Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in moderate to severe plaque psoriasis: correlations between patient-reported outcomes and clinical responses in the phase 3 clinical trials POETYK PSO-1 and POETYK PSO-2

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Synopsis

- In the phase 3 clinical trials POETYK PSO-1 and PSO-2, deucravacitinib was compared for efficacy and safety with placebo and apremilast in the treatment of patients with moderate to severe plaque psoriasis[1]
  - Deucravacitinib is an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor approved by the US Food and Drug Administration for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
  - In each clinical trial, greater proportions of patients who received deucravacitinib achieved ≥75% reduction from baseline in the Psoriasis Area and Severity Index score (PASI 75)[1] and static Physician's Global Assessment scores of 0 or 1 (sPGA 0/1),[1] and showed meaningful improvements on Psoriasis Symptoms and Signs Diary (PSSD) total scores (≥25 points)[2] and Dermatology Life Quality Index (DLQI) total scores (≥4 points)[3] compared with patients receiving placebo or apremilast
- In this post hoc analysis of data pooled from both trials, clinical and patient-reported outcomes (PROs) were found to be correlated
- When analyzed by the deucravacitinib or placebo treatment arm, greater proportions of patients who received deucravacitinib reported symptom reduction and improved quality of life, both in patients who did and who did not achieve PASI 75 and sPGA 0/1 responses

Objective

- To explore the correlations between responses on clinical and PRO measures in pooled data from POETYK PSO-1 and PSO-2

Methods

- In POETYK PSO-1 (N = 666) and PSO-2 (N = 1020) adults (aged ≥18 years) with moderate to severe psoriasis were randomized 2:1:1 to deucravacitinib 6 mg once daily, placebo, or apremilast 30 mg twice daily
  - At Week 16 in each trial, patients who received placebo crossed over to deucravacitinib
- Using data pooled from both trials, we evaluated the correlation between responses measured by PASI and sPGA on one hand, and the PRO measures PSSD (≥25 points)[2] and DLQI (≥4 points)[3] on the other
  - The analysis populations for the PSSD and DLQI included all patients from the full analysis set who completed ≥1 item on the respective questionnaire at baseline and ≥1 post-baseline visit
    - At baseline, 1659 patients had a DLQI score recorded and 1553 had a PSSD score recorded
- Spearman correlation coefficients between clinical and PRO score changes from baseline to Week 16 were calculated with all treatment groups combined
- Mean PSSD and DLQI scores were determined within relative PASI and sPGA response levels
- The proportions of patients achieving meaningful improvement (ie, response) in PSSD total scores and on the DLQI were summarized by whether they did or did not achieve PASI 75 and sPGA 0/1, and were further analyzed by treatment arm
  - Results are reported for patients receiving deucravacitinib or placebo

Outcome measures

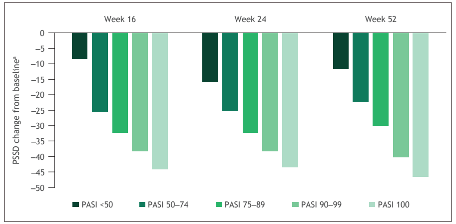
- PASI
  - Clinician evaluated
  - Range: 0-72, with higher scores indicating more severe disease
- sPGA
  - Clinician evaluated
  - Range: 0 (clear) to 4 (severe)
- PSSD
  - Patient rated
  - 5 skin symptoms (itch, tightness, burning, stinging, and pain) and 6 skin signs (dryness, cracking, scaling, shedding/flaking, redness, and bleeding) associated with psoriasis were rated 0 (absent) to 10 (worst imaginable); averages within each domain were multiplied by 10, then averaged across both domains to obtain a total score
  - Range: 0-100, with higher scores indicating heavier disease burden
- DLQI
  - Patient rated
  - 10 questions that assess the extent to which skin disease affects patients' lives
  - Range: 0-30, with higher scores indicating more severe impact of disease

