Once-daily oral zasocitinib demonstrates rapid and reproducible skin clearance with a consistent safety profile in moderate-to-severe plaque psoriasis: results from two randomized phase 3 trials (LATITUDE-PsO-3001 and 3002)

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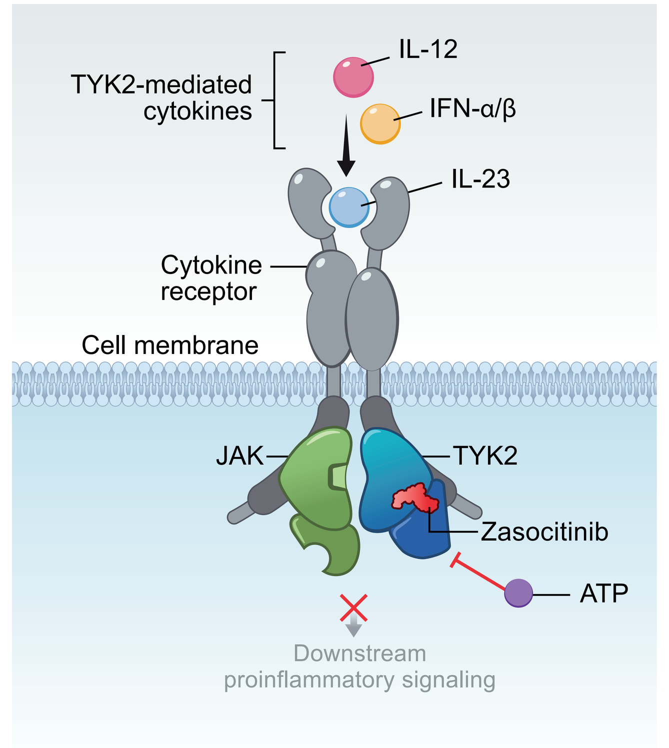
Introduction

- Zasocitinib is an investigational, next-generation, highly selective, once-daily oral TYK2 inhibitor that maintains 24-hour inhibition of IL-23 plus other core disease-driving immune pathways.[1,2]
- In a phase 2b trial (NCT04999839), zasocitinib demonstrated efficacy and had an acceptable safety and tolerability profile in patients with moderate-to-severe plaque psoriasis.[3]

Figure 1. Zasocitinib has more than 1-millionfold greater binding selectivity for TYK2 versus JAK1, JAK2 and JAK3, thereby selectively inhibiting downstream proinflammatory signaling.[1,2,4]



Objective

- To evaluate the efficacy and safety of zasocitinib in adults with moderate-to-severe plaque psoriasis enrolled in two pivotal phase 3 studies, LATITUDE-PsO-3001 (NCT06088043) and LATITUDE-PsO-3002 (NCT06108544).

