

Effects of the Janus Kinase 1 Inhibitor Povorcitinib (INCB054707) on Patient-Reported Quality of Life in Hidradenitis Suppurativa: Results From a Randomized, Placebo-Controlled, Phase 2 Dose-Ranging Study

Joslyn S. Kirby, MD, MS, MEd,^{1*} Martin M. Okun, MD, PhD,² Afsaneh Alavi, MD,³ Falk G. Bechara, MD,⁴ Christos C. Zouboulis, MD, PhD,⁵ Kurt Brown, MD,⁶ Leandro L. Santos, MS,⁶ Annie Wang, PhD,⁶ Alexa B. Kimball, MD,⁷ Martina L. Porter, MD,⁷ Kristen Bibeau, PhD, MSPH⁶

¹Penn State Health Milton S. Hershey Medical Center, Hershey, PA, USA; ²Fort Memorial Hospital, Fort Atkinson, WI, USA; ³Mayo Clinic, Rochester, MN, USA; ⁴Ruhr-University Bochum, Bochum, Germany; ⁵Dessau Medical Center, Brandenburg Medical School Theodor Fontane, Dessau, Germany; ⁶Incyte Corporation, Wilmington, DE, USA; ⁷Harvard Medical School and Beth Israel Deaconess Medical Center, Boston, MA, USA

*Presenting author

Background

- Hidradenitis suppurativa (HS) is a chronic, debilitating inflammatory condition characterized by painful nodules and abscesses that can lead to tunnels and scarring¹
- HS has a profound negative impact on patients’ quality of life (QoL), including psychosocial components^{2,3}
 - Patients with HS have high rates of depression, anxiety, and fatigue^{4,5}
- Dysregulation of the Janus kinase (JAK)/signal transducer and activator of transcription (STAT) pathway is involved in a wide variety of inflammatory disorders, including HS
- Povorcitinib (INCB054707) is an oral, JAK1-selective, small-molecule inhibitor that demonstrated proof of concept over 8 weeks of treatment in two phase 2 studies in moderate to severe HS; doses of 30 mg, 60 mg, and 90 mg were generally well tolerated, with no serious adverse events