Results

Correlations between clinical and PRO measures

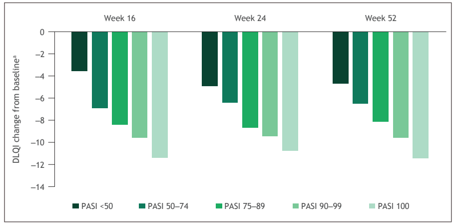
- At Week 16, change from baseline in relative PASI score was correlated with changes in the PSSD total score (Spearman's rank correlation coefficient [r_s] = 0.536) and DLQI total score (r_s = 0.421) in the total study population
- At Week 16, change from baseline in sPGA score was correlated with changes in the PSSD total score (r_s = 0.496) and DLQI total score (r_s = 0.380) in the total study population
- Higher PASI or sPGA response was associated with greater PSSD and DLQI responses at Weeks 16, 24, and 52 in the total study population (**Figures 1-4**)

Figure 1. PSSD total score change from baseline by PASI response group (treatment arms and trials pooled, n = 1536)



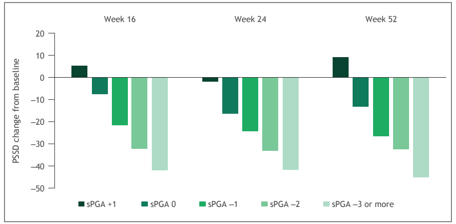
[a]At baseline, the mean PSSD total score (SD) was 54.4 (23.30) in the deucravacitinib arm, 53.1 (23.09) in the placebo arm, and 55.7 (22.90) in the apremilast arm.
PASI 50-100, 50%-100% improvement from baseline in the Psoriasis Area and Severity Index score; PSSD, Psoriasis Symptoms and Signs Diary.

Figure 2. DLQI Change from baseline by PASI response group (treatment arms and trials pooled, n = 1643)



[a]The mean baseline DLQI score (SD) among all patients in the study population was 12.0 (6.7).
DLQI, Dermatology Life Quality Index; PASI 50-100, 50%-100% improvement from baseline Psoriasis Area and Severity Index score.

Figure 3. PSSD change from baseline by sPGA[a] change group (treatment arms and trials pooled, n = 1536)



[a]At baseline, 1345 patients in the total study population had an sPGA score of 3, and 340 had an sPGA score of 4. One patient had an sPGA score of 2; this patient was randomized but not treated. The mean baseline PSSD total score (SD) was 54.4 (23.30) in the deucravacitinib arm, 53.1 (23.09) in the placebo arm, and 55.7 (22.90) in the apremilast arm.
PSSD, Psoriasis Symptoms and Signs Diary; sPGA, static Physician's Global Assessment.

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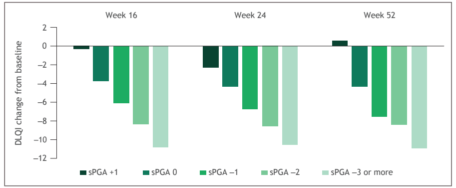


[a]At baseline, 1345 patients in the total study population had an sPGA score of 3 and 340 had an sPGA score of 4. One patient had an sPGA score of 2; this patient was randomized but not treated. The mean baseline DLQI score (SD) among all patients in the study population was 12.0 (6.7).
DLQI, Dermatology Life Quality Index; sPGA, static Physician's Global Assessment.

PSSD Response by Clinical Response

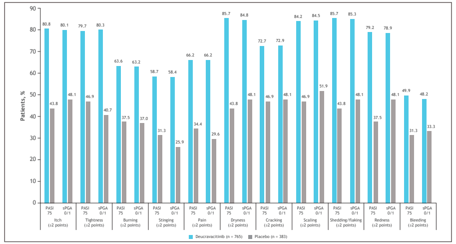
- At Week 16, PSSD total score response (≥25-point reduction from baseline) was reported by 64.8% and 65.3% of all patients across both trials who achieved PASI 75 (356/549) and/or sPGA 0/1 (330/505), respectively (**Table 1**)
  - Greater proportions of patients who received deucravacitinib and achieved clinical response reported PSSD total score response (68.6% of patients who achieved PASI 75 and 68.7% of patients who achieved sPGA 0/1) compared with patients who received placebo (31.3% of patients who achieved PASI 75 and 37.0% of patients who achieved sPGA 0/1) (**Table 1**)
  - On the PSSD itch item, meaningful improvement (≥2 points) was reported by 80.8% of patients receiving deucravacitinib who achieved PASI 75 and 80.1% of deucravacitinib-treated patients who achieved sPGA 0/1, compared with 43.8% of patients receiving placebo who achieved PASI 75 and 48.1% of placebo-treated patients who achieved sPGA 0/1 (**Figure 5**)
- At Week 16, 27.9% and 29.8% of all patients across both trials who did not achieve PASI 75 (188/674) and/or did not achieve sPGA 0/1 (214/718), respectively, nonetheless reported PSSD total score response
  - Greater proportions of patients who received deucravacitinib and did not achieve clinical response nonetheless reported PSSD total score response (41.8% of patients who did not achieve PASI 75 and 44.1% of patients who did not achieve sPGA 0/1) compared with patients who received placebo (10.4% of patients who did not achieve PASI 75 and 10.3% who did not achieve sPGA 0/1)
  - On the PSSD itch item, meaningful improvement was reported by 54.9% of patients receiving deucravacitinib who did not achieve PASI 75 compared with 22.0% of patients receiving placebo who did not achieve PASI 75

Table 1. PSSD response at Week 16 in patients who achieved clinical response

PSSD Domain	Total patients N = 1536	Deucravacitinib n = 765	Placebo n = 383
Total score (≥25-point reduction), n/N[a] (%)			
PASI 75	356/549 (64.8)[b]	264/385 (68.6)	10/32 (31.3)
sPGA 0/1	330/505 (65.3)[b]	248/361 (68.7)	10/27 (37.0)
Symptom score (≥25-point reduction), n/N[a] (%)			
PASI 75	323/549 (58.8)[b]	240/385 (62.3)	10/32 (31.3)
sPGA 0/1	296/505 (58.6)[b]	223/361 (61.8)	8/27 (29.6)
Sign score (≥25-point reduction), n/N[a] (%)			
PASI 75	383/549 (69.8)[b]	284/385 (73.8)	10/32 (31.3)
sPGA 0/1	354/505 (70.1)[b]	267/361 (74.0)	10/27 (37.0)

[a]The denominator represents the patients who achieved clinical response and who completed ≥1 PSSD item at baseline and ≥1 PSSD item at a post-baseline visit.
[b]Total denominator includes patients who received apremilast.
PASI 75, ≥75% improvement from baseline in Psoriasis Area and Severity Index score; PSSD, Psoriasis Symptoms and Signs Diary; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

Figure 5. PSSD individual item response at Week 16 in patients[a] who achieved clinical response



[a]Denominators include patients who achieved clinical response and completed ≥1 PSSD item at baseline and ≥1 PSSD item at a post-baseline visit.
PASI 75, 75% reduction from baseline in Psoriasis Area and Severity Index score; PSSD, Psoriasis Symptoms and Signs Diary; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

DLQI Response by Clinical Response

- At Week 16, DLQI response (≥4-point reduction from baseline) was reported by 83.3% and 82.5% of all patients across both trials who achieved PASI 75 (553/664) and/or sPGA 0/1 (496/601), respectively (**Table 2**)
  - Greater proportions of patients who received deucravacitinib and achieved clinical response reported meaningful DLQI improvement (84.7% of patients who achieved PASI 75 and 83.3% of patients who achieved sPGA 0/1) compared with patients who received placebo (72.7% of patients who achieved PASI 75 and 70.6% of patients who achieved sPGA 0/1)
- At Week 16, 54.7% and 57.3% of all patients across both trials who did not achieve PASI 75 (444/811) and/or did not achieve sPGA 0/1 (501/874), respectively, nonetheless reported DLQI response
  - Greater proportions of patients who received deucravacitinib and did not achieve clinical response nonetheless reported meaningful DLQI improvement (67.1% of patients who did not achieve PASI 75 and 70.8% of patients who did not achieve sPGA 0/1) compared with patients who received placebo (40.5% of patients who did not achieve PASI 75 and 41.7% who did not achieve sPGA 0/1)

Table 2. DLQI response at Week 16 in patients who achieved clinical response

DLQI ≥4-point reduction	Total patients N = 1643	Deucravacitinib n = 824	Placebo n = 409
PASI 75, n/N[a] (%)	553/664 (83.3)[b]	393/464 (84.7)	32/44 (72.7)
sPGA 0/1, n/N[a] (%)	496/601 (82.5)[b]	359/431 (83.3)	24/34 (70.6)

[a]The denominator includes the patients who achieved clinical response and completed ≥1 DLQI item at baseline and ≥1 DLQI item at a post-baseline visit.
[b]Total denominator includes patients who received apremilast.
DLQI, Dermatology Life Quality Index; PASI 75, ≥75% improvement from baseline in Psoriasis Area and Severity Index score; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

Conclusions

- Psoriasis skin clearance, symptom reduction, and improved patient quality of life were correlated in the POETYK PSO-1 and PSO-2 trials
  - This correlation is consistent with that determined in other studies[4-7]
- Higher clinical response was associated with greater PRO measure response
- PRO measures capture patient-perceived treatment benefits that may not be ascertained by measuring rates of skin clearance with clinical assessments alone[4]
  - Psoriasis bears symptoms, such as pruritus, for which there are no validated objective measures,[8] or which are best assessed by patients themselves[9] in order to evaluate treatment efficacy
  - Among patients who achieved PASI 75 at Week 16, 80.8% of patients who received deucravacitinib reported meaningful itch improvement on the PSSD compared with 43.8% of patients who received placebo
- Among patients with and without clinical response, greater proportions of patients treated with deucravacitinib recorded improvement in their self-reported symptoms, signs, and quality of life compared with patients treated with placebo

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Acknowledgments

- This study was sponsored by Bristol Myers Squibb
- Medical writing and editorial assistance was provided by Eleanor Bush, MA, of Peloton Advantage, LLC, an OPEN Health company, and funded by Bristol Myers Squibb

Disclosures

- **AWA:** Grants and personal fees: AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, and Novartis; Personal fees: Boehringer Ingelheim/Parexel, Celgene, Dermavant, Genentech, GlaxoSmithKline, Menlo Therapeutics, Merck, Modernizing Medicine, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Science 37, Sun Pharma, and Valeant; Grants: Dermira, Kyowa Hakko Kirin, and UCB, outside the submitted work
- **KAP:** Speakers bureau: AbbVie, Amgen, Astellas, Celgene, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, Leo Pharma, Merck Sharp & Dohme, Novartis, Pfizer, and Valeant; Grant/research support: AbbVie, Akros, Allergan, Amgen, Anacor, Arcutis, AstraZeneca, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, Leo Pharma, MedImmune, Meiji Seika Pharma, Merck Serono, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Takeda, UCB, and Valeant; Consultant: AbbVie, Akros, Amgen, Arcutis, Astellas, AstraZeneca, Baxalta, Baxter, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Forward Pharma, Galderma, Genentech, Janssen, Kyowa Hakko Kirin, Leo Pharma, Meiji Seika Pharma, Merck Serono, Merck Sharp & Dohme, Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Takeda, UCB, and Valeant; Honoraria: AbbVie, Akros, Amgen, Baxter, Boehringer Ingelheim, Celgene, Coherus, Eli Lilly, Forward Pharma, Galderma, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, Merck Sharp & Dohme, Merck Serono, Novartis, Pfizer, Takeda, UCB, and Valeant; Scientific officer/steering committee/advisory board: AbbVie, Akros, Amgen, Anacor, Astellas, Baxter, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dow Pharma, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, Merck Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Sanofi Genzyme, and Valeant
- **JZ, BB, YZ, RMK, and SB:** Employees and shareholders of Bristol Myers Squibb
- **JLB and MD:** Employees of Clinical Outcomes Solutions, which has received consulting fees from Bristol Myers Squibb
- **BS:** Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, Leo Pharma, Maruho, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyx Biosciences, and vTv Therapeutics; Speaker: AbbVie, Eli Lilly, Janssen, and Sanofi Genzyme; Co-scientific director (consulting fee): CorEvitas' (Corrona) Psoriasis Registry; Investigator: AbbVie, Cara, CorEvitas' (Corrona) Psoriasis Registry, Dermavant, Dermira, and Novartis

Presented at the Fall Clinical Dermatology Conference; October 20–23, 2022; Las Vegas, NV

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Synopsis

- At Week 16, change from baseline in sPGA score was correlated with changes in the PSSD total score

