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Impact of Povorcitinib on DLQI and DLQI Subdomains in Patients With Hidradenitis Suppurativa: Results From a Randomized, Placebo-Controlled Phase 2 Study

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Background

- HS is a chronic, debilitating, inflammatory condition that has a profound negative impact on multiple aspects of patients' QoL[1-3]
- DLQI is a validated, self-reported questionnaire used to measure the impact of dermatologic conditions on patients' QoL[4]
- Povorcitinib is an oral, small-molecule, selective JAK 1 inhibitor[5]
- Povorcitinib demonstrated dose-dependent efficacy in patients with HS at Week 16 in a randomized, placebo-controlled, phase 2 dose-ranging study[6-8]

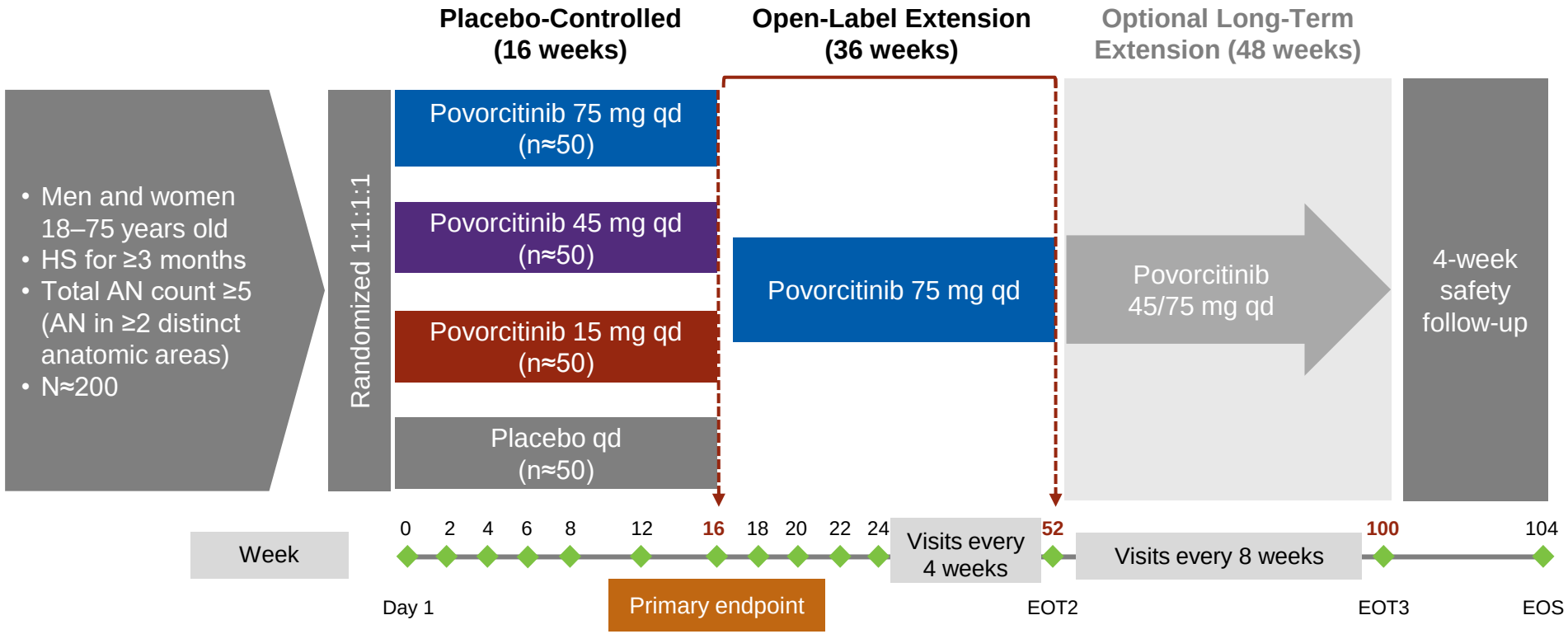
Objective: To determine the impact of povorcitinib on QoL based on improvements in DLQI scores in patients with HS from the phase 2, dose-ranging study

DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; JAK, Janus kinase; QoL, quality of life.

1. Sabat R, et al. *Nat Rev Dis Primers*. 2020;6(1):18. **2.** Matusiak Ł. *Br J Dermatol*. 2020;183(6):e171-e177. **3.** van Straalen KR, et al. *J Allergy Clin Immunol*. 2022;149(4):1150-1161. **4.** Basra MK, et al. *Dermatology*. 2015;230(1):27-33. **5.** Alavi A, et al. *Br J Dermatol*. 2022;186(5):803-813. **6.** Kirby JS, et al. P0004. Presented at: 31st Annual European Academy of Dermatology and Venereology Congress (EADV); September 7-10, 2022; Milan, Italy and online. **7.** Kirby JS, et al. P0005. Presented at: 31st Annual European Academy of Dermatology and Venereology Congress (EADV); September 7-10, 2022; Milan, Italy and online. **8.** Kirby JS, et al. P0006. Presented at: 31st Annual European Academy of Dermatology and Venereology Congress (EADV); September 7-10, 2022; Milan, Italy and online.

Study Design

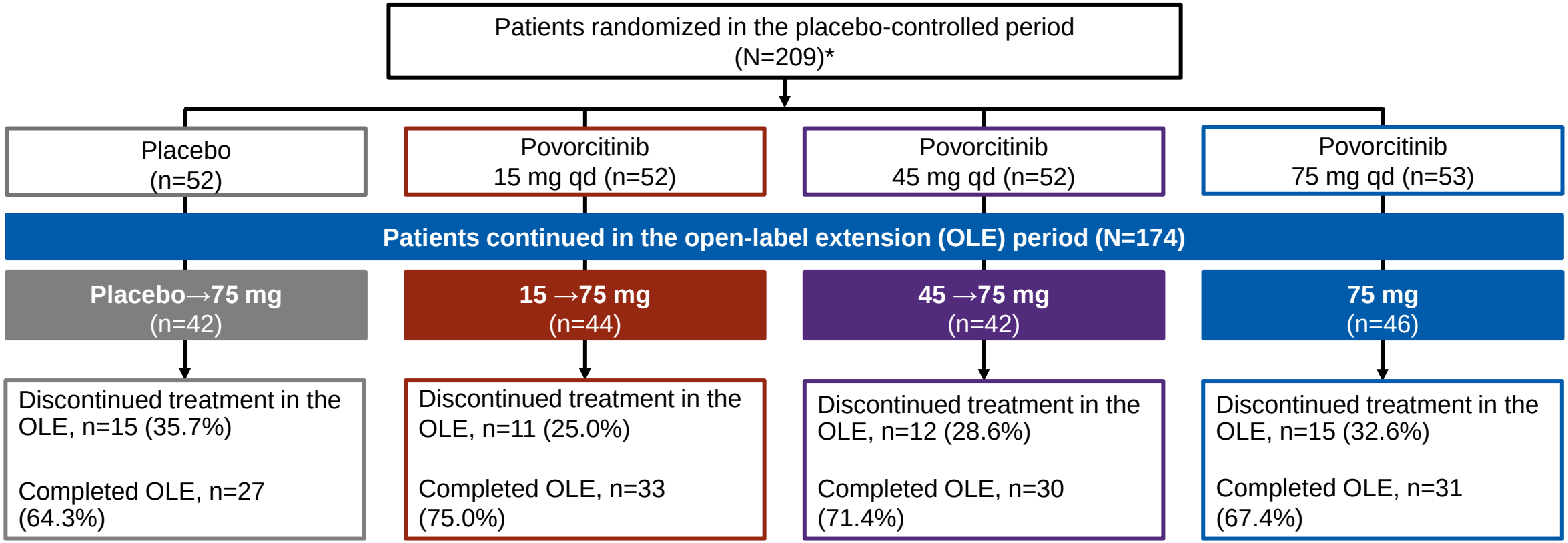
Trial Identifiers: NCT04476043; EudraCT 2020-001981-13



- DLQI was evaluated at baseline (Day 1) and Weeks 4, 8, 16, 24, 32, and 52
- The open-label extension and long-term extension periods were designed to further evaluate the effects of povorcitinib with longer-term use

AN, abscess and inflammatory nodule; DLQI, Dermatology Life Quality Index; EOS, end of study; EOT, end of treatment; HS, hidradenitis suppurativa; qd, once daily.