Objective

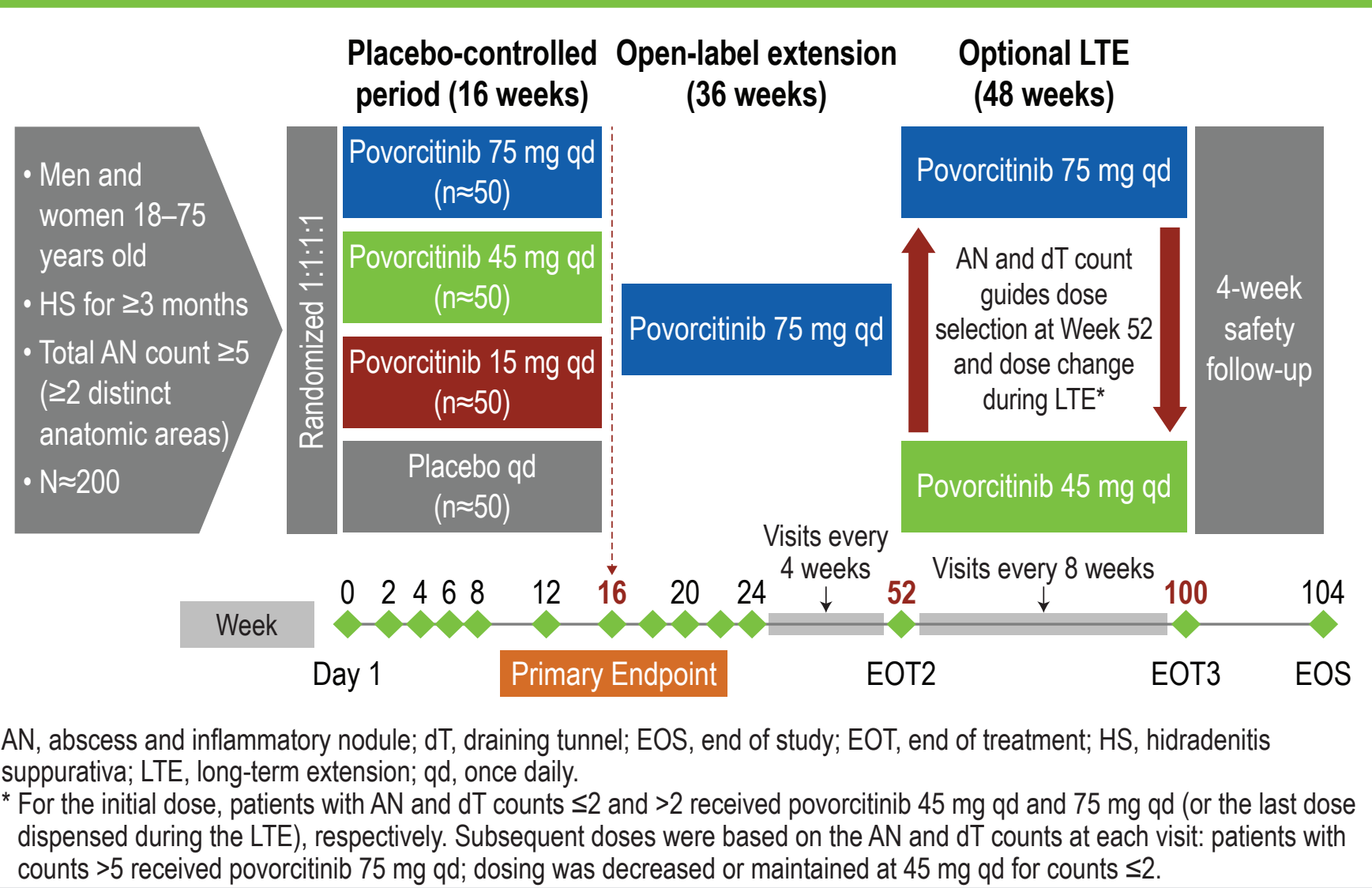
- To describe the effects of povorcitinib on selected patient-reported QoL assessments in a randomized, placebo-controlled, phase 2 dose-ranging study of povorcitinib over 16 weeks of treatment (NCT04476043; EudraCT 2020-001981-13)

Methods

Patients and Study Design

- Eligible patients were men and women aged 18–75 years, with HS (Hurley stage I, II, or III) for ≥3 months before screening (**Figure 1**)
 - Diagnosis of HS was defined as total abscess and inflammatory nodule count ≥5 in ≥2 distinct anatomic areas at screening and baseline
- Patients were excluded if they had >20 draining tunnels, decreased blood cell counts at screening (leukocytes <3.0 × 10⁹/L, absolute neutrophil count <1.5 × 10⁹/L, lymphocytes <0.8 × 10⁹/L, hemoglobin <9 g/dL, or platelet count <150 × 10⁹/L), had previously failed to respond to any JAK inhibitor, or had used immunomodulating biologic drugs within 12 weeks (or 5 half-lives)
- Patients were randomized (1:1:1:1) to receive 1 of 3 doses of povorcitinib (15, 45, or 75 mg) or placebo once daily for 16 weeks of double-blind treatment

Figure 1. Study Design



Endpoints and Assessments

- QoL was assessed using the following patient-reported outcomes:
 - Hidradenitis Suppurativa Quality of Life (HiSQoL), a 17-item HS-specific instrument with a total score range from 0–68, assessing disease symptoms and impact on QoL over a 7-day recall period; higher scores indicate greater QoL impairment^{6,7}
 - Dermatology Life Quality Index (DLQI), a 10-question dermatology-specific instrument with a total score range from 0–30, assessing the extent to which disease symptoms and treatments affect QoL over a 7-day recall period; higher scores indicate greater QoL impairment
 - DLQI scores >10 indicate that HS has moderate to very large effects on patients’ lives

- Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F), a 13-item questionnaire with a total score ranging from 0–52, assessing disease-associated fatigue over the past 7 days, with lower scores indicating more fatigue
- Mean change from baseline in all 3 scores and the percentage of patients achieving a minimal clinically important difference (≥4-point) improvement in total DLQI⁸ and FACIT-F⁹ scores were assessed at Weeks 4, 8, and 16