Methods

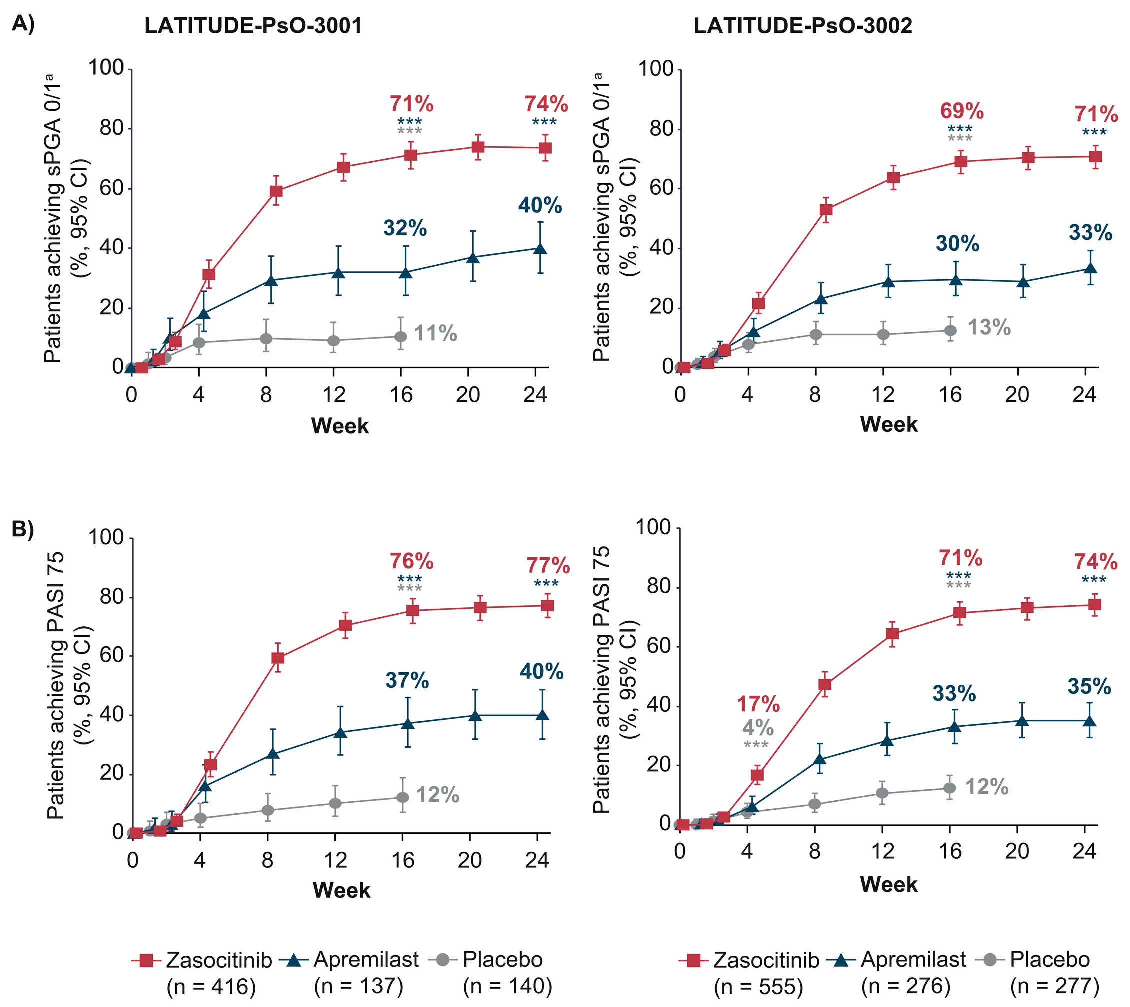
- LATITUDE-PsO-3001 and LATITUDE-PsO-3002 were phase 3 randomized, double-blinded, multicenter trials that compared zasocitinib 30 mg once daily (with or without food) with placebo or apremilast 30 mg twice daily over 52 (LATITUDE-PsO-3001) or 60 weeks (LATITUDE-PsO-3002) (**Figure S1**).
- Co-primary endpoints were sPGA 0/1 (≥ 2-point improvement) and PASI 75 versus placebo (Week 16).
- Secondary endpoints included:
  - PASI 75 versus placebo at Week 4 (LATITUDE-PsO-3002 only)
  - PASI 75 or sPGA 0/1 versus apremilast at Weeks 16 or 24
  - PASI 90, PASI 100, sPGA 0 or DLQI 0/1 versus placebo or apremilast at Weeks 16 or 24
  - sPGA 0/1 or PASI 75 maintenance at Week 60.
- Safety endpoints included TEAEs and laboratory parameters.

Scan the QR code in the top right-hand corner of this poster to see the **supplementary material** for further details of the study designs and results included in this poster.