Figure 4. DLQI change from baseline by sPGA[a] change group (treatment arms

DLQI Response by Clinical Response

Synopsis

- In the phase 3 clinical trials POETYK PSO-1 and PSO-2, deucravacitinib was compared for efficacy and safety with placebo and apremilast in the treatment of patients with moderate to severe plaque psoriasis[1]
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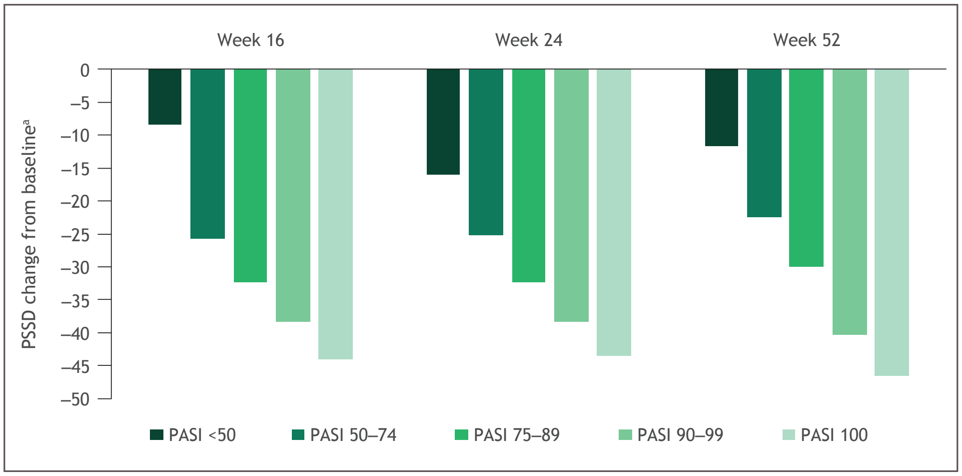

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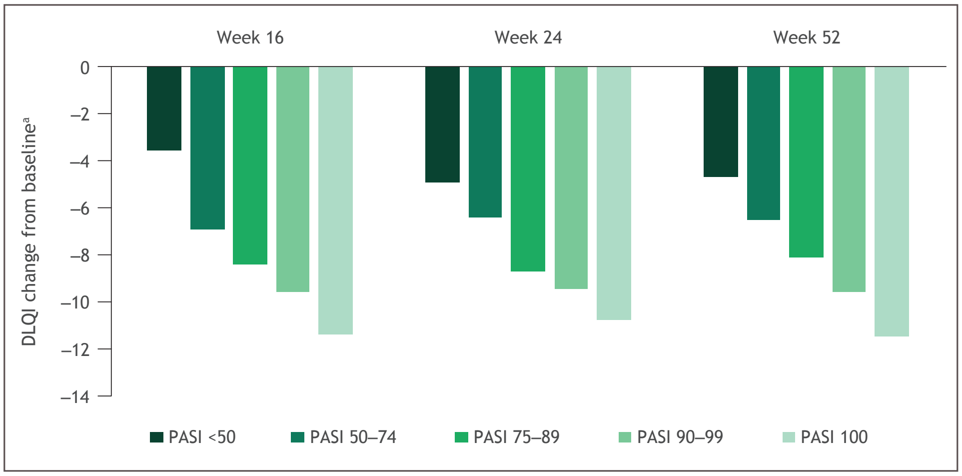

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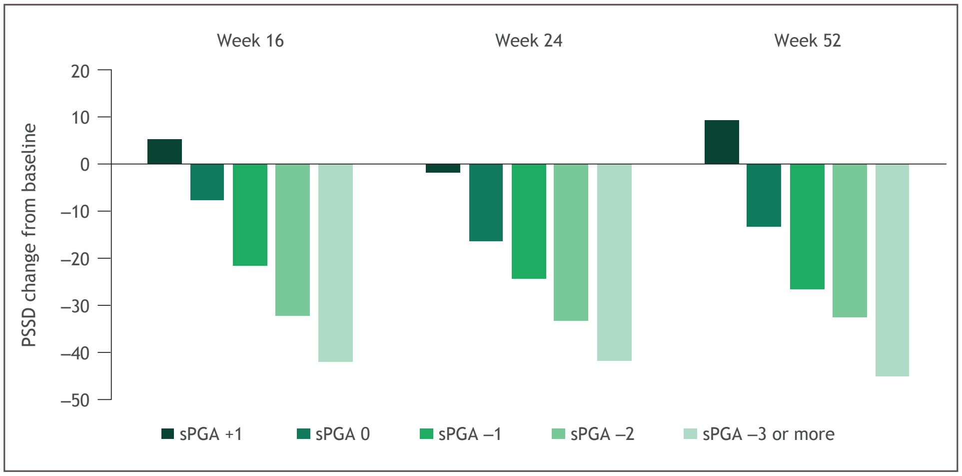