Statistical Analysis

- All analyses are presented through 16 weeks of placebo-controlled, double-blind treatment
- All randomized patients were included in the intent-to-treat population, which was used for all patient-reported outcomes
- All patient-reported outcomes were summarized using descriptive statistics

Results

Patients

- In total, 209 patients were randomized (placebo, n=52; povorcitinib, n=157 [15 mg, n=52; 45 mg, n=52; 75 mg, n=53]; **Table 1**); baseline demographics and clinical characteristics were typical for patients with HS¹⁰
 - Median (range) age was 36 (19–70) years
 - Median (range) body mass index was 35.0 (19.8–66.6) kg/m²
 - 81.8% of patients were from North America
 - 75.6% were women
 - 70.3% were White, 24.4% were Black/African American, and 2.9% were Asian
- At baseline, 69.9% of patients were Hurley stage II, and 23.0% were Hurley stage III
 - Median (range) disease duration was 7.2 (0.1–48.4) years
 - Baseline HiSQoL, DLQI, and FACIT-F scores were generally balanced across treatment groups (range of medians across 4 groups: HiSQoL, 25.5–32.0; DLQI, 10.0–13.0; FACIT-F, 31.5–36.5)

HiSQoL

- At Week 16, mean (SD) HiSQoL score change from baseline was –4.0 (12.3), –9.1 (15.2), and –8.3 (17.9) for 15, 45, and 75 mg povorcitinib, respectively, vs –4.0 (14.0) for placebo (**Figure 2**)
 - Decreases from baseline were observed for all HiSQoL subscores

DLQI

- At Week 16, mean (SD) DLQI score change from baseline was –2.0 (5.3), –4.0 (6.9), and –3.7 (8.3) for 15, 45, and 75 mg povorcitinib, respectively, vs –1.2 (4.8) for placebo (**Figure 3A**)
- Among patients treated with 15, 45, and 75 mg povorcitinib, 14 (31.1%), 20 (46.5%), and 24 (55.8%), respectively, achieved a ≥4-point improvement from baseline in total DLQI at Week 16 vs 13 (31.0%) for placebo (**Figure 3B**)

FACIT-F

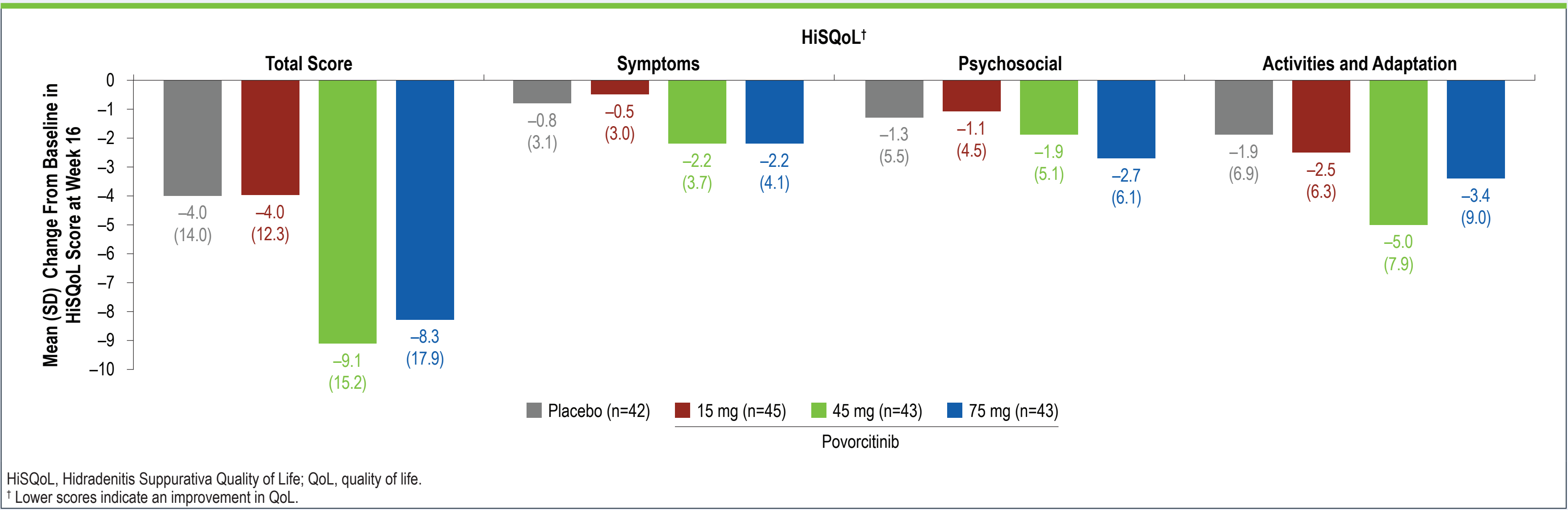
- Dose-dependent improvements from baseline in FACIT-F score were observed with povorcitinib at Week 16 (mean [SD] change from baseline, 15 mg, 0.7 [9.9]; 45 mg, 1.9 [9.1]; 75 mg, 4.7 [12.0] vs 0.7 [9.4] for placebo; **Figure 4A**)
- Among patients treated with 15, 45, and 75 mg povorcitinib, 12 (26.7%), 22 (51.2%), and 20 (46.5%), respectively, achieved a ≥4-point improvement from baseline in FACIT-F score at Week 16 vs 13 (31.0%) for placebo (**Figure 4B**)
- Among patients who had a baseline FACIT-F score <30, of those treated with 15, 45, and 75 mg povorcitinib, 5 (55.6%), 12 (66.7%), and 14 (73.7%), respectively, achieved a ≥4-point improvement from baseline in FACIT-F score at Week 16 vs 7 (38.9%) for placebo

