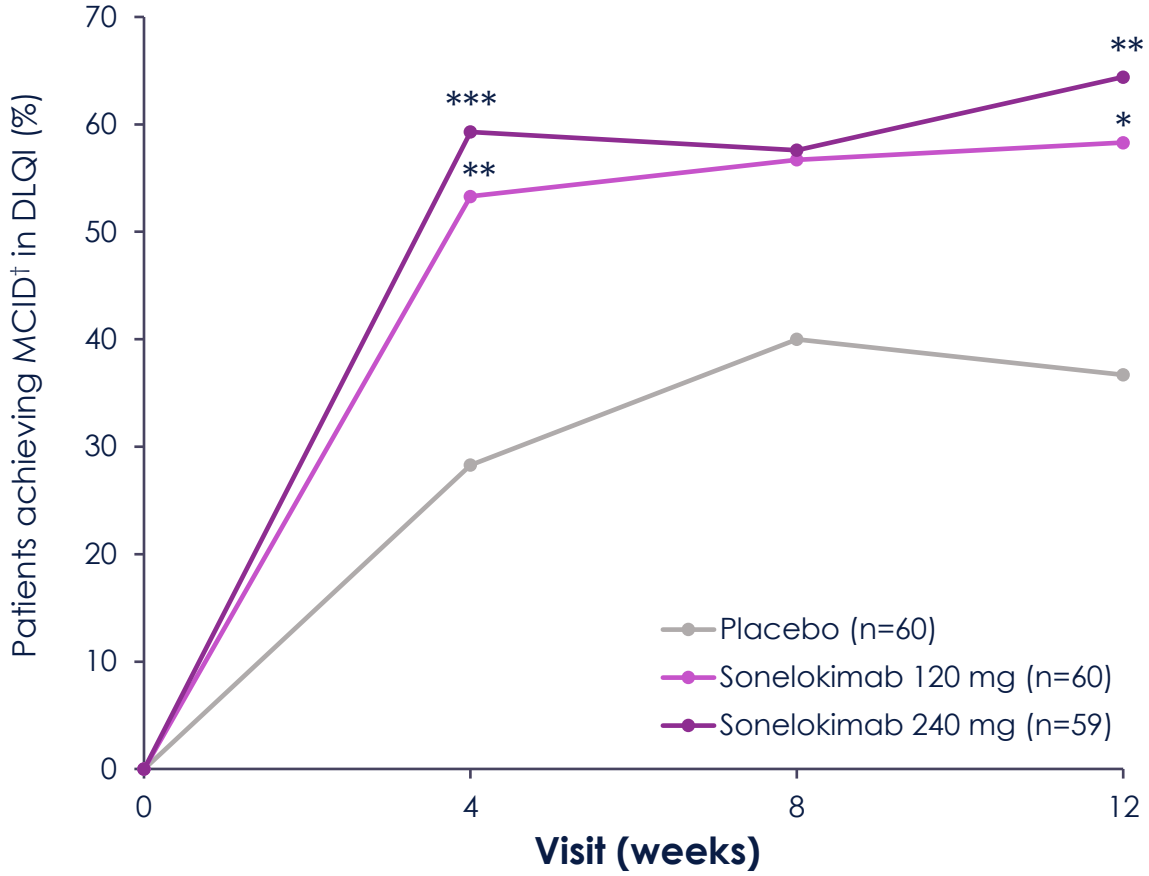


Among patients who had draining tunnels at baseline, a greater proportion treated with sonelokimab vs. placebo experienced complete resolution of draining tunnels at Week 12 (NRI)

