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

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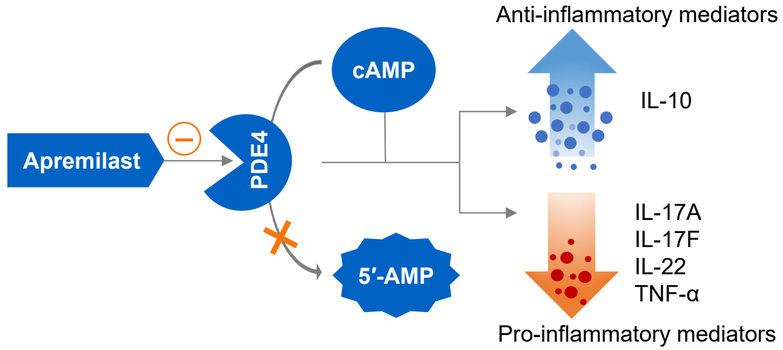
Key takeaways

Apremilast was well tolerated and effectively reduced psoriasis severity in children aged 6 to 17 years with moderate to severe plaque psoriasis that was inadequately controlled by or intolerant to medications applied to the skin

What do we know?

Approved oral or injectable therapies for children with moderate to severe psoriasis are limited

Apremilast, an oral immunomodulator that inhibits PDE4, is approved for use in adults with psoriasis, psoriatic arthritis, and oral ulcers associated with Behçet's disease



AMP, adenosine monophosphate; cAMP, cyclic adenosine monophosphate; IL, interleukin; PDE, phosphodiesterase; TNF-α, tumor necrosis factor alpha.

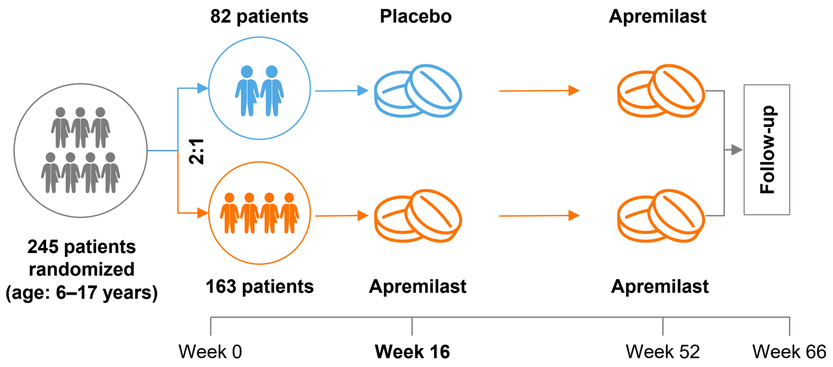
Apremilast has shown favorable effects over risks in **706,585** adults globally, across the indications for which it is approved

What was our aim?

To evaluate how well apremilast works and how safe it is in children with moderate to severe psoriasis that was inadequately controlled by or intolerant to medications applied to the skin

What did we do?

This phase 3 study included **245 participants** from **99 centers** in **10 countries** (NCT03701763)



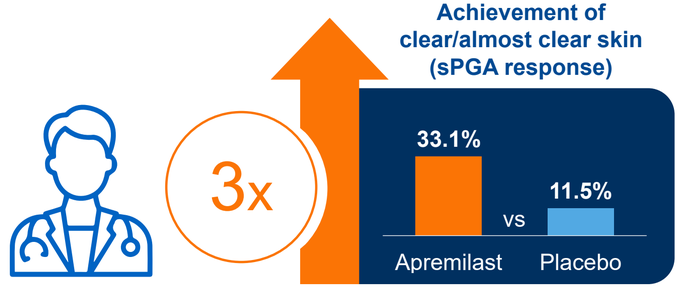
Primary outcome: Psoriasis severity assessed by the proportion of patients achieving an sPGA response at week 16 (sPGA response: a score of 0/1 [clear/almost clear skin] with a ≥ 2-point reduction from baseline)

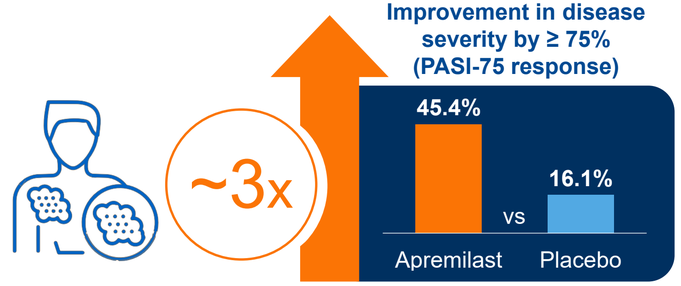
Key secondary outcome: Psoriasis improvement assessed by the proportion of patients achieving a PASI-75 response at week 16 to assess psoriasis severity

PASI-75 response: a ≥ 75% reduction in PASI scores from baseline.
PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

What were our findings at week 16?

The percentage of patients in the age and weight categories was similar between apremilast and placebo groups





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

PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

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