Patient Disposition



- At the end of the OLE period, 69.5% (n=121) of patients who started the OLE completed the full 36 weeks of additional treatment

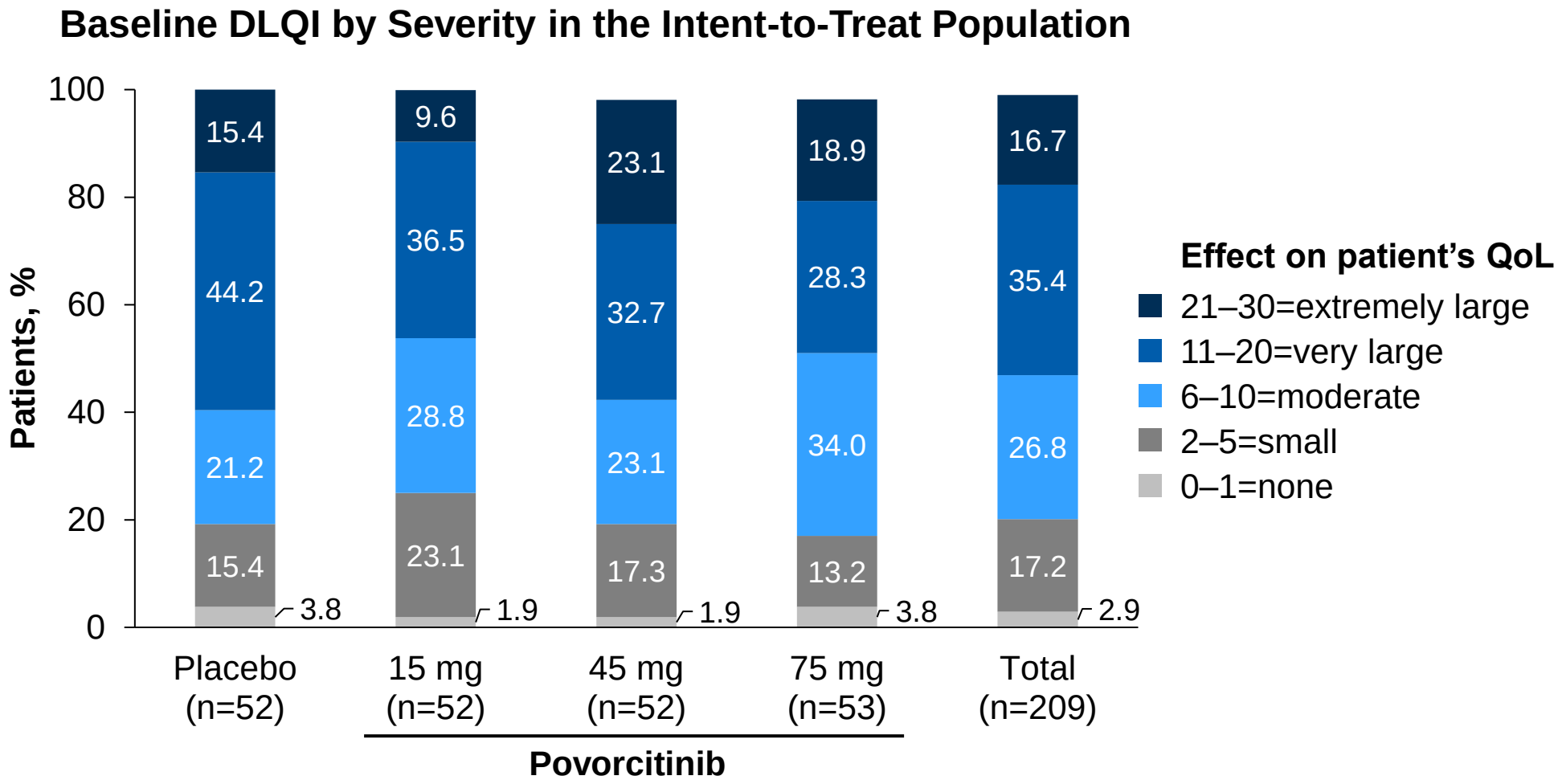
* 2 patients were randomized but did not receive treatment.
qd, once daily.

Day 1 Baseline Demographic and Clinical Characteristics (Placebo-Controlled Population)

