Presentation #D1T01.1C

Povorcitinib for Moderate to Severe Hidradenitis Suppurativa: Week 24 Interim Phase 3 Results

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European Academy of Dermatology and Venereology Congress; 17–20 September 2025; Paris, France

Introduction

- HS is a chronic, recurrent, debilitating inflammatory condition that causes painful skin nodules and abscesses, leading to tunnels, irreversible tissue damage, and scarring[1]
  - Disease course is marked by flares, which can be unpredictable[1]
  - HS pathophysiology is complex, involving multiple cell types and cytokines, many of which are mediated through JAK1 signaling[2]
- Povorcitinib is an oral, highly selective JAK1 inhibitor in clinical development for several inflammatory conditions, including HS[3,4]

Objective: Evaluate the efficacy and safety of povorcitinib through Week 24 from the registrational phase 3 STOP-HS1/STOP-HS2 studies in patients with moderate to severe HS

HS, hidradenitis suppurativa; JAK, Janus kinase.

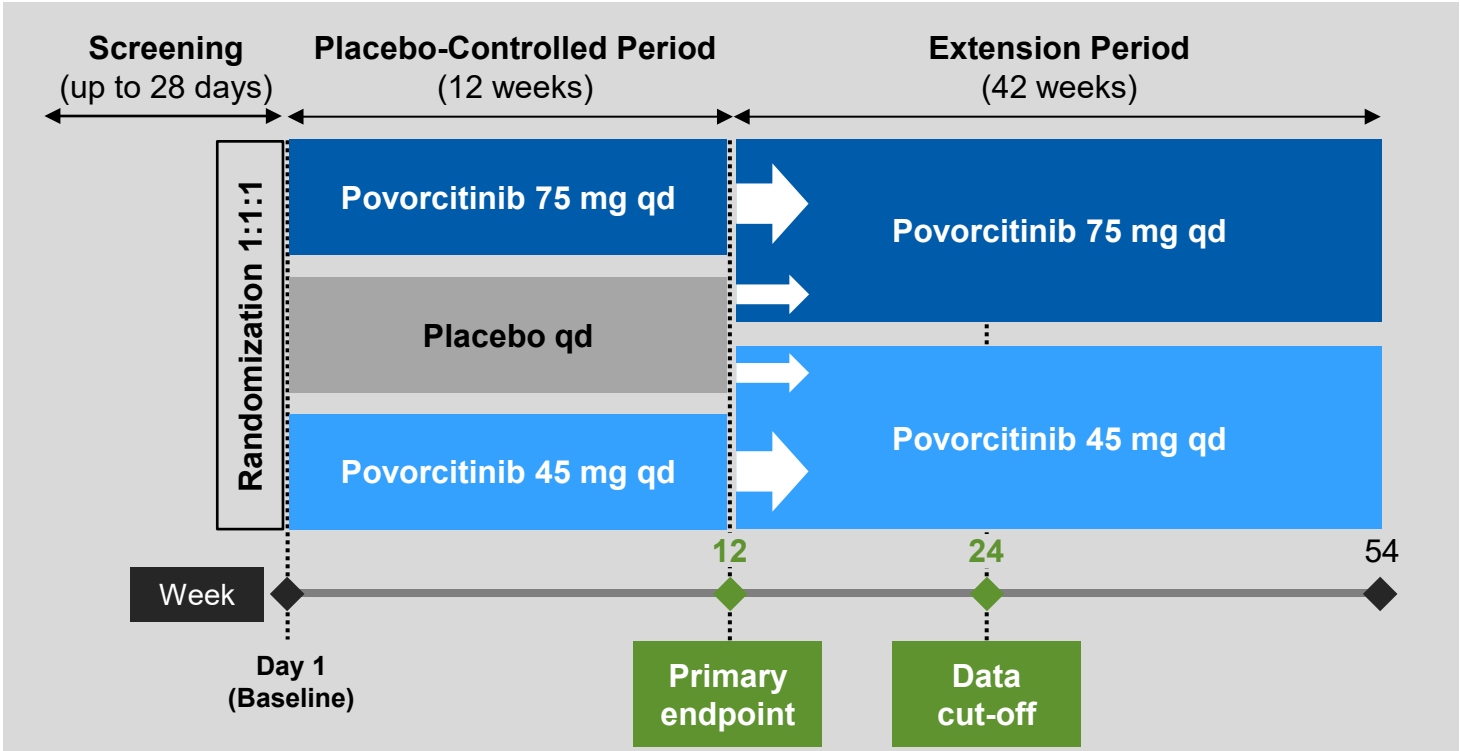
1. Sabat R, et al. *Lancet*. 2025;405:420-438. **2.** Krueger JG, et al. *Br J Dermatol*. 2024;190:149-162. **3.** Kirby JS, et al. *J Am Acad Dermatol*. 2024;90:521-529. **4.** Pandya A, et al. *J Am Acad Dermatol*. 2025. doi: 10.1016/j.jaad.2025.06.027.

