Efficacy of Apremilast in Patients With Moderate to Severe Genital Psoriasis: Body Surface Area Subgroup Results From the Phase 3 DISCREET Trial

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Introduction and Objective

- Genital psoriasis, which affects up to 63% of adults with psoriasis, remains highly stigmatized, underdiagnosed, and undertreated[1-3]
- Studies regarding therapies for genital psoriasis are limited, and treatment is challenging[4]
- In the DISCREET study, apremilast 30 mg twice daily (BID) (APR) significantly improved genital psoriasis and quality of life compared with placebo (PBO) at week 16 and was well tolerated in patients with moderate to severe genital psoriasis; it is the first trial to study an oral treatment for moderate to severe genital psoriasis
- We analyzed the efficacy endpoints for prespecified subgroups of patients with baseline psoriasis-involved body surface area (BSA) < 10% or ≥ 10%

Study Design and Patient Population

- **Design:** Phase 3, multicenter, randomized, double-blind, PBO-controlled, parallel-group study (NCT03777436)
  - Randomization was stratified by baseline BSA < 10% or ≥ 10%
  - A maximum of 60% of patients were to have BSA < 10%
- **Main Inclusion Criteria:** Moderate or severe genital psoriasis (modified static Physician Global Assessment of Genitalia [sPGA-G] score ≥ 3); moderate or severe psoriasis (overall sPGA score ≥ 3); nongenital plaque psoriasis on ≥ 1% of BSA; intolerant to or inadequately controlled by topical therapy for genital psoriasis
- **Primary Endpoint:** Modified sPGA-G response (score of 0 [clear] or 1 [almost clear] with ≥ 2-point reduction from baseline) at week 16
- **Secondary Endpoints:** sPGA response (score of 0 or 1 with ≥ 2-point reduction from baseline), Genital Psoriasis Itch Numeric Rating Scale (GPI-NRS) response (≥ 4-point improvement), change from baseline in BSA, change from baseline in Dermatology Life Quality Index (DLQI) score, and change from baseline in Genital Psoriasis Symptoms Scale (GPSS) score

Subgroup Analysis

- Efficacy endpoints at week 16 were analyzed by baseline BSA (< 10% and ≥ 10%)

Baseline Disease Characteristics

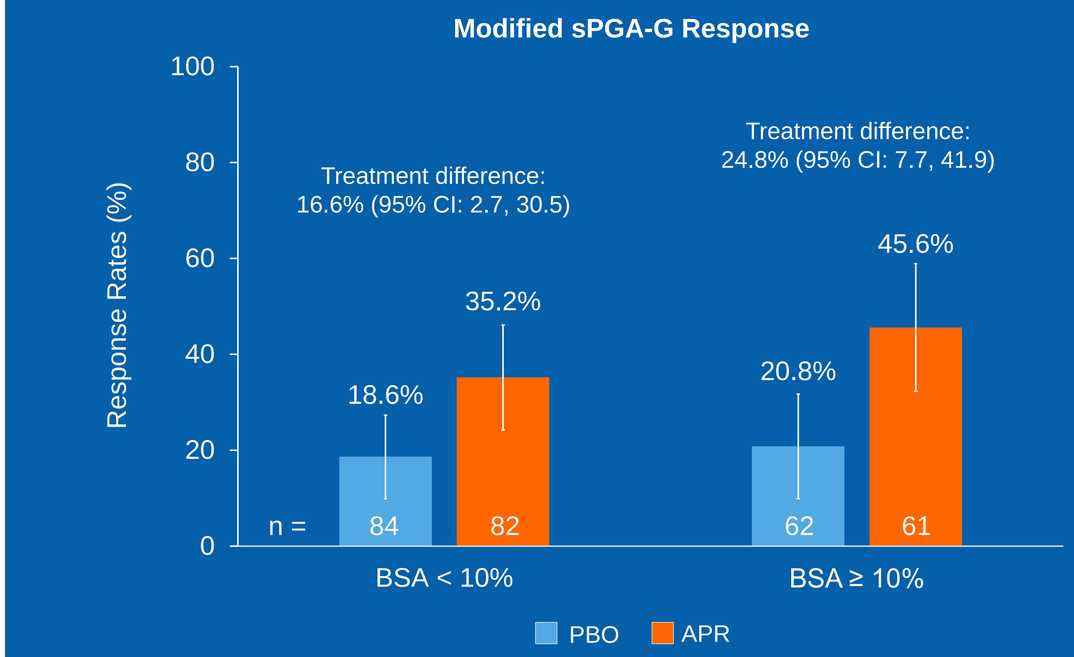
	BSA < 10%		BSA ≥ 10%	
Score at baseline	**PBO n = 84**	**APR n = 82**	**PBO n = 62**	**APR n = 61**
sPGA-G	3.11	3.12	3.15	3.16
sPGA	3.08	3.06	3.11	3.20
GPI-NRS	6.39	6.42	6.18	7.05
BSA, %, mean	5.04	4.57	13.19	19.02
DLQI, mean	11.6	12.0	14.3	14.9
GPSS, mean	41.8	44.7	43.8	49.7

