Zasocitinib IR Event

Phase 3 Psoriasis Data Presented at AAD

March 28th, 2026 ET / March 29th, 2026 JST

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AGENDA

1. **Opening Remarks**
   Julie Kim, CEO-Elect

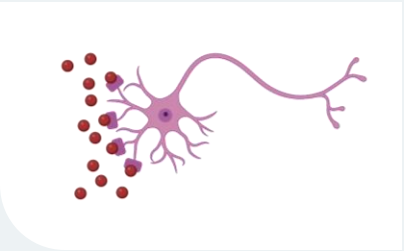
2. **Phase 3 Psoriasis Results**
   Chinwe Ukomadu, Head of GI&I Therapeutic Area

3. **Market Opportunity**
   Rhonda Pacheco, President, U.S. Business Unit;
   U.S. Country Head

4. **Question & Answer Session**

Preparing to launch 3 transformative medicines in the next 15 months setting Takeda on a new growth trajectory

Oveporexton
Narcolepsy Type 1



First orexin agonist to NDA submission with compelling efficacy across the broad spectrum of NT1 symptoms

Primed to trigger a paradigm shift in the treatment of NT1

Expected launch
2026 (H2)

Rusfertide
Polycythemia Vera

Hepcidin mimetic delivering durable & sustained hematocrit control addressing major unmet need

Set to revolutionize outcomes at each step in the treatment landscape

Expected launch
2026 (H2)

Zasocitinib
Psoriasis

Next-generation, highly selective oral TYK2 inhibitor delivering rapid and durable skin clearance in a convenient once-daily pill

Poised to be a leading oral option in an expanding oral market

Expected launch
2027 (H1)

Estimated launch timings are all pending regulatory approval.

● *Breakthrough Designation* ● *Fast Track Designation* ● *Orphan Drug Designation*

Zasocitinib: Poised to be a leading oral treatment option for patients with psoriasis – significantly expanding the oral market

1

Rapid and durable skin clearance, with no new safety signals

2

Convenient once-daily pill without fasting restrictions

3

Next-generation, highly selective oral TYK2 inhibitor

Zasocitinib U.S. and global filings on track to start in FY26

Zasocitinib

Phase 3 Psoriasis Results

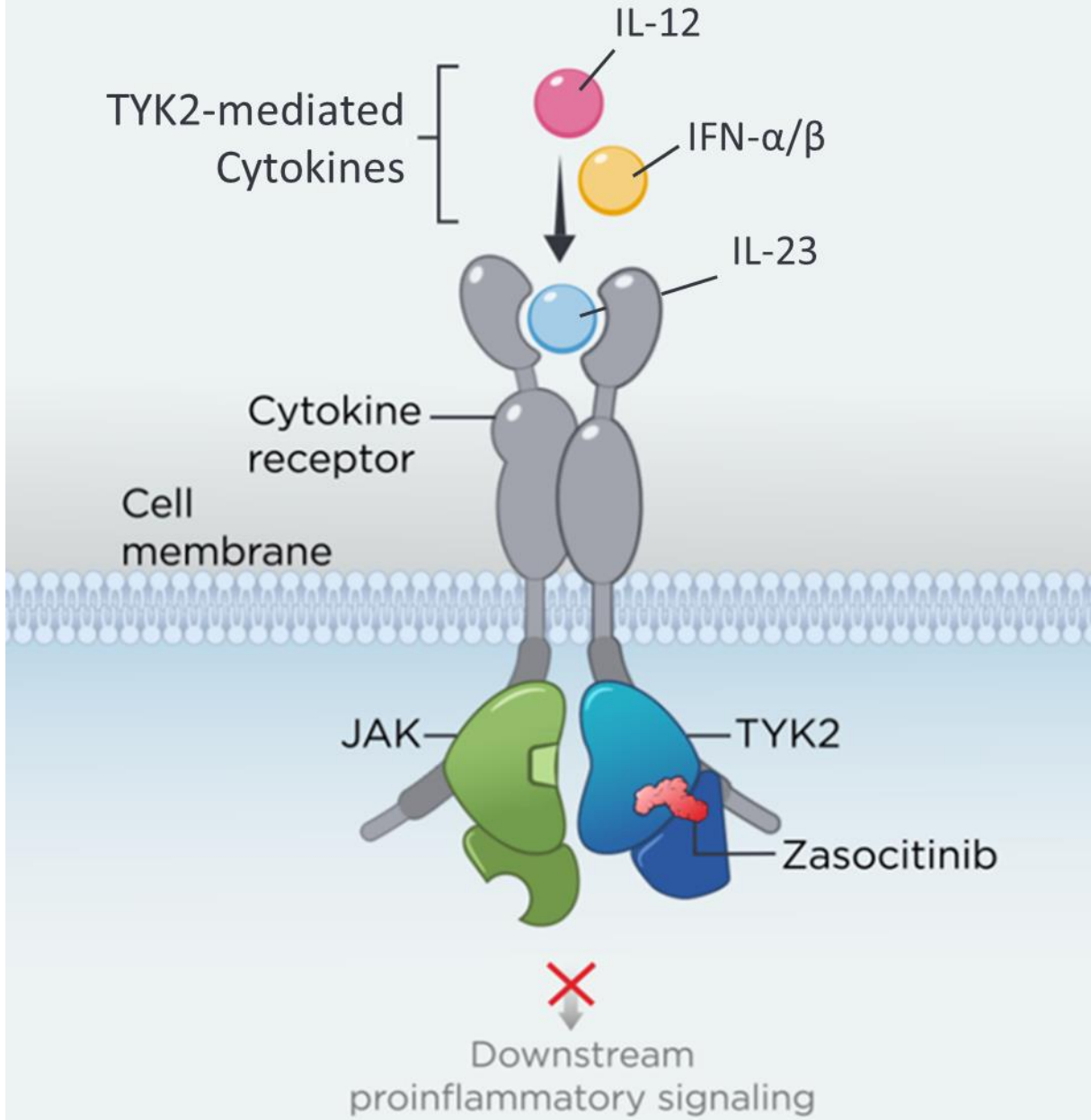
Better Health, Brighter Future

Zasocitinib: Next-generation, highly selective oral TYK2 inhibitor[1,2]

- More than 1 millionfold greater binding selectivity for TYK2 versus JAK1, JAK2 and JAK3[1,2]
- Maintains 24-hour inhibition of IL-23 plus other core disease-driving immune pathways without any inhibition of JAK1, JAK2 and JAK3 pathways.[2,3]
- Well tolerated and efficacious in a phase 2b trial in patients with moderate-to-severe plaque psoriasis[4]

Objective:

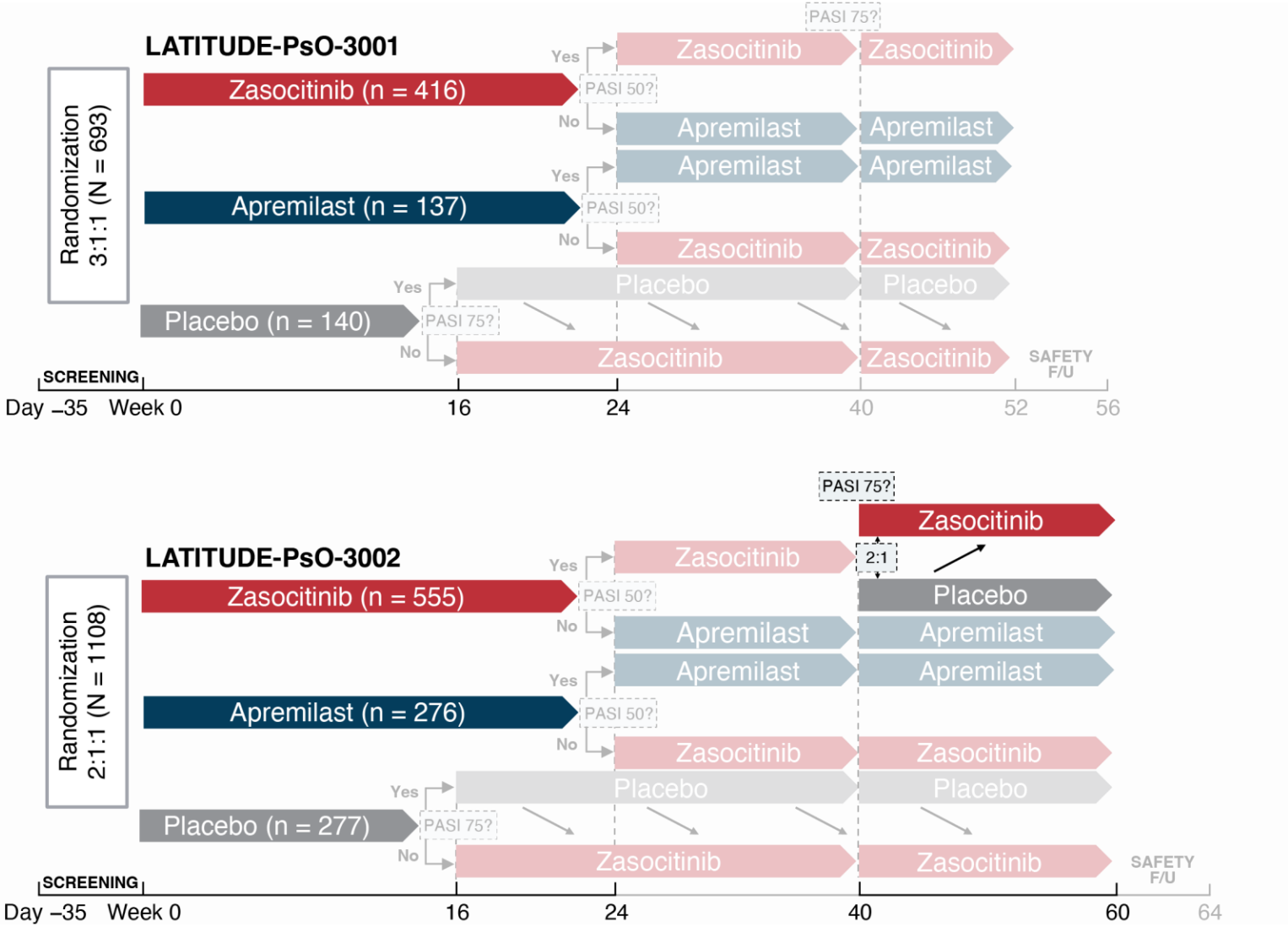
To evaluate the efficacy and safety of zasocitinib in adults with moderate-to-severe plaque psoriasis in two pivotal phase 3 studies: LATITUDE-PsO-3001 (NCT06088043) and LATITUDE-PsO-3002 (NCT06108544)



IFN, interferon; IL, interleukin; JAK, Janus kinase; TYK, tyrosine kinase

1. Leit S *et al. J Med Chem* 2023;66:10473–96; 2. Mehrotra S et al. *J Invest Dermatol* 2025;146:214–22;
3. Rusiñol L and Puig L. *Int J Mol Sci* 2023;24:3391. 4. Armstrong A *et al. JAMA Dermatol* 2024;160:1066–74.

LATITUDE-PsO-3001 and 3002 were randomized, multicenter, double-blind, placebo- and apremilast-controlled phase 3 trials



Eligibility

- Adults (≥ 18 years)
- Plaque psoriasis diagnosis for ≥ 6 months prior to screening
- PASI ≥ 12, sPGA ≥ 3, ≥ 10% BSA
- Candidate for phototherapy or systemic therapy

Endpoints

Co-primary endpoints at Week 16 (versus placebo):

- **sPGA 0/1[a]**
- **PASI 75**

Key secondary endpoints (versus placebo or apremilast) included:

- PASI 75 at Week 4
- sPGA 0, PASI 75/90/100 or DLQI 0/1[b] at Week 16/24
- sPGA 0/1 or PASI 75 maintenance at Week 60

Safety endpoints included:

- TEAEs; laboratory parameters

[a]With a ≥ 2-point decrease from baseline. [b]With a baseline DLQI score ≥2.
BSA, body surface area; DLQI, Dermatology Life Quality Index; F/U, follow-up; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse events.

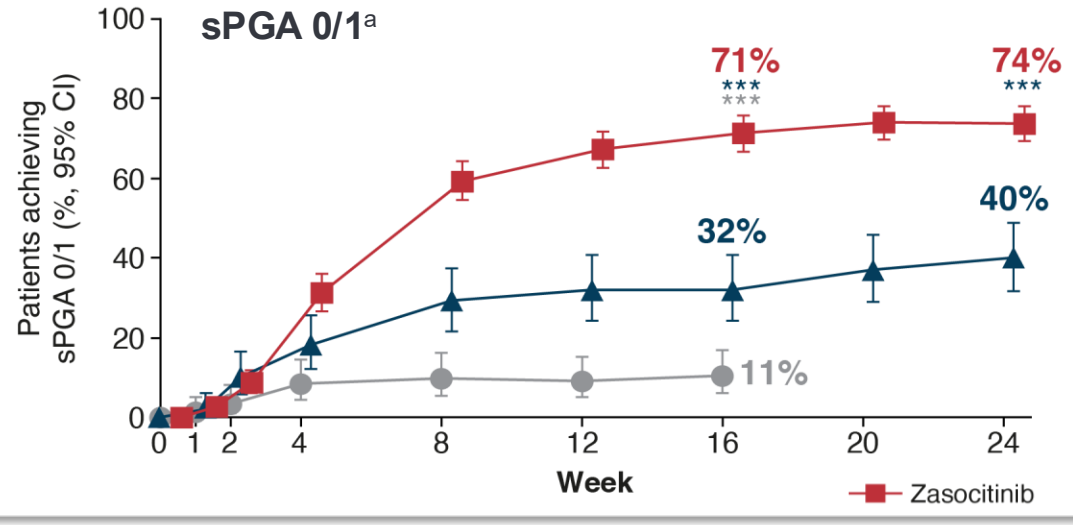
Baseline demographics and characteristics were generally similar across treatment arms in each study

