U.S. FDA Accepts New Drug Application Under Priority Review for Takeda's Zasocitinib in Moderate-to-Severe Plaque Psoriasis, with Potential to Redefine Oral Treatment Expectations

- Acceptance is based on pivotal Phase 3 data demonstrating rapid, durable and consistent skin clearance, including in high-impact sites, in a convenient once-daily pill
- Results from nearly 3,000 patients support potential for next-generation TYK2 inhibitor to redefine oral treatment expectations in psoriasis
- The Prescription Drug User Fee Act (PDUFA) target action date is in the first quarter of calendar year 2027

OSAKA, Japan AND CAMBRIDGE, Massachusetts, September 14, 2026 - Takeda **(TSE:4502/NYSE:TAK)** announced that the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) under Priority Review for zasocitinib (TAK-279) for the treatment of adults with moderate-to-severe plaque psoriasis. Zasocitinib is an investigational, next-generation, highly selective and potent oral tyrosine kinase 2 (TYK2) inhibitor, which demonstrated rapid, durable and consistent skin clearance in Phase 3 plaque psoriasis studies.[1-3]

Addressing unmet needs in psoriasis treatment

"Despite progress in psoriasis care, there remains a need for highly effective oral therapies that also address the diverse and often challenging manifestations of psoriasis, including involvement of high-impact sites like the scalp," said Andy Plump, M.D., Ph.D., president of R&D at Takeda. "Our Phase 3 data demonstrated rapid and durable skin clearance across various patient types and in high-impact and hard-to-treat areas. Based on the results across nearly 3,000 patients, zasocitinib has the potential to be a leading oral treatment option in psoriasis."

Phase 3 clinical data supporting the zasocitinib NDA for moderate-to-severe plaque psoriasis

The NDA filing is supported by a comprehensive data package including the pivotal global Phase 3 LATITUDE PsO 3001 (NCT06088043) and 3002 (NCT06108544) studies, in which all primary and ranked secondary endpoints were met.[1-2] The submission also included supportive data from LATITUDE PsO 3003 (NCT06550076), an open-label study to evaluate zasocitinib's long-term safety, tolerability and efficacy.[4] Zasocitinib data demonstrated:[1-2]

- Statistically significant and clinically meaningful improvements across multiple measures of skin clearance and symptom relief, with about 70% of patients achieving clear or almost clear skin (sPGA 0/1) at week 16.
- Rapid and durable skin clearance for the majority of patients, with clearance observed as early as week 4 and increasing through week 24 and further through week 52.
- High levels of skin clearance across hard-to-treat and high-impact sites, including the scalp, nails, palms and soles, which can result in reduced quality of life for patients.[5]
- Zasocitinib was generally well tolerated, with a safety profile consistent with previous studies. No new safety signals were identified.

Next steps for zasocitinib

The European Medicines Agency (EMA) also accepted Takeda's new marketing authorization application (MAA) for zasocitinib, initiating the review process for the treatment of moderate-to-severe plaque psoriasis. Takeda plans to submit additional applications for plaque psoriasis with global regulatory authorities to bring zasocitinib to people living with psoriasis worldwide.

The NDA filing has no significant impact on the full year consolidated financial forecast for the fiscal year ending March 31, 2027.

Q&A:

What specific data supports the zasocitinib FDA acceptance?

The NDA filing is supported by the pivotal Phase 3 LATITUDE PsO 3001 (NCT06088043) and 3002 (NCT06108544) studies, in which the co-primary and all 44 ranked secondary endpoints were met.[1-2,6-7] The studies are global, multicenter, randomized, double-blind, placebo- and active comparator-controlled studies to evaluate the efficacy, safety and tolerability of zasocitinib in adult patients with moderate-to-severe plaque psoriasis.[6-7] Co-primary and select secondary endpoints at week 16 included:[1-2]

Co-primary Endpoints and Select Secondary Endpoints at Week 16	**LATITUDE PsO 3001 Results**	**LATITUDE PsO 3002 Results**
static Physician Global Assessment (sPGA) 0/1	71% zasocitinib vs 11% placebo and 32% apremilast (p<0.001)	69% zasocitinib vs 13% placebo and 30% apremilast (p<0.001)
Psoriasis Area and Severity Index (PASI) 75	76% zasocitinib vs 12% placebo and 37% apremilast (p<0.001)	71% zasocitinib vs 12% placebo and 33% apremilast (p<0.001)
Select Secondary Endpoints at Week 16		
PASI 90	61% zasocitinib vs 5% placebo and 17% apremilast (p<0.001)	52% zasocitinib vs 4% placebo and 16% apremilast (p<0.001)
sPGA 0	40% zasocitinib vs 0.7% placebo and 8% apremilast (p<0.001)	34% zasocitinib vs 1% placebo and 7% apremilast (p<0.001)
PASI 100	33% zasocitinib vs 0.7% placebo and 3% apremilast (p<0.001)	25% zasocitinib vs 1% placebo and 4% apremilast (p<0.001)
Scalp-specific PGA (ssPGA) 0/1	77% zasocitinib vs 7% placebo and 42% apremilast (p<0.001)	74% zasocitinib vs 13% placebo and 30% apremilast (p<0.001)
Nail Psoriasis Severity Index (NAPSI), Least-squares mean change from baseline	-7.1 zasocitinib vs 1.8 placebo (p<0.001)	-8.6 zasocitinib vs -1.4 placebo (p<0.001)

Palmoplantar (hands and/or feet response) PGA (hfPGA) 0/1*	71% zasocitinib vs 22% placebo and 44% apremilast*	69% zasocitinib vs 10% placebo and 43% apremilast*
PASI 75 at Week 4	N/A	17% zasocitinib vs 4% for placebo ($p<0.001$)
Most Common Adverse Events (≥5%)	Upper respiratory tract infection (10.1%), nasopharyngitis (6.2%) and acne (6.5%), with no new safety signals identified**	

*Not a multiplicity controlled secondary endpoint. Comparisons with apremilast are descriptive and should be interpreted accordingly.
**Sample size adjusted incidence proportion across the two studies.