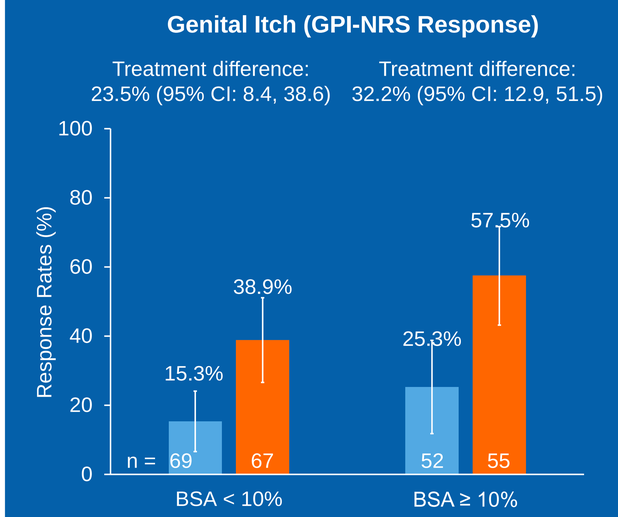
APR, apremilast 30 mg BID; BID, twice daily; BSA, body surface area; DLQI, Dermatology Life Quality Index; GPI-NRS, Genital Psoriasis Itch Numeric Rating Scale; GPSS, Genital Psoriasis Symptoms Scale; PBO, placebo; sPGA, static Physician Global Assessment; sPGA-G, static Physician Global Assessment of Genitalia.

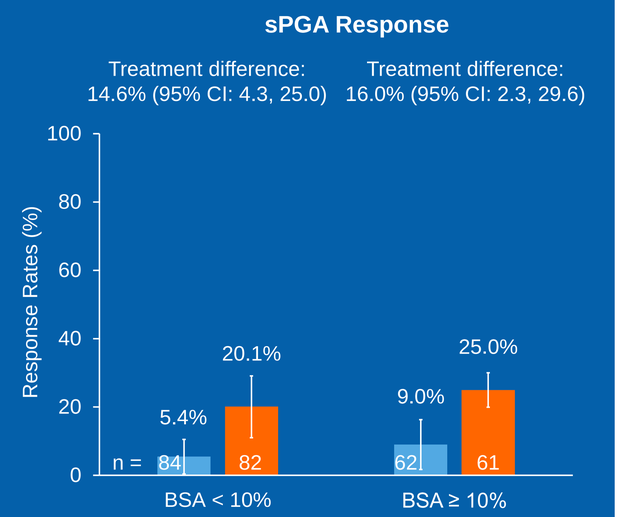
Key Takeaways

- **Regardless of baseline BSA, APR patients had consistent improvements in genital psoriasis symptoms and severity and quality of life at week 16**
- **Patients with limited BSA and genital psoriasis benefited from systemic treatment with APR**

APR patients experienced greater improvements in genital psoriasis symptoms and severity than PBO patients, regardless of baseline BSA







ITT population. Error bars represent 95% CI. Multiple imputation used for missing data. Two-sided *P* values are based on the Cochran-Mantel-Haenszel test. Modified sPGA-G response is defined as a score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline. GPI-NRS scores range from 0 (no) to 10 (worst imaginable). sPGA response is defined as a score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline.

APR, apremilast 30 mg BID; BID, twice daily; BSA, body surface area; CI, confidence interval; GPI-NRS, Genital Psoriasis Itch Numeric Rating Scale; ITT, intent-to-treat; PBO, placebo; sPGA, static Physician Global Assessment; sPGA-G, static Physician Global Assessment of Genitalia.