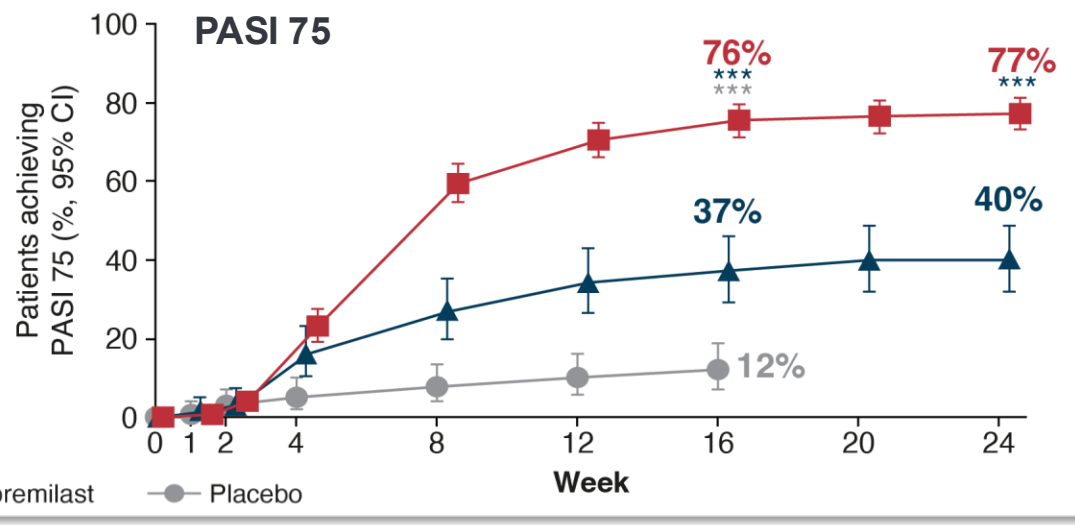
	LATITUDE-PsO-3001			LATITUDE-PsO-3002		
	Zasocitinib (n = 416)	Apremilast (n = 137)	Placebo (n = 140)	Zasocitinib (n = 555)	Apremilast (n = 276)	Placebo (n = 277)
Age, years	43.8 (13.26)	46.0 (14.10)	45.3 (13.54)	45.8 (13.33)	46.1 (13.37)	46.5 (13.19)
Sex, male, n (%)	295 (70.9)	95 (69.3)	93 (66.4)	367 (66.1)	187 (67.8)	188 (67.9)
Race, White, n (%)	255 (61.3)	88 (64.2)	87 (62.1)	472 (85.0)	233 (84.4)	240 (86.6)
BMI, kg/m^2	29.7 (6.8)	28.5 (6.3)	28.2 (6.5)	30.2 (6.8)	30.1 (6.5)	30.4 (7.2)
Psoriasis duration, median (range) years[a]	13.6 (0.6–62.4)	14.0 (0.6–71.3)	12.5 (0.6–59.3)	15.1 (0.5–69.2)	16.5 (0.6–60.5)	15.1 (0.6–65.9)
PASI score	19.7 (7.5)	20.5 (9.0)	20.3 (7.4)	21.3 (9.3)	21.4 (8.6)	21.1 (8.5)
sPGA score						
3 (moderate), n (%)	329 (79.1)	116 (84.7)	112 (80.0)	473 (85.2)	237 (85.9)	228 (82.3)
4 (severe), n (%)	85 (20.4)	21 (15.3)	28 (20.0)	80 (14.4)	39 (14.1)	48 (17.3)
BSA, %	24.0 (14.0)	25.8 (15.9)	24.2 (14.4)	27.9 (17.9)	27.8 (16.5)	27.0 (16.3)
DLQI score[b]	12.7 (7.2)	11.1 (6.5)	12.2 (7.3)	11.6 (7.2)	11.5 (6.7)	12.2 (7.4)
Bio-experienced, n (%)	141 (33.9)	40 (29.2)	45 (32.1)	155 (27.9)	80 (29.0)	83 (30.0)

Data are mean (SD) unless otherwise stated. [a]Data missing for one patient receiving zasocitinib (LATITUDE-PsO-3002). [b]Data missing for three patients receiving zasocitinib and one receiving apremilast (LATITUDE-PsO-3001), and for three patients receiving zasocitinib, one patient receiving apremilast, and four patients receiving placebo (LATITUDE-PsO-3002).
BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static Physician's Global Assessment.

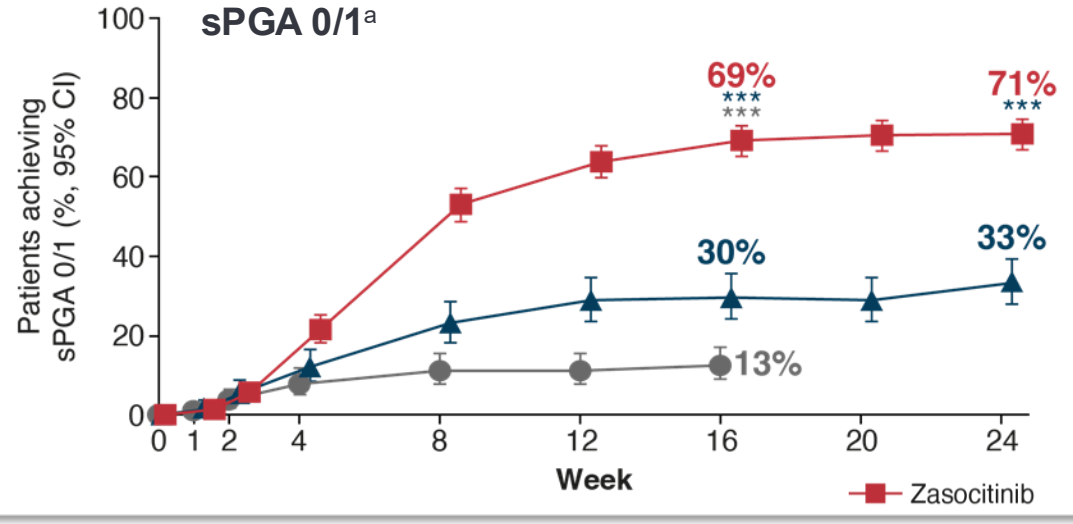
Zasocitinib met the co-primary endpoints in both studies (sPGA 0/1 and PASI 75 versus placebo at Week 16)

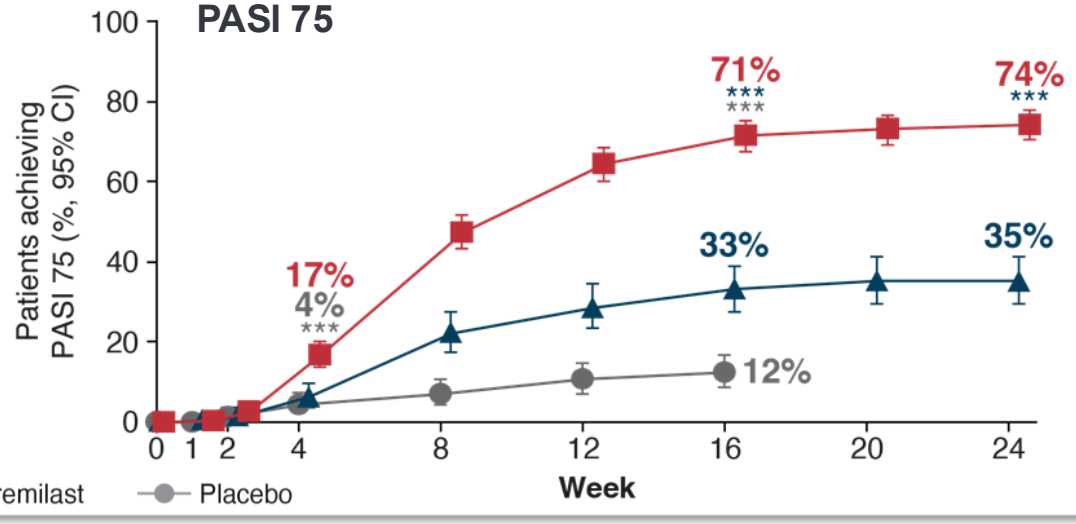
LATITUDE-PsO-3001





LATITUDE-PsO-3002

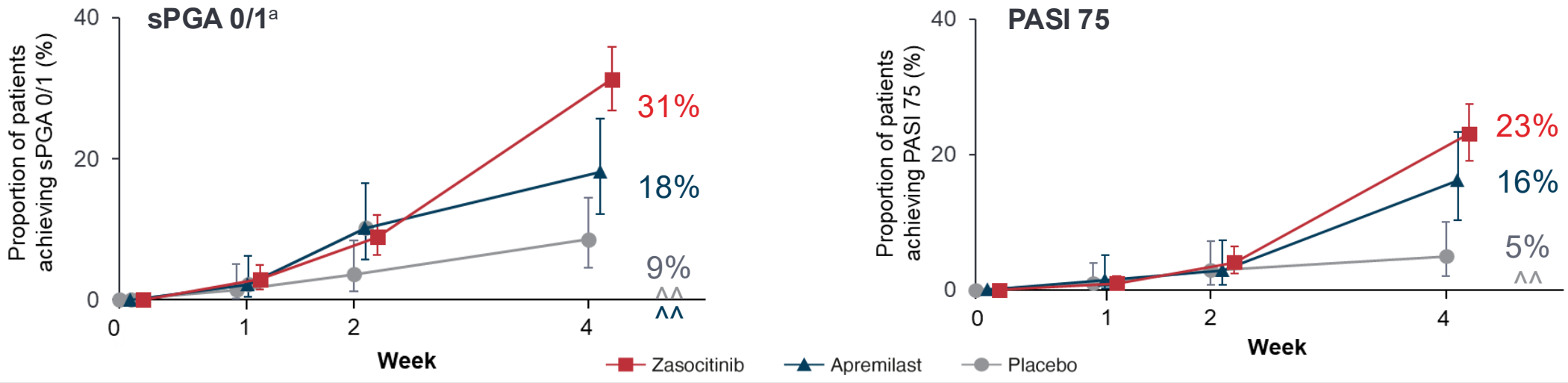




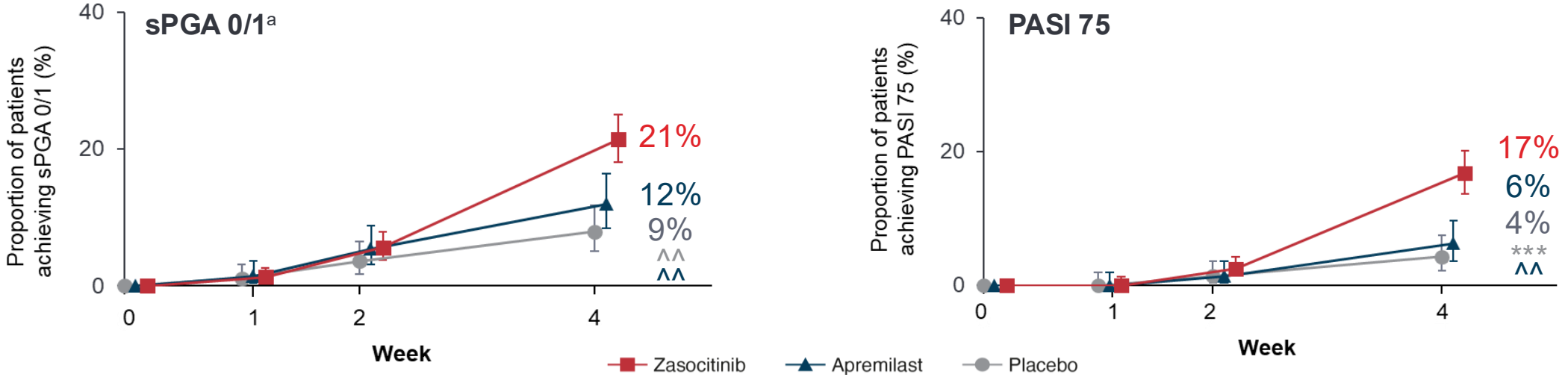
aWith a ≥ 2-point decrease from baseline. Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: Zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: Zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). P values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$. CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Rapid skin clearance as early as week 4 with zasocitinib

LATITUDE-PsO-3001



LATITUDE-PsO-3002



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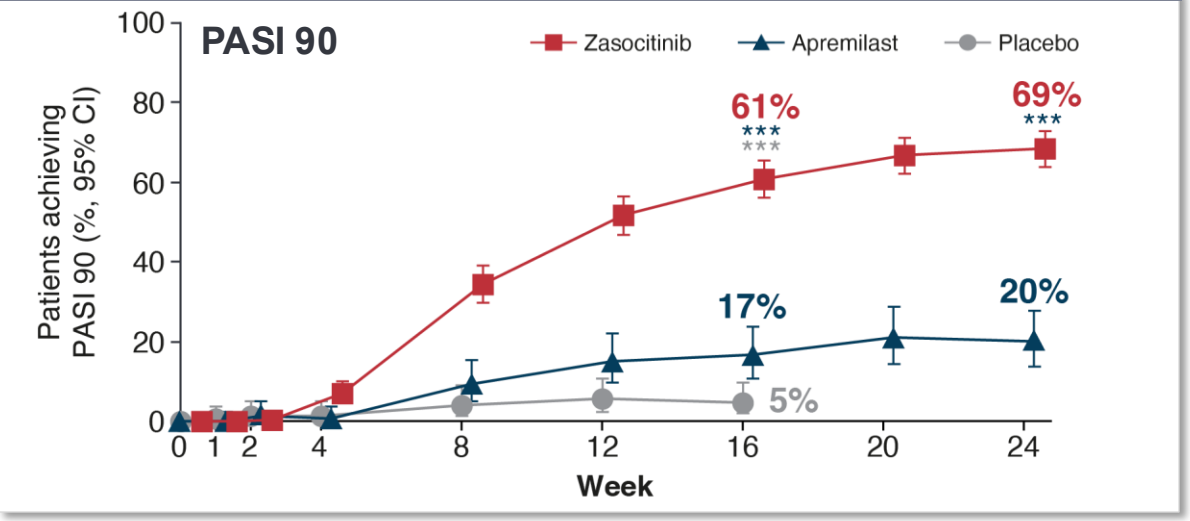
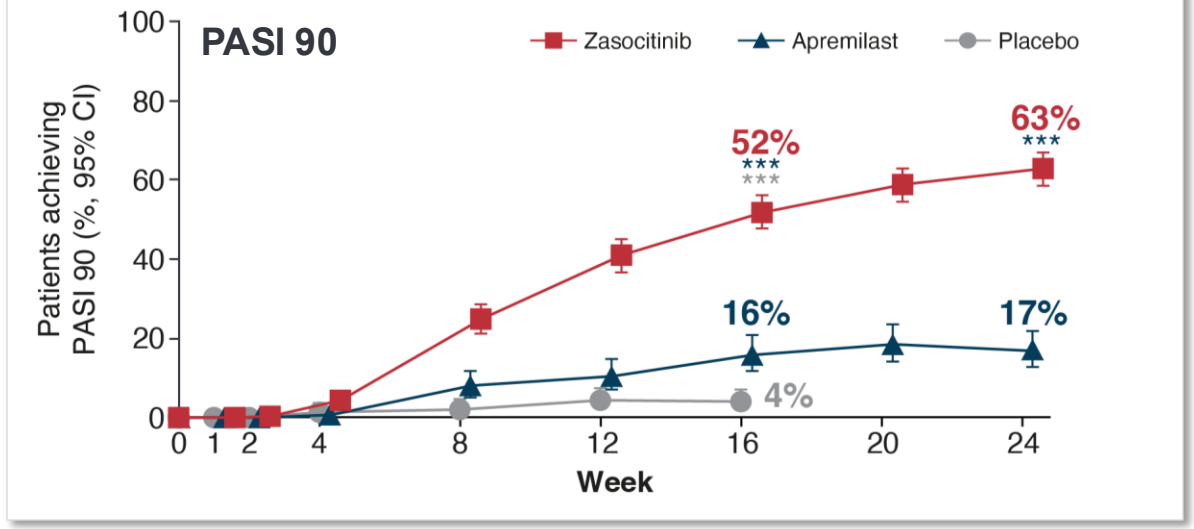
Zasocitinib led to greater proportions of patients achieving PASI 90 than apremilast or placebo as early as Week 4

