Presentation 80034

Povorcitinib in Patients With Moderate to Severe Hidradenitis Suppurativa: 54-Week Efficacy and Safety Results From the STOP-HS1 & STOP-HS2 Phase 3 Studies

Martina L. Porter, MD,[1] Antonio Martorell, MD, PhD,[2] Christopher J. Sayed, MD,[3] Falk G. Bechara, MD,[4] Hadar Lev-Tov, MD, MAS,[5] Jennifer L. Hsiao, MD,[6] John W. Frew, MBBS, MMed, MSc, PhD,[7-9] Christos C. Zouboulis, MD, PhD,[10] Joslyn S. Kirby, MD, MS, MEd,[11] Huiling Zhen, PhD,[11] Leandro L. Santos, MS[11]

[1]Harvard Medical School and Beth Israel Deaconess Medical Center, Boston, MA, USA; [2]Department of Dermatology, Hospital de Manises, Valencia, Spain; [3]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [4]ICH – International Center for Hidradenitis Suppurativa/Acne Inversa, Department of Dermatology, Venereology and Allergology, Ruhr-University Bochum, Bochum, Germany; [5]Dr. Philip Frost Department of Dermatology and Cutaneous Surgery, University of Miami, Miami, FL, USA; [6]Department of Dermatology, University of Southern California, Los Angeles, CA, USA; [7]Laboratory of Translational Cutaneous Medicine, Ingham Institute for Applied Medical Research, Liverpool, Sydney, NSW, Australia; [8]Department of Dermatology, Liverpool Hospital, Liverpool, Sydney, NSW, Australia; [9]School of Clinical Medicine, University of New South Wales, Sydney, NSW, Australia; [10]Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Neuruppin, Germany; [11]Incyte Corporation, Wilmington, DE, USA

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Presenting Author Disclosures

- Martina L. Porter has served as a consultant for AbbVie, Almirall, Arcutis, Aristea Therapeutics, Avalo Therapeutics, Eli Lilly and Company, FIDE, Incyte, Janssen, Merck, MoonLake Immunotherapeutics, Navigator Biosciences, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, Trifecta Clinical/WCG, UCB, and Zura Bio; and as an investigator for AbbVie, AnaptysBio, Arcutis, Aristea Therapeutics, Avalo Therapeutics, Bayer, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Janssen, Merck, MoonLake Immunotherapeutics, Navigator Biosciences, Novartis, OASIS Pharmaceuticals, Otsuka, Pfizer, Prometheus, Propeller Biosciences, Regeneron, Sanofi, Sonoma Biotherapeutics, UCB, and Zura Bio. She has received royalties from Beth Israel Deaconess Medical Center and fellowship funding to institution from AbbVie

Introduction

- HS is a chronic, recurrent inflammatory condition that involves multiple immune pathways and cytokines signaling through JAK1[1,2]
- Povorcitinib is an oral, highly selective JAK1 inhibitor in clinical development for inflammatory conditions, including HS[3,4]
- In the phase 3 STOP-HS1/STOP-HS2 studies, both povorcitinib doses met the primary endpoint (HiSCR50) at Week 12[5]
- All key secondary endpoints were met, for both doses, in STOP-HS2; results were numerically superior to placebo in STOP-HS1[5]

Objective: Evaluate the efficacy and safety of povorcitinib through Week 54 in the registrational phase 3 STOP-HS1/STOP-HS2 studies in patients with moderate to severe HS

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

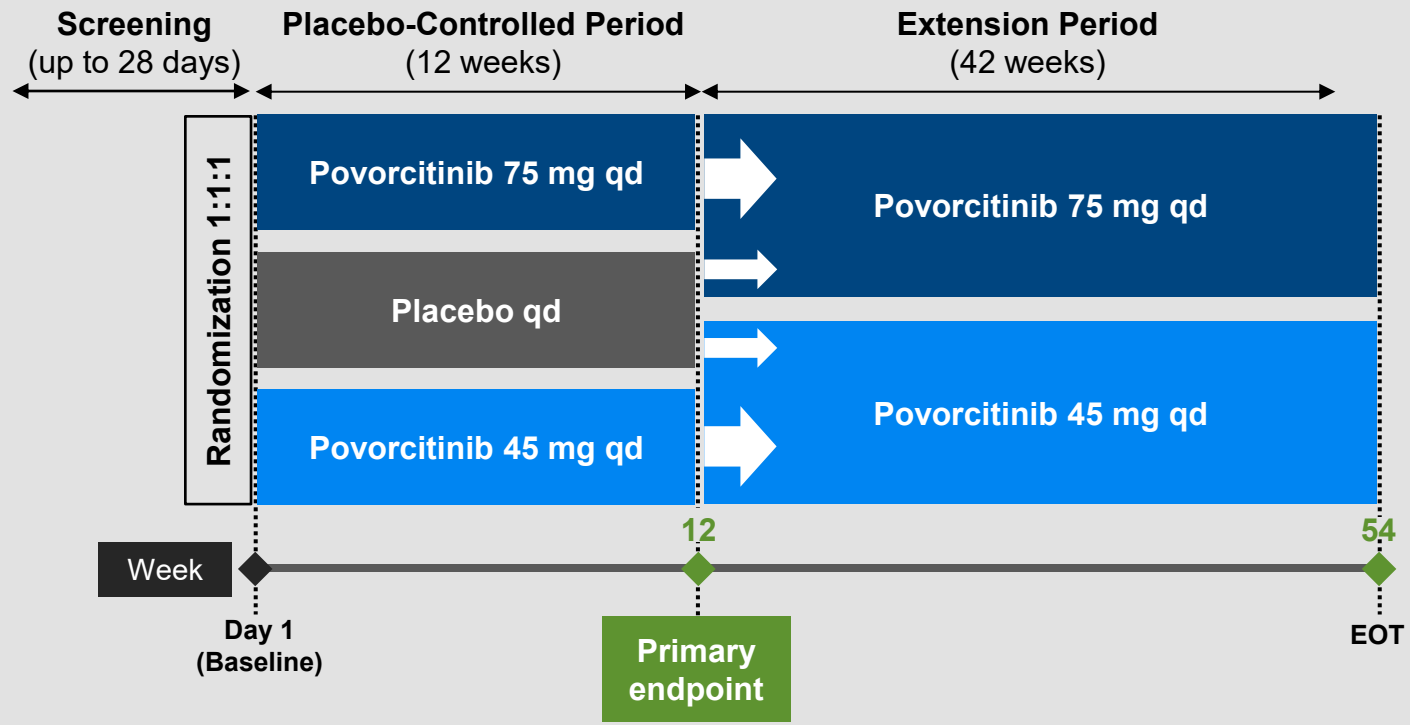
1. Sabat R, et al. *Lancet*. 2025;405:420-438. **2.** Krueger JG, et al. *Br J Dermatol.* 2024;190:149-162. **3.** Kirby JS, et al. *J Am Acad Dermatol*. 2024;90:521-529. **4.** Pandya A, et al. *J Am Acad Dermatol*. 2025;93:946-955. **5.** Porter ML, et al. Presented at: European Academy of Dermatology and Venereology Congress; 17–20 September 2025; Paris, France.

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; EOT, end of treatment; 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

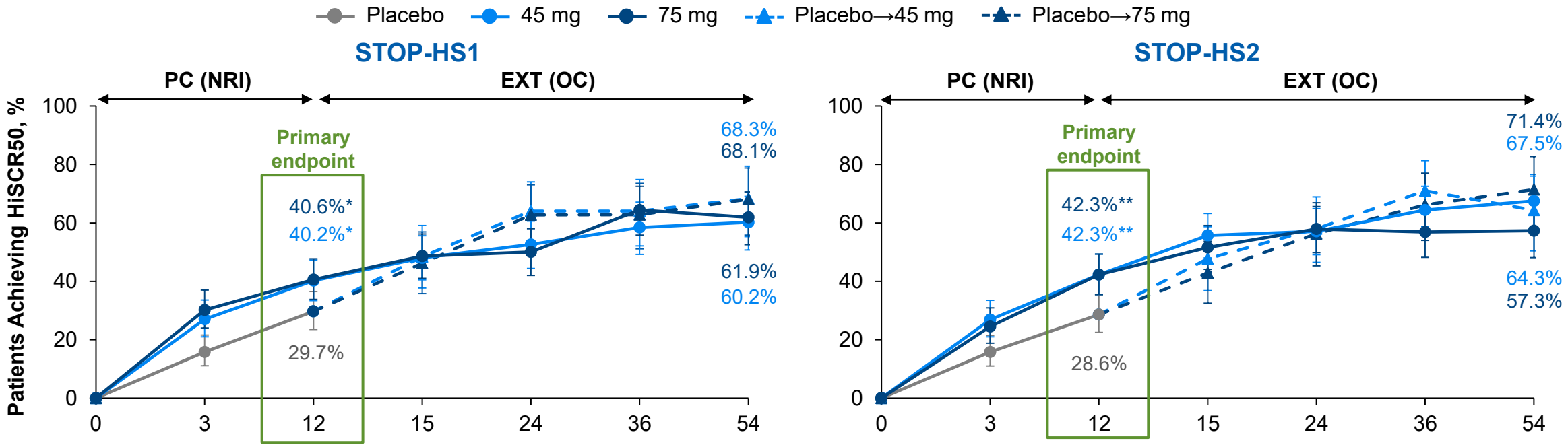
Characteristic	Overall (N=1227)	STOP-HS1 (n=608)	STOP-HS2 (n=619)
Age, median (range), y	37.0 (18–77)	37.0 (18–77)	37.0 (18–70)
Female, n (%)	770 (62.8)	403 (66.3)	367 (59.3)
Race, n (%): White / Black	915 (74.6) / 174 (14.2)	438 (72.0) / 98 (16.1)	477 (77.1) / 76 (12.3)
BMI, mean (SD), kg/m^2	34.0 (8.6)	34.6 (8.9)	33.4 (8.3)
BMI ≥40 kg/m^2, n (%)	269 (21.9)	148 (24.3)	121 (19.5)
Current smoker, n (%)	580 (47.3)	297 (48.8)	283 (45.7)
Disease duration, mean (SD), y	10.3 (9.4)	10.5 (9.4)	10.0 (9.3)
Hurley stage, n (%): II / III	796 (64.9) / 431 (35.1)	373 (61.3) / 235 (38.7)	423 (68.3) / 196 (31.7)
AN count, mean (SD)	12.0 (8.8)	12.5 (9.3)	11.6 (8.2)
dT count, mean (SD)	2.8 (3.3)	2.9 (3.5)	2.7 (3.2)
≥1 dT, n (%)	926 (75.5)	458 (75.3)	468 (75.6)
Prior biologic use, n (%)	457 (37.2)	218 (35.9)	239 (38.6)
Prior HS excision surgery, n (%)	256 (20.9)	121 (19.9)	135 (21.8)
FACIT-F score, mean (SD)	31.3 (12.1)	31.4 (12.2)	31.1 (12.0)
DLQI score, mean (SD)	12.9 (7.3)	12.8 (7.4)	13.1 (7.2)
HiSQoL score, mean (SD)	31.7 (14.7)	31.4 (15.0)	31.9 (14.3)
Skin Pain NRS, mean (SD)	5.0 (2.5)	5.1 (2.5)	5.0 (2.5)

FACIT-F total score ranges from 0–52, with higher scores indicating less fatigue and better QoL. DLQI scores range from 0–30, HiSQoL from 0–68, and Skin Pain NRS from 0–10, with higher scores indicating greater negative impact on QoL.

AN, abscess and inflammatory nodule; BMI, body mass index; DLQI, Dermatology Life Quality Index; dT, draining tunnel; FACIT-F, Functional Assessment of Chronic Illness Therapy–Fatigue; HiSQoL, Hidradenitis Suppurativa Quality of Life; HS, hidradenitis suppurativa; NRS, numerical rating scale; QoL, quality of life.