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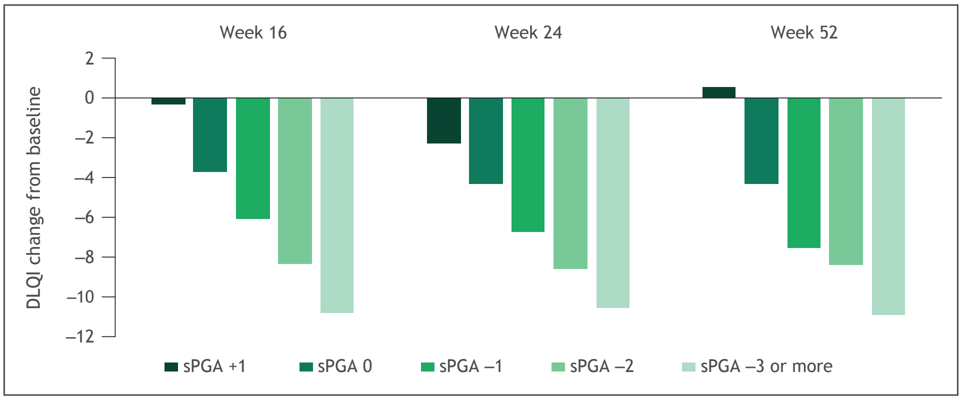

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  - Greater proportions of patients who received deucravacitinib and achieved clinical response reported PSSD total score response (68.6% of patients who achieved PASI 75 and 68.7% of patients who achieved sPGA 0/1) compared with patients who received placebo (31.3% of patients who achieved PASI 75 and 37.0% of patients who achieved sPGA 0/1) (**Table 1**)
  - On the PSSD itch item, meaningful improvement (≥2 points) was reported by 80.8% of patients receiving deucravacitinib who achieved PASI 75 and 80.1% of deucravacitinib-treated patients who achieved sPGA 0/1, compared with 43.8% of patients receiving placebo who achieved PASI 75 and 48.1% of placebo-treated patients who achieved sPGA 0/1 (**Figure 5**)
- At Week 16, 27.9% and 29.8% of all patients across both trials who did not achieve PASI 75 (188/674) and/or did not achieve sPGA 0/1 (214/718), respectively, nonetheless reported PSSD total score response
  - Greater proportions of patients who received deucravacitinib and did not achieve clinical response nonetheless reported PSSD total score response (41.8% of patients who did not achieve PASI 75 and 44.1% of patients who did not achieve sPGA 0/1) compared with patients who received placebo (10.4% of patients who did not achieve PASI 75 and 10.3% who did not achieve sPGA 0/1)
  - On the PSSD itch item, meaningful improvement was reported by 54.9% of patients receiving deucravacitinib who did not achieve PASI 75 compared with 22.0% of patients receiving placebo who did not achieve PASI 75

