Better Health, Brighter Future

News Release

Takeda's Zasocitinib Landmark Phase 3 Plaque Psoriasis Data Show Promise to Deliver Clear Skin in a Once-Daily Pill, Catalyzing a New Era of Treatment

- Pivotal Phase 3 studies of once-daily oral zasocitinib met all primary and ranked secondary endpoints in patients with moderate-to-severe plaque psoriasis
- More than half of study participants treated with zasocitinib achieved clear or almost clear skin (PASI 90), and on average about 30 percent achieved completely clear skin (PASI 100) by week 16
- Zasocitinib was generally well-tolerated with a safety profile consistent with previous clinical studies

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OSAKA Japan AND CAMBRIDGE, Massachusetts, December 18, 2025 – Takeda (TSE:4502/NYSE:TAK) today announced positive topline results for the two pivotal Phase 3 randomized, multicenter, double-blind, placebo- and active comparator-controlled studies of zasocitinib (TAK-279), a next-generation, highly selective oral tyrosine kinase 2 (TYK2) inhibitor, in adults with moderate-to-severe plaque psoriasis (PsO). The studies demonstrated superiority of zasocitinib compared to placebo for the co-primary endpoints, static Physician Global Assessment (sPGA) 0/1 and Psoriasis Area and Severity Index (PASI) 75, at week 16, with a significantly greater PASI 75 response rate seen as early as week 4 and continuing to increase through week 24. The studies also met all 44 ranked secondary endpoints, including PASI 90, PASI 100 and sPGA 0 against placebo and apremilast, showing the potential of a convenient once-daily pill to deliver complete skin clearance for patients with PsO.

"People living with psoriasis continue to seek safe, effective and fast-acting oral therapies. These landmark results support zasocitinib's promise to become a leading oral treatment option that can deliver clear skin for patients with plaque psoriasis," said Christophe Weber, president and chief executive officer at Takeda. "This marks the third positive Phase 3 readout from our overarching pipeline this year. Each of these programs – zasocitinib, oveporexton and rusfertide – has potential to transform patient lives, redefine medical practice and deliver significant revenue growth in the future."

Zasocitinib was generally well-tolerated. The safety and tolerability profile of zasocitinib in the Phase 3 studies remained consistent with prior studies, including the Phase 2b plaque psoriasis study. The most common adverse events through week 24 were upper respiratory tract infection, nasopharyngitis and acne, with no new safety signals identified.

“It is incredibly rewarding and exciting to see our Phase 2 results validated in Phase 3, with more than half of patients treated with zasocitinib achieving clear or almost clear skin (PASI 90) and about 30 percent achieving completely clear skin (PASI 100) at week 16, with response rates continuing to increase through week 24,” said Andy Plump, M.D., Ph.D., president of R&D at Takeda. “These findings help demonstrate that highly selective inhibition of TYK2, a key mediator of IL-23 and other signaling pathways fundamental to psoriasis, may provide patients with significant reductions in their disease burden, including for many, the possibility of complete skin clearance.”

Takeda intends to present the results at upcoming medical congresses and plans to submit a New Drug Application with the United States Food and Drug Administration and other regulatory authorities starting in fiscal year 2026.

Zasocitinib is also being evaluated in a head-to-head study against deucravacitinib in plaque psoriasis, Phase 3 studies in psoriatic arthritis and Phase 2 studies in Crohn’s disease and ulcerative colitis, among other indications.[1-6] Results from the Phase 3 studies have no significant impact on the full-year consolidated forecast for the fiscal year ending March 31, 2026.

About Plaque Psoriasis

Psoriasis is a chronic immune-mediated inflammatory disease in which the body’s immune system causes inflammation which results in skin cells that multiply too quickly.[7] Plaque psoriasis, the most common form of psoriasis, is characterized by raised, red, gray or purple patches of skin that are itchy, painful and covered by scales.[8-10] Psoriatic plaques can cover any part of the skin surface but are mostly found on the scalp, face, arms and elbows, legs, knees, torso, genitals, nails and in skin folds.[7,11] Many people living with psoriasis experience intense itching and burning from their psoriasis plaques that disrupt their daily lives.[9,10] Patients also report that their symptoms negatively impact their mental health and quality of life and can lead to social isolation.[12] Globally, an estimated 64 million people are living with psoriasis and about 80-90% of those have plaque psoriasis.[13,14]

About Zasocitinib (TAK-279)

Zasocitinib is an investigational, next-generation, highly selective oral TYK2 inhibitor that maintains 24-hour inhibition of IL-23 plus other core disease-driving immune pathways.[15,16] It

has the potential to be a leading oral treatment option for people living with immune-mediated inflammatory diseases. 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.[15,17] Takeda is currently evaluating the safety and efficacy of zasocitinib in a head-to-head study against deucravacitinib in plaque psoriasis and in Phase 3 studies in psoriatic arthritis. In addition, Phase 2 studies are ongoing in Crohn's disease, ulcerative colitis and vitