Efficacy and Safety of Apremilast in Patients With Genital Psoriasis: Results From the Phase 3, Randomized, Placebo-Controlled, Double-blind DISCREET Study

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Key takeaways

Apremilast, the first oral treatment to be studied for genital psoriasis, significantly improved disease symptoms, including skin, itch, and QoL and was well-tolerated in patients who were inadequately controlled by or intolerant to medications applied to the skin

What do we know?

Up to 63% of patients with psoriasis report **genital psoriasis**,[1,2] which can lead to:

- Itching
- Discomfort
- Impaired QoL
- Negative impact on sexual health

Limited treatment options are available for patients with moderate to severe genital psoriasis

Apremilast, an oral immunomodulator, is approved in adults with psoriasis, psoriatic arthritis, and oral ulcers associated with Behçet's disease

What was our aim?

To evaluate the benefit, safety, tolerability, and effect on health-related QoL of apremilast in patients with moderate to severe genital psoriasis after 16 weeks of treatment in the DISCREET study (NCT03777436)

References:
1. Ryan C, et al. *J Am Acad Dermatol*. 2015;72:978-983. 2. Meeuwis KAP, et al. *J Dermatol Treat*. 2018;29:754-760.

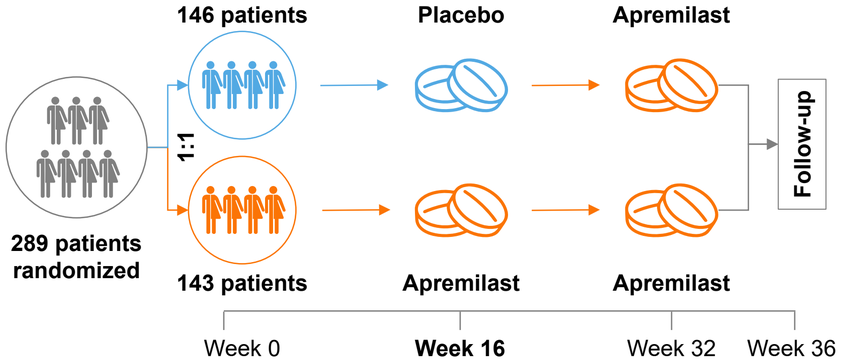
Abbreviations:
BSA, body surface area; DLQI, Dermatology Life Quality Index; GPI-NRS, Genital Psoriasis Itch Numeric Rating Scale; QoL, quality of life; sPGA, static Physician Global Assessment; sPGA-G, static Physician Global Assessment of Genitalia.

What did we do?

Phase 3, multicenter study

Patient population:

- Genital psoriasis severity (modified sPGA-G) score ≥ 3
- Overall psoriasis severity (sPGA) score ≥ 3
- Nongenital plaque psoriasis on ≥ 1% of BSA
- Intolerant to/or not controlled by medications applied to the skin for genital psoriasis



Primary outcome: Modified **sPGA-G response** (score 0 [clear] or 1 [almost clear] with a ≥ 2-point reduction from baseline) to assess genital psoriasis severity at week 16

Key secondary outcomes:

- **sPGA response** to assess overall psoriasis severity
- **GPI-NRS response** to assess genital itch severity
- **Change from baseline in DLQI score** to assess the impact of psoriasis on QoL at week 16

What were our findings at week 16?

Baseline characteristics were similar between treatment groups

Apremilast, n = 143
70% male; mean age: 44 years
Genital psoriasis duration: 11 years
DLQI: 13.3
sPGA-G: 86% moderate; 14% severe

Placebo, n = 146
70% male; mean age: 46 years
Genital psoriasis duration: 12 years
DLQI: 12.8
sPGA-G: 88% moderate; 12% severe

All outcomes at week 16 improved with apremilast vs placebo

	Apremilast vs Placebo
Genital psoriasis severity (sPGA-G response rate)	2x — 38.7% vs 19.1%
Overall psoriasis severity (sPGA response rate)	3x — 21.5% vs 7.2%
Genital itch (GPI-NRS response rate)	2x — 46.0% vs 19.6%
QoL (reduction in DLQI score from baseline)	2x — –5.3 vs –2.6

No new safety signals were identified, and adverse events were consistent with the known apremilast safety profile

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