STOP-HS Study Design

NCT05620823 and NCT05620836

- **S**elective **T**reatment of **O**ral **P**ovorcitinib In **H**idradenitis **S**uppurativa Study 1 and Study 2 are identical in design
  - N=1227 adults
- Global studies (North America, Europe, Japan, and Australia) with approximately 200 sites
- Moderate to severe HS, AN count ≥5 in ≥2 anatomic areas, Hurley stage II or III
- HS diagnosis for ≥3 months
- Prior treatment with a systemic therapy (oral antibiotic or biologic)
- Concomitant antibiotic for HS use not allowed, except rescue (imputed as nonresponder)
- Stratification for ANdT count (<11 or ≥11) and previous biologic use for HS

STOP-HS1 (N=608) and STOP-HS2 (N=619)



Primary Endpoint: HiSCR50 at Week 12

Key Secondary Endpoints: HiSCR75 at Week 12, ≥3-point decrease in Skin Pain NRS at Week 12, and flare by Week 12

AN, abscess and inflammatory nodule; dT, draining tunnel; HiSCR, Hidradenitis Suppurativa Clinical Response; HiSCR50/75, ≥50%/≥75% decrease from baseline in abscess and inflammatory nodule count with no increase in the number of abscesses or draining tunnels; HS, hidradenitis suppurativa; NRS, numerical rating scale; qd, once daily.

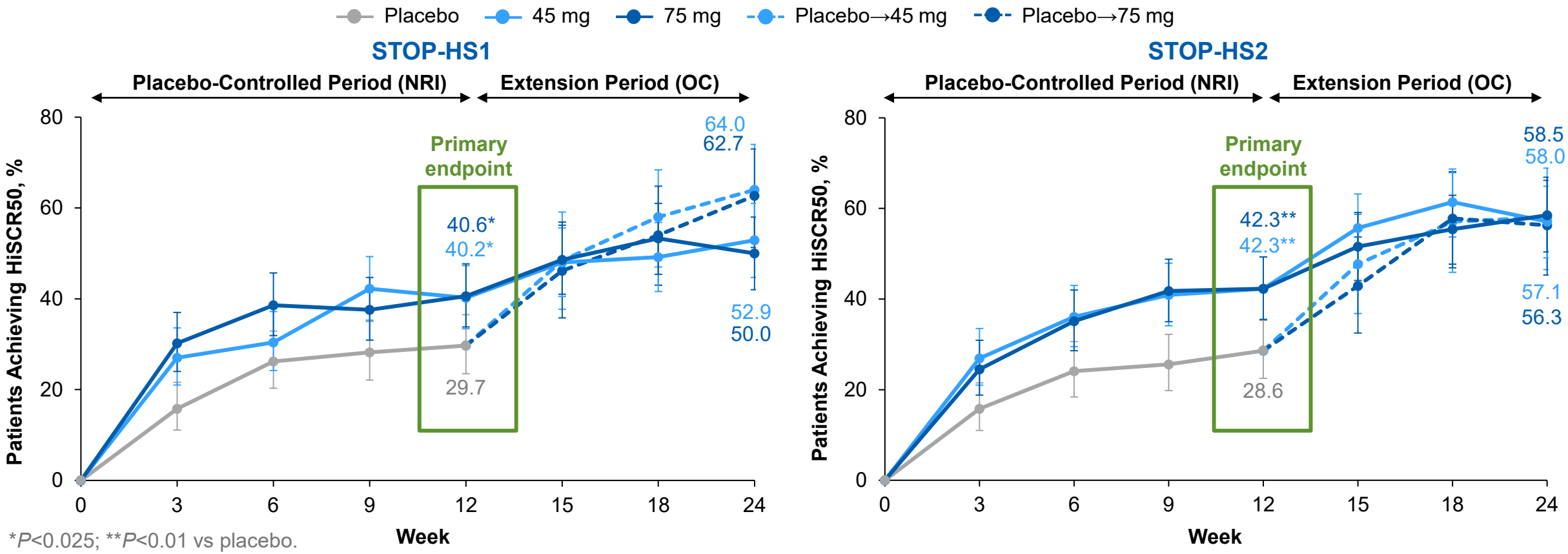
Demographics and Baseline Clinical Characteristics

Characteristic	STOP-HS1 (N=608)			STOP-HS2 (N=619)		
	Placebo n=202	Povorcitinib 45 mg n=204	Povorcitinib 75 mg n=202	Placebo n=203	Povorcitinib 45 mg n=208	Povorcitinib 75 mg n=208
Age, median (range), y	36.5 (18–71)	36.0 (18–76)	38.5 (18–77)	39.0 (18–68)	37.0 (18–70)	35.0 (18–68)
Female, n (%)	138 (68.3)	131 (64.2)	134 (66.3)	110 (54.2)	134 (64.4)	123 (59.1)
Race, n (%)						
White	152 (75.2)	139 (68.1)	147 (72.8)	162 (79.8)	156 (75.0)	159 (76.4)
Black	29 (14.4)	43 (21.1)	26 (12.9)	21 (10.3)	30 (14.4)	25 (12.0)
BMI, mean (SD), kg/m^2	34.9 (9.3)	35.2 (8.8)	33.7 (8.6)	33.3 (8.2)	33.4 (8.3)	33.5 (8.6)
BMI ≥40 kg/m^2, n (%)	54 (26.7)	55 (27.0)	39 (19.3)	42 (20.7)	37 (17.8)	42 (20.2)
Current smoker, n (%)	96 (47.5)	101 (49.5)	100 (49.5)	94 (46.3)	98 (47.1)	91 (43.8)
Duration of HS, mean (SD), y	10.8 (8.9)	10.6 (9.9)	10.4 (10.2)	9.7 (9.5)	10.7 (10.4)	9.8 (8.1)
Hurley stage, n (%)						
II	118 (58.4)	128 (62.7)	127 (62.9)	144 (70.9)	135 (64.9)	144 (69.2)
III	84 (41.6)	76 (37.3)	75 (37.1)	59 (29.1)	73 (35.1)	64 (30.8)
Lesions, mean (SD)						
AN count	12.3 (8.2)	13.0 (11.2)	12.1 (8.3)	11.1 (7.1)	11.6 (8.4)	12.0 (9.0)
dT count	2.9 (3.4)	3.0 (3.5)	2.8 (3.5)	2.9 (3.4)	2.7 (3.2)	2.5 (3.0)
≥1 dT, n (%)	152 (75.2)	156 (76.5)	150 (74.3)	155 (76.4)	158 (76.0)	155 (74.5)
Prior biologic use, n (%)	73 (36.1)	74 (36.3)	71 (35.1)	77 (37.9)	82 (39.4)	80 (38.5)
TNF-α inhibitor	51 (25.2)	60 (29.4)	56 (27.7)	65 (32.0)	65 (31.3)	67 (32.2)
Prior HS excision surgery, n (%)	37 (18.3)	41 (20.1)	43 (21.3)	49 (24.1)	42 (20.2)	44 (21.2)
IHS4 score, mean (SD)	26.0 (20.4)	27.2 (23.2)	25.6 (20.8)	25.4 (19.5)	24.5 (16.5)	24.0 (17.6)
Skin Pain NRS, mean (SD)	5.0 (2.7)	5.2 (2.5)	5.2 (2.3)	4.9 (2.5)	5.0 (2.5)	5.0 (2.5)