Table 1. PSSD response at Week 16 in patients who achieved clinical response

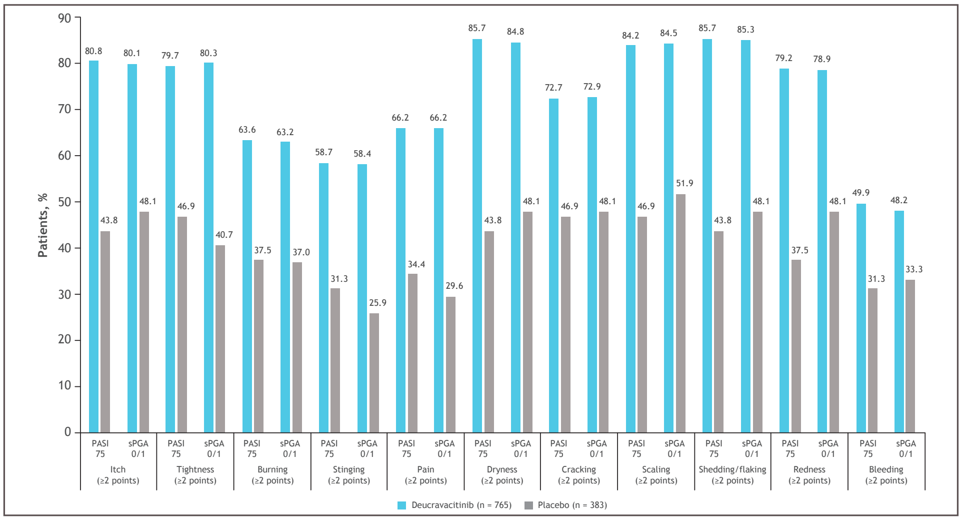
PSSD Domain	Total patients N = 1536	Deucravacitinib n = 765	Placebo n = 383
Total score (≥25-point reduction), n/N[a] (%)			
PASI 75	356/549 (64.8)[b]	264/385 (68.6)	10/32 (31.3)
sPGA 0/1	330/505 (65.3)[b]	248/361 (68.7)	10/27 (37.0)
Symptom score (≥25-point reduction), n/N[a] (%)			
PASI 75	323/549 (58.8)[b]	240/385 (62.3)	10/32 (31.3)
sPGA 0/1	296/505 (58.6)[b]	223/361 (61.8)	8/27 (29.6)
Sign score (≥25-point reduction), n/N[a] (%)			
PASI 75	383/549 (69.8)[b]	284/385 (73.8)	10/32 (31.3)
sPGA 0/1	354/505 (70.1)[b]	267/361 (74.0)	10/27 (37.0)

[a]The denominator represents the patients who achieved clinical response and who completed ≥1 PSSD item at baseline and ≥1 PSSD item at a post-baseline visit.

[b]Total denominator includes patients who received apremilast.

PASI 75, ≥75% improvement from baseline in Psoriasis Area and Severity Index score; PSSD, Psoriasis Symptoms and Signs Diary; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

Figure 5. PSSD individual item response at Week 16 in patients[a] who achieved clinical response



[a]Denominators include patients who achieved clinical response and completed ≥1 PSSD item at baseline and ≥1 PSSD item at a post-baseline visit.

PASI 75, 75% reduction from baseline in Psoriasis Area and Severity Index score; PSSD, Psoriasis Symptoms and Signs Diary; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

- At Week 16, DLQI response (≥4-point reduction from baseline) was reported by 83.3% and 82.5% of all patients across both trials who achieved PASI 75 (553/664) and/or sPGA 0/1 (496/601), respectively (**Table 2**)
  - — Greater proportions of patients who received deucravacitinib and achieved clinical response reported meaningful DLQI improvement (84.7% of patients who achieved PASI 75 and 83.3% of patients who achieved sPGA 0/1) compared with patients who received placebo (72.7% of patients who achieved PASI 75 and 70.6% of patients who achieved sPGA 0/1)
- At Week 16, 54.7% and 57.3% of all patients across both trials who did not achieve PASI 75 (444/811) and/or did not achieve sPGA 0/1 (501/874), respectively, nonetheless reported DLQI response
  - — Greater proportions of patients who received deucravacitinib and did not achieve clinical response nonetheless reported meaningful DLQI improvement (67.1% of patients who did not achieve PASI 75 and 70.8% of patients who did not achieve sPGA 0/1) compared with patients who received placebo (40.5% of patients who did not achieve PASI 75 and 41.7% who did not achieve sPGA 0/1)

Table 2. DLQI response at Week 16 in patients who achieved clinical response

DLQI ≥4-point reduction	Total patients N = 1643	Deucravacitinib n = 824	Placebo n = 409
PASI 75, n/N[a] (%)	553/664 (83.3)[b]	393/464 (84.7)	32/44 (72.7)
sPGA 0/1, n/N[a] (%)	496/601 (82.5)[b]	359/431 (83.3)	24/34 (70.6)

[a] The denominator includes the patients who achieved clinical response and completed ≥1 DLQI item at baseline and ≥1 DLQI item at a post-baseline visit.
[b] Total denominator includes patients who received apremilast.
DLQI, Dermatology Life Quality Index; PASI 75, ≥75% improvement from baseline in Psoriasis Area and Severity Index score; sPGA 0/1, static Physician's Global Assessment score of 0 or 1.