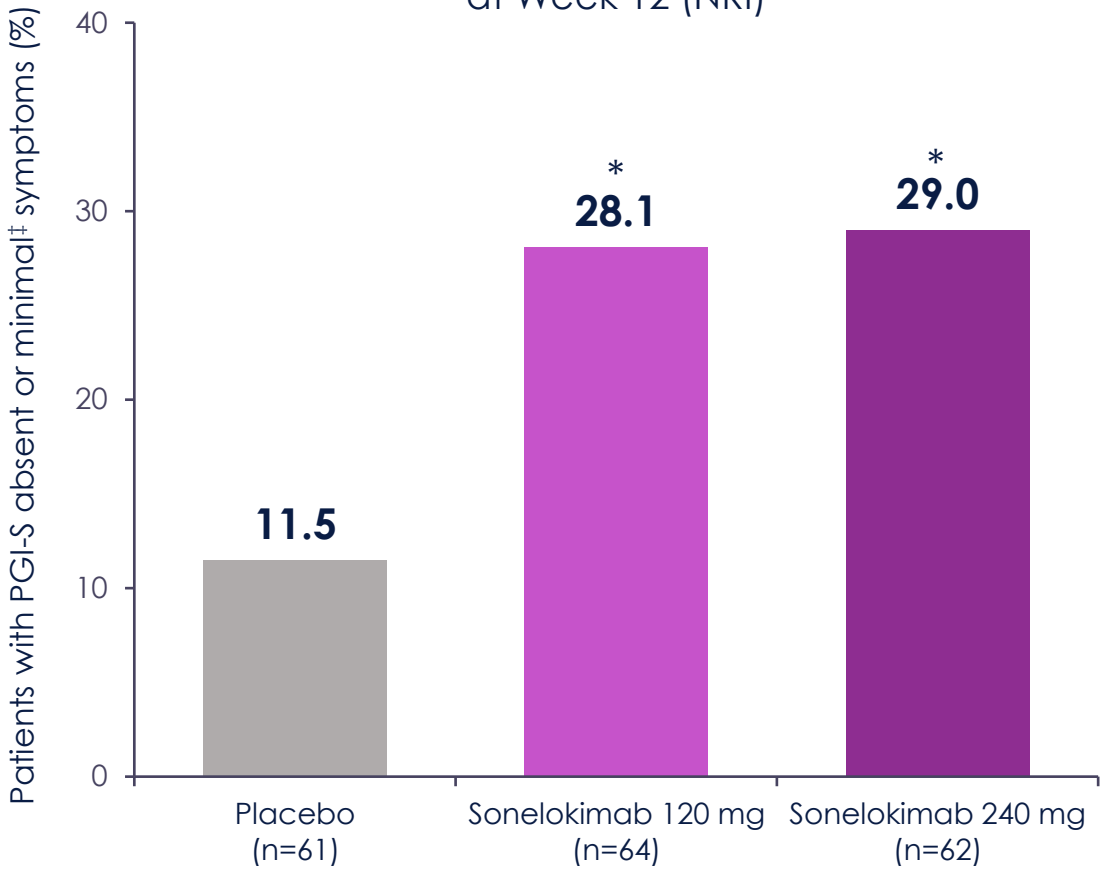
*Nominal *P*<0.05, estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use. DT 100 is defined as a 100% improvement in draining tunnel count from baseline in participants with ≥1 draining tunnel at baseline (85% of participants in the MIRA trial had ≥1 draining tunnel at baseline); missing data are imputed as a non-response (NRI).
DT, draining tunnel; n, number of participants; NRI, non-responder imputation.

Patient QoL improved as early as Week 4 with sonelokimab vs. placebo (NRI)

DLQI: MCID (NRI)



PGI-S: Absent or minimal symptoms at Week 12 (NRI)

