Apremilast in Pediatric Patients With Moderate to Severe Plaque Psoriasis: 16-Week Efficacy and Safety Results From the Phase 3, Randomized, Double-Blind, Placebo-Controlled SPROUT Study

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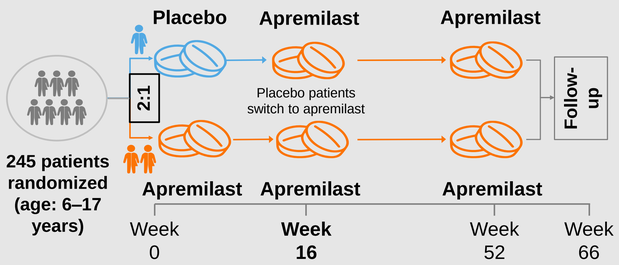
Introduction and Objective

- Treatment options for pediatric patients with moderate to severe plaque psoriasis are limited
- SPROUT evaluated the efficacy and safety of apremilast (APR) compared with placebo (PBO) in pediatric patients

Study Design and Patient Population

- Design: Phase 3, multicenter, randomized, double-blind, PBO-controlled, parallel-group study (NCT03701763)
  - Randomization (2:1) was stratified by age group
  - Patients weighing ≥ 20 to < 50 kg received APR 20 mg twice daily (BID); patients weighing ≥ 50 kg received APR 30 mg BID



- **Main Inclusion Criteria:** 6–17 years of age with moderate to severe psoriasis (Psoriasis Area and Severity Index [PASI] ≥ 12, body surface area [BSA] ≥ 10%, static Physician Global Assessment [sPGA] ≥3) inadequately controlled or intolerant to topical therapy
- **Primary Endpoint:** sPGA response (score of 0 [clear] or 1 [almost clear] with a ≥ 2-point reduction from baseline) at week 16
- **Major Secondary Endpoint:** ≥ 75% reduction from baseline in PASI score (PASI-75)
- **Analysis:** Efficacy endpoints were analyzed for the intent-to-treat population; safety was analyzed for the safety population

Baseline Characteristics

- There were 120 patients in the ≥ 20- to < 50-kg group and 125 in the ≥ 50-kg group

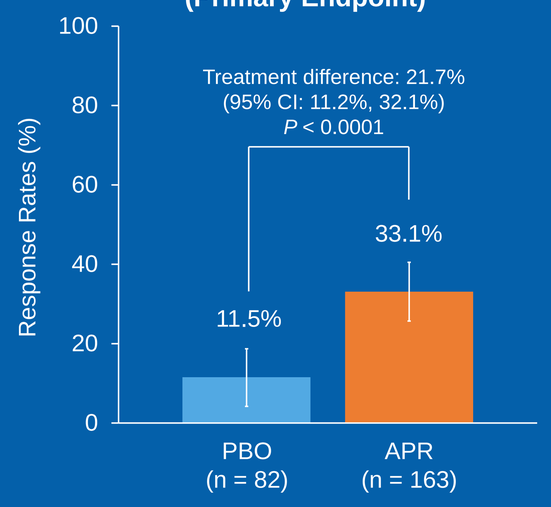
	PBO (n = 82)	APR (n = 163)	Total (N = 245)
Age, mean (SD), y	12.2 (3.25)	12.3 (3.32)	12.2 (3.29)
6–11, n (%)	34 (41.5)	67 (41.1)	101 (41.2)
12–17, n (%)	48 (58.5)	96 (58.9)	144 (58.8)
Male, n (%)	43 (52.4)	74 (45.4)	117 (47.8)
Duration of plaque psoriasis, mean (SD), y	4.0 (3.39)	4.3 (3.35)	4.2 (3.36)
sPGA score, n (%)			
3 (Moderate)	63 (76.8)	122 (74.8)	185 (75.5)
4 (Severe)	19 (23.2)	41 (25.2)	60 (24.5)
PASI score, mean (SD)	19.5 (7.94)	20.0 (8.16)	19.8 (8.07)
Affected BSA, mean (SD), %	30.8 (19.04)	31.9 (18.45)	31.5 (18.62)