Characteristic	Placebo (n=52)	Povorcitinib 15 mg (n=52)	Povorcitinib 45 mg (n=52)	Povorcitinib 75 mg (n=53)	Total (N=209)
Age, mean (SD), y	35.2 (10.0)	38.2 (10.9)	37.3 (12.5)	37.5 (10.8)	37.1 (11.1)
Women, n (%)	43 (82.7)	37 (71.2)	39 (75.0)	39 (73.6)	158 (75.6)
Race, n (%)					
White	40 (76.9)	36 (69.2)	35 (67.3)	36 (67.9)	147 (70.3)
Black	10 (19.2)	13 (25.0)	12 (23.1)	16 (30.2)	51 (24.4)
Other	2 (3.8)	3 (5.8)	5 (9.6)	1 (1.9)	11 (5.3)
HS duration, mean (SD), y	8.1 (6.5)	9.9 (8.1)	11.2 (11.5)	12.1 (9.7)	10.3 (9.2)
BMI, mean (SD), kg/m^2	34.1 (9.0)	35.0 (8.1)	36.8 (9.6)	37.1 (8.6)	35.7 (8.9)
Hurley stage, n (%)					
I	4 (7.7)	3 (5.8)	4 (7.7)	4 (7.5)	15 (7.2)
II	36 (69.2)	37 (71.2)	36 (69.2)	37 (69.8)	146 (69.9)
III	12 (23.1)	12 (23.1)	12 (23.1)	12 (22.6)	48 (23.0)
AN count, mean (SD)	11.2 (5.9)	11.8 (7.1)	12.9 (12.3)	10.6 (7.2)	11.6 (8.5)
Draining tunnel count, mean (SD)	2.4 (4.0)	2.3 (4.4)	2.2 (4.0)	1.6 (2.9)	2.1 (3.9)
DLQI total score [range, 0–30; higher=more impaired], mean (SD)	12.7 (7.3)	11.2 (7.1)	13.0 (7.6)	12.1 (7.3)	12.2 (7.3)
Previous biologic treatment, n (%)	12 (23.1)	12 (23.1)	17 (32.7)	9 (17.0)	50 (23.9)

AN, abscess and inflammatory nodule; BMI, body mass index; DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa.

Day 1 Baseline DLQI (Placebo-Controlled Population)

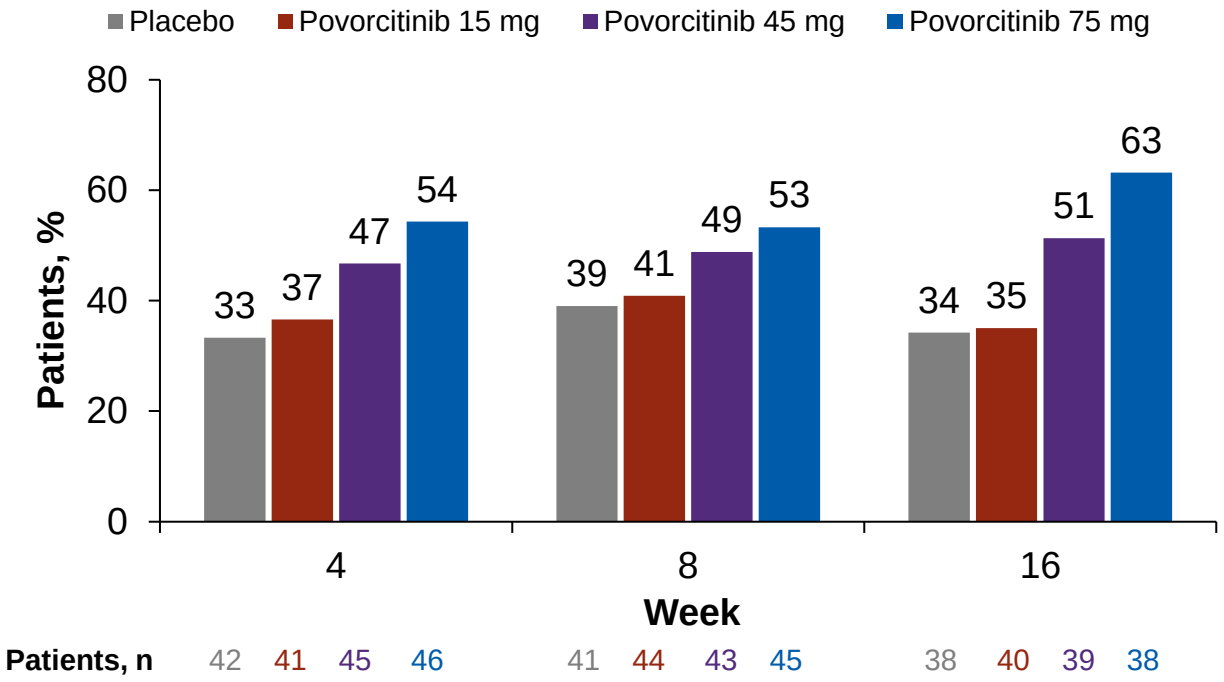


- Median (range) DLQI baseline total score in the overall population was 11.0 (0–30.0), indicating that HS had a "very large" or "extremely large" effect on QoL for most patients

DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; QoL, quality of life.