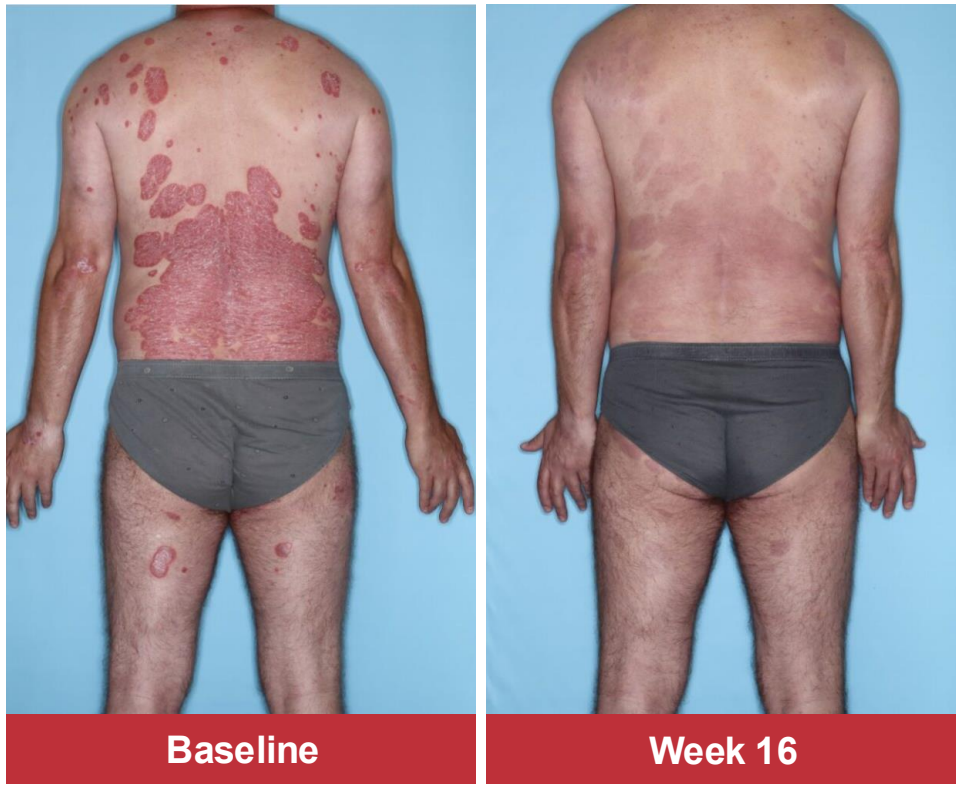
LATITUDE-PsO-3001



LATITUDE-PsO-3002



PASI 90 Responder: Baseline BSA 25%



Baseline

PASI: 15.8

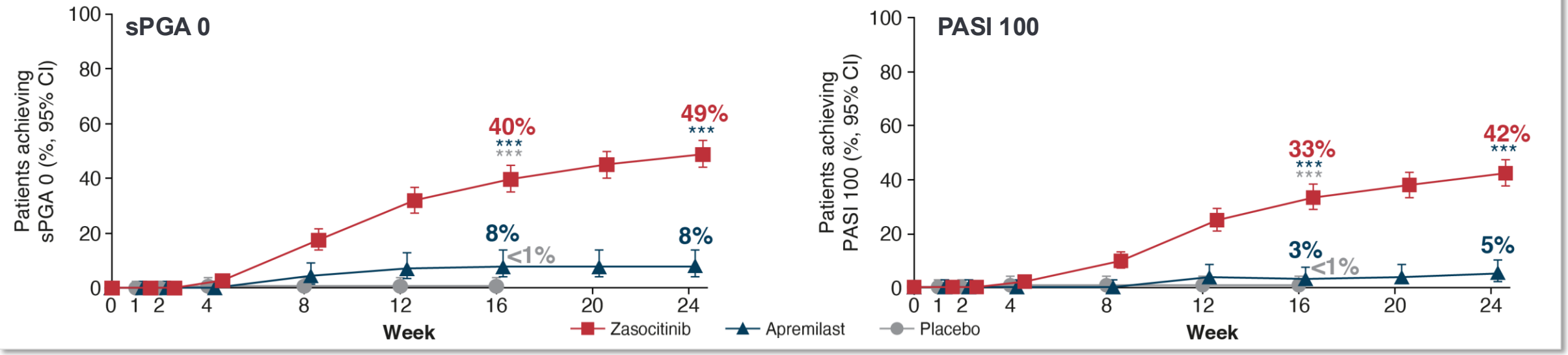
Week 16

PASI: 0.7 (CfB 95.6%)

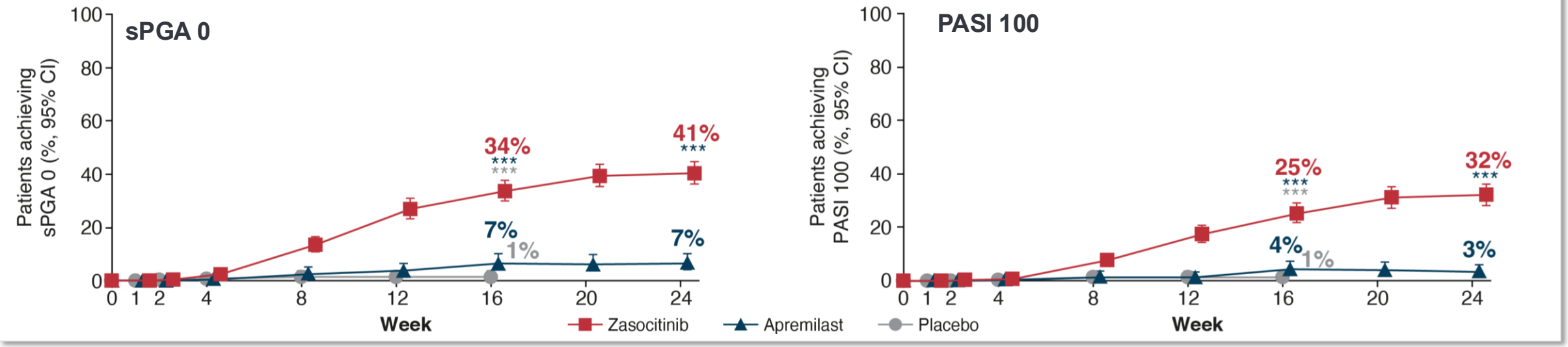
Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: Zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: Zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277).
P values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
CfB, change from baseline; CI, confidence interval; PASI, Psoriasis Area and Severity Index; BSA, body surface area.

Zasocitinib led to greater proportions of patients achieving clear skin versus apremilast or placebo as early as Week 8

LATITUDE-PsO-3001



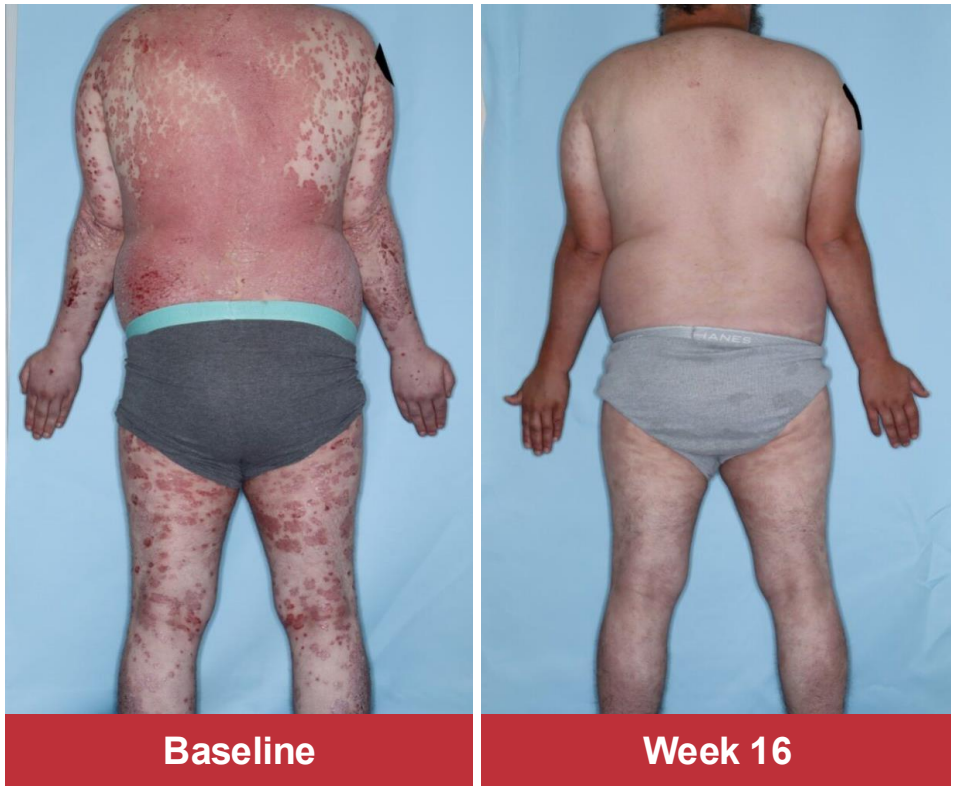
LATITUDE-PsO-3002



Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: Zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: Zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$. CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Zasocitinib led to greater proportions of patients achieving clear skin versus apremilast or placebo as early as Week 8

PASI 100 Responder: Baseline BSA 62%



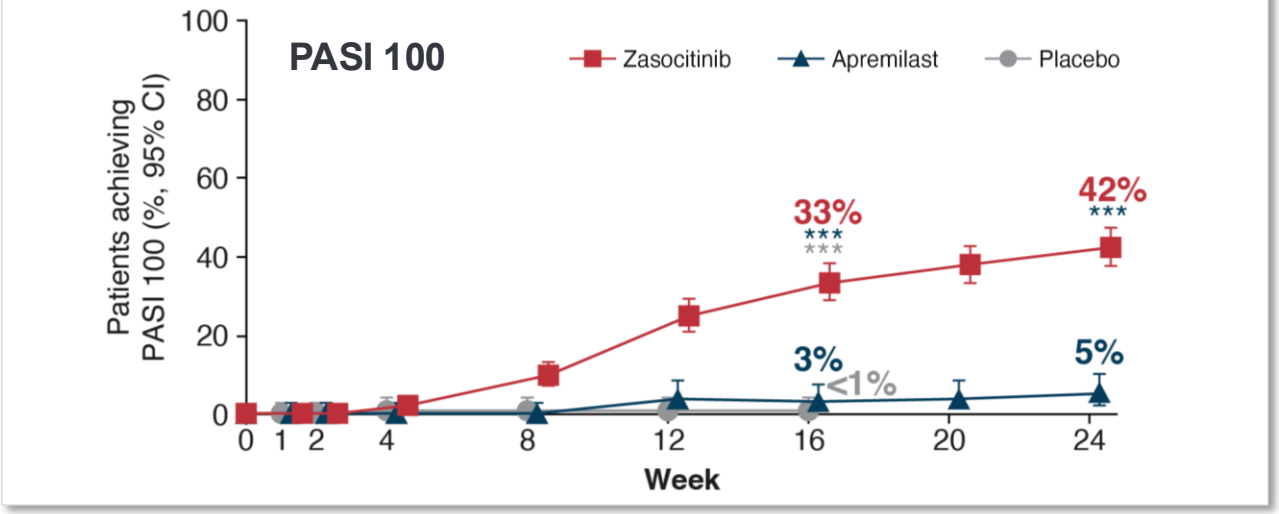
Baseline

PASI: 31.3

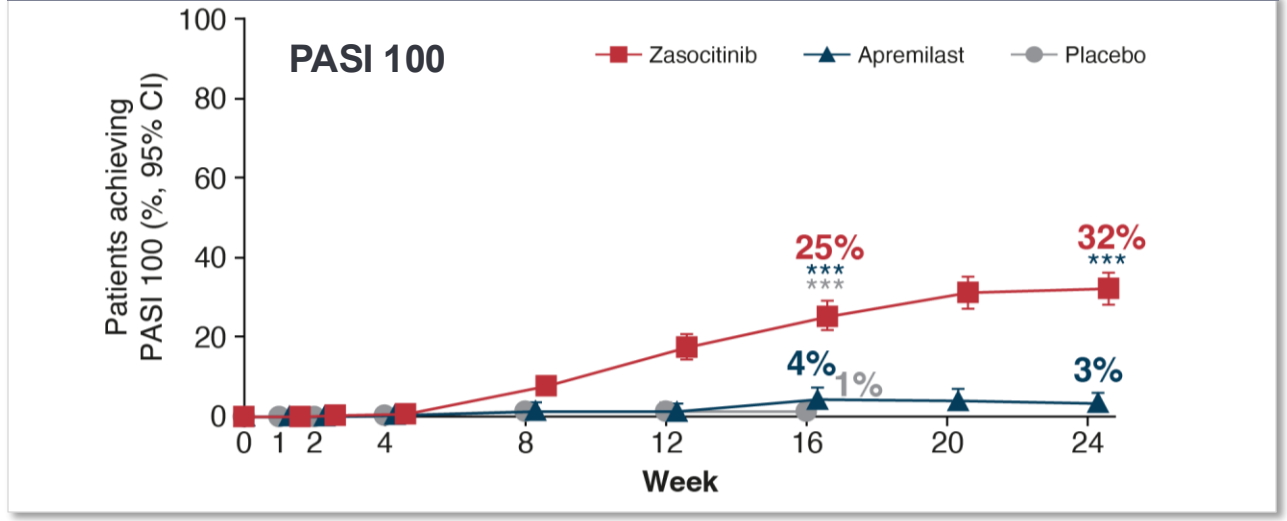
Week 16

PASI: 0

LATITUDE-PsO-3001



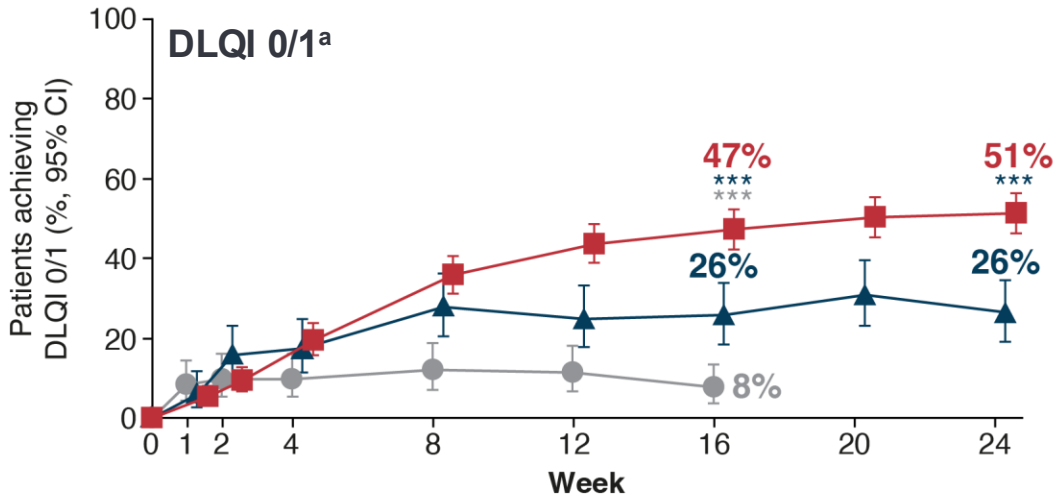
LATITUDE-PsO-3002



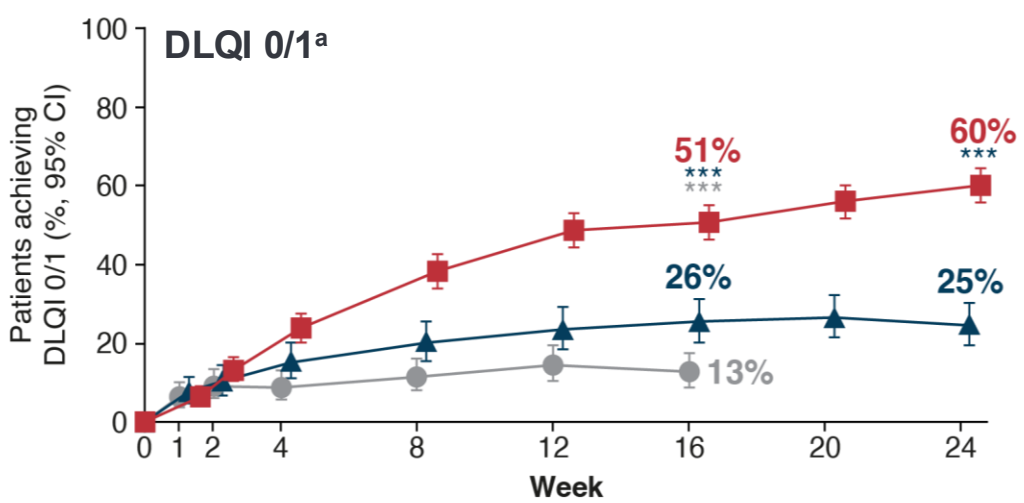
Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: Zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: Zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$. CI, confidence interval; PASI, Psoriasis Area and Severity Index; BSA, body surface area.