AN, abscess and inflammatory nodule; BMI, body mass index; dT, draining tunnel; HS, hidradenitis suppurativa; IHS4, International Hidradenitis Suppurativa Severity Score System; NRS, numerical rating scale; TNF-α, tumor necrosis factor alpha.

Povorcitinib Met the Primary Endpoint: HiSCR50 at Week 12

- In both studies, **HiSCR50 primary endpoint** met **statistical significance** with both povorcitinib doses vs placebo at Week 12 and continued to improve through Week 24



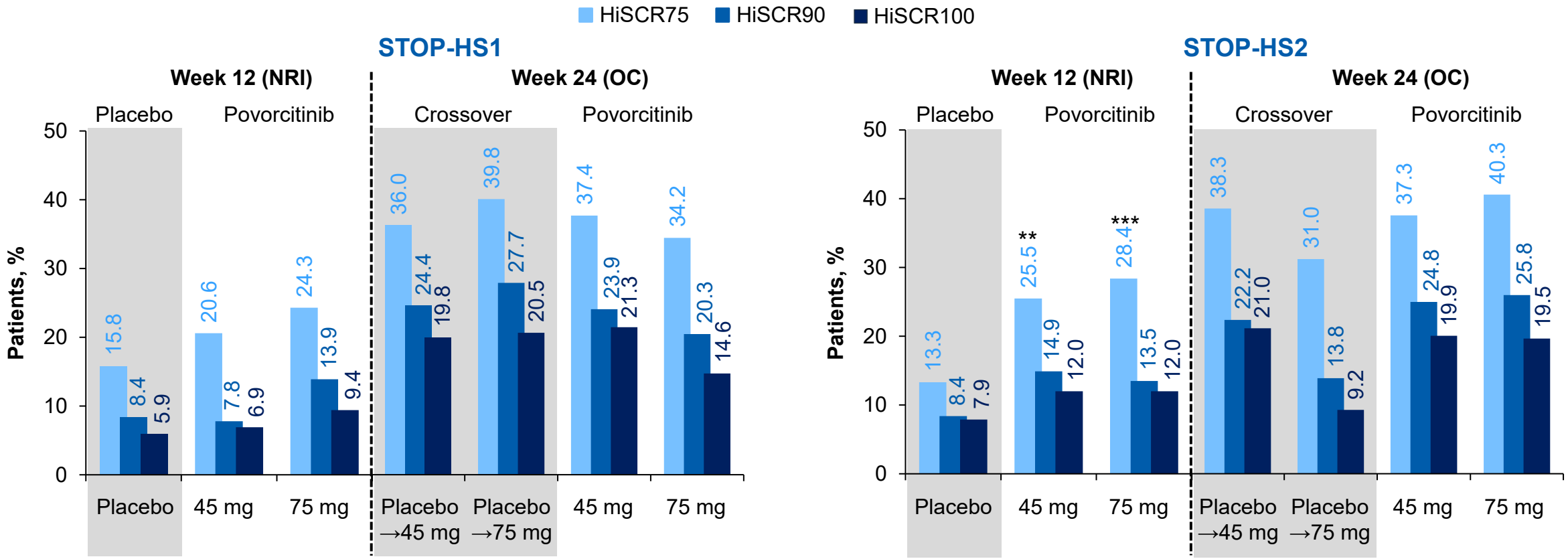
*P<0.025; **P<0.01 vs placebo.

Evaluable patients; STOP-HS1: Week 15, n=540; Week 18, n=521; Week 24, n=482; STOP-HS2: Week 15, n=535; Week 18, n=520; Week 24, n=488.

HiSCR50, ≥50% decrease from baseline in abscess and inflammatory nodule count with no increase in number of abscesses or draining tunnels; NRI, nonresponder imputation; OC, observed cases.