Improvement in DLQI (Placebo-Controlled Period)

Percentage of Patients With ≥4-Point Decrease From Baseline in Total DLQI Score (MCID)*



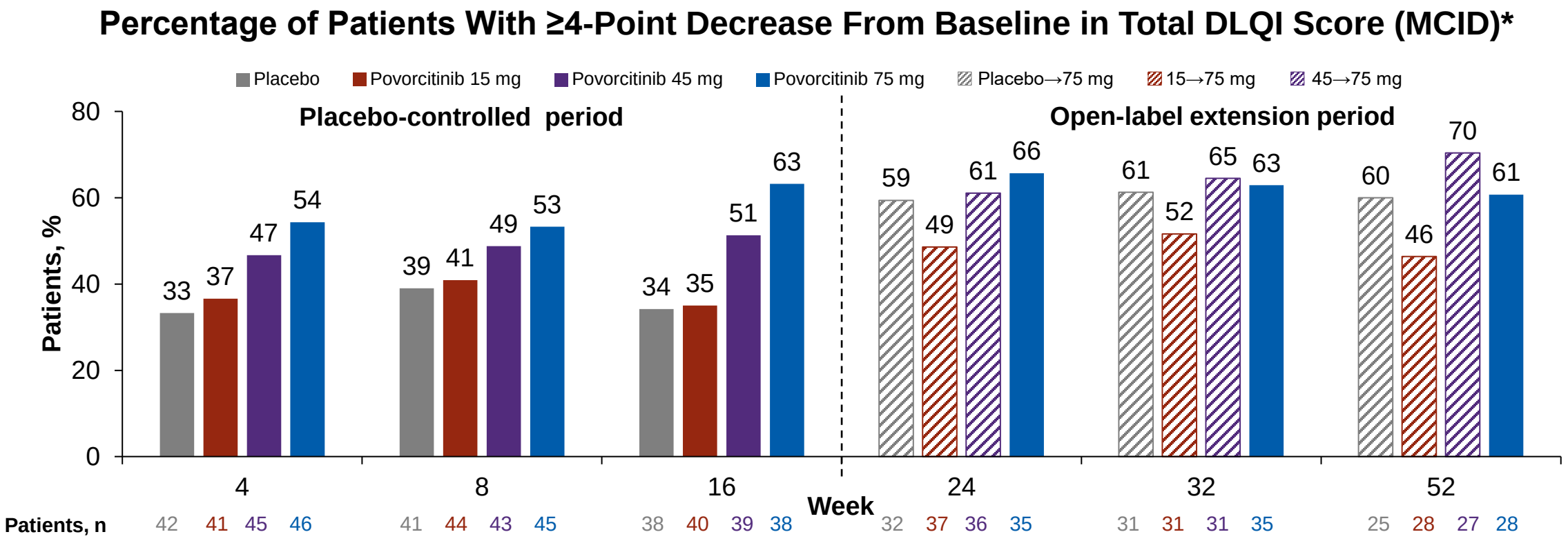
Change in DLQI Total Score*

		Povorcitinib		
	Placebo	15 mg	45 mg	75 mg
DLQI Week 4				
Mean (SD) change	−1 (5.4)	−1.9 (5.1)	−3.8 (6.7)	−4.3 (6.8)
Mean (SD) % change	2.7 (59.7)	−15.9 (41.2)	−16.9 (46.1)	−26.2 (51.0)
DLQI Week 16				
Mean (SD) change	−1.3 (5.0)	−2.3 (5.6)	−4.3 (7.1)	−4.6 (8.3)
Mean (SD) % change	−6.8 (45.3)	−17.2 (43.3)	−18 (71.0)	−27.3 (65.6)

- Rates of DLQI MCID at Week 16 were dose dependent, with superior responses for povorcitinib 75 mg (63.2%) or 45 mg (51.3%) vs povorcitinib 15 mg (35.0%) or placebo (34.2%)
- Improvements in DLQI at the 75-mg dose were already apparent at Week 4 and maintained at Week 16

DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; MCID, minimal clinically important difference.
* Intent-to-treat population with a baseline DLQI total score ≥4. Data reported as observed; nonresponder imputation was not used for the analysis of DLQI MCID.