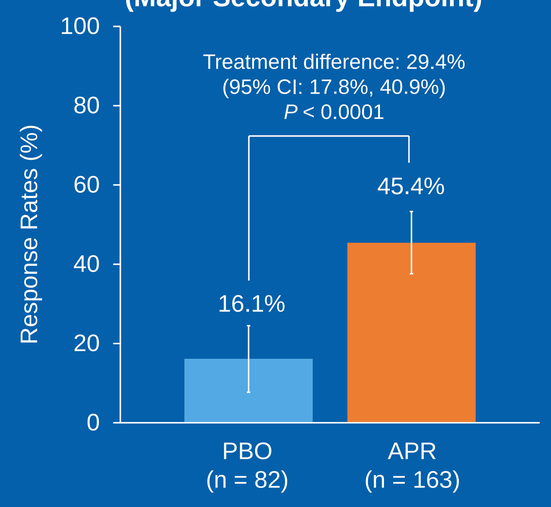
APR, apremilast; BSA, body surface area; PASI, Psoriasis Area and Severity Index; PBO, placebo; SD, standard deviation; sPGA, static Physician Global Assessment.

Key Takeaways

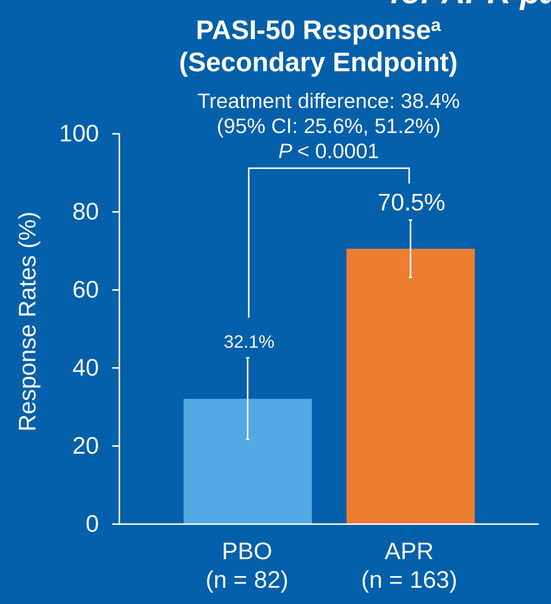
- **APR significantly reduced the psoriasis severity in pediatric patients with moderate to severe plaque psoriasis inadequately controlled or intolerant to topical therapy compared with PBO**
- **No new safety signals were identified; AEs were consistent with the known safety profile of APR**

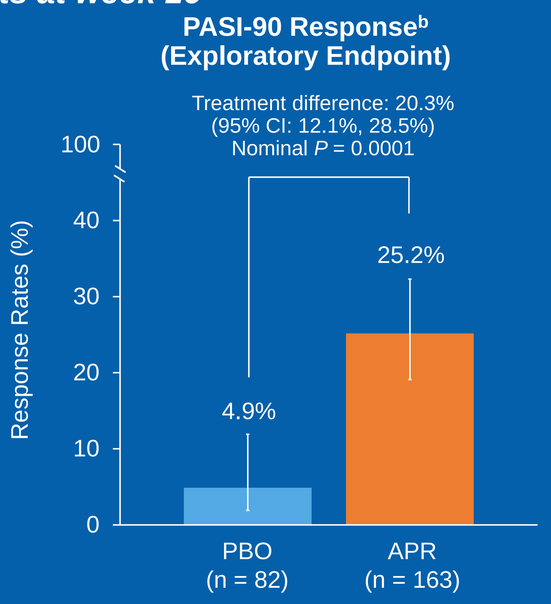
sPGA and PASI-75 response rates at week 16 were nearly three times greater in patients receiving APR versus PBO