Povorcitinib Achieved High-Level HiSCR Responses

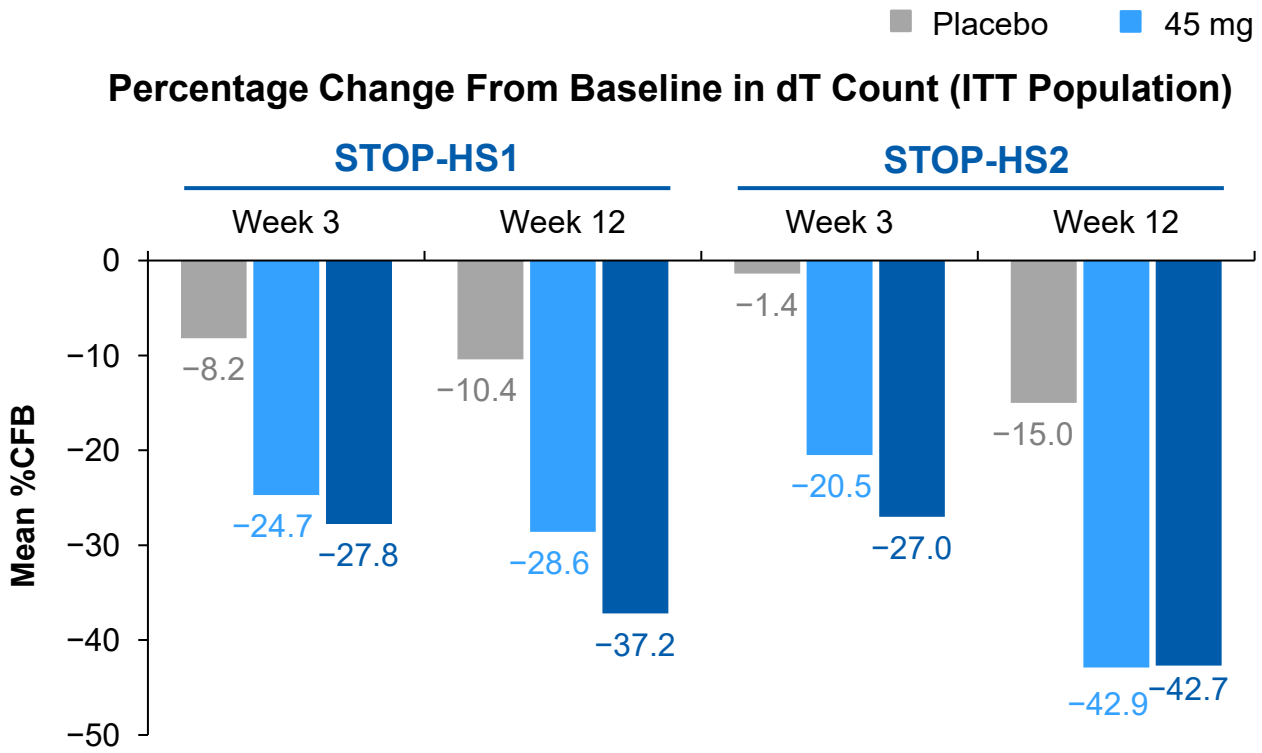
- Povorcitinib met the **key secondary endpoint** of **HiSCR75** at Week 12 in STOP-HS2
- Responses continued to improve through Week 24 in both studies

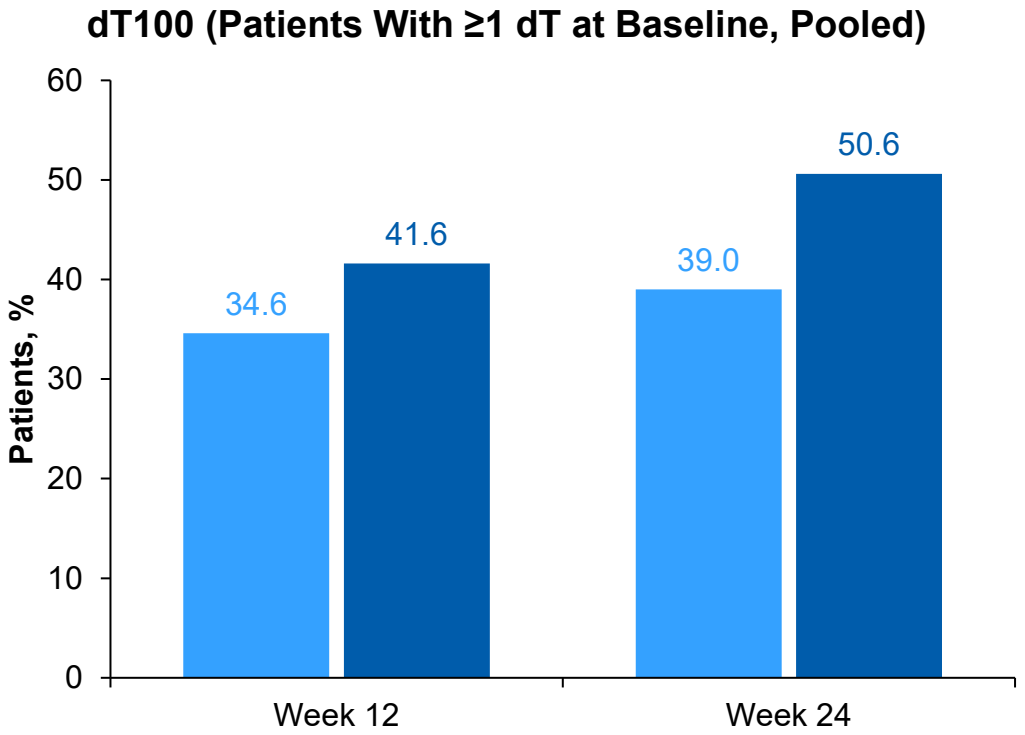


***P*<0.01; ****P*<0.001 vs placebo.
HiSCR75/90/100, ≥75%/ ≥90%/100% decrease from baseline in abscess and inflammatory nodule count with no increase in number of abscesses or draining tunnels; NRI, nonresponder imputation; OC, observed cases.

