Apremilast for the Treatment of Psoriasis in Special Areas in Pediatric Patients in the SPROUT Study

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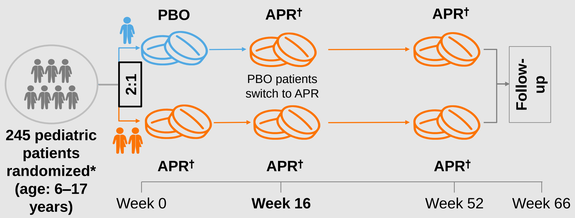
Background and Objective

- Psoriasis in special areas is difficult to treat and causes significant disease burden[1]
- Approved systemic therapies for moderate to severe plaque psoriasis in pediatric patients are limited and require subcutaneous injection
- APR, a unique oral immunomodulator that inhibits phosphodiesterase-4, is approved in multiple countries for use in adults with psoriasis
- This analysis assessed APR efficacy for psoriasis in special areas (scalp and genitals) in pediatric patients in the SPROUT study over 16 weeks

SPROUT Study Design and Patient Population

- Phase 3, multicenter, randomized, double-blind, PBO-controlled study (NCT03701763)



*Randomization was stratified by age group. †Patients weighing ≥20 to <50 kg received APR 20 mg BID and patients weighing ≥50 kg received APR 30 mg BID.

- **Inclusion criteria:** Ages 6–17 years with moderate-to-severe plaque psoriasis (PASI ≥12, BSA ≥10%, and sPGA ≥3) inadequately controlled by or inappropriate for topical therapy
- **Analyses:** For clinical endpoints, LOCF was used at week 16 assessments and NRI was used in longitudinal assessments; multiple imputations were used for CDLQI analyses

Baseline Characteristics

	PBO (n=82)	APR (n=163)
Age, mean (SD), y	12.2 (3.2)	12.3 (3.3)
Female, n (%)	39 (47.6)	89 (54.6)
Weight, mean (SD), kg	51.8 (22.2)	52.0 (21.1)
ScPGA ≥3, n (%)	69 (84.1)	132 (81.0)
sPGA-G ≥3, n (%)	36 (43.9)	74 (45.4)
WBI-NRS, mean (SD)	5.1 (2.8)	5.4 (2.9)
CDLQI, mean (SD)	7.6 (5.0)	8.8 (5.8)

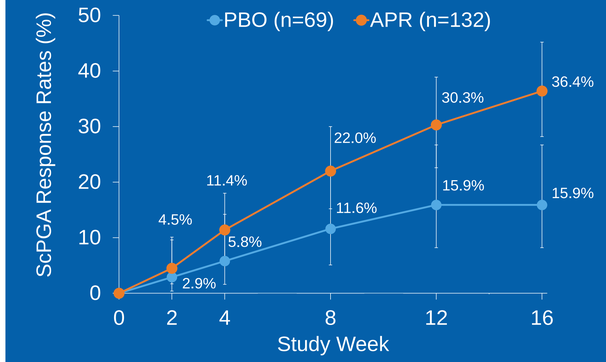
Scan the QR code for additional baseline characteristics

Abbreviations: APR, apremilast; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; LOCF, last observation carried forward; NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; ScPGA, Scalp Physician's Global Assessment; sPGA, static Physician Global Assessment; sPGA-G, static Physician Global Assessment of Genitalia; WBI-NRS, Whole Body Itch Numeric Rating Scale.

Key Takeaways

- **Apremilast significantly improved scalp psoriasis, itch, and quality of life in pediatric patients with moderate to severe psoriasis**
- **At week 16, patients with moderate to severe genital psoriasis showed a trend toward improvement, although not significant in part due to sample size**

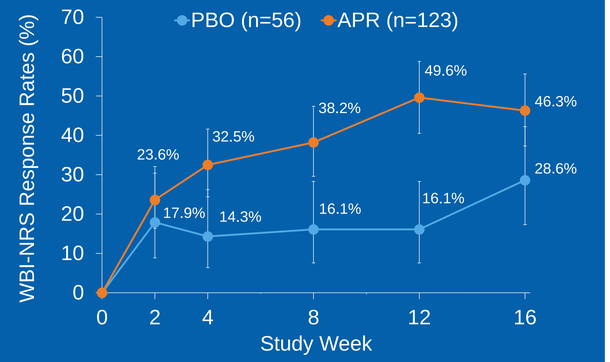
Twice as many pediatric patients achieved ScPGA response at week 16 with APR vs PBO



PBO n/N=	2/69	4/69	8/69	11/69	11/69
APR n/N=	6/132	15/132	29/132	40/132	48/132

ScPGA response=score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline. Intent-to-treat population with a baseline score ≥3. NRI used for missing data. Error bars represent 95% CI.