HiSCR50 Responses Improved Through Week 54

- The HiSCR50 primary endpoint at Week 12 was statistically significant vs placebo for both povorcitinib doses in both studies, with continuous improvement through Week 54



Patients, n							
PBO	202	202	202	--	--	--	--
45 mg	204	204	204	179	156	125	118
75 mg	202	202	202	177	158	135	118
PBO→45 mg	--	--	--	91	86	75	63
PBO→75 mg	--	--	--	93	83	78	69

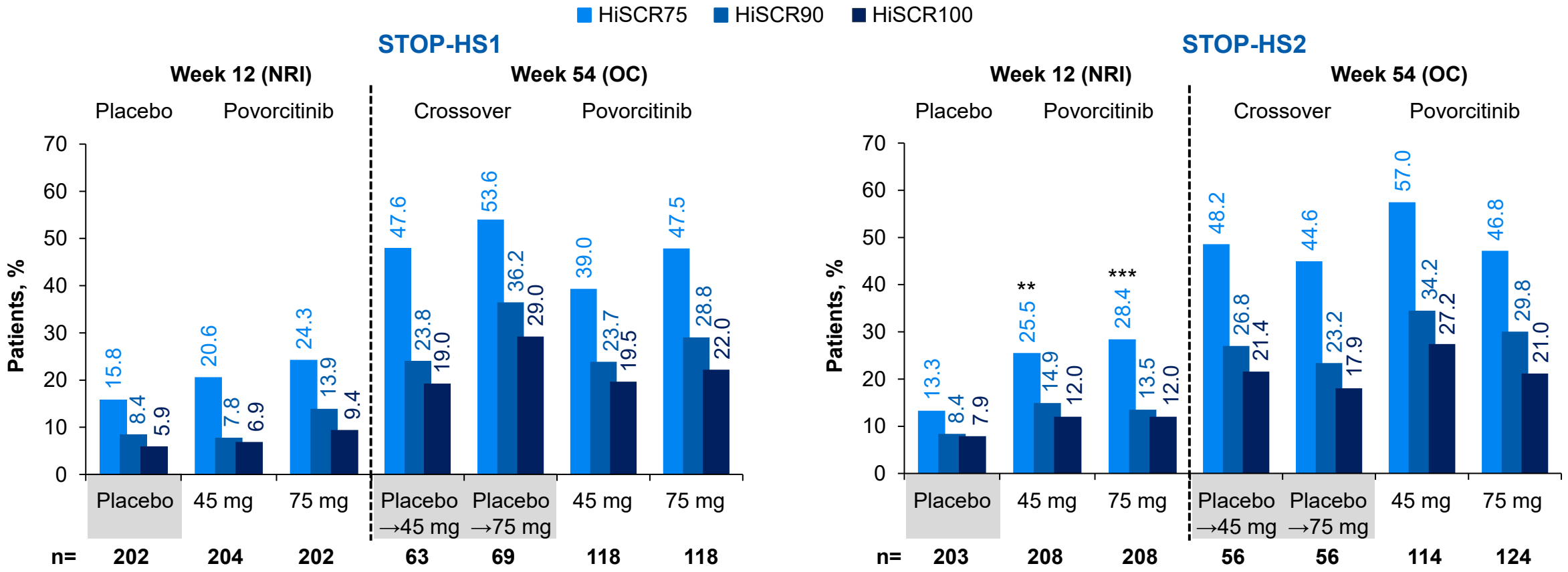
PBO	203	203	203	--	--	--	--
45 mg	208	208	208	176	161	135	114
75 mg	208	208	208	182	159	137	124
PBO→45 mg	--	--	--	86	81	69	56
PBO→75 mg	--	--	--	91	87	71	56

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

EXT, extension; 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; PBO, placebo; PC, placebo-controlled.