Povorcitinib Effectively Reduced Draining Tunnels and Flares

- Povorcitinib **improved draining tunnel (dT) counts** vs placebo as early as Week 3





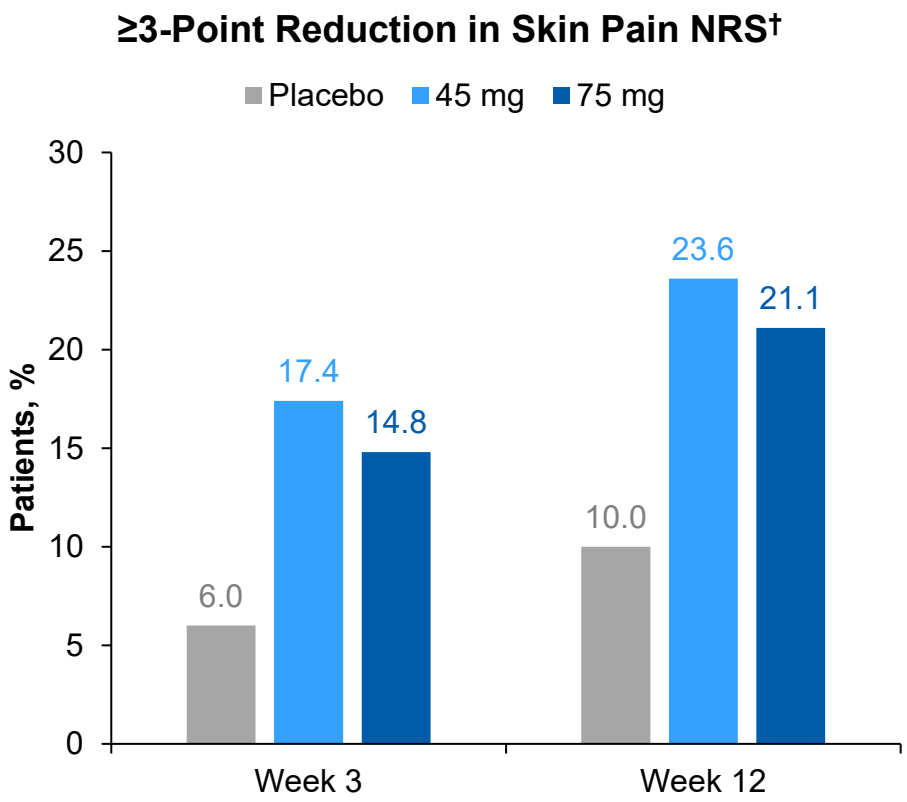
During the placebo-controlled period, **fewer flares** occurred in patients receiving povorcitinib (20.7%–26.2%) vs placebo (33.5%–33.7%) [statistically significant in STOP-HS2]

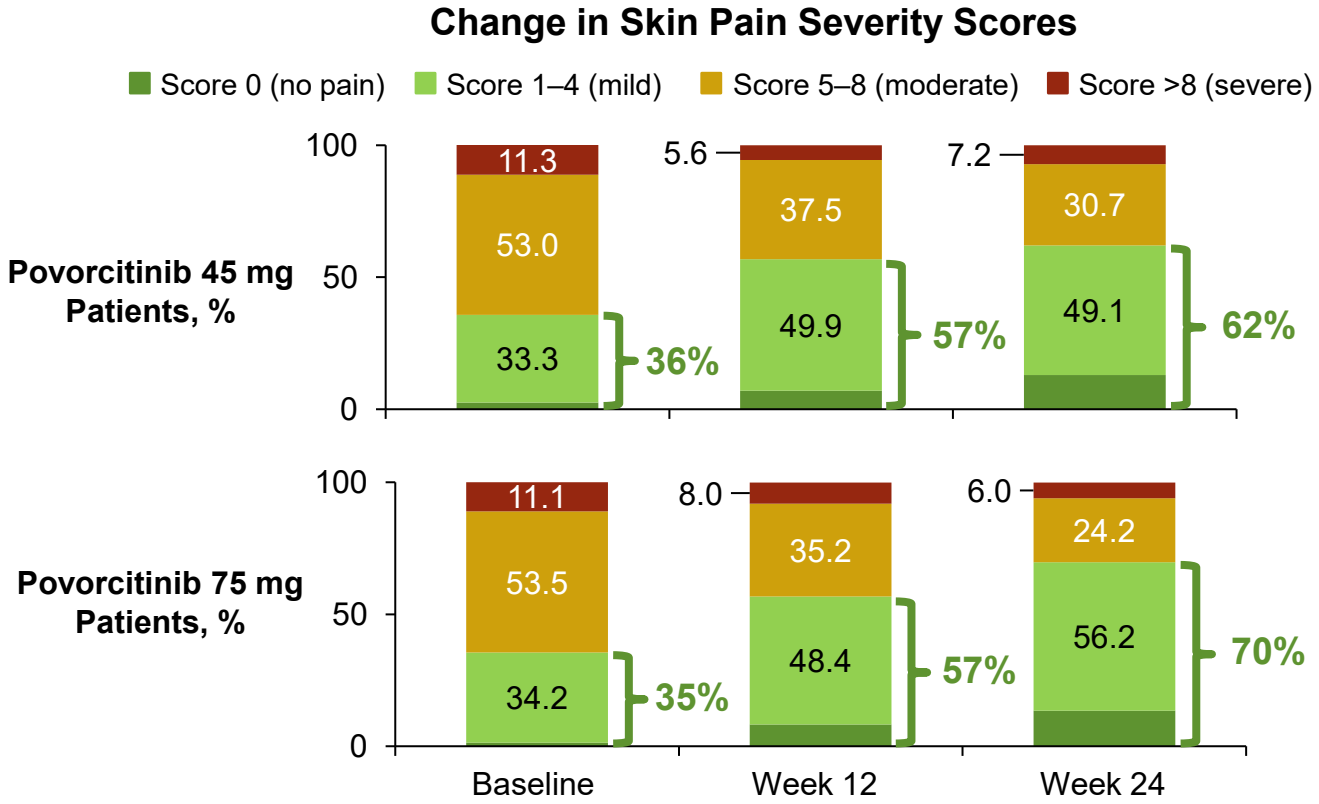
CFB, change from baseline; ITT, intent to treat.