Zasocitinib demonstrated superior improvement in DLQI versus apremilast or placebo as early as Week 4

LATITUDE-PsO-3001



LATITUDE-PsO-3002



Zasocitinib Apremilast Placebo

[a]Based on evaluable patients defined as a subset of full analysis set with a baseline DLQI score ≥2 (with nonresponder imputation). Number of evaluable patients for LATITUDE-PsO-3001: zasocitinib (n = 406), apremilast (n = 133), placebo (n = 133). Number of evaluable patients for LATITUDE-PsO-3002: zasocitinib (n = 525), apremilast (n = 263), placebo (n = 260). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$. CI, confidence interval, DLQI, Dermatology Life Quality Index.

Zasocitinib was well tolerated with no new safety signals identified through Week 16

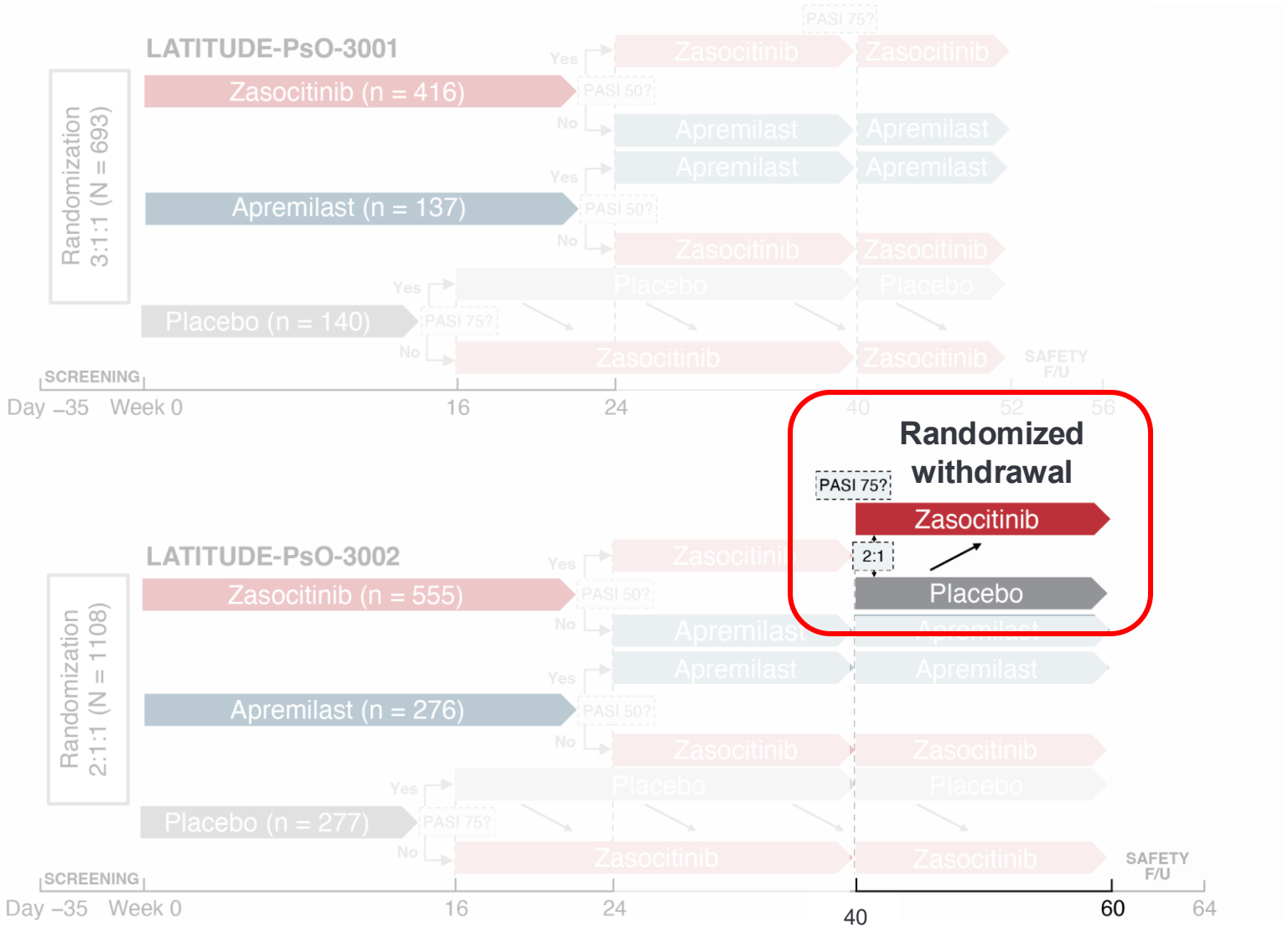
TEAEs from LATITUDE-PsO-3001 and 3002[a]	Day 0 to Week 16					
	Zasocitinib (n = 970)		Apremilast (n = 412)		Placebo (n = 417)	
	n	%[b], (95% CI)[c]	n	%[b], (95% CI)[c]	n	%[b], (95% CI)[c]
Any TEAE	605	**62.1** (59.0–65.1)	207	**50.5** (45.7–55.4)	196	**46.9** (42.0–51.7)
Leading to discontinuation	31	**3.2** (2.1–4.3)	11	**2.6** (1.1–4.2)	3	**< 1** (0.0–1.6)
SAE	29	**3.0** (1.9–4.1)	6	**1.5** (0.3–2.7)	2	**< 1** (0.1–1.7)
Death	1[d]	**< 1** (0.0–0.6)[d]	0	**0** (0.0–0.9)	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)
Acne	62	**6.5** (5.0–8.1)	3	**< 1** (0.0–1.7)	1	**< 1** (0.0–1.3)
Nasopharyngitis	60	**6.2** (4.7–7.7)	23	**5.4** (3.2–7.5)	20	**4.7** (2.7–6.6)
Diarrhea	30	**3.1** (2.0–4.2)	33	**8.2** (5.5–10.9)	8	**1.8** (0.6–3.1)
Headache	27	**2.8** (1.8–3.9)	26	**6.3** (4.0–8.7)	8	**1.9** (0.6–3.2)
Nausea	20	**2.1** (1.2–3.0)	23	**5.5** (3.3–7.8)	5	**1.2** (0.1–2.2)

- **No new safety signals** observed through **week 24**
- Most TEAEs were **mild** or **moderate**
- **Laboratory parameters** (e.g. lymphocytes, liver enzymes, lipids) demonstrated **no clinically meaningful trends** over time in both studies

TEAEs were coded using MedDRA v28.1.

[a]Events starting while on initial treatment are included. [b]Sample size adjusted incidence rate 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. CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event; SAE, serious adverse event; URTI, upper respiratory tract infection.

LATITUDE-PsO-3001 and 3002 were randomized, multicenter, double-blind, placebo- and apremilast-controlled phase 3 trials



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- Adults (≥ 18 years)
- Plaque psoriasis diagnosis for ≥ 6 months prior to screening
- PASI ≥ 12, sPGA ≥ 3, ≥ 10% BSA
- Candidate for phototherapy or systemic therapy

Endpoints

Co-primary endpoints at Week 16 (versus placebo):

- **sPGA 0/1[a]**
- **PASI 75**

Key secondary endpoints (versus placebo or apremilast) included:

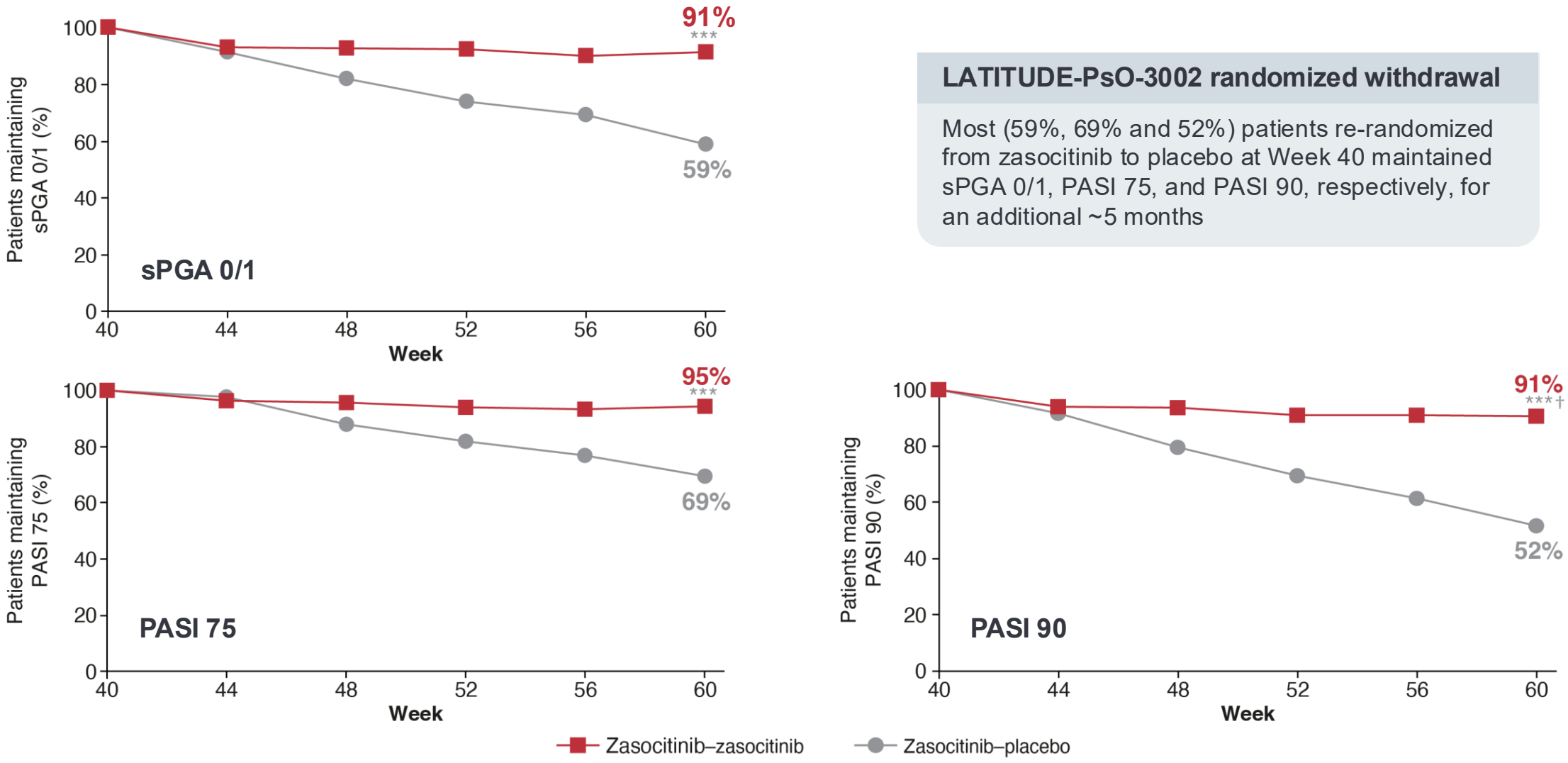
- PASI 75 at Week 4
- sPGA 0, PASI 75/90/100 or DLQI 0/1[b] at Week 16/24
- sPGA 0/1 or PASI 75 maintenance at Week 60

Safety endpoints included:

- TEAEs; laboratory parameters

[a]With a ≥ 2-point decrease from baseline. [b]With a baseline DLQI score ≥2.
BSA, body surface area; DLQI, Dermatology Life Quality Index; F/U, follow-up; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse events.

More than 90% of patients continuing zasocitinib at Week 40 maintained sPGA 0/1, PASI 75 and PASI 90 through Week 60



LATITUDE-PsO-3002 randomized withdrawal

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

Evaluable patients based on the full analysis set for randomized withdrawal with nonresponder imputation. Number of patients for sPGA 0/1: zasocitinib–zasocitinib (n = 255), zasocitinib–placebo (n = 126). Number of patients for PASI 75: zasocitinib–zasocitinib (n = 273), zasocitinib–placebo (n = 134). Number of patients for PASI 90: zasocitinib–zasocitinib (n = 238), zasocitinib–placebo (n = 122) . *P* values for comparison versus zasocitinib–placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$; ***† nominal $p < 0.001$. PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Zasocitinib: Enabling expansion with focused LCM programs

Latitude	PHASE 2 START	PHASE 2b READOUT	PHASE 3 START	PHASE 3 READOUT	FILING
Psoriasis		March 2023 ✓	Nov 2023 ✓	Dec 2025 ✓	Target FY2026
Psoriasis H2H vs deucravacitinib			July 2025 ✓	Target FY2026	
Psoriasis Pediatric			Dec 2025 ✓		
Psoriatic Arthritis		Sept 2023 ✓	March 2024 ✓		Target FY2027
Crohn's Disease	March 2024 (Ph2b) ✓	Target FY2026			
Ulcerative Colitis	June 2024 (Ph2b) ✓	Target FY2026			
Vitiligo	Dec 2025 (Ph2b) ✓				
Hidradenitis Suppurativa	Feb 2026 (Ph2a) ✓				

✓ Milestone achieved

All timelines are approximate estimates as of March 28, 2026 are subject to change and are subject to clinical and regulatory success. Table is not comprehensive. For full glossary of abbreviations please refer to appendix.