Improvement in DLQI (Placebo-Controlled and Open-Label Extension Period)

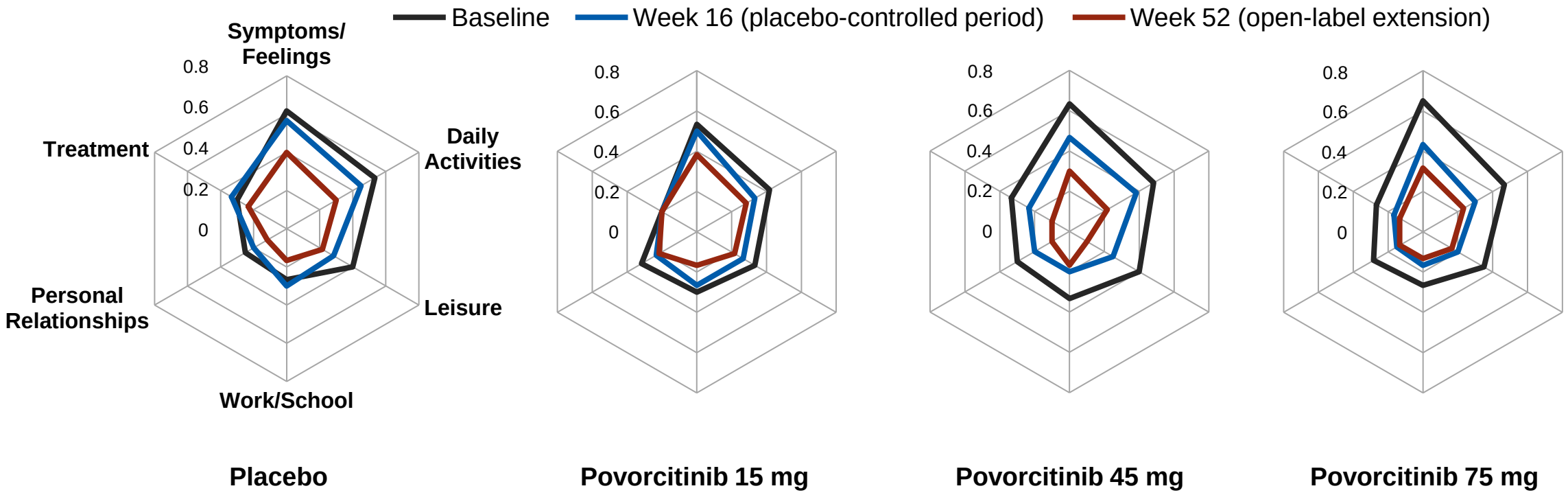


- Early and substantial improvement in DLQI was observed in the placebo→75 mg group, with 60.0% of patients achieving MCID at Week 52
- A large percentage of crossover patients achieved MCID in DLQI during the OLE, with improvements remaining relatively constant over time

DLQI, Dermatology Life Quality Index; MCID, minimal clinically important difference; OLE, open-label extension.
* Intent-to-treat population with a baseline DLQI total score ≥4. Data reported as observed; nonresponder imputation was not used for the analysis of DLQI MCID.

Improvement in DLQI Subdomains

Spider Plot of Mean Scores* in DLQI Subdomains Based on Original Randomization Treatment Groups



- At Week 16, improvements were seen in each of the 6 DLQI subdomain scores in the povorcitinib groups vs placebo; Treatment, Work/School, and Personal Relations subdomains had the highest-magnitude improvements
- Continued improvements in all DLQI subdomain scores were observed in the OLE and were maintained through Week 52

DLQI, Dermatology Life Quality Index; OLE, open-label extension.
* Higher scores=more impaired quality of life. To facilitate direct comparison across the 6 DLQI subdomains, the scale was unified to 0–1. To alter the scale for each of the Symptoms/Feelings, Daily Activities, Leisure, and Personal Relationships subdomains, the score was divided by 6 (the maximum possible score), and for each of the Work/School performance and Treatment subdomains, the score was divided by 3 (the maximum possible score).

Authors' Conclusions

- Most patients enrolled in this phase 2 study had a DLQI baseline score representative of "very large" or "extremely large" impairment in QoL
- More patients in daily povorcitinib 45-mg and 75-mg groups achieved clinically meaningful improvement in DLQI vs placebo through 16 weeks of randomized treatment
- A large proportion of patients randomized to placebo achieved improvements in DLQI after crossing over to povorcitinib 75 mg in the OLE period
- Povorcitinib treatment was associated with early, dose-proportional, and sustained improvements in total DLQI and in each DLQI subdomain
- Povorcitinib has the potential to provide clinically meaningful and sustained improvements in QoL among patients with HS

DLQI, Dermatology Life Quality Index; HS, hidradenitis suppurativa; OLE, open-label extension; QoL, quality of life.