Other PASI response rates were significantly greater for APR patients at week 16





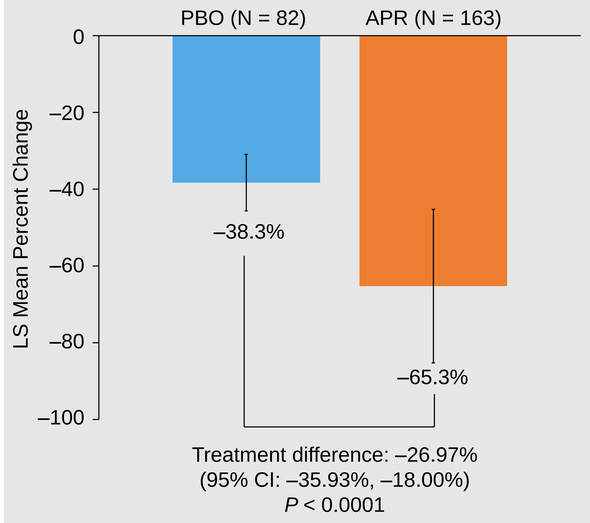
Intent-to-treat population. Error bars represent 95% CI. aMissing values imputed using multiple imputation. bMissing values imputed using last observation carried forward method. sPGA response is defined as sPGA score of 0 (clear) or 1 (almost clear) with a ≥2-point reduction from baseline. PASI-50 response is defined as ≥ 50% reduction in total PASI score from baseline. PASI-75 response is defined as ≥ 75% reduction in total PASI score from baseline. PASI-90 response is defined as ≥ 90% reduction in total PASI score from baseline. Two-sided P value is based on the Cochran-Mantel-Haenszel test adjusting for the stratification factors. APR, apremilast; CI, confidence interval; PASI, Psoriasis Area and Severity Index; PBO, placebo; sPGA, static Physician Global Assessment.

- Results were consistent among subgroups of patients weighing ≥ 20 kg to < 50 kg at baseline (receiving APR 20 mg BID) and patients weighing ≥ 50 kg at baseline (receiving APR 30 mg BID) (*Scan QR code*)

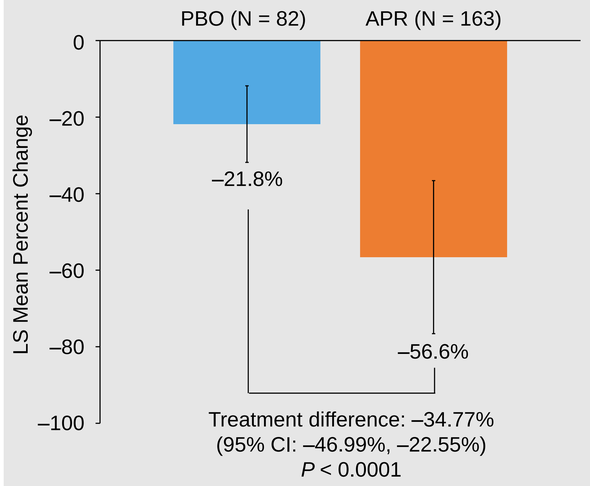
Additional Results

PASI scores and affected BSA were significantly improved in patients treated with APR at week 16

PASI Total Score Percent Change From Baseline



Affected BSA Percent Change From Baseline



Intent-to-treat population. Error bars represent 95% CI. Missing values imputed using multiple imputation. The SAS procedure PROC MIANALYZE was used to derive values for each treatment group and difference in LS mean, 95% CI, and two-sided P value for treatment comparison. APR, apremilast; BSA, body surface area; CI; confidence interval; LS, least squares; PASI, Psoriasis Area and Severity Index; PBO, placebo.

Safety

- No new safety signals were identified, and adverse events (AEs) were consistent with the known APR safety profile[1,2]
- Rates of treatment-emergent AEs (TEAEs) leading to drug withdrawal were low (APR: 3.1%; PBO: 1.3%)
- Reasons for withdrawal included primarily gastrointestinal disorders for APR and suicidal ideation for PBO
- The most common TEAE was diarrhea
- 70% of these events of diarrhea in the APR group resolved within 3 days during the PBO-controlled period
- For a table of overall safety and TEAEs occurring in ≥ 5% of patients, scan the QR code

Disclosures and Funding Statement

LF: Pfizer, Amgen, Galderma, and Leo – investigator, received honoraria, and advisory board member; Pierre Fabre and Galderma – speaker. **EB:** Amgen – investigator; Pfizer, Regeneron, and Sanofi – speaker. **RdL:** None **ABF:** Sanofi, Janssen, Novartis, AbbVie, and Pfizer – consultant and received fees and honorarium. **PM, RKO, MP, WZ, and ZZ:** Amgen Inc. – employees and stockholders. **LA:** Candela – received research equipment; Celgene and Amgen – investigator; AbbVie, Amgen, Regeneron and Verrica – consultant.

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References: 1. Papp K, et al. *J Am Acad Dermatol*. 2015;73:37-49. **2.** Paul C, et al. *Br J Dermatol*. 2015;173:1387-1399.

For further information on the study, scan the QR code or follow the URL:

https://contents-amgen.com/prd/user-screen.html?content_id=326

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