Zasocitinib: Rapid and durable skin clearance in a convenient once-daily pill

Zasocitinib demonstrated rapid and durable skin clearance

- 49% of patients achieved clear skin, sPGA 0, by week 24
- **Rapid response**, demonstrated by early separation for PASI 75 and sPGA 0/1 at week 4
- **Durable response**, >90% of patients continuing zasocitinib at week 40 maintained sPGA 0/1 and PASI 90 through week 60
- **Improved quality of life** was observed by week 4, with responses continuing to increase over time, reaching up to 60% of patients reporting no impact of psoriasis on daily life (DLQI 0/1) at week 24

Week 24	3001 Study	3002 Study
sPGA 0/1	74%	71%
PASI 90	69%	63%
sPGA 0	49%	41%
PASI 100	42%	32%

Zasocitinib was generally well-tolerated

- The safety profile of zasocitinib was consistent with that previously reported[1]
- No observed trends in labs over time such as cholesterol or lipids increases[2]

1. Armstrong AW, Gooderham M, Lynde C, et al. Tyrosine Kinase 2 Inhibition With Zasocitinib (TAK-279) in Psoriasis: A Randomized Clinical Trial. *JAMA Dermatol*. 2024;160(10):1066-1074. doi:10.1001/jamadermatol.2024.2701
2. Increases in lipids such as cholesterol and triglycerides are known to be associated with JAK inhibition

Zasocitinib

Market Opportunity & Commercialization

Transformational efficacy with next-generation orals can give patients an opportunity to achieve clear skin without proceeding to biologics

Today many moderate-to-severe psoriasis patients are sub-optimally treated with only ~50% on advanced therapies

Patients often delay initiating biologic therapy due to concerns about injections, safety, and lifestyle impact, resulting in prolonged use of ineffective conventional treatments[1]

Next-generation orals can provide efficacious options positioned to drive significant growth of the oral segment

~3x the number of patients treated with an oral therapy over the next decade (~100K to ~300K)[2]

US Psoriasis Market Growth
Moderate-to-Severe (M2S) Treated Patients

1. Conventional therapies include Oral + Topical Steroid, DMARD, & Retinoid 2. US Claim Data (IQVIA SOB Report) and Takeda Forecasting Insights

Zasocitinib: Meeting patient needs with a treatment that fits effortlessly into daily life

It's very exciting for our community to have a potential new oral systemic option to treat their psoriasis. ***People living with psoriasis deserve treatment options that help them manage this disease so that they can maintain a high quality of life.*** *It's great for them and their health care provider to have another option to turn to.*

Leah M. Howard, J.D.
President and CEO of the National Psoriasis Foundation

This transition towards oral therapies could lead to ***more convenient treatment*** *regimens for patients,* ***enhancing adherence*** *and* ***improving their quality of life.***[1]

Orhan Yilmaz
College of Medicine, University of Saskatchewan

Rapid and Durable Skin Clearance in a Convenient Once-Daily Pill, No Fasting Restrictions[2]

Zasocitinib delivered clear to almost clear skin for ~70% of patients by week 16

- Rapid onset
- Durable skin clearance
- No new safety signals

Fits effortlessly into daily life

- Once daily oral dosing
- Can be taken any time; no fasting restrictions

2. Profile based on Ph3 data

Photos: IFPA | All the Colors We Are

1. Yilmaz O, Pinto JP, Torres T. New and emerging oral therapies for psoriasis. *Drugs Context*. 2024;13:2024-5-6.

Takeda's proven immunology leadership positions it to execute a successful zasocitinib launch

Demonstrated success in an adjacent, highly competitive autoimmune market with Entyvio – #1 prescribed IBD treatment (UC and Crohn's combined)[1]

In-depth knowledge and experience of payer dynamics to drive effective market access strategies and pull-through

Early external engagement with KOLs & patient advocacy as well as continuing to build awareness of the strong safety profile consistent with selective TYK2 inhibition

Continued investment to maximize zasocitinib's commercial impact and market potential

1. Source: US IBD Patient Share – IQVIA

Zasocitinib is positioned to transform and expand the oral advanced therapy market in psoriatic disease

Poised to Lead Among Oral Options in the Growing Psoriasis Market

PsO

US Pso Market Evolution Over the Next Decade

1.0M → 1.3M Moderate to Severe Psoriasis treated patients growing at low single digits

10% → 22% Significant expansion of the oral market driven by next-gen oral entrants

~3x more patients treated with an oral therapy

\+

Rapidly Expanding Within Psoriatic Disease

PsA

Ph3 Psoriatic Arthritis (PsA) data expected in FY27

=

Global Peak Revenue Potential For PsO + PsA

PsO
PsA

$3-6B[1]

Enabling Expansion with Focused LCM Programs that Unlock Significant Future Upside

\+

Dermatology →

- **Vitiligo** *Ph2 started FY25*
- **Hidradenitis Suppurativa** *Ph2 started FY25*

Gastroenterology →

- **Crohn's Disease** *Ph2 data expected FY26*
- **Ulcerative Colitis** *Ph2 data expected FY26*

1. Please refer to the Important Notice at the start of this presentation for more information about peak revenue estimates.

Zasocitinib: Poised to be a leading oral treatment option for patients with psoriasis – significantly expanding the oral market

1

Rapid and durable skin clearance, with no new safety signals

2

Convenient once-daily pill without fasting restrictions

3

Next-generation, highly selective oral TYK2 inhibitor

Zasocitinib U.S. and global filings on track to start in FY26

Q&A Session

JULIE KIM
CEO Elect

RHONDA PACHECO
President, U.S. Business Unit;
U.S. Country Head

CHINWE UKOMADU
Head of GI&I Therapeutic
Area Unit

Medical Presentation
as presented at AAD 2026

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)

Melinda Gooderham, Vivian Laquer, Jianzhong Zhang, Joanna Narbutt, Akimichi Morita, Paula Luna, Wenwen Zhang, Warren Winkelman, Edith Angellotti, Kim Papp, April Armstrong

Presenting author: Dr Melinda Gooderham

SKiN Centre for Dermatology, Queen's University and Probity Medical Research, Peterborough, Ontario, Canada

Presented at the 2026 AAD Annual Meeting, 27–31 March 2026, Denver, Colorado, USA
Presentation #79730

Disclosures

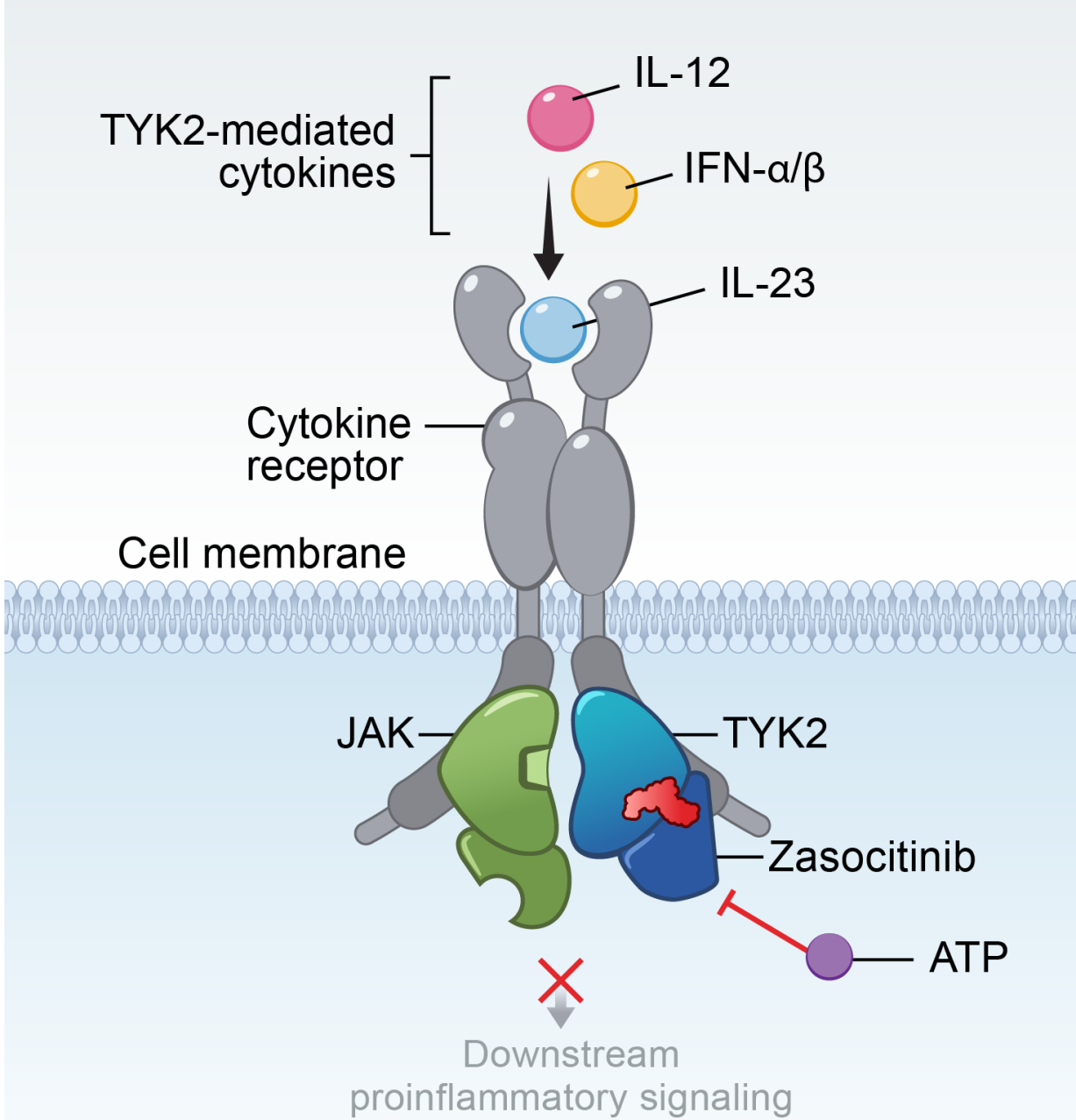
Dr Melinda Gooderham has been an investigator, speaker and/or advisor for: AbbVie, Acelyrin, Akros, Alumis, Amgen, AnaptysBio, Apogee, Arcutis, Aristea, Bausch Health, Bristol Myers Squibb, Boehringer Ingelheim, Dermavant, Dermira, Eli Lilly, Galderma, GSK, Incyte, Inmagene, JAMP Pharma, Janssen, L'Oreal, LEO Pharma, MedImmune, Meiji, Moonlake, Nektar, Nimbus, Novartis, Organon, Oruka, Pfizer, Q32 Bio, Regeneron, Sanofi Genzyme, Sun Pharma, Takeda, Tarsus, UCB, Union, Ventyx and Vyne

Zasocitinib is an investigational, oral, allosteric, highly selective and potent TYK2 inhibitor[1,2]

- More than 1 millionfold greater binding selectivity for TYK2 versus JAK1, JAK2 and JAK3[1,2]
- Maintains 24-hour inhibition of IL-23 plus other core disease-driving immune pathways[2,3]
- Well tolerated and efficacious in a phase 2b trial in patients with moderate-to-severe plaque psoriasis[4]

Objective:

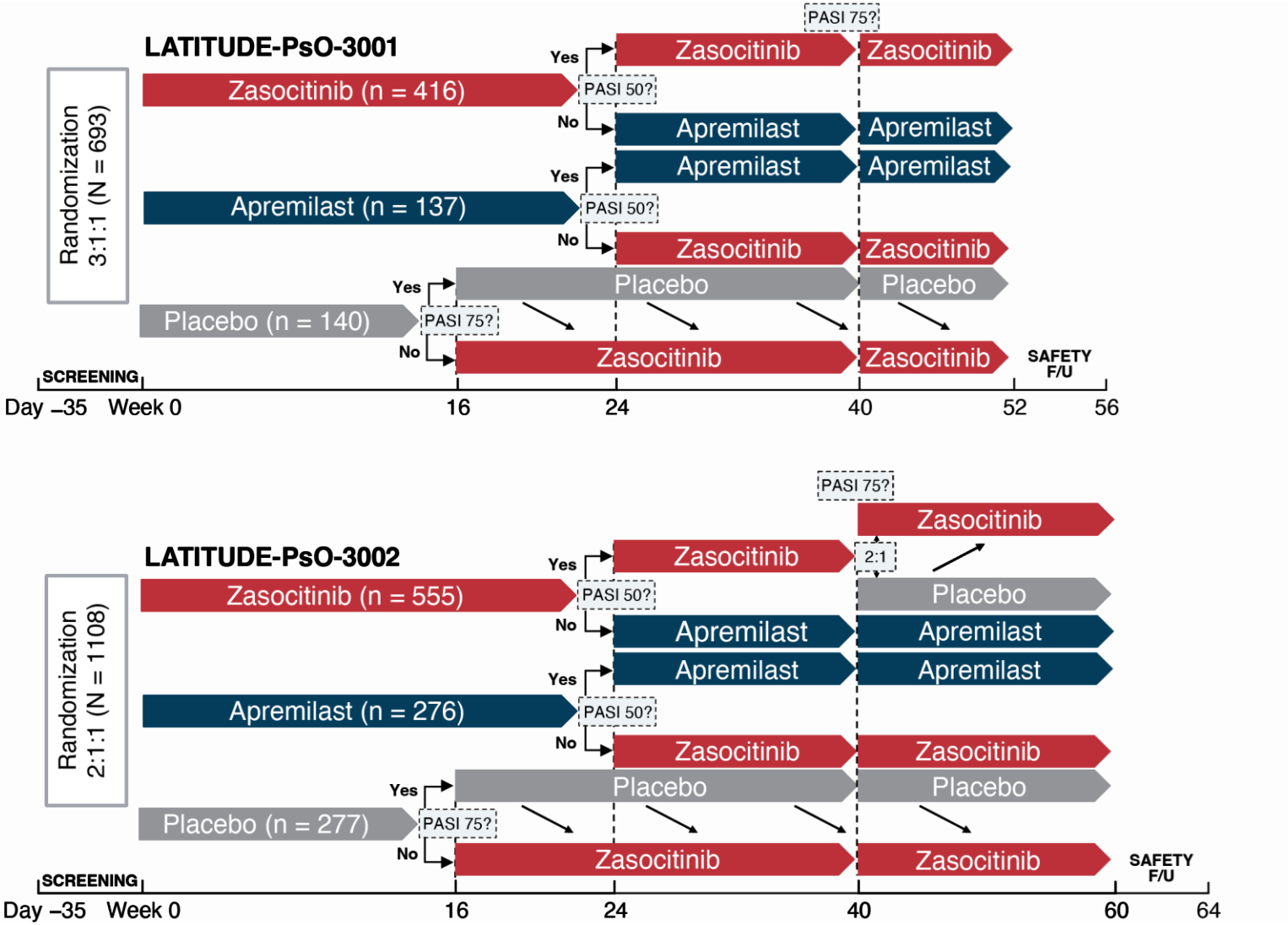
To evaluate the efficacy and safety of zasocitinib in adults with moderate-to-severe plaque psoriasis in two pivotal phase 3 studies: LATITUDE-PsO-3001 (NCT06088043) and LATITUDE-PsO-3002 (NCT06108544)



ATP, adenosine triphosphate; IFN, interferon; IL, interleukin; JAK, Janus kinase; TYK, tyrosine kinase.

1. Leit S *et al*. *J Med Chem* 2023;66:10473–96; 2. Mehrotra S et al. *J Invest Dermatol* 2025;146:214–22; 3. Rusiñol L and Puig L. *Int J Mol Sci* 2023;24:3391. 4. Armstrong A *et al. JAMA Dermatol* 2024;160:1066–74.