Table 1. Patient Demographics and Baseline Clinical Characteristics

Characteristic	Placebo (n=52)	Povorcitinib 15 mg (n=52)	Povorcitinib 45 mg (n=52)	Povorcitinib 75 mg (n=53)	Total (N=209)
Age, median (range), y	33.5 (21–65)	36.5 (21–70)	35.0 (19–66)	38.0 (19–65)	36.0 (19–70)
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/African American	10 (19.2)	13 (25.0)	12 (23.1)	16 (30.2)	51 (24.4)
Asian	1 (1.9)	2 (3.8)	2 (3.8)	1 (1.9)	6 (2.9)
Other	1 (1.9)	1 (1.9)	3 (5.8)*	0	5 (2.4)*
Ethnicity, n (%)					
Hispanic or Latino	10 (19.2)	5 (9.6)	7 (13.5)	6 (11.3)	28 (13.4)
Not Hispanic or Latino	41 (78.8)	47 (90.4)	44 (84.6)	47 (88.7)	179 (85.6)
Unknown/Other	1 (1.9)	0	1 (1.9)	0	2 (1.0)
Geographic region, n (%)					
North America	43 (82.7)	42 (80.8)	43 (82.7)	43 (81.1)	171 (81.8)
Europe	9 (17.3)	10 (19.2)	9 (17.3)	10 (18.9)	38 (18.2)
BMI, median (range), kg/m ²	34.3 (20.2–60.6)	34.6 (19.8–52.9)	35.1 (21.6–66.6)	36.5 (22.8–61.2)	35.0 (19.8–66.6)
≥30 kg/m ²	34 (65.4)	38 (73.1)	41 (78.8)	43 (81.1)	156 (74.6)
Disease duration, mean (SD), y	8.1 (6.5)	9.9 (8.1)	11.2 (11.5)	12.1 (9.7)	10.3 (9.2)
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)
HiSQoL total score, mean (SD)	32.8 (16.3)	26.8 (14.2)	32.6 (16.8)	31.9 (14.9)	31.0 (15.7)
Symptoms subscale score	8.1 (4.1)	7.1 (3.9)	8.4 (4.1)	8.4 (3.9)	8.0 (4.0)
Psychosocial subscale score	10.3 (5.5)	7.8 (5.0)	9.6 (6.0)	10.0 (5.1)	9.4 (5.5)
Activities and adaptations subscale score	14.5 (8.4)	11.9 (6.6)	14.6 (8.4)	13.5 (7.9)	13.6 (7.9)
DLQI score, mean (SD)	12.7 (7.3)	11.2 (7.1)	13.0 (7.6)	12.1 (7.3)	12.2 (7.3)
FACIT-F score, mean (SD)	30.8 (13.3)	36.8 (10.0)	30.9 (13.2)	31.1 (12.4)	–

BMI, body mass index; DLQI, Dermatology Life Quality Index; FACIT-F, Functional Assessment of Chronic Illness Therapy–Fatigue; HiSQoL, Hidradenitis Suppurativa Quality of Life; HS, hidradenitis suppurativa. * Includes one patient who identified as American Indian/Alaska native.