Povorcitinib Achieved Greater Improvements in Skin Pain

Pooled STOP-HS1 and STOP-HS2

- Povorcitinib reduced pain by the first visit (Week 3) in both studies [statistically significant in STOP-HS2]
- Patients with **mild or no pain** increased from ~35% at baseline to **~70% by Week 24**

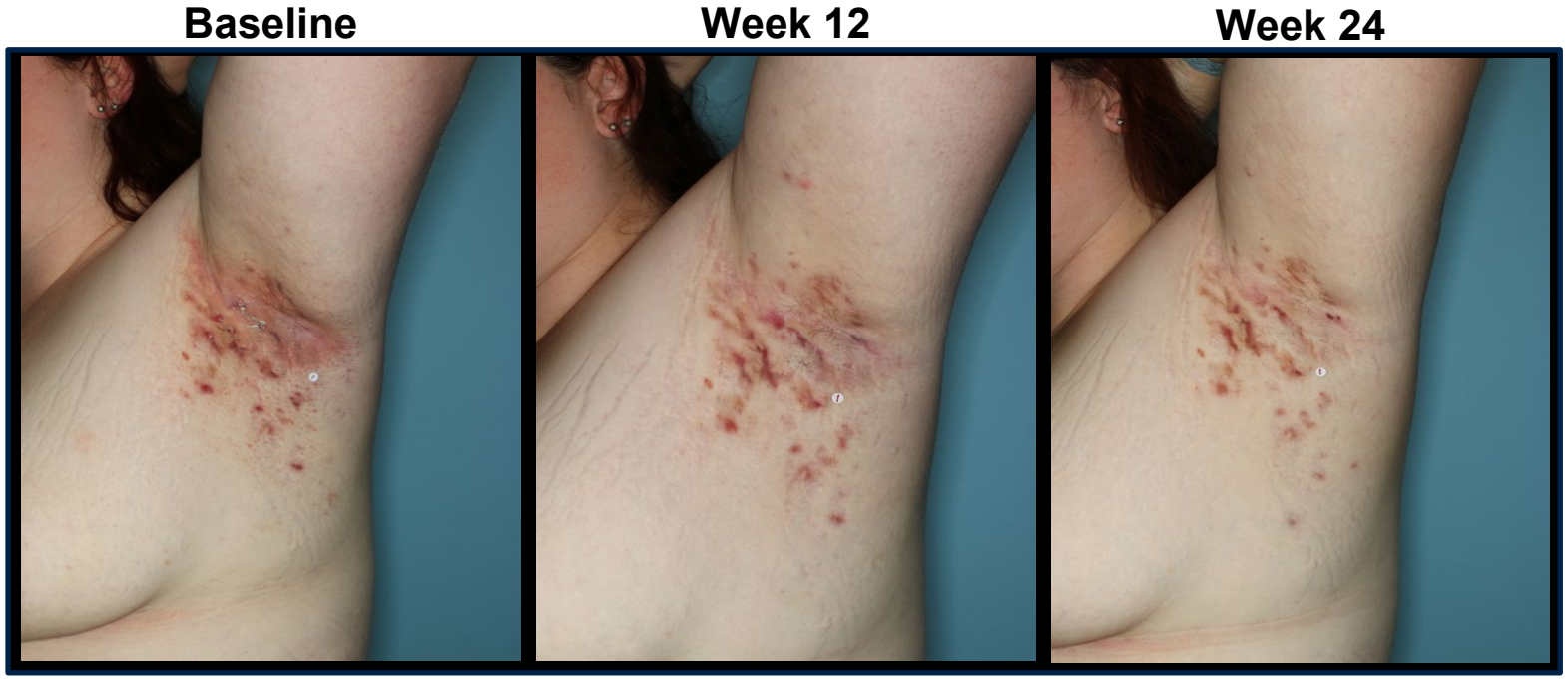




† Assessed in patients with baseline Skin Pain NRS score ≥3.
NRS, numerical rating scale.