LATITUDE-PsO-3001 and 3002 were randomized, multicenter, double-blind, placebo- and apremilast-controlled phase 3 trials



Eligibility

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- PASI ≥ 12, sPGA ≥ 3, ≥ 10% BSA
- Candidate for phototherapy or systemic therapy

Endpoints

Co-primary endpoints at Week 16 (versus placebo):

- **sPGA 0/1**[a]
- **PASI 75**

Key secondary endpoints (versus placebo or apremilast) included:

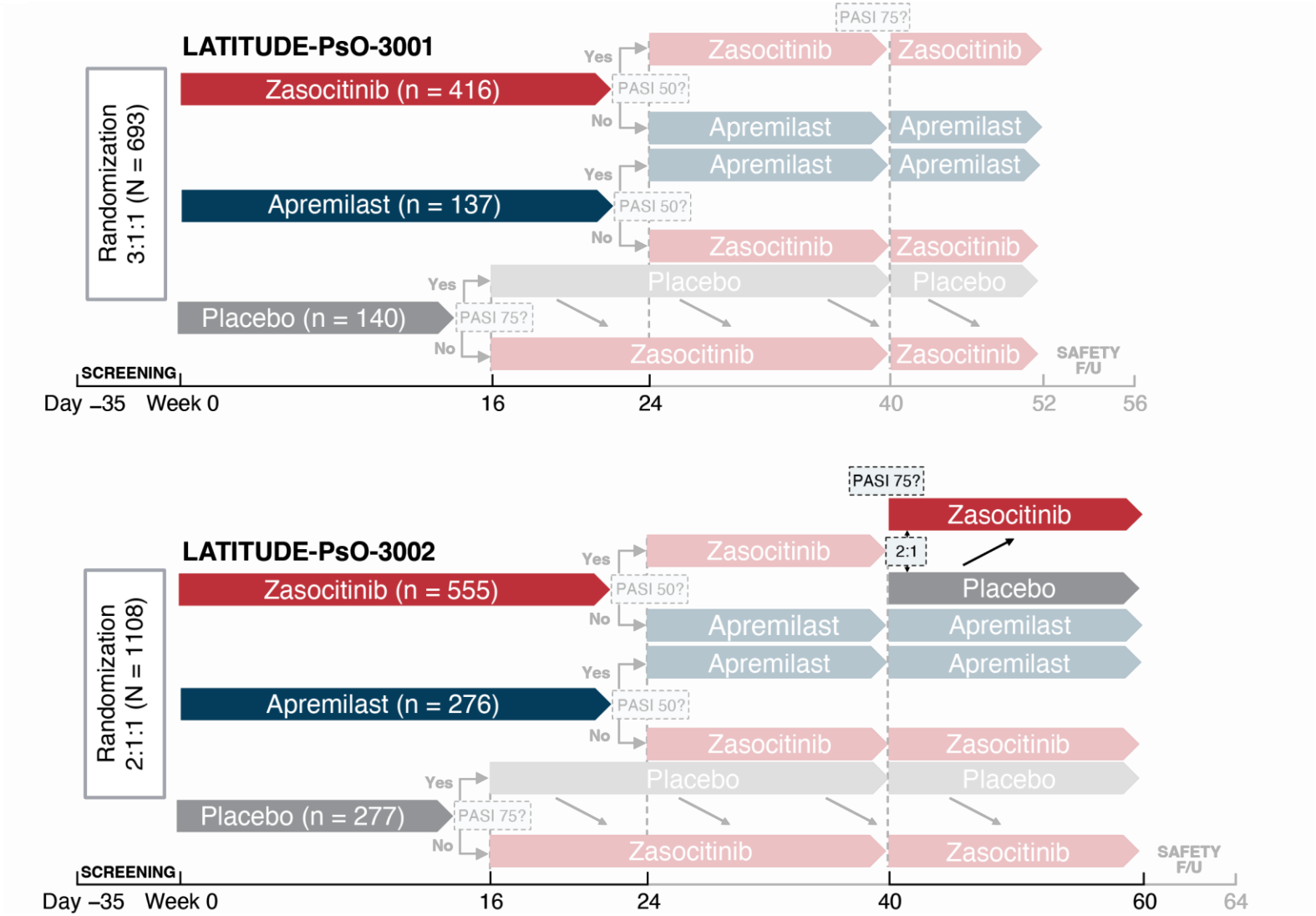
- PASI 75 at Week 4
- sPGA 0, PASI 75/90/100 or DLQI 0/1[b] at Week 16 or 24
- sPGA 0/1 or PASI 75 maintenance at Week 60

Safety endpoints included:

- TEAEs; laboratory parameters

[a]With a ≥ 2-point decrease from baseline. [b]With a baseline DLQI score ≥2.
BSA, body surface area; DLQI, Dermatology Life Quality Index; F/U, follow-up; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse events.

LATITUDE-PsO-3001 and 3002 were randomized, multicenter, double-blind, placebo- and apremilast-controlled phase 3 trials



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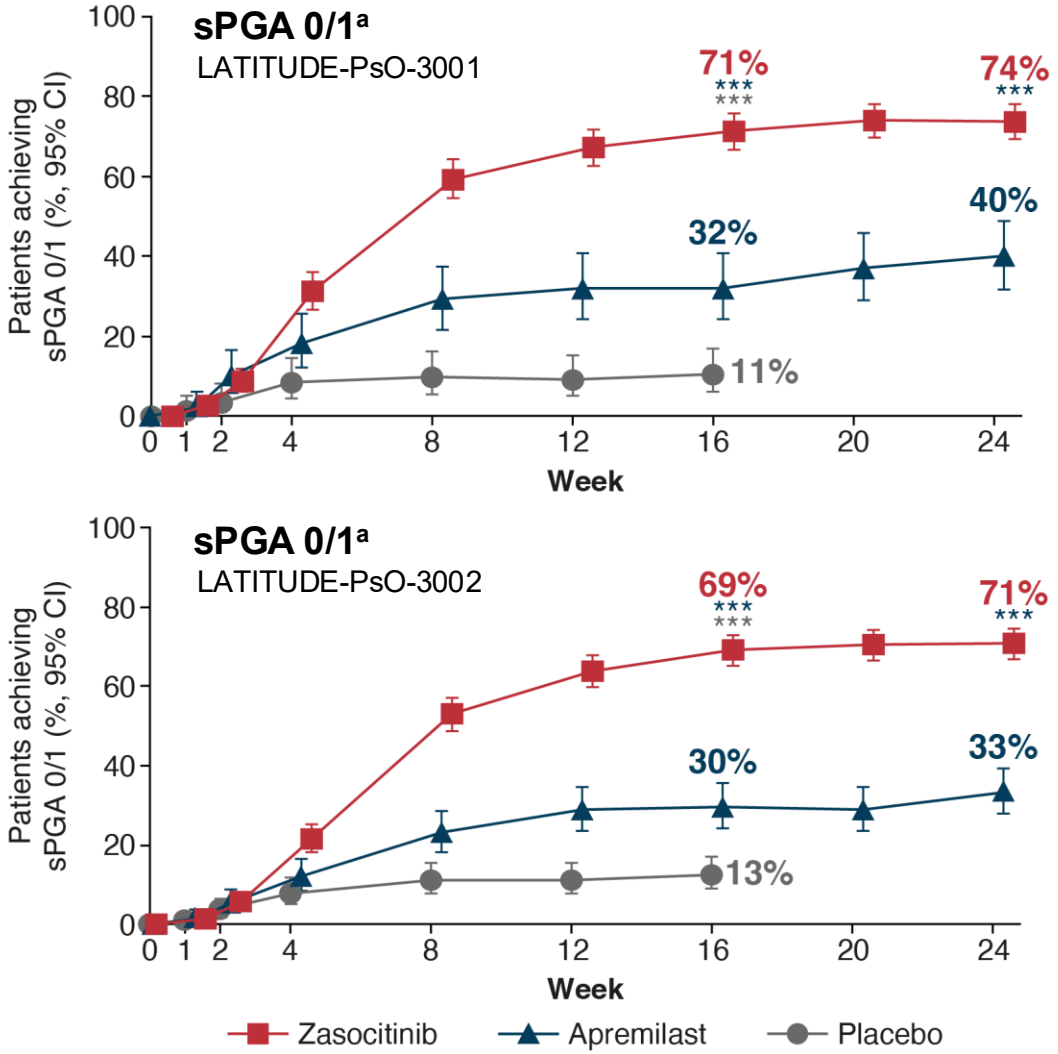
BSA, body surface area; DLQI, Dermatology Life Quality Index; F/U, follow-up; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TEAE, treatment-emergent adverse events.

Baseline demographics and characteristics were generally similar across treatment arms in each study

	LATITUDE-PsO-3001			LATITUDE-PsO-3002		
	Zasocitinib (n = 416)	Apremilast (n = 137)	Placebo (n = 140)	Zasocitinib (n = 555)	Apremilast (n = 276)	Placebo (n = 277)
Age, years	43.8 (13.26)	46.0 (14.10)	45.3 (13.54)	45.8 (13.33)	46.1 (13.37)	46.5 (13.19)
Sex, male, n (%)	295 (70.9)	95 (69.3)	93 (66.4)	367 (66.1)	187 (67.8)	188 (67.9)
Race, White, n (%)	255 (61.3)	88 (64.2)	87 (62.1)	472 (85.0)	233 (84.4)	240 (86.6)
BMI, kg/m^2	29.7 (6.8)	28.5 (6.3)	28.2 (6.5)	30.2 (6.8)	30.1 (6.5)	30.4 (7.2)
Psoriasis duration, median (range) years[a]	13.6 (0.6–62.4)	14.0 (0.6–71.3)	12.5 (0.6–59.3)	15.1 (0.5–69.2)	16.5 (0.6–60.5)	15.1 (0.6–65.9)
PASI score	19.7 (7.5)	20.5 (9.0)	20.3 (7.4)	21.3 (9.3)	21.4 (8.6)	21.1 (8.5)
sPGA score						
3 (moderate), n (%)	329 (79.1)	116 (84.7)	112 (80.0)	473 (85.2)	237 (85.9)	228 (82.3)
4 (severe), n (%)	85 (20.4)	21 (15.3)	28 (20.0)	80 (14.4)	39 (14.1)	48 (17.3)
BSA, %	24.0 (14.0)	25.8 (15.9)	24.2 (14.4)	27.9 (17.8)	27.8 (16.5)	27.0 (16.3)
DLQI score[b]	12.7 (7.2)	11.1 (6.5)	12.2 (7.3)	11.6 (7.2)	11.5 (6.7)	12.2 (7.4)
Bio-experienced, n (%)	141 (33.9)	40 (29.2)	45 (32.1)	155 (27.9)	80 (29.0)	83 (30.0)

Data are mean (SD) unless otherwise stated. [a]Data missing for one patient receiving zasocitinib (LATITUDE-PsO-3002). [b]Data missing for three patients receiving zasocitinib and one receiving apremilast (LATITUDE-PsO-3001), and for three patients receiving zasocitinib, one patient receiving apremilast, and four patients receiving placebo (LATITUDE-PsO-3002).
BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static Physician's Global Assessment.

Zasocitinib met the co-primary endpoints in both studies (sPGA 0/1 and PASI 75 versus placebo at Week 16)



[a]With a ≥ 2-point decrease from baseline. Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

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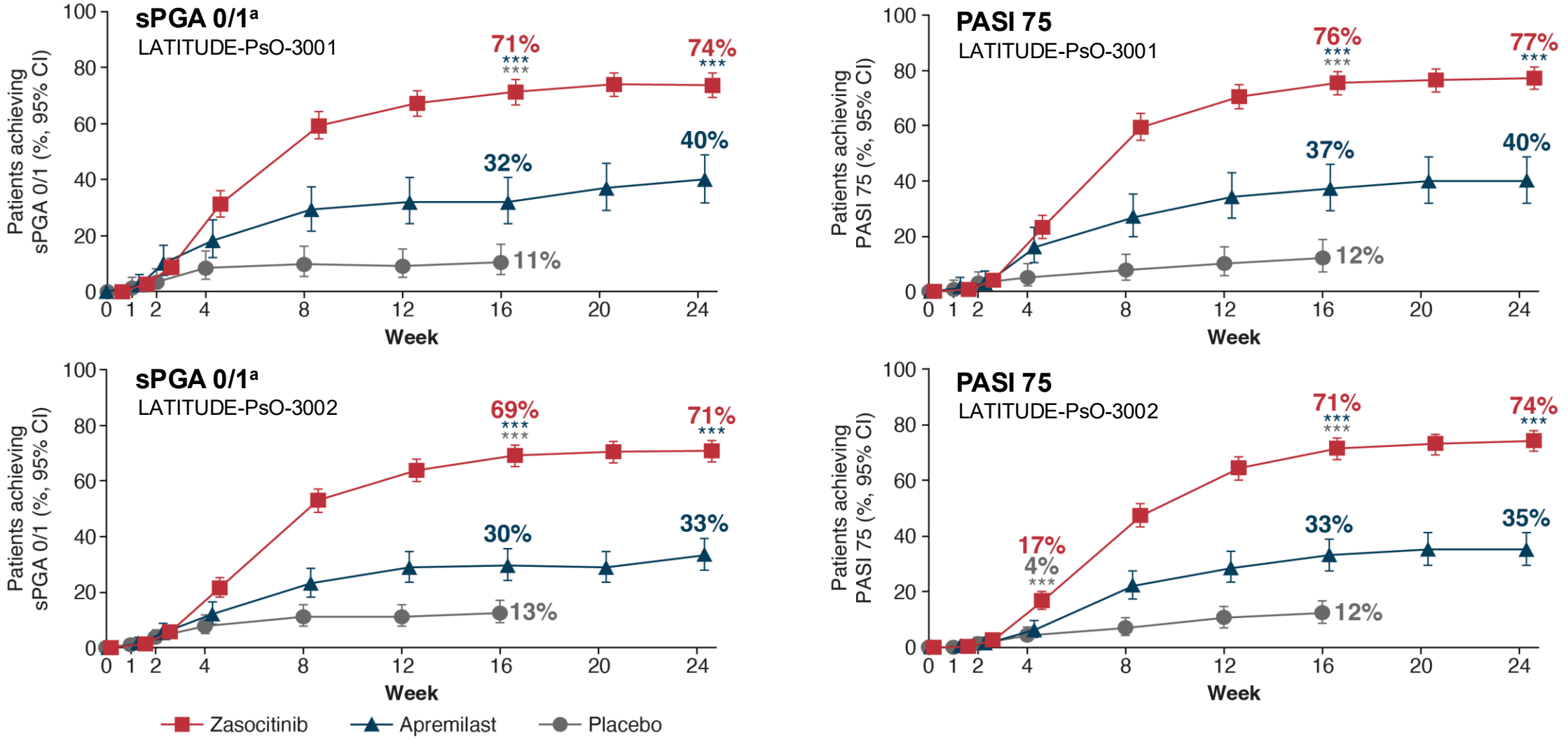