When could zasocitinib become available to patients?
Zasocitinib is currently under FDA Priority Review, with a decision anticipated in the first quarter of 2027. If approved, zasocitinib could become available to appropriate patients after FDA approval.

About Plaque Psoriasis
Psoriasis is a chronic, systemic immune-mediated inflammatory disease characterized by itchy, painful, disfiguring and disabling skin lesions that impact one's physical, emotional and psychological wellbeing.[7,8,14] Globally, an estimated 66.4 million people are living with psoriasis, and about 80-90% of those have plaque psoriasis.[15-17] Persistent itch, the appearance and location of skin lesions — especially in highly visible or high-impact sites — and related comorbidities, like psoriatic arthritis, play a major role in reducing quality of life and can lead to significant impacts on daily living.[8,12-14] Psoriasis is also a heterogeneous disease driven by complex, interconnected immune pathways, genetics and environmental factors that differ across patients and over time, leading to variability in disease course, symptoms and treatment response.[18-22]

About Zasocitinib (TAK-279)
Zasocitinib is an investigational, next-generation, highly selective and potent oral TYK2 inhibitor that maintains 24-hour inhibition of IL-23 plus other core disease-driving immune pathways.[23-27] It has the potential to be a leading oral treatment option for people living with psoriasis that may deliver rapid and durable skin clearance in a convenient once-daily pill.[1-2] Zasocitinib has more than 1-million-fold greater selectivity for TYK2 compared to other JAK enzymes, which could maximize TYK2 inhibition without impacting JAK1, 2 and 3 signaling, based on *in vitro* data.[23-24] Takeda is currently evaluating the safety and efficacy of zasocitinib in Phase 3 studies in psoriatic arthritis and Phase 2 studies in Crohn's disease, ulcerative colitis, vitiligo and hidradenitis suppurativa.[28-33] Zasocitinib is an investigational compound that has not been approved for use by any regulatory authority.

About Tyrosine Kinase 2 (TYK2) Inhibitors

TYK2 is a central mediator of core inflammatory pathways in psoriasis — IL-23/IL-17 axis and type I interferon signaling — making it a promising target as inhibition of a single pathway may not fully control disease for every patient.[22,26,34] TYK2 is an intracellular enzyme and member of the Janus kinase (JAK) protein family.[22-23] However, TYK2 is distinct from JAK1, 2 and 3 as it primarily regulates immune responses, whereas JAK1, 2 and 3 regulate broader biological processes such as lipid metabolism and hematopoiesis.[22-23] Highly selective allosteric inhibition of TYK2, with minimal inhibition of JAK1, 2 and 3, is a promising therapeutic approach to target immune-mediated inflammation.[27]

About the Phase 3 LATITUDE PsO 3001 and 3002 Studies

The Phase 3 LATITUDE PsO 3001 (NCT06088043) and 3002 (NCT06108544) studies are global, multicenter, randomized, double-blind, placebo- and active comparator-controlled studies to evaluate the efficacy, safety and tolerability of zasocitinib in adult patients with moderate-to-severe plaque psoriasis.[6-7] The studies were conducted in 21 countries, with LATITUDE PsO 3001 enrolling 693 participants and LATITUDE PsO 3002 enrolling 1,108 participants, respectively. The co-primary endpoints were the proportion of zasocitinib-treated patients achieving sPGA 0/1 and PASI 75 response compared to placebo at week 16.[6-7] Ranked secondary endpoints included comparisons versus placebo (week 16) and apremilast (week 16 and week 24).[6-7]

About the Phase 3 LATITUDE PsO 3003 Study

The LATITUDE PsO 3003 (NCT06550076) study is a Phase 3, multicenter, open-label study evaluating the long-term safety, tolerability and efficacy of zasocitinib in adults with moderate-to-severe plaque psoriasis.[4] The study enrolled approximately 2,100 participants and consists of two parts.[4] In Part A (de novo cohort), adult patients who had not been exposed to zasocitinib before received zasocitinib 30 mg once daily for up to 52 weeks.[4] Patients who completed Part A or the treatment period in the Phase 3 LATITUDE PsO 3001 (NCT06088043) and 3002 (NCT06108544) studies received zasocitinib for up to 156 weeks in Part B.[4] The primary endpoint was the number of zasocitinib-treated patients with treatment-emergent and serious adverse events.[4] Secondary endpoints were the proportion of zasocitinib-treated patients achieving sPGA 0/1 and PASI 75 response.[4]

About Takeda

Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline. As a leading values-based, R&D-driven biopharmaceutical company headquartered in Japan, we are guided by our commitment to patients, our people and the planet. Our employees in approximately 80 countries and regions are driven by our purpose and are grounded in the values that have defined us for more than two centuries. For more information, visit www.takeda.com.

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