Disclosures and Funding Statement

JFM: AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharmaceuticals, and UCB – consultant and/or investigator. **LCP:** AbbVie, Alfasigma, Amgen, Amytrx, Eli Lilly, Bristol Myers Squibb, Fibrocell, Galderma, GlaxoSmithKline, Kiniksa, Olix, Oneness, Pfizer, Trevi, and UCB – investigator. **LG:** AbbVie, Amgen, Bausch Health, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Janssen, LEO Pharma, Merck Frosst, Novartis, Pfizer, Sun Pharmaceuticals, and UCB – consultant, investigator, and/or speaker. **CL:** AbbVie, Actelion, Amgen, Astella, Boehringer Ingelheim, Bausch Health, Celgene, Dermira, Eli Lilly, Galderma, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Takeda, UCB, and Valeant – principal investigator and/or consultant. **J-PL:** AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Galderma, Janssen, LEO Pharma, Lilly, Novartis, Pfizer, and Sanofi – grants, personal fees, and/or research support. **PS:** AbbVie, Allergika, Almirall-Hermal, Amgen, Beiersdorf, Biocryst, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, CSL Behring, Eli Lilly, Galderma, Hexal, Janssen, Klinge, LEO Pharma, LETI Pharma, L´Oreal, Neubourg, Novartis, Octapharma, Pfizer, Pflüger, Pharming, Regeneron, Sanofi Genzyme, Shire, Takeda, and UCB Pharma – grants. **SC, CD, & MC:** Amgen Inc. – employees and stockholders. **KAP:** AbbVie, Actelion, Amgen, Astellas Pharma US, Boehringer Ingelheim, Bausch Health, Celgene, Dermira, Dow Pharmaceuticals, Eli Lilly, Frontier, Galderma, Janssen, Kyowa Hakko Kirin Pharma, LEO Pharma, MedImmune, Merck & Co., Inc., Novartis, Pfizer, Regeneron, Roche Laboratories, Sanofi Genzyme, Takeda, UCB, and Valeant – honoraria, grants, and/or research funding as a speaker, investigator, advisory board member, data safety monitoring board member, and/or consultant; PSLOAR, PURE – steering committee member.

Funding: This study was funded by Amgen Inc. Writing support was funded by Amgen Inc. and provided by Christina Mulvihill, PharmD, of Peloton Advantage, LLC, an OPEN Health company, and Dawn Nicewarner, PhD, employee of and stockholder in Amgen Inc.

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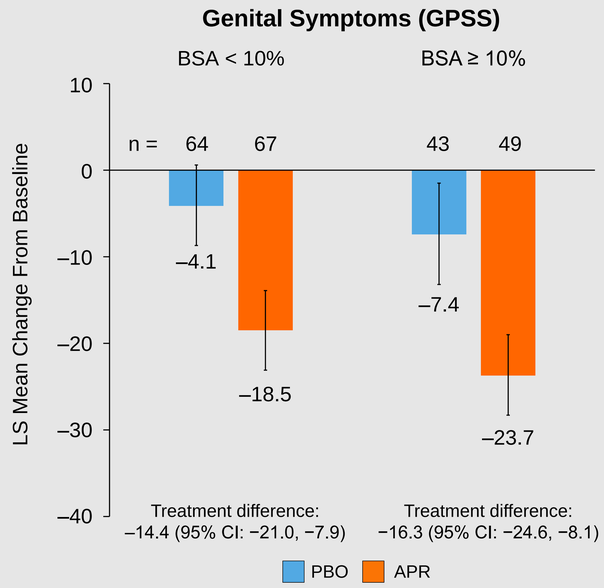
Baseline Characteristics

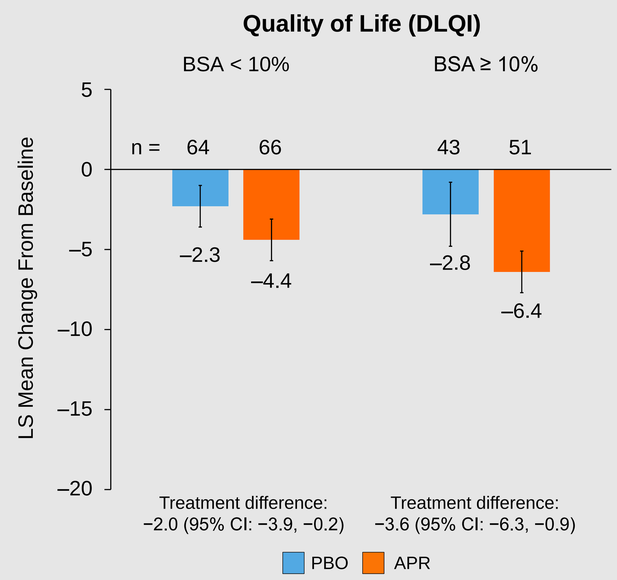
PBO (n = 146)		APR (n = 143)
46	Mean age, years	44
102 (70)	Male, n (%)	100 (70)
12	Mean duration of genital psoriasis, years	11

Additional Results

At week 16, treatment differences in BSA LS mean change from baseline favored APR in both subgroups (BSA < 10%: −0.8; BSA ≥ 10%: −6.9)

Similarly, across subgroups, week 16 treatment differences in change from baseline in GPSS and DLQI favored APR





ITT population. Error bars represent 95% CI. Mixed-effect model for repeated measures used for missing data. DLQI total scores range from 0 to 30. Higher scores correspond to poorer quality of life. GPSS is a patient-administered assessment of eight symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking; total scores range from 0 (no genital psoriasis symptoms) to 80 (worst imaginable genital psoriasis symptoms).
APR, apremilast 30 mg BID; BID, twice daily; BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; GPSS, Genital Psoriasis Symptoms Scale; ITT, intent-to-treat; LS, least-squares; PBO, placebo.

Presented at: 2023 Fall Clinical Dermatology Conference (FC23); October 19–22, 2023; Las Vegas, NV, USA