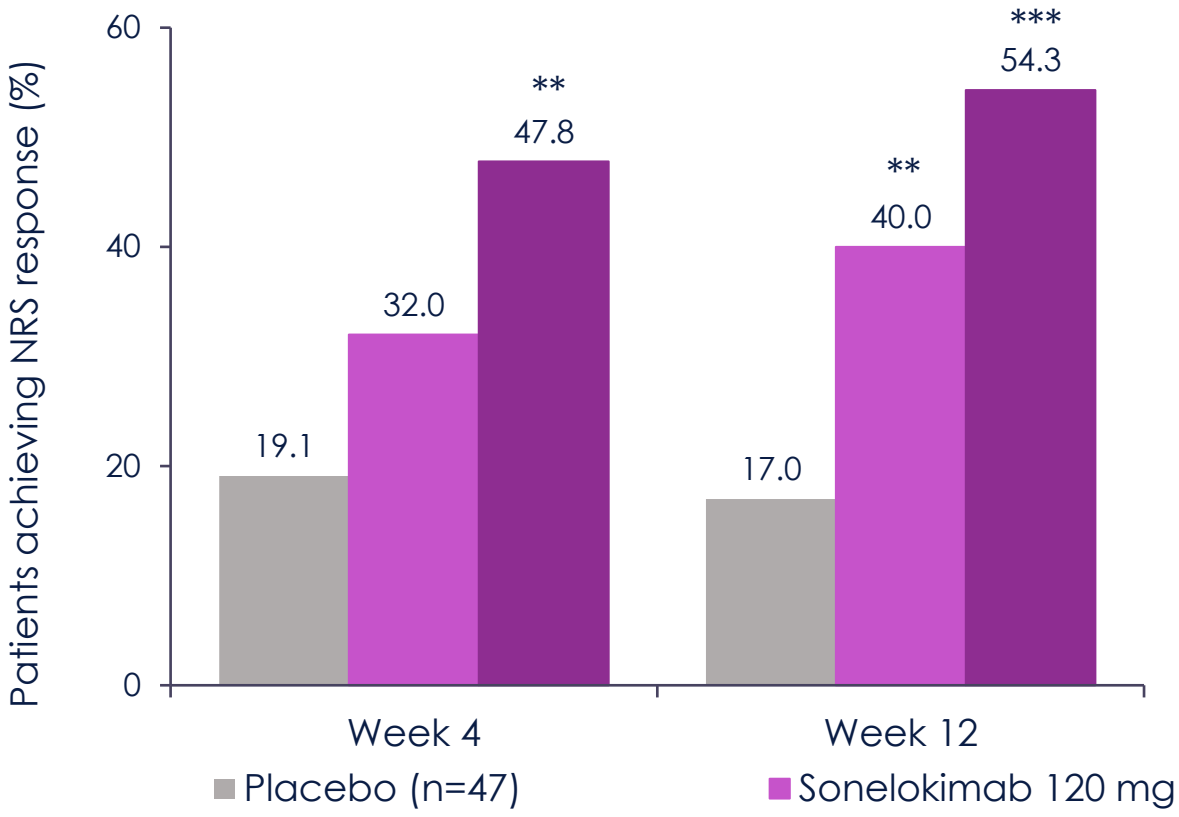


More than 50% of patients reported a ≥4-point reduction in DLQI (MCID) as early as Week 4, while nearly 30% of patients reported absent or minimal symptoms by Week 12

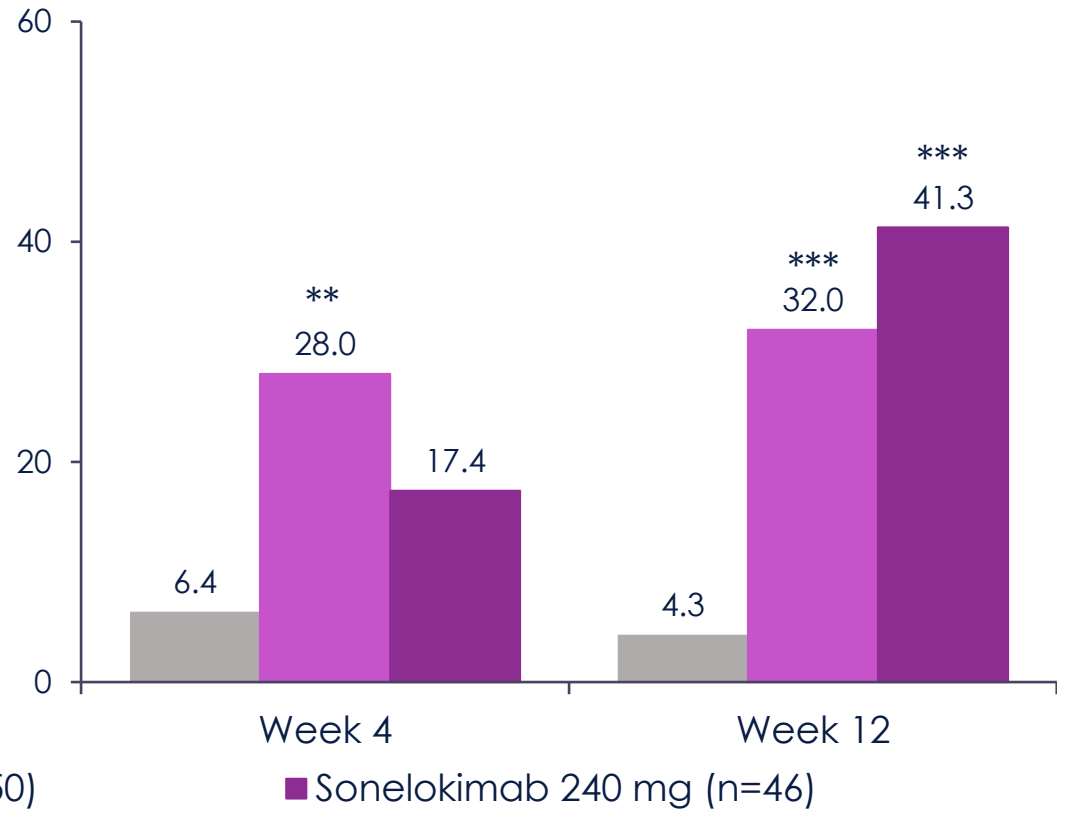
***Nominal *P*<0.001, **nominal *P*<0.01, *nominal *P*<0.05, estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use. †MCID is defined as a DLQI improvement (reduction) of ≥4 points in participants with DLQI ≥4 at baseline. ‡PGI-S absent or minimal symptoms is defined as a PGI-S score of ≤1 in participants with a PGI-S score of >1 at baseline. Missing data are imputed as a non-response (NRI).
DLQI, Dermatology Life Quality Index; MCID, minimal clinically important difference; NRI, non-responder imputation; PGI-S, Patient Global Impression of Severity; QoL, quality of life.