Results

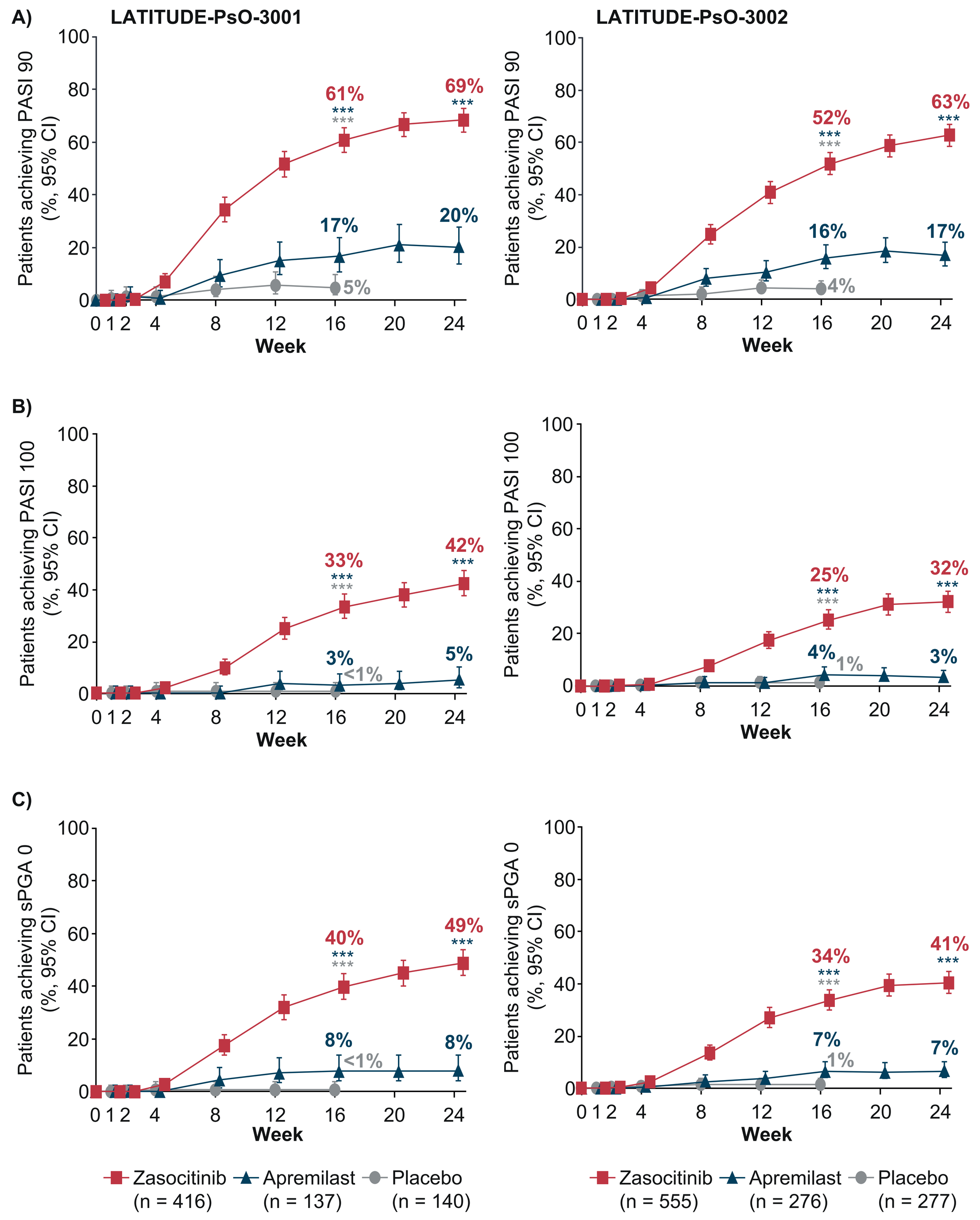
- Baseline demographics and characteristics were generally similar across treatment arms in each study (**Table S1**).

Figure 2. Zasocitinib met the co-primary endpoints of A) sPGA 0/1 and B) PASI 75 versus placebo at Week 16 in both studies.