Povorcitinib Achieved High-Threshold HiSCR Responses

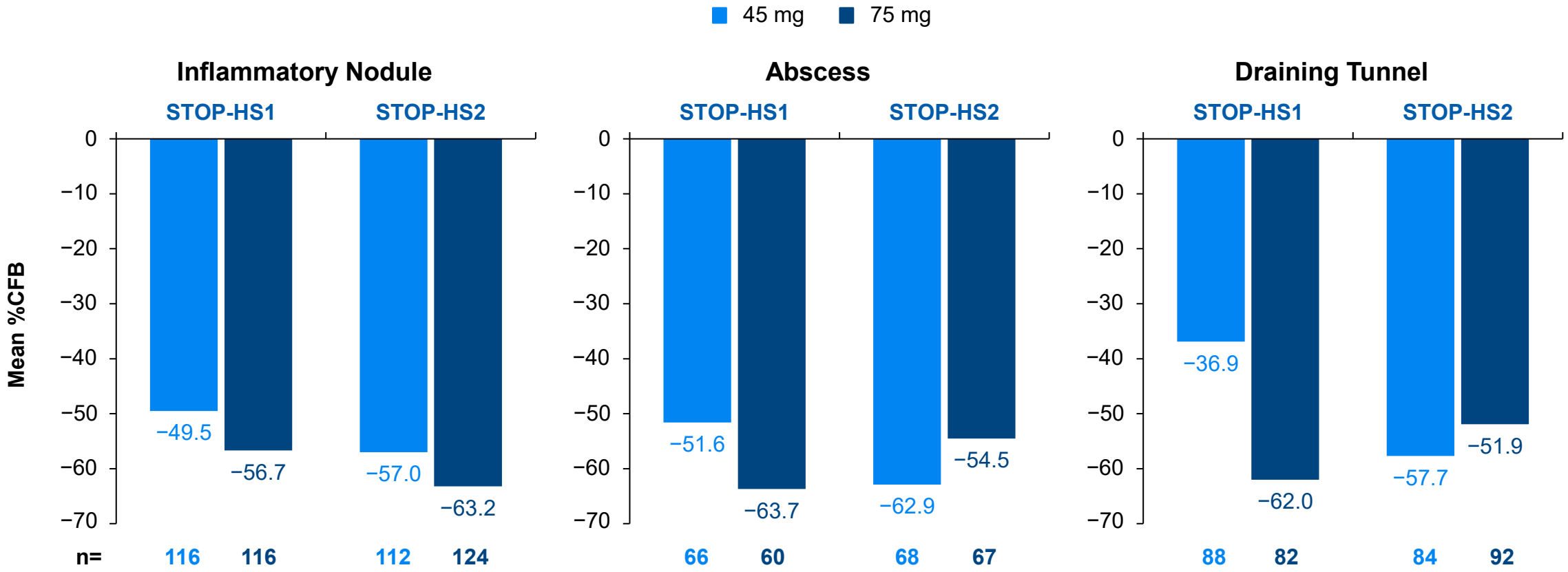
- Increase in high-threshold HiSCR responses was observed, with up to 29.0% of povorcitinib-treated patients achieving HiSCR100 at Week 54



** *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 Consistently Decreased Lesion Counts at Week 54

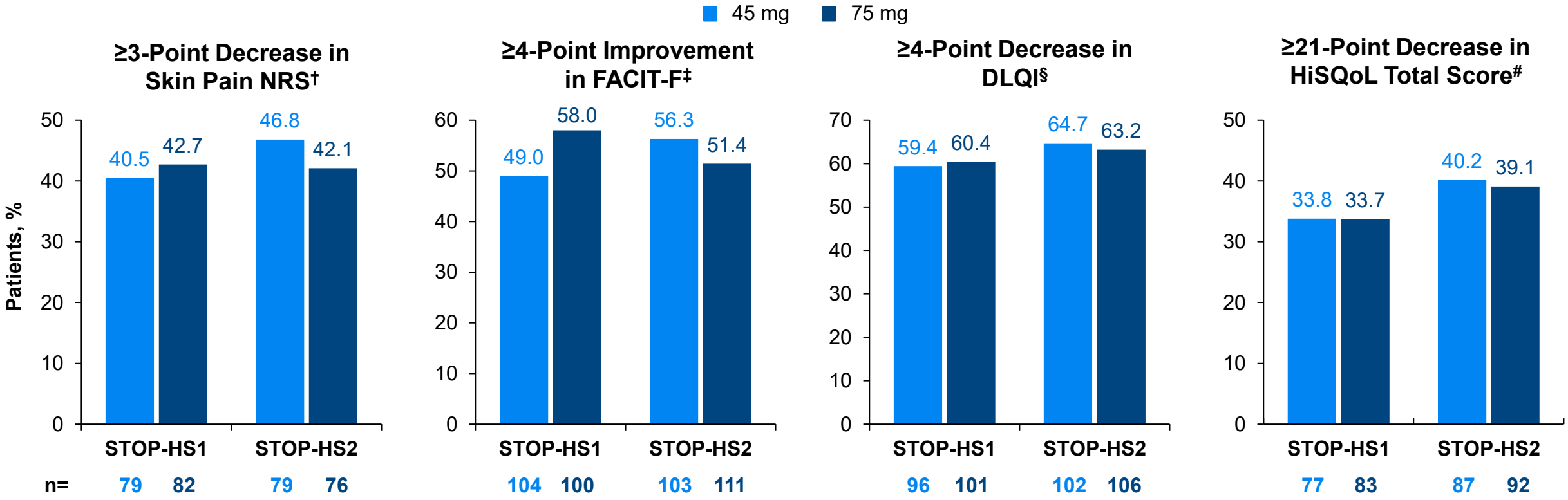
- Across both studies, full clearance of inflammatory lesions (ANdT=0) was achieved in 16.1%–20.2% of patients, with improvements observed in all lesion types through Week 54



Analyses were based on observed values.
A, abscess; CFB, change from baseline; dT, draining tunnel; N, inflammatory nodule.

Patient-Reported Outcomes at Week 54

- A high percentage of patients achieved clinically meaningful improvements in several measures of QoL



Analyses were based on observed values. † Assessed in patients with baseline Skin Pain NRS score ≥3. ‡ Assessed in patients with baseline FACIT-F score ≤48. § Assessed in patients with baseline DLQI total score ≥4. # Assessed in patients with baseline HiSQoL total score ≥21.

DLQI, Dermatology Life Quality Index; FACIT-F, Functional Assessment of Chronic Illness Therapy−Fatigue; HiSQoL, Hidradenitis Suppurativa Quality of Life; HS, hidradenitis suppurativa; NRS, numerical rating scale; QoL, quality of life.

Safety Summary: Povorcitinib-Treated (Up to Week 54)

Patients, n (%)	STOP-HS1		STOP-HS2	
	Povorcitinib 45 mg n=296†	Povorcitinib 75 mg n=295‡	Povorcitinib 45 mg n=298†	Povorcitinib 75 mg n=299‡
Any TEAE	**232 (78.4)**	**246 (83.4)**	**227 (76.2)**	**242 (80.9)**
Treatment-related TEAE	116 (39.2)	141 (47.8)	110 (36.9)	144 (48.2)
Serious TEAE	11 (3.7)	19 (6.4)	19 (6.4)	19 (6.4)
Grade ≥3 TEAE	16 (5.4)	22 (7.5)	23 (7.7)	24 (8.0)
Fatal TEAE	1 (0.3)§	0	0	0
TEAE leading to discontinuation	23 (7.8)	18 (6.1)	26 (8.7)	28 (9.4)
Most frequent TEAEs#				
Acne	50 (16.9)	56 (19.0)	49 (16.4)	63 (21.1)
Nasopharyngitis	33 (11.1)	40 (13.6)	28 (9.4)	32 (10.7)
URTI	36 (12.2)	28 (9.5)	27 (9.1)	33 (11.0)
AEs of special interest	**24 (8.1)**	**25 (8.5)**	**33 (11.1)**	**33 (11.0)**
MACE	0	0	1 (0.3)	0
Other embolic/thromboembolic events	1 (0.3)	1 (0.3)	1 (0.3)	2 (0.7)
DVT/PE	1 (0.3)	0	0	2 (0.7)
Malignancy, excluding NMSC	0	0	0	0
NMSC	2 (0.7)	1 (0.3)	2 (0.7)	0
Serious infections	2 (0.7)	5 (1.7)	4 (1.3)	7 (2.3)
Opportunistic infections	2 (0.7)	1 (0.3)	3 (1.0)	0
Herpes zoster	5 (1.7)	6 (2.0)	6 (2.0)	6 (2.0)