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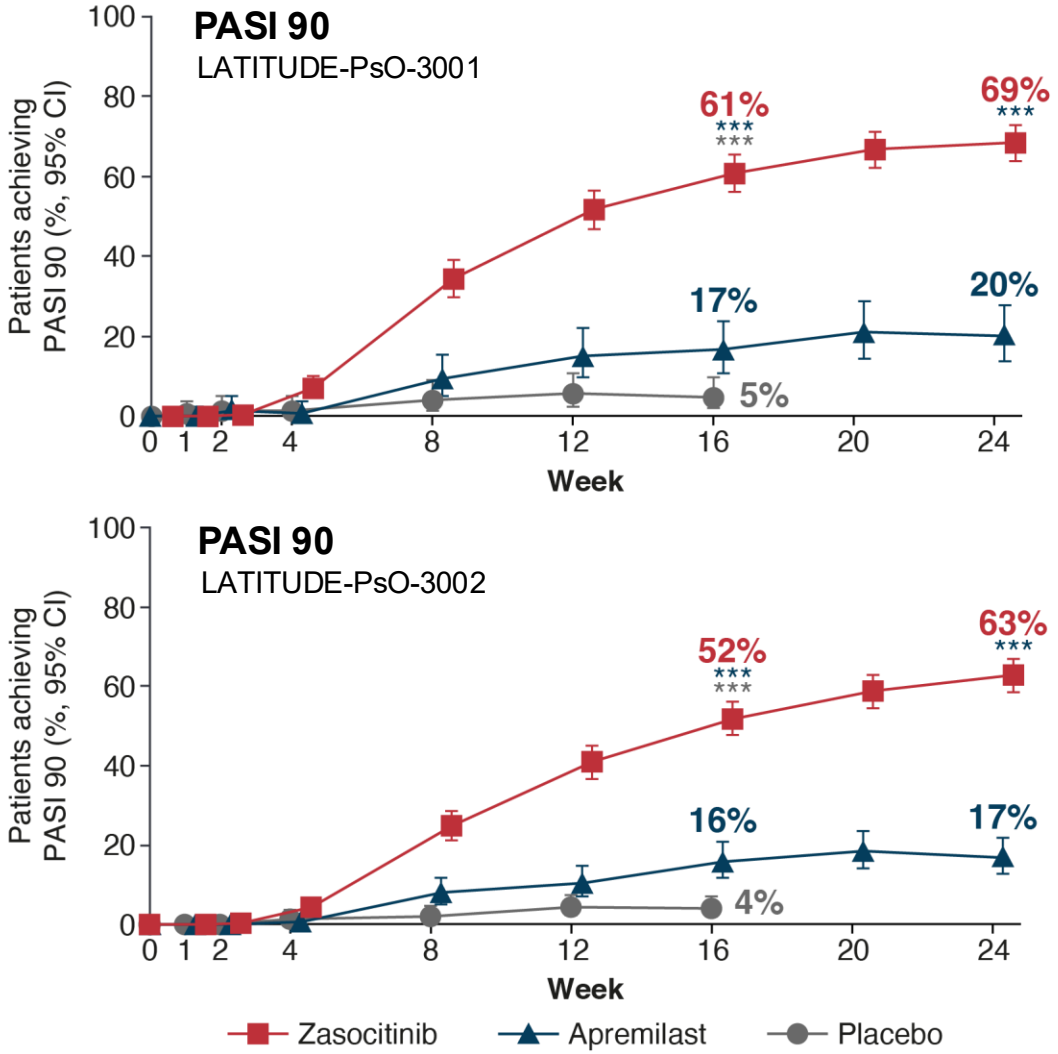
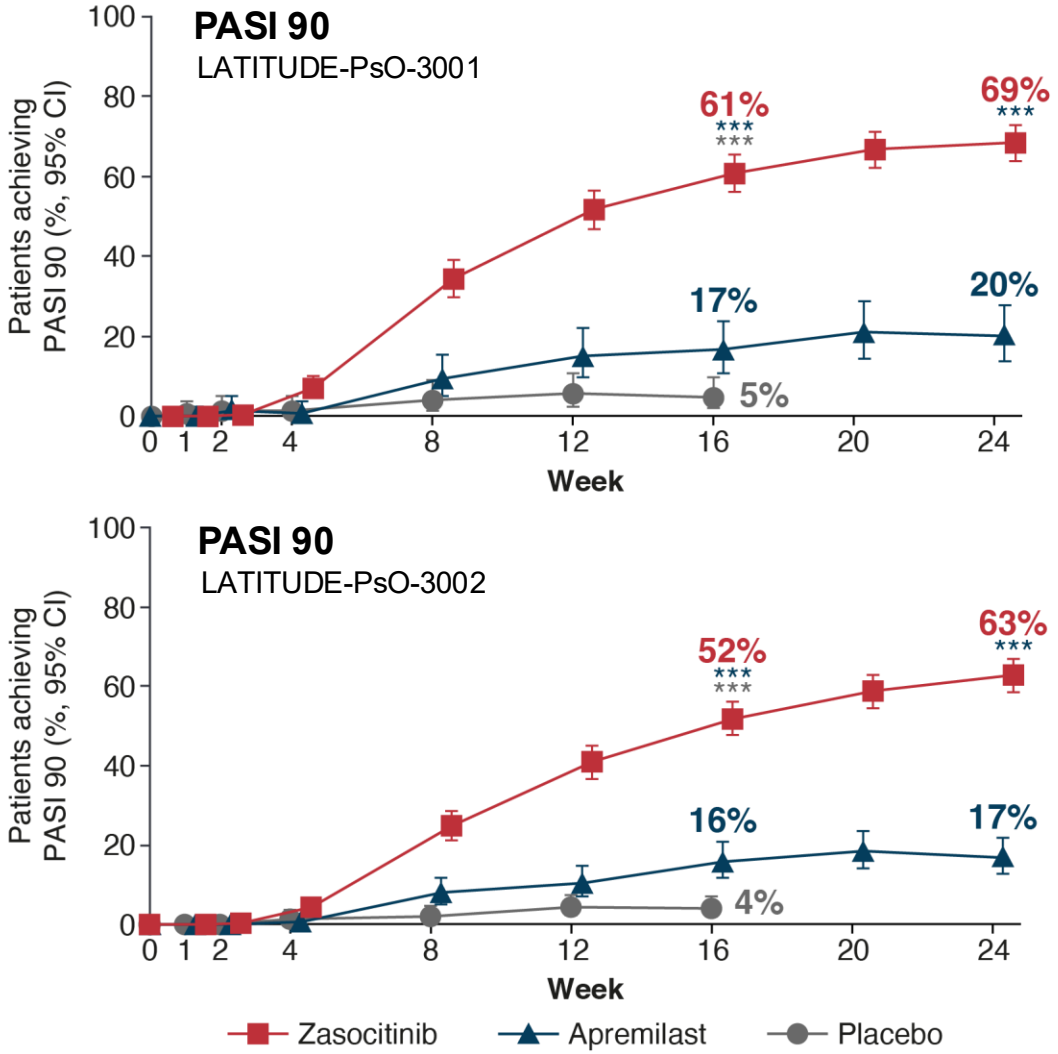
CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

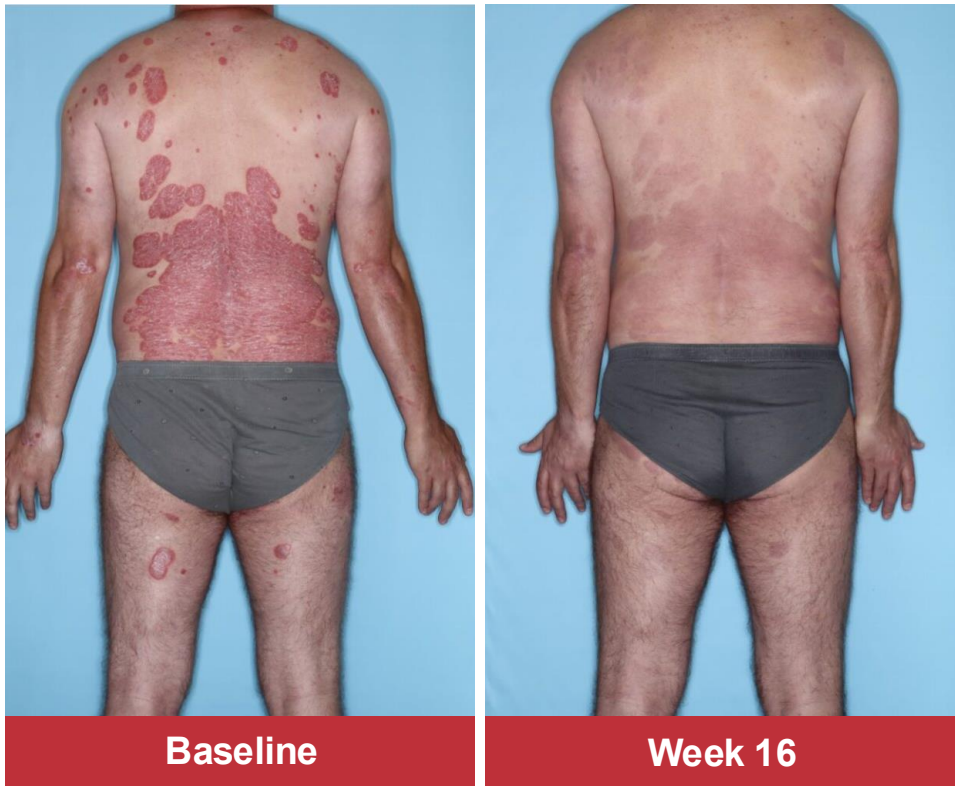
Zasocitinib led to greater proportions of patients achieving PASI 90 than apremilast or placebo as early as Week 4



Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
CfB, change from baseline; CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Zasocitinib led to greater proportions of patients achieving PASI 90 than apremilast or placebo as early as Week 4



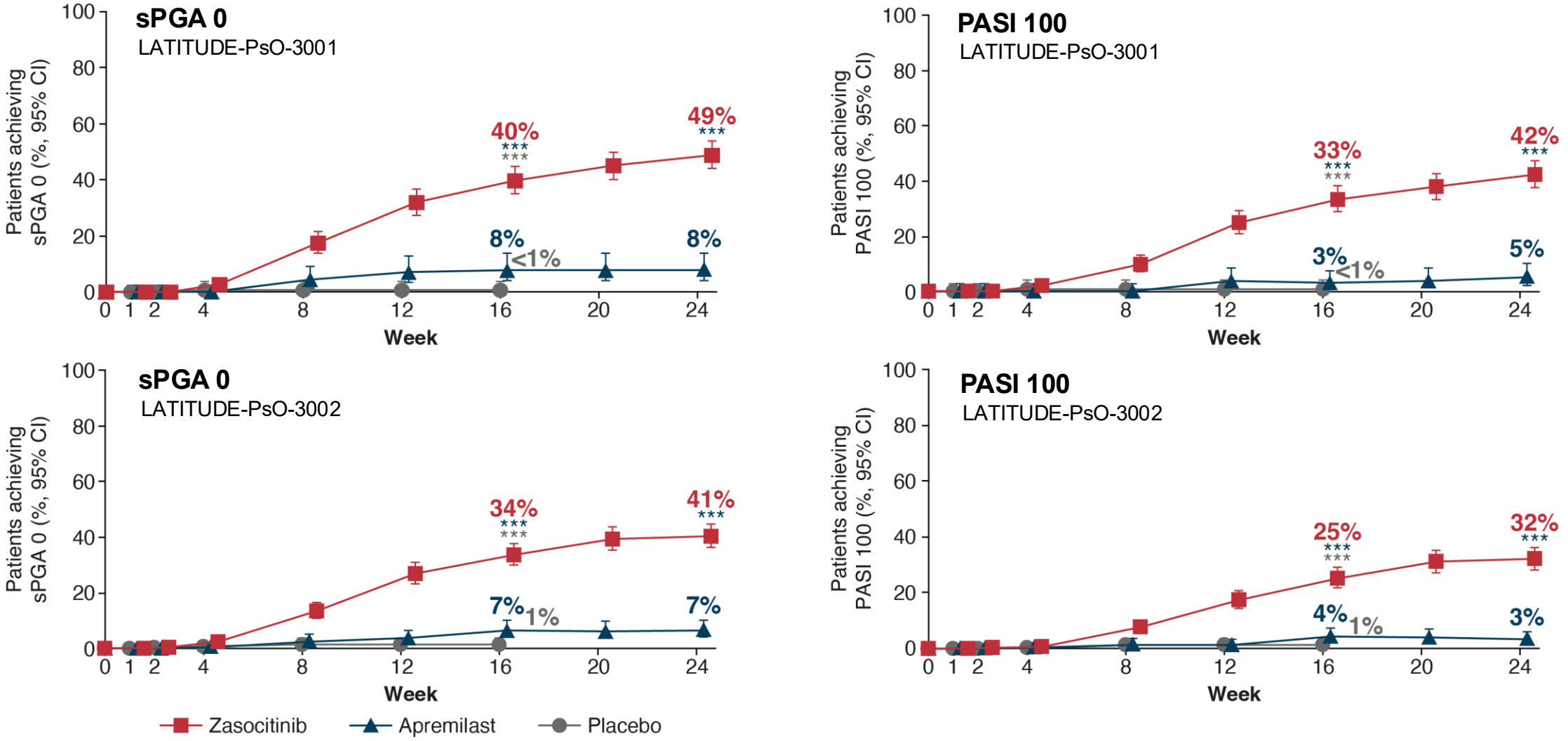


PASI: 15.8
sPGA: 3

PASI: 0.7 (CfB 95.6%)
sPGA: 0

Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
CfB, change from baseline; CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Zasocitinib led to greater proportions of patients achieving clear skin versus apremilast or placebo as early as Week 8



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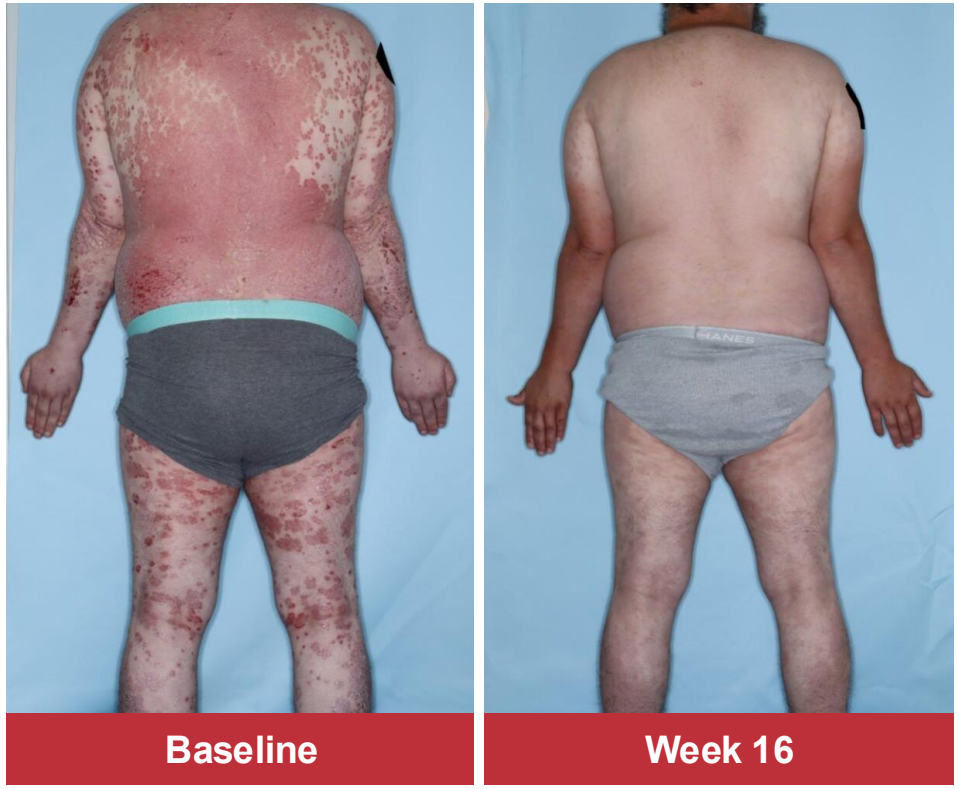
Zasocitinib led to greater proportions of patients achieving clear skin versus apremilast or placebo as early as Week 8

