STUDY | **COMFORT-1 trial: Piclidenson for plaque psoriasis**

Population: N = 955

Primary endpoint: Proportion of patients achieving PASI 75 at Week 16.
Secondary endpoint: PASI 50 rates and the proportion of patients achieving a PGA2 score of 0–1

Eligibility: Aged 18–80 years; PASI ≥12; static PGA ≥3; chronic moderate-to-severe plaque psoriasis for ≥6 months; BSA involvement ≥10%

TRIAL DESIGN

Patients randomized 3:3:3:2

- **Piclidenoson** (n = 151) | **2 mg**
- **Piclidenoson** (n = 142) | **3 mg**
- **Apremilast** (n = 142) | **30 mg** BID*

Placebo (n = 94)

Randomized 1:1:1

- **Piclidenoson** (n = 28) | **2 mg** BID
- **Piclidenoson** (n = 31) | **3 mg** BID
- **Apremilast** (n = 35) | **30 mg** BID*

Week 0 — Week 16 — Week 32

Patients were evaluated: Every 2 weeks for efficacy and safety; at Week 16 for the primary and secondary endpoints; at Week 32 for secondary endpoints.

*dose titrated over 6 days

Piclidenoson 2mg | Piclidenoson 3 mg | Apremilast | Placebo

N = 426 EFFICACY

Week 16

PASI 75 (mITT population)

7.9%	p = 0.075
9.7%	p = 0.037
2.6%	vs placebo

PGA2 0–1

11.8%	p = 0.027
10.7%	p = 0.068
3.8%	vs placebo

Week 32

PASI 75 (mITT population)

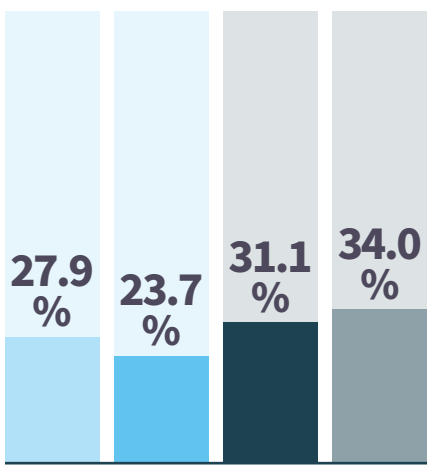
20.8%	p = 0.43
17.0%	p = 0.88
26.2%	vs apremilast

PGA2 0–1

18.9%	p = 0.42
15.9%	p = 0.78
24.3%	vs apremilast

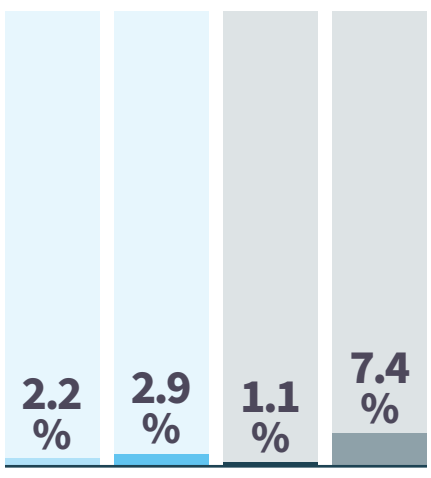
In the pic 3 mg arm; the test for noninferiority trended towards significance (p = 0.072) vs apremilast for improvement from baseline in PDI

N = 529 SAFETY



Any TEAE | **Infections and infestations**

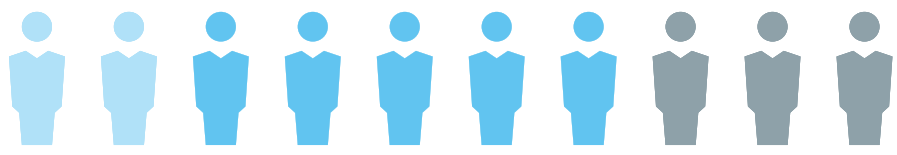
Most common TEAEs (any grade)



Nasopharyngitis | Urinary tract infection

TEAEs leading to discontinuation

10/529 patients (**1.89%**)



Pic 2 mg = **2** | Pic 3 mg = **5** | Placebo = **3** 1 in each arm

None of the events were considered drug related

The phase III COMPFORT-1 trial met its primary endpoint for the 3 mg BID dose of piclidenoson (superiority over placebo in PASI 75 at Week 16). Both doses of piclidenoson were well-tolerated up to 32 weeks.

Abbreviations: BID, twice daily; mITT, modified intention-to-treat population; PASI 75, 75% improvement in Psoriasis Area and Severity; Index; PDI, Psoriasis Disability Index; PGA2, Physician's Global Assessment 2; pic, piclidenoson; TEAE, treatment-emergent adverse event.

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