† Includes patients receiving povorcitinib 45 mg from Day 1 and those who crossed over from placebo to 45 mg at Week 12. ‡ Includes patients receiving povorcitinib 75 mg from Day 1 and those who crossed over from placebo to 75 mg at Week 12. § 1 death (treatment-unrelated) was reported in the placebo to povorcitinib crossover group. # Top 3 most frequent TEAEs in any of the povorcitinib-randomized groups.

AE, adverse event; DVT, deep vein thrombosis; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PE, pulmonary embolism; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.

TEAEs Associated With Laboratory Parameters: PC Period and Povorcitinib-Treated (Up to Week 54)

	PC Period, POOLED (up to 12 weeks)			PC+EXT Periods, POOLED (up to 54 weeks)	
Patients, n (%)	Placebo n=405	Povorcitinib 45 mg n=412	Povorcitinib 75 mg n=409	Povorcitinib 45 mg n=594†	Povorcitinib 75 mg n=594‡
Anemia*	2 (0.5)	6 (1.5)	1 (0.2)	23 (3.9)	27 (4.5)
Lymphopenia	0	0	0	0	2 (0.3)
Neutropenia	0	0	1 (0.2)	1 (0.2)	1 (0.2)
Thrombocytopenia	0	0	4 (1.0)	0	7 (1.2)
Hyperlipidemia*	11 (2.7)	13 (3.2)	10 (2.4)	27 (4.5)	24 (4.0)
Alanine aminotransferase increased	0	4 (1.0)	3 (0.7)	10 (1.7)	17 (2.9)
Aspartate aminotransferase increased	0	3 (0.7)	3 (0.7)	4 (0.7)	10 (1.7)
Blood CPK increased	3 (0.7)	13 (3.2)	11 (2.7)	27 (4.5)	27 (4.5)
Myositis	0	0	0	0	0
Rhabdomyolysis	0	0	0	0	0

* Anemia and hyperlipidemia represent grouped preferred terms (PTs); other TEAEs are reported as unique PTs. † Includes patients receiving povorcitinib 45 mg from Day 1 and those who crossed over from placebo to 45 mg at Week 12. ‡ Includes patients receiving povorcitinib 75 mg from Day 1 and those who crossed over from placebo to 75 mg at Week 12.

CPK, creatine phosphokinase; EXT, extension double-blinded period; PC, placebo-controlled double-blinded period; TEAE, treatment-emergent adverse event.

Conclusions

- Povorcitinib demonstrated substantial clinical efficacy in moderate to severe HS through Week 54
  - Patients treated with povorcitinib achieved high levels of response across HiSCR thresholds at Week 54, with up to 29% achieving HiSCR100
  - Consistent resolution of inflammatory nodules (N), abscesses (A), and draining tunnels (dT) was observed with povorcitinib
  - Up to 20% of patients achieved complete inflammatory lesion resolution (ANdT=0)
  - Povorcitinib led to meaningful improvements in skin pain, fatigue, and QoL
- Both doses of povorcitinib were generally well tolerated through 54 weeks of treatment
- These data support the potential of oral povorcitinib for the treatment of moderate to severe HS

HiSCR, Hidradenitis Suppurativa Clinical Response; HS, hidradenitis suppurativa; QoL, quality of life.

Thank You For Your Attention

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