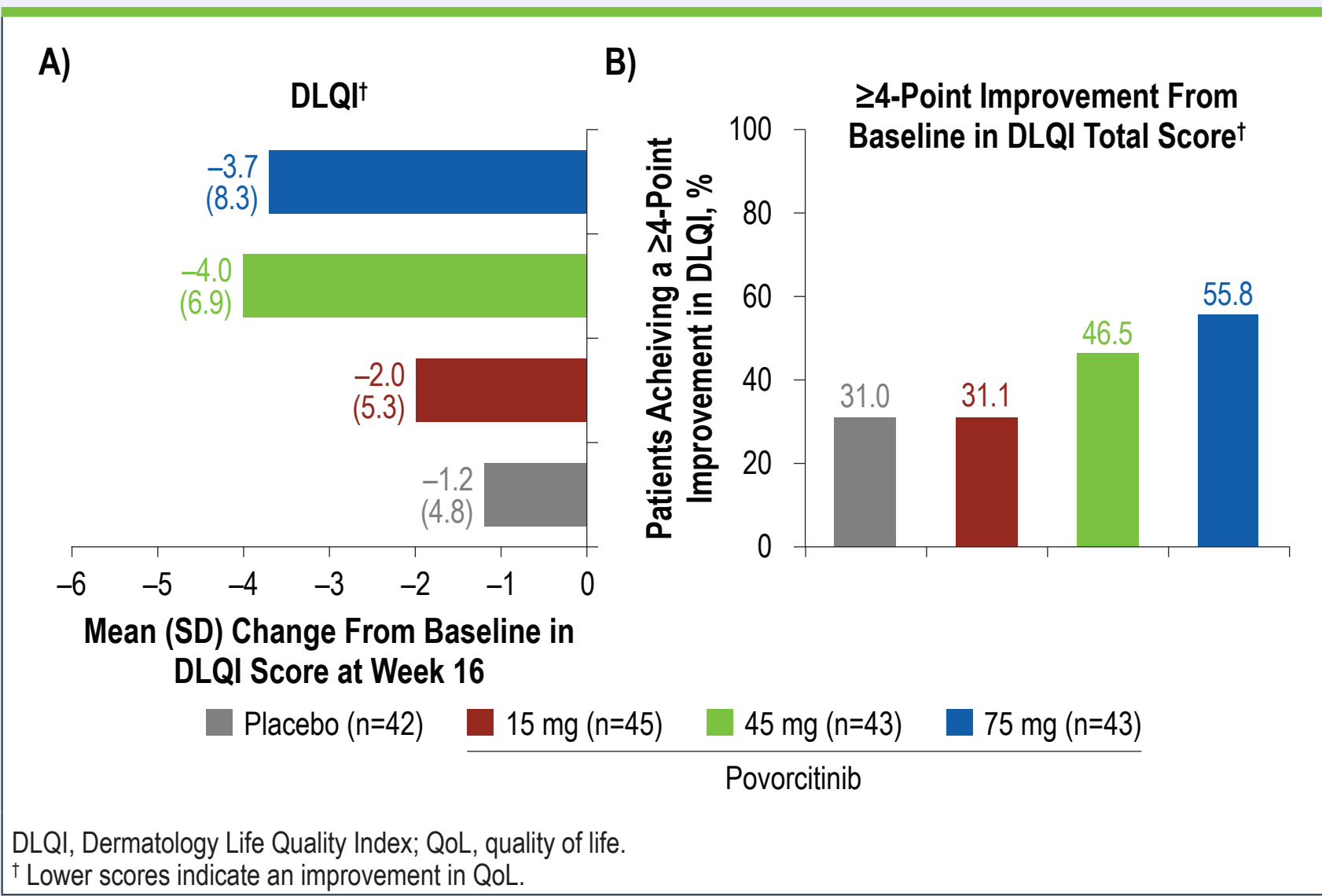
Figure 2. Change From Baseline in HiSQoL Total Score and Subscores



HiSQoL, Hidradenitis Suppurativa Quality of Life; QoL, quality of life.