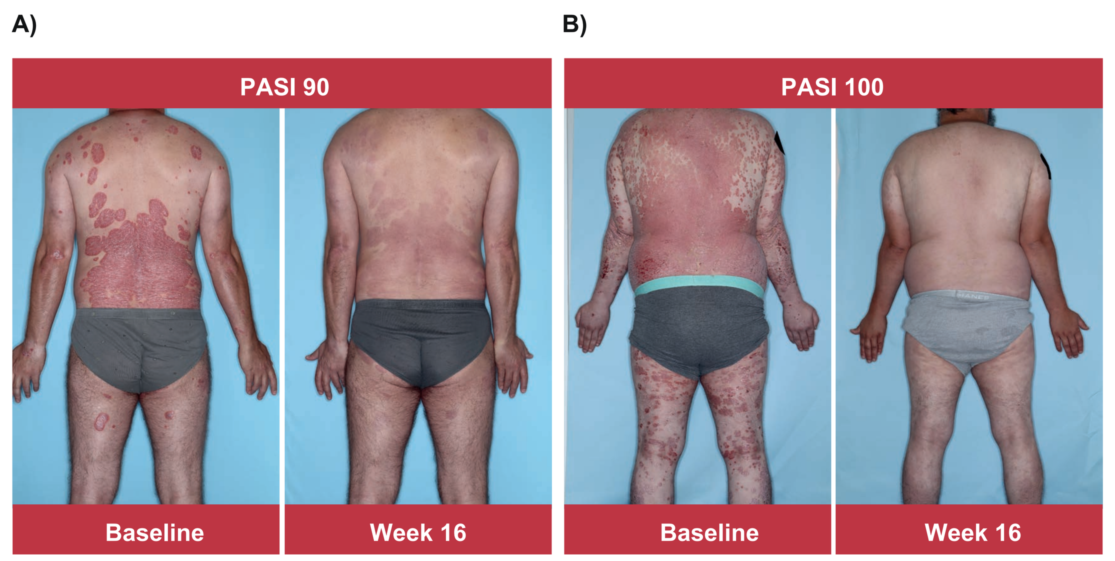
Number of patients based on full analysis set with nonresponder imputation.
P values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
[a]With a ≥ 2-point decrease from baseline.

Figure 3. Zasocitinib led to significantly greater proportions of patients achieving A) PASI 90, B) PASI 100 or C) sPGA 0 than apremilast or placebo at Weeks 16 or 24.



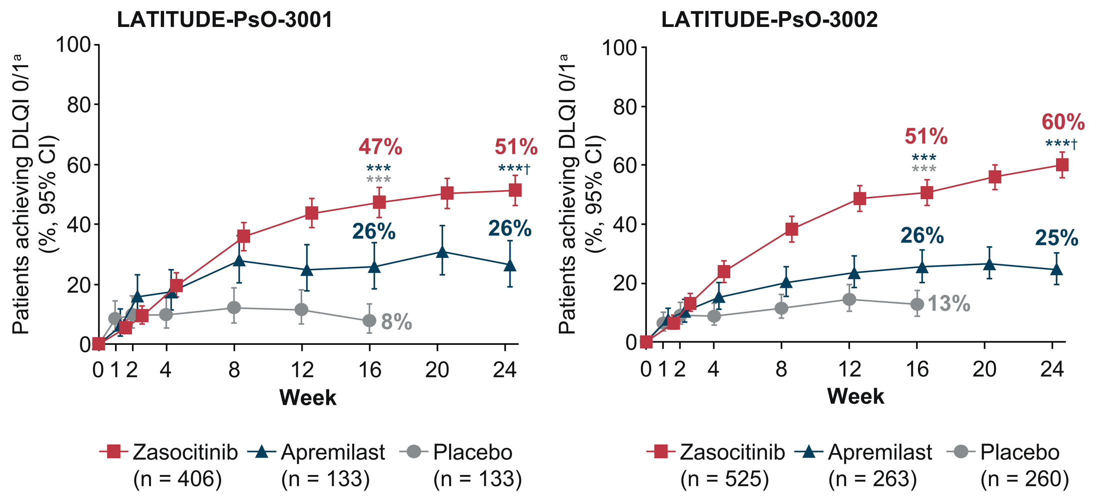
Number of patients based on full analysis set with nonresponder imputation.
P values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.

Figure 4. Representative images showing A) PASI 90 and B) PASI 100 at Week 16 following treatment with zasocitinib 30 mg once daily.