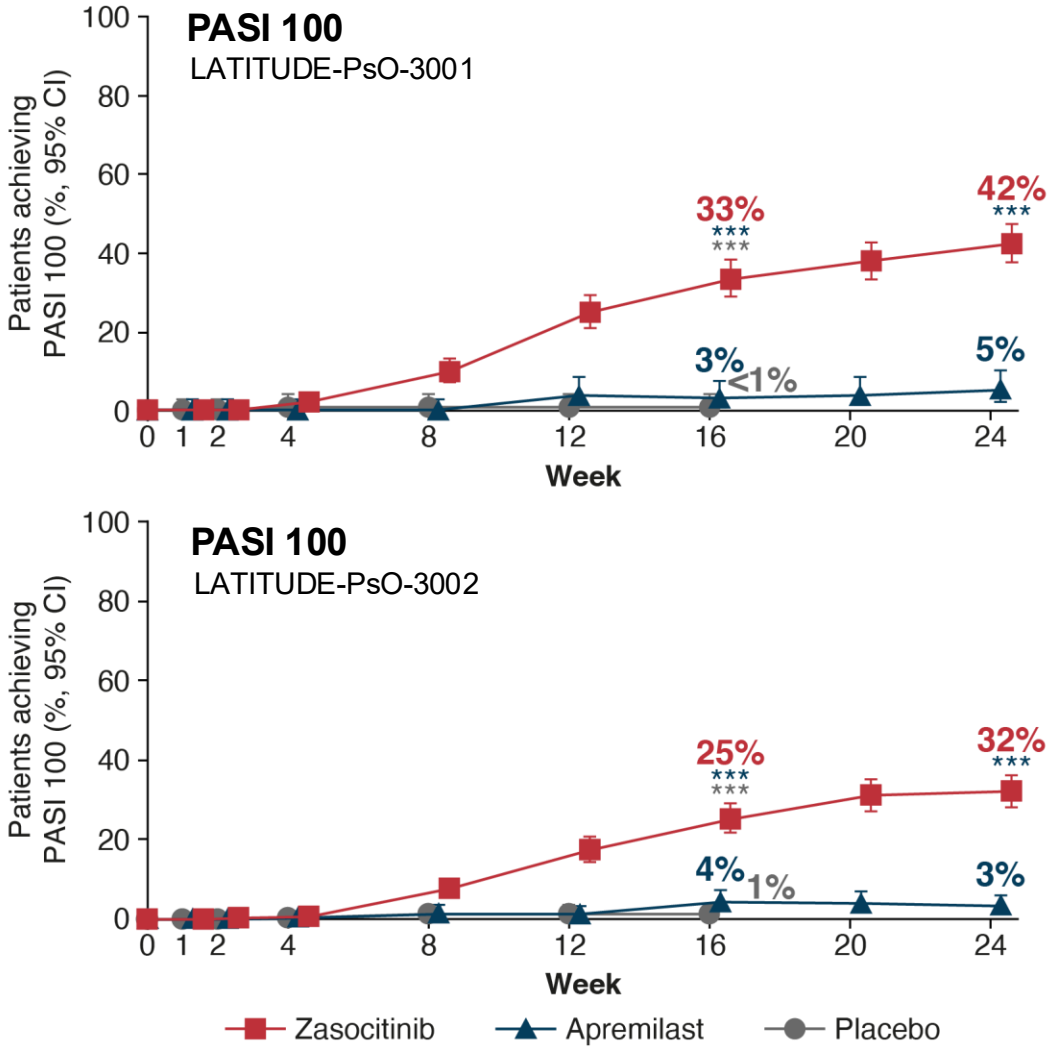


Baseline

PASI: 31.3
sPGA: 3

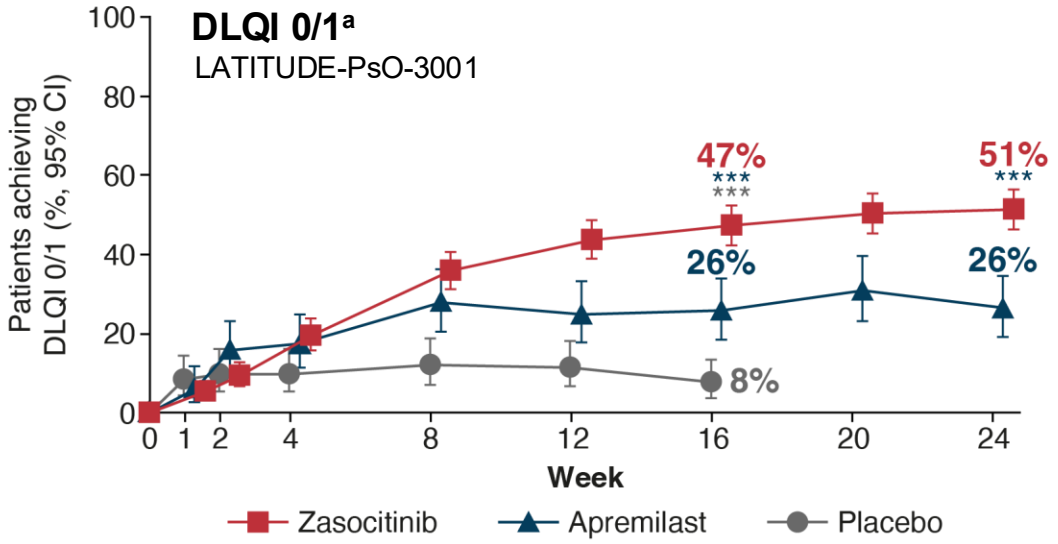
Week 16

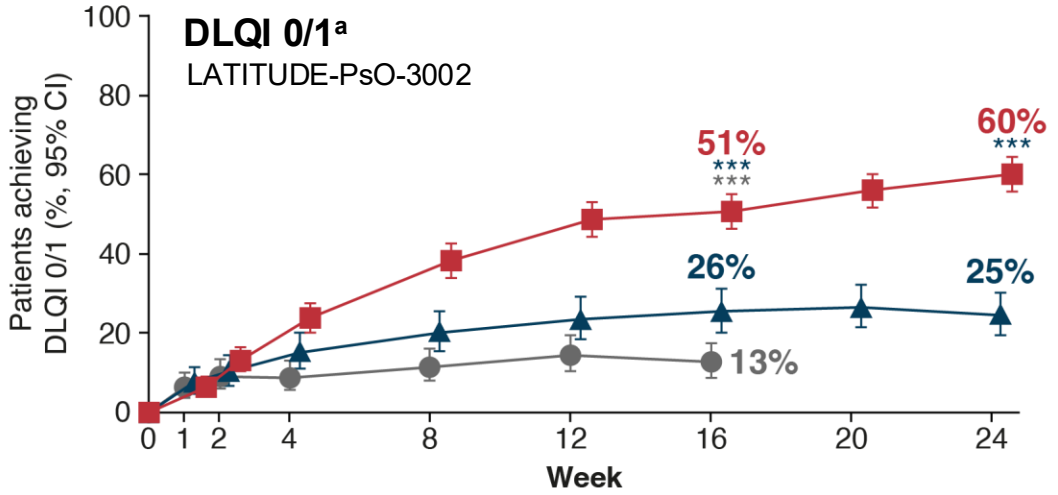
PASI: 0
sPGA: 0



Number of patients based on the full analysis set with non-responder imputation. LATITUDE-PsO-3001: zasocitinib (n = 416), apremilast (n = 137), placebo (n = 140). LATITUDE-PsO-3002: zasocitinib (n = 555), apremilast (n = 276), placebo (n = 277). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$.
CI, confidence interval; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Zasocitinib demonstrated superior improvement in DLQI versus apremilast or placebo as early as Week 4





[a]Based on evaluable patients defined as a subset of full analysis set with a baseline DLQI score ≥2 (with nonresponder imputation). Number of evaluable patients for LATITUDE-PsO-3001:zasocitinib (n = 406), apremilast (n = 133), placebo (n = 133). Number of evaluable patients for LATITUDE-PsO-3002: zasocitinib (n = 525), apremilast (n = 263), placebo (n =260). *P* values for comparison versus apremilast (in blue) and versus placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ***$p < 0.001$. CI, confidence interval; DLQI, Dermatology Life Quality Index.

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

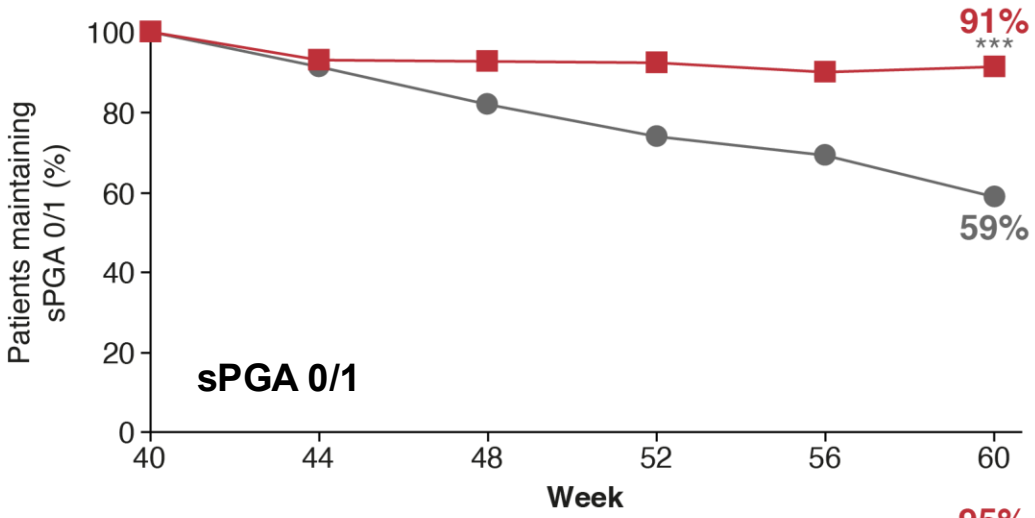
TEAEs from LATITUDE-PsO-3001 and 3002[a]	Day 0 to Week 16						Day 0 to Week 24			
	Zasocitinib (n = 970)		Apremilast (n = 412)		Placebo (n = 417)		Zasocitinib (n = 970)		Apremilast (n = 412)	
	n	%[b] (95% CI)[c]	n	%[b] (95% CI)[c]	n	%[b] (95% CI)[c]	n	%[b] (95% CI)[c]	n	%[b] (95% CI)[c]
Any TEAE	605	**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)

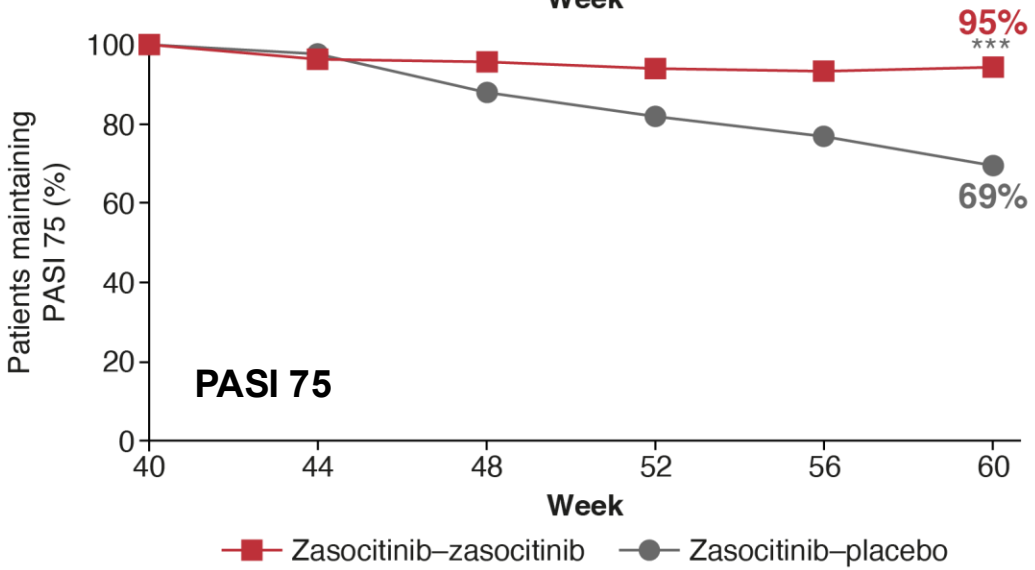
- Most TEAEs were **mild** or **moderate**
- **Laboratory parameters (e.g. lymphocytes, liver enzymes, lipids) demonstrated no clinically meaningful trends over time in both studies**

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. CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities; SAE, serious adverse event; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.

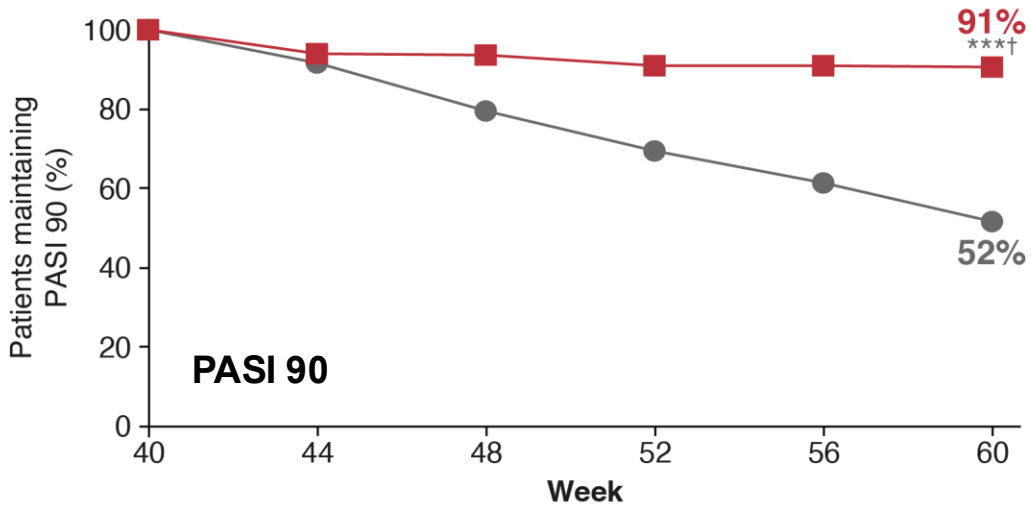
More than 90% of patients continuing zasocitinib at Week 40 maintained sPGA 0/1, PASI 75 and PASI 90 through Week 60





LATITUDE-PsO-3002 randomized withdrawal

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



Evaluable patients based on the full analysis set for randomized withdrawal with nonresponder imputation Number of patients for sPGA 0/1: zasocitinib–zasocitinib (n = 255), zasocitinib–placebo (n = 126). Number of patients for PASI 75: zasocitinib–zasocitinib (n = 273), zasocitinib–placebo (n = 134). Number of patients for PASI 90: zasocitinib–zasocitinib (n = 238), zasocitinib–placebo (n = 122) . *P* values for comparison versus zasocitinib–placebo (in gray) based on a stratified Cochran–Mantel–Haenszel test: ****p* < 0.001; ***† nominal *p* <0.001. PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment.

Conclusions

Once-daily oral zasocitinib demonstrated rapid reproducible and durable skin clearance, and a consistent safety and laboratory parameter profile, across two pivotal phase 3 trials

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

Zasocitinib efficacy and safety will be further evaluated in patients 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)

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

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Zasocitinib-related presentations at AAD 2026

Oral presentation slides:
LATITUDE-PsO-3001 and 3002 phase 3 topline results

ePoster:
Phase 2b study early onset of response correlated to biomarkers

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