† Lower scores indicate an improvement in QoL.

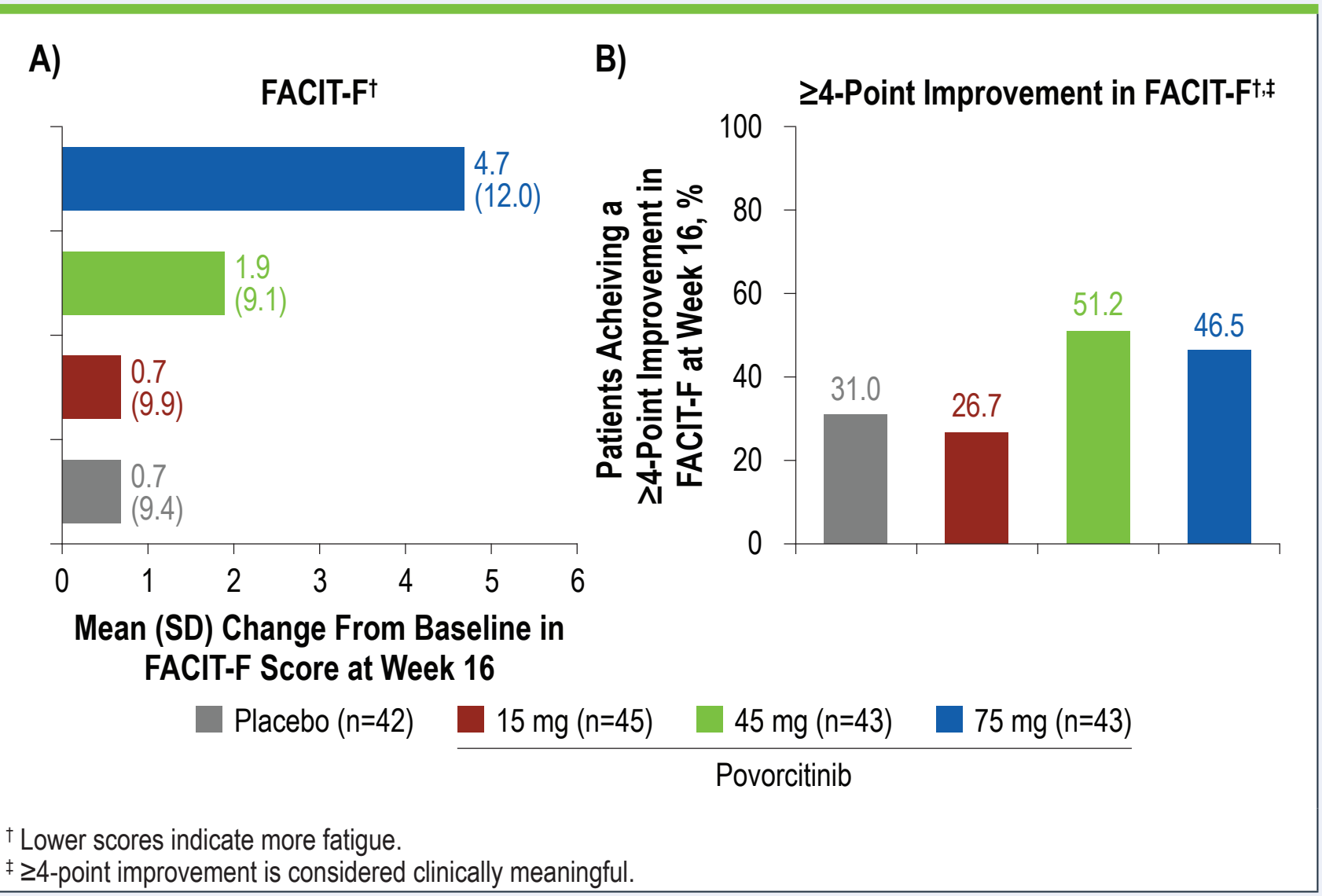
Figure 3. (A) Mean Change From Baseline in DLQI Total Score and (B) Percentage of Patients Who Achieved a ≥4-Point Improvement in DLQI Total Score From Baseline



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

† Lower scores indicate an improvement in QoL.