The WBI-NRS response rate was significantly greater with APR vs PBO at week 16



PBO n/N=	10/56	8/56	9/56	9/56	16/56
APR n/N=	29/123	40/123	47/123	61/123	57/123

WBI-NRS response = ≥4-point reduction from baseline. Intent-to-treat population with a baseline score ≥4. NRI used for missing data. Error bars represent 95% CI.

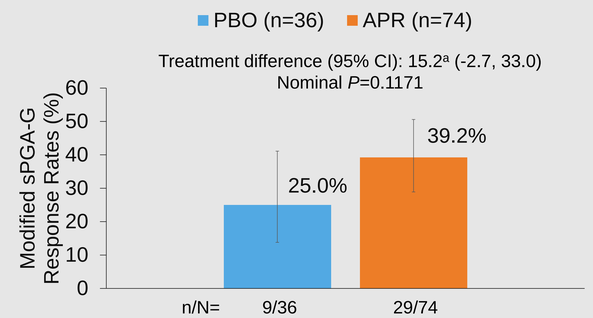
Week 16, LOCF	PBO (n=69) n (%)	APR (n=132) n (%)	Adjusted difference (95% CI)	Nominal *P* value
ScPGA response	13 (18.8)	48 (36.4)	17.8 (5.3, 30.3)	0.0091

Intent-to-treat population with baseline score ≥3. Two-sided *P* value is based on the Cochran-Mantel-Haenszel test adjusting for baseline age group (6–11 years or 12–17 years).

Week 16, LOCF	PBO (n=56) n (%)	APR (n=123) n (%)	Adjusted difference (95% CI)	Nominal *P* value
WBI-NRS response	18 (32.1)	64 (52.0)	20.4 (4.9, 35.8)	0.0110

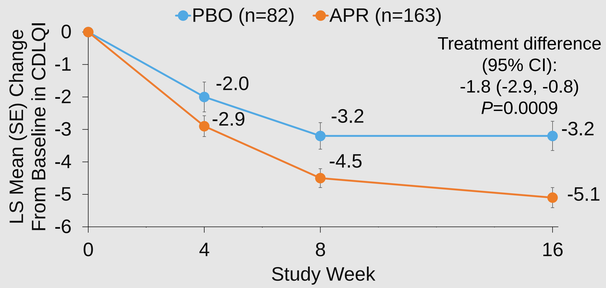
Intent-to-treat population with baseline score ≥4. Two-sided *P* value is based on the Cochran-Mantel-Haenszel test adjusting for baseline age group (6–11 years or 12–17 years).

sPGA-G response rates were numerically greater with APR than with PBO



Modified sPGA-G response=score of 0 (clear) or 1 (almost clear) with ≥2-point reduction from baseline. Intent-to-treat population with baseline score ≥3. LOCF used for missing data. Error bars represent 95% CI. [a]Two-sided *P* value is based on the Cochran-Mantel-Haenszel test adjusting for baseline age group (6–11 years or 12–17 years).

Decreases in CDLQI were significantly greater with APR than with PBO



Intent-to-treat population. Multiple imputations used for missing data. Error bars represent SE. Two-sided *P* value is based on the Cochran-Mantel-Haenszel test adjusting for baseline age group (6–11 years or 12–17 years).

Safety

- No new safety signals were identified, and adverse events were consistent with the known APR safety profile.
  Scan the QR code for the adverse event table
- In 21 patients vaccinated during the study (including for COVID-19, influenza, diphtheria, pertussis, tetanus, meningococcus, and hepatitis B), no new safety issues occurred

Limitation

- Use of LOCF and NRI for sensitivity analyses

Disclosures and Funding Statement

LF: Amgen, Galderma, LEO Pharma, and Pfizer – investigator, received honoraria, and advisory board member; Pierre Fabre and Galderma – speaker; EB: Amgen – principal investigator; Pfizer, Regeneron, and Sanofi – speaker; **AB-F**: AbbVie, Janssen, Novartis, Pfizer, and Sanofi – consultant and received fees and honoraria; **SA**: Amgen, Janssen, LEO Pharma, and Novartis – speaker and advisory board member; **PM, AK, MP, WZ, & ZZ**: Amgen – employees and stockholders; **LA**: Candela – received research equipment; Amgen and Celgene – investigator; AbbVie, Amgen, Regeneron, and Verrica – consultant funding.

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Reference: 1. Merola JF, et al., *Dermatol Ther.* 2018;31:e12589.

Scan the QR code or follow the URL for additional baseline characteristics and adverse event data.

https://contents-amgen.com/prd/user-screen.html?content_id=344

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