Conclusions

- Psoriasis skin clearance, symptom reduction, and improved patient quality of life were correlated in the POETYK PSO-1 and PSO-2 trials
  - — This correlation is consistent with that determined in other studies[4-7]
- Higher clinical response was associated with greater PRO measure response
- PRO measures capture patient-perceived treatment benefits that may not be ascertained by measuring rates of skin clearance with clinical assessments alone[4]
  - — Psoriasis bears symptoms, such as pruritus, for which there are no validated objective measures,[8] or which are best assessed by patients themselves[9] in order to evaluate treatment efficacy
  - — Among patients who achieved PASI 75 at Week 16, 80.8% of patients who received deucravacitinib reported meaningful itch improvement on the PSSD compared with 43.8% of patients who received placebo
- Among patients with and without clinical response, greater proportions of patients treated with deucravacitinib recorded improvement in their self-reported symptoms, signs, and quality of life compared with patients treated with placebo

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Acknowledgments

- This study was sponsored by Bristol Myers Squibb
- Medical writing and editorial assistance was provided by Eleanor Bush, MA, of Peloton Advantage, LLC, an OPEN Health company, and funded by Bristol Myers Squibb

Disclosures

- **AWA:** Grants and personal fees: AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Leo Pharma, and Novartis; Personal fees: Boehringer Ingelheim/Parexel, Celgene, Dermavant, Genentech, GlaxoSmithKline, Menlo Therapeutics, Merck, Modernizing Medicine, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Science 37, Sun Pharma, and Valeant; Grants: Dermira, Kyowa Hakko Kirin, and UCB, outside the submitted work
- **KAP:** Speakers bureau: AbbVie, Amgen, Astellas, Celgene, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, Leo Pharma, Merck Sharp & Dohme, Novartis, Pfizer, and Valeant; Grant/research support: AbbVie, Akros, Allergan, Amgen, Anacor, Arcutis, AstraZeneca, Baxalta, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, Leo Pharma, MedImmune, Meiji Seika Pharma, Merck Serono, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Takeda, UCB, and Valeant; Consultant: AbbVie, Akros, Amgen, Arcutis, Astellas, AstraZeneca, Baxalta, Baxter, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Forward Pharma, Galderma, Genentech, Janssen, Kyowa Hakko Kirin, Leo Pharma, Meiji Seika Pharma, Merck Serono, Merck Sharp & Dohme, Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Takeda, UCB, and Valeant; Honoraria: AbbVie, Akros, Amgen, Baxter, Boehringer Ingelheim, Celgene, Coherus, Eli Lilly, Forward Pharma, Galderma, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, Merck Sharp & Dohme, Merck Serono, Novartis, Pfizer, Takeda, UCB, and Valeant; Scientific officer/steering committee/advisory board: AbbVie, Akros, Amgen, Anacor, Astellas, Baxter, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dow Pharma, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, Merck Serono, Merck Sharp & Dohme, Novartis, Pfizer, Regeneron, Sanofi Genzyme, and Valeant
- **JZ, BB, YZ, RMK, and SB:** Employees and shareholders of Bristol Myers Squibb
- **JLB and MD:** Employees of Clinical Outcomes Solutions, which has received consulting fees from Bristol Myers Squibb
- **BS:** Consultant (honoraria): AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Connect Biopharma, Dermavant, Eli Lilly, Equillium, GlaxoSmithKline, Immunic Therapeutics, Janssen, Leo Pharma, Maruho, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, UCB, Ventyx Biosciences, and vTv Therapeutics; Speaker: AbbVie, Eli Lilly, Janssen, and Sanofi Genzyme; Co-scientific director (consulting fee): CorEvitas' (Corrona) Psoriasis Registry; Investigator: AbbVie, Cara, CorEvitas' (Corrona) Psoriasis Registry, Dermavant, Dermira, and Novartis

Presented at the Fall Clinical Dermatology Conference; October 20–23, 2022; Las Vegas, NV

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