Higher levels of skin pain response were achieved with sonelokimab vs. placebo by Week 4 (NRI)

NRS 30 (30% improvement) (NRI)
Patient Global Assessment of skin pain



NRS 50 (50% improvement) (NRI)
Patient Global Assessment of skin pain



More than 1 in 3 patients reported a ≥50% improvement in skin pain by Week 12

***P<0.001, **P<0.01, estimated from a Cochran–Mantel–Haenszel test stratified by Hurley stage and prior biologic use; P-values for NRS 30 at Week 12 are multiplicity controlled, while P-values for NRS 50 at all time points, and for NRS 30 at Week 4, are nominal. NRS is based on the Patient Global Assessment of skin pain. NRS 30 is defined as a ≥30% and a ≥1-point improvement from baseline in NRS score in participants with NRS ≥3 at baseline. NRS 50 (*post hoc* analysis) is defined as a ≥50% and a ≥1-point improvement from baseline in NRS score in participants with NRS ≥3 at baseline.
n, number of participants; NRI, non-responder imputation; NRS, numerical rating scale.

Sonelokimab was well tolerated with no unexpected safety findings

Participants with event, n (%)	Placebo n=68	Sonelokimab 120 mg n=67	Sonelokimab 240 mg n=66	Adalimumab reference‡ n=33
Any TEAE	45 (66.2)	53 (79.1)	52 (78.8)	27 (81.8)
Any serious TEAE	2 (2.9)	2 (3.0)	1 (1.5)	0
Any TEAE leading to treatment discontinuation	1 (1.5)	3 (4.5)	0	0
Fatal TEAEs	0	0	0	0
Most frequent TEAEs*				
Nasopharyngitis	10 (14.7)	10 (14.9)	6 (9.1)	2 (6.1)
Headache	8 (11.8)	6 (9.0)	8 (12.1)	3 (9.1)
Injection site reaction	0	6 (9.0)	6 (9.1)	0
Adverse events of special interest				
IBD	0	0	0	0
Diarrhea	1 (1.5)	2 (3.0)	2 (3.0)	2 (6.1)
Candidiasis				
Oral candidiasis	0	4 (6.0)	8 (12.1)	0
Oropharyngeal candidiasis	0	0	0	0
Esophageal candidiasis	0	0	0	0
Vulvovaginal candidiasis	0	2 (3.0)	0	0
Skin candidiasis	0	0	1 (1.5)	0
Genital candidiasis	0	1 (1.5)†	0	0
Other adverse events of interest				
Serious hypersensitivity	0	0	0	0
Serious infection	1 (1.5)	0	0	0
Suicidal ideation and behavior	0	0	0	0
MACE	0	0	0	0
Liver ALT/AST >3× ULN	1 (1.5)/0	0	0	0/0

All candidiasis cases were mild to moderate, and no cases led to treatment withdrawal

*Top 3 most frequent TEAEs in the sonelokimab groups. †A vulvovaginal candidiasis event coded as 'genital candidiasis'. ‡The adalimumab therapy used in the MIRA trial was the originator drug (citrate-free formulation).
ALT, alanine aminotransferase; AST, aspartate transaminase; IBD, inflammatory bowel disease; MACE, major adverse cardiovascular event; TEAE, treatment-emergent adverse event; ULN, upper limit of normal.

Conclusions

- Nanobodies represent a new generation of antibody-derived therapies
- In the Phase 2 MIRA trial, sonelokimab met the primary endpoint of HiSCR 75 at Week 12 (ITT-NRI)
- Sonelokimab rapidly achieved high levels of response across HiSCR thresholds (including HiSCR 90) and IHS4
- Significantly greater resolution of draining tunnels (DT 100) was observed with sonelokimab over placebo
- There were significant improvements in patient QoL, skin pain, and HS symptoms with sonelokimab compared with placebo
- Sonelokimab was well tolerated, with no new safety signals
- Maximum clinical responses were observed in the sonelokimab 120 mg dose group, with indication of a preferred benefit–risk profile
- The findings of the MIRA trial warrant further investigation in Phase 3 trials

DT, draining tunnel; HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; IHS4, International Hidradenitis Suppurativa Severity Score System; ITT, intention-to-treat; NRI, non-responder imputation; QoL, quality of life.

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