Figure 4. (A) Mean Change From Baseline in FACIT-F Score and (B) Patients Who Achieved a ≥4-Point Improvement in FACIT-F Total Score



† Lower scores indicate more fatigue.

† † ≥4-point improvement is considered clinically meaningful.

Conclusions

- Results from this phase 2 study of povorcitinib in patients with HS suggest improvement of HS- and dermatology-specific QoL and reduced fatigue over 16 weeks at doses of 45 mg and 75 mg**
- The open-label extension period is ongoing and will provide further information on key patient-reported outcome measures with longer-term povorcitinib administration**

Disclosures

JSK has served as a speaker for AbbVie and as a consultant for AbbVie, Bayer, ChemoCentryx, Incyte, InflaRx, Janssen, Novartis, Pfizer, and UCB. MMO is a consultant for AbbVie, Azora, Bluefin, Boehringer Ingelheim, ChemoCentryx, Incyte, Innovadern, InflaRx, Pfizer, and Vyne. AA received honoraria as a consultant or advisory board participant from AbbVie, Janssen, Novartis, Boehringer Ingelheim, InflaRx, and UCB; and received honoraria as an investigator for Boehringer Ingelheim and Processa. FGB has received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie Inc., AbbVie Deutschland GmbH & Co. KG, Boehringer Ingelheim Pharma GmbH & Co. KG, Novartis Pharma GmbH, UCB Pharma, Incyte, and Janssen-Cilag GmbH. CCZ declares that none of the mentioned conflicts of interest had any influence on this poster. He reports consultancy/advisory board disease-relevant honoraria from AbbVie, Bayer, Incyte, InflaRx, Janssen-Cilag, Novartis, Regeneron, and UCB. He has received speaker fees from AbbVie and UCB; is President of the EHSF e.V., coordinator of the ALLOCATE Skin group of the ERN Skin and chair of the ARHS Task Force group of the EADV. He is Editor of the EADV News; is co-copyright holder of IHS4 on behalf of the EHSF e.V. His employer has received disease-relevant grants from AbbVie, Boehringer Ingelheim, InflaRx, Novartis, and UCB for his participation as clinical investigator. KBrown, LLS, AW, and KBibeau are employees and shareholders of Incyte. ABK is a consultant and investigator for AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB; investigator for AnaptysBio and Incyte; consultant for Bayer, Boehringer Ingelheim, Concert, Evolmune, Moonlake, Sonoma Bio, and Ventyx; receives fellowship funding from AbbVie and Janssen; and serves on the Board of Directors for Almirall. MLP is a consultant and/or investigator for AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, Novartis, Pfizer, Trifecta Clinical (in conjunction with Acelyrin, Moonlake, and Aristea), and UCB.

Acknowledgments

This study was funded by Incyte (Wilmington, DE, USA). Writing assistance was provided by Erin McClure, PhD, an employee of ICON (Blue Bell, PA, USA) and was funded by Incyte.

References

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. Gooderham M, Papp K. *J Am Acad Dermatol*. 2015;73(5):S19–S22. 4. Kimball AB, et al. *J Eur Acad Dermatol Venereol*. 2020;34(6):1302–1308. 5. Matusiak Ł, et al. *Acta Derm Venereol*. 2010;90(3):264–268. 6. Kirby J, et al. Confirmation of Validity and Reliability of the Hidradenitis Suppurativa Quality of Life (HiSQoL) Tool. Presented at: 6th Annual Symposium on Hidradenitis Suppurativa Advances (SHSA); September 24–26, 2021; Virtual. 7. Kirby JS, et al. *Br J Dermatol*. 2020;183(2):340–348. 8. Basra MK, et al. *Dermatology*. 2015;230(1):27–33. 9. Cella D, et al. *J Patient Rep Outcomes*. 2019;3(1):30. 10. Prens EP, et al. *Am J Clin Dermatol*. 2020;21(4):579–590.



To download a copy of this poster, scan code.