Clinical Response to Povorcitinib 75 mg

- 29-year-old female, non-smoker, with Hurley Stage II, 13.4 years' HS duration, and BMI 39.4 kg/m²
  - Inadequate response or intolerance to 3 prior biologic treatments
- Patient achieved **meaningful reduction in disease activity and symptom burden** with 24 weeks of continuous povorcitinib 75 mg treatment



Variable	Baseline	Week 12	Week 24
AN count	6	3	1
dT count	2	1	0
HiSCR50	NA	Yes	Yes
HiSCR75	NA	No	Yes
HiSCR100	NA	No	No
Skin Pain NRS	7.3	4.5	3.2

AN, abscess and inflammatory nodule; BMI, body mass index; dT, draining tunnel; HiSCR50/75/100, ≥50%/≥75%/100% decrease from baseline in abscess and inflammatory nodule count with no increase in number of abscesses or draining tunnels; HS, hidradenitis suppurativa; NA, not available; NRS, numerical rating scale.

Safety

Placebo-Controlled Period

Patients, n (%)	STOP-HS1 (N=608)			STOP-HS2 (N=619)		
	Placebo n=202	Povorcitinib 45 mg n=204	Povorcitinib 75 mg n=202	Placebo n=203	Povorcitinib 45 mg n=208	Povorcitinib 75 mg n=208
Any TEAE	**106 (52.5)**	**121 (59.3)**	**134 (66.3)**	**95 (46.8)**	**127 (61.1)**	**129 (62.3)**
Treatment-related TEAE	32 (15.8)	43 (21.1)	60 (29.7)	40 (19.7)	61 (29.3)	78 (37.7)
Serious TEAE	6 (3.0)	3 (1.5)	3 (1.5)	4 (2.0)	4 (1.9)	4 (1.9)
Grade ≥3 TEAE	7 (3.5)	5 (2.5)	5 (2.5)	5 (2.5)	8 (3.8)	6 (2.9)
Fatal TEAE	0	0	0	0	0	0
TEAE leading to discontinuation	3 (1.5)	4 (2.0)	7 (3.5)	4 (2.0)	12 (5.8)	8 (3.9)
Most frequent TEAEs[†]						
Acne	6 (3.0)	17 (8.3)	30 (14.9)	11 (5.4)	18 (8.7)	23 (11.1)
Headache	12 (5.9)	13 (6.4)	16 (7.9)	7 (3.4)	14 (6.7)	16 (7.7)
Nasopharyngitis	18 (8.9)	11 (5.4)	14 (6.9)	9 (4.4)	10 (4.8)	15 (7.2)
AEs of special interest	**9 (4.5)**	**2 (1.0)**	**4 (2.0)**	**8 (3.9)**	**5 (2.4)**	**8 (3.9)**
MACE	0	0	0	0	0	0
Embolic/thromboembolic events	0	0	0	0	0	0
Any malignancy	0	0	0	2 (1.0)	0	0
Serious infections	4 (2.0)	0	2 (1.0)	2 (1.0)	0	0
Opportunistic infections	0	0	0	0	1 (0.5)	0
Herpes zoster	0	0	1 (0.5)	0	2 (1.0)	2 (1.0)

[†] Top 3 most frequent TEAEs in the povorcitinib groups.

AE, adverse event; HS, hidradenitis suppurativa; MACE, major adverse cardiovascular event; TEAE, treatment-emergent adverse event.

Safety up to Week 24

Extension Period

- Povorcitinib was well tolerated; the safety profile was consistent with that seen in the PC period