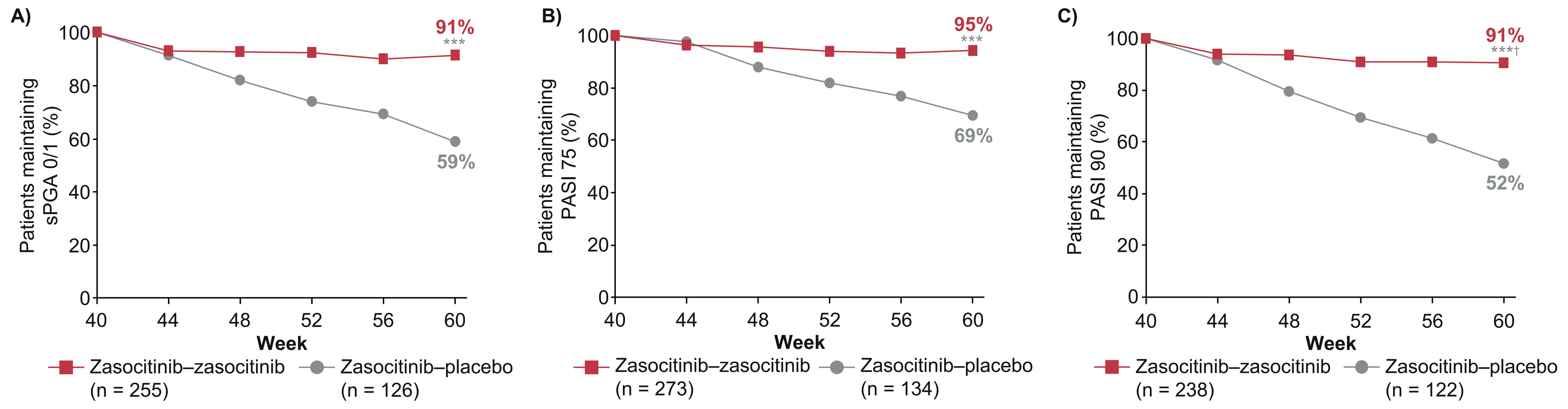
PASI: 15.8 **sPGA:** 3 | **PASI:** 0.7 (CfB 95.6%) **sPGA:** 0 | **PASI:** 31.3 **sPGA:** 3 | **PASI:** 0 **sPGA:** 0

Figure 5. Zasocitinib demonstrated superior improvement in DLQI 0/1 versus apremilast or placebo as early as Week 4.



n numbers based on number of evaluable patients, defined as a subset of full analysis set with nonresponder imputation.
P values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$; ***† nominal $p < 0.001$.
[a]With a baseline DLQI score ≥ 2.

Figure 6. More than 90% of patients continuing zasocitinib at Week 40 maintained A) sPGA 0/1, B) PASI 75 and C) PASI 90 through Week 60.



n numbers based on number of evaluable patients, based on the full analysis set for randomized withdrawal with nonresponder imputation.
P values for comparison versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$; ***† nominal $p < 0.001$.

- Most patients (59%, 69% and 52%) re-randomized from zasocitinib to placebo at Week 40 maintained sPGA 0/1, PASI 75 and PASI 90, respectively, for around an additional 5 months.

Table 1. Zasocitinib was well tolerated with no new safety signals identified through Week 24.