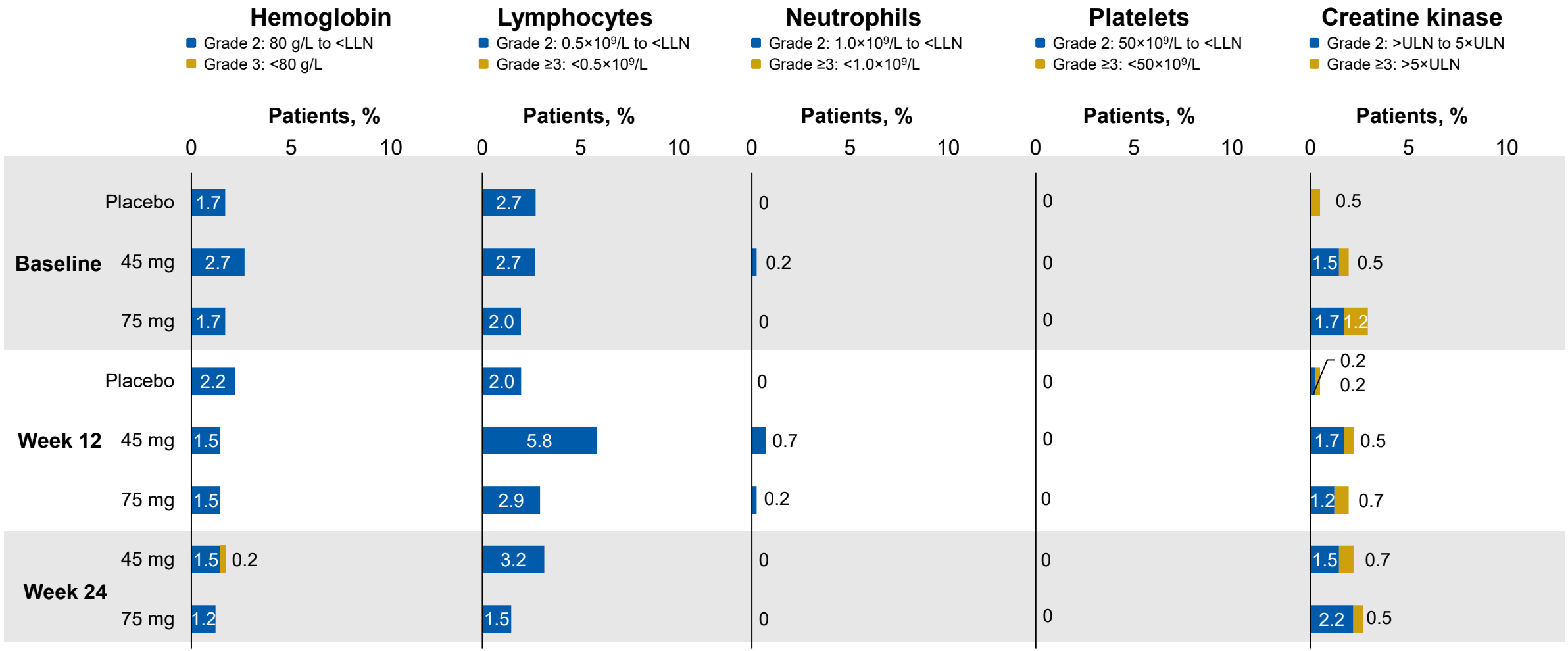
	STOP-HS1 (N=591)				STOP-HS2 (N=597)			
Patients, n (%)	Placebo→45 mg n=92†	Placebo→75 mg n=93†	45 mg n=204‡	75 mg n=202‡	Placebo→45 mg n=90†	Placebo→75 mg n=92†	45 mg n=208‡	75 mg n=207‡
Any TEAE	**50 (54.3)**	**48 (51.6)**	**146 (71.6)**	**159 (78.7)**	**42 (46.7)**	**39 (42.4)**	**146 (70.2)**	**157 (75.8)**
Treatment-related TEAE	22 (23.9)	24 (25.8)	62 (30.4)	79 (39.1)	14 (15.6)	21 (22.8)	74 (35.6)	100 (48.3)
Serious TEAE	0	2 (2.2)	6 (2.9)	8 (4.0)	4 (4.4)	2 (2.2)	10 (4.8)	9 (4.3)
Grade ≥3 TEAE	0	2 (2.2)	10 (4.9)	8 (4.0)	2 (2.2)	3 (3.3)	13 (6.3)	11 (5.3)
Fatal TEAE	0	0	0	0	0	0	0	0
TEAE leading to discontinuation	1 (1.1)	2 (2.2)	11 (5.4)	9 (4.5)	1 (1.1)	4 (4.3)	18 (8.7)	12 (5.8)
AEs of special interest	**1 (1.1)**	**2 (2.2)**	**12 (5.9)**	**7 (3.5)**	**4 (4.4)**	**4 (4.3)**	**15 (7.2)**	**14 (6.8)**
MACE	0	0	0	0	0	0	0	0
Embolic/thromboembolic events	0	0	0	0	0	1 (1.1)	0	0
Any malignancy	0	0	1 (0.5)	1 (0.5)	1 (1.1)	0	0	0
Serious infections	0	0	0	2 (1.0)	0	1 (1.1)	2 (1.0)	2 (1.0)
Opportunistic infections	0	0	1 (0.5)	0	0	0	1 (0.5)	0
Herpes zoster	1 (1.1)	0	0	1 (0.5)	0	2 (2.2)	3 (1.4)	2 (1.0)

† TEAEs reported after Week 12 (placebo crossovers). ‡ TEAEs reported over 24 weeks of povorcitinib treatment.
AE, adverse event; HS, hidradenitis suppurativa; MACE, major adverse cardiovascular event; PC, placebo controlled; TEAE, treatment-emergent adverse event.

Laboratory Abnormalities

Pooled STOP-HS1 and STOP-HS2

- Low rates of grade ≥3 laboratory abnormalities with 24 weeks of povorcitinib treatment



LLN, lower limit of normal; ULN, upper limit of normal.

Conclusions

- Povorcitinib demonstrated clinically meaningful superiority over placebo in patients with HS within 12 weeks, with continued improvements through Week 24
  - **Primary endpoint (HiSCR50 at Week 12) was met** in both STOP-HS1 and STOP-HS2 across both doses
  - Greater resolution of draining tunnels was observed with povorcitinib
  - Povorcitinib led to rapid reductions in skin pain
  - Flare control was observed among povorcitinib-treated patients
- Povorcitinib demonstrated deep clinical responses through Week 24, based on stringent, high-threshold clinical outcomes such as HiSCR90 and HiSCR100
- Both doses were well tolerated, with a very low frequency of laboratory abnormalities

HiSCR50/90/100, ≥50%/90%/100% decrease from baseline in abscess and inflammatory nodule count with no increase in the number of abscesses or draining tunnels; HS, hidradenitis suppurativa.

Thank You For Your Attention

- The authors wish to thank the patients and their families, the investigators, and the site personnel who participated in this study
- They also thank Chenwei Tian, PhD, Jennifer Kelley, PhD, and Kurt Brown, MD, of Incyte Corporation (Wilmington, DE, USA) for their contributions to the study

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This study was sponsored by Incyte Corporation (Wilmington, DE, USA).

Medical writing support was provided by Mitali Choudhury, PhD, of ICON (Blue Bell, PA, USA), and was funded by Incyte Corporation.