TEAEs from LATITUDE-PsO-3001 and 3002[a]	Day 0 to Week 16: Zasocitinib (n = 970) n	%[b] (95% CI)[c]	Apremilast (n = 412) n	%[b] (95% CI)[c]	Placebo (n = 417) n	%[b] (95% CI)[c]	Day 0 to Week 24: Zasocitinib (n = 970) n	%[b] (95% CI)[c]	Apremilast (n = 412) n	%[b] (95% CI)[c]
Any TEAE	605	**62.1** (59.0–65.1)	207	**50.5** (45.7–55.4)	196	**46.9** (42.0–51.7)	674	**69.3** (66.4–72.2)	232	**56.5** (51.7–61.4)
Leading to discontinuation	31	**3.2** (2.1–4.3)	11	**2.6** (1.1–4.2)	3	**< 1** (0.0–1.6)	36	**3.7** (2.5–4.9)	13	**1.3** (1.4–4.7)
SAE	29	**3.0** (1.9–4.1)	6	**1.5** (0.3–2.7)	2	**< 1** (0.1–1.7)	35	**3.6** (2.4–4.8)	7	**1.7** (0.5–3.0)
Death	1[d]	**< 1** (0.0–0.6)[d]	0	**0** (0.0–0.9)	0	**0** (0.0–0.9)	1[d]	**< 1** (0.0–0.6)[d]	0	**0** (0.0–0.9)
Most frequent TEAE (≥ 5%)[e]										
URTI	100	**10.1** (8.2–12.0)	24	**6.0** (3.7–8.3)	13	**3.2** (1.5–4.8)	123	**12.5** (10.4–14.6)	29	**7.4** (4.8–10.0)
Acne	62	**6.5** (5.0–8.1)	3	**< 1** (0.0–1.7)	1	**< 1** (0.0–1.3)	70	**7.3** (5.6–8.9)	3	**< 1** (0.0–1.7)
Nasopharyngitis	60	**6.2** (4.7–7.7)	23	**5.4** (3.2–7.5)	20	**4.7** (2.7–6.6)	80	**8.3** (6.5–10.0)	34	**7.9** (5.4–10.5)
Diarrhea	30	**3.1** (2.0–4.2)	33	**8.2** (5.5–10.9)	8	**1.8** (0.6–3.1)	36	**3.7** (2.5–4.9)	33	**8.2** (5.5–10.9)
Headache	27	**2.8** (1.8–3.9)	26	**6.3** (4.0–8.7)	8	**1.9** (0.6–3.2)	32	**3.3** (2.2–4.5)	28	**6.8** (4.4–9.3)
Nausea	20	**2.1** (1.2–3.0)	23	**5.5** (3.3–7.8)	5	**1.2** (0.1–2.2)	23	**2.4** (1.4–3.4)	24	**5.8** (3.5–8.1)

TEAEs were coded using MedDRA v28.1.
[a]Events starting while on initial treatment are included. [b]Sample size adjusted incidence proportion x 100. [c]95% Wald CI unless 0 events occur in either trial, in which case a 95% exact binomial CI is used. [d]Death occurred 1 day after first dose date (unrelated to treatment). [e]Most frequently reported adverse events occurring in ≥ 5% of patients in any treatment group, based on individual preferred term.

- Most TEAEs were mild or moderate.
- Laboratory parameters (e.g. lymphocytes, liver enzymes, lipids) demonstrated no clinically meaningful trends over time in both studies.

Conclusions

Once-daily oral zasocitinib provided rapid, reproducible and durable skin clearance, and a consistent safety (including laboratory parameters) profile, across the two pivotal phase 3 trials.

- Clear skin was achieved by approximately one-third of patients treated with zasocitinib by Week 16.
- Zasocitinib demonstrated superior improvement in QoL versus placebo or apremilast.
- More than 90% of patients continuing zasocitinib at Week 40 maintained sPGA 0/1, PASI 75 and PASI 90 through Week 60.
- Zasocitinib was generally well tolerated with no new safety signals identified.

Zasocitinib efficacy and safety will be further evaluated in adults with moderate-to-severe plaque psoriasis in a 3-year long-term extension study (NCT06550076) and an ongoing head-to-head trial versus deucravacitinib (NCT06973291).

Abbreviations

ATP, adenosine triphosphate; CfB, change from baseline; CI, confidence interval; DLQI, Dermatology Life Quality Index; IFN, interferon; IL, interleukin; IMID, immune-mediated inflammatory disease; JAK, Janus kinase; MedDRA, Medical Dictionary for Regulatory Activities; PASI, Psoriasis Area and Severity Index; QoL, quality of life; SAE, serious adverse event; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse event; TYK2, tyrosine kinase 2; URTI, upper respiratory tract infection.

Disclosures

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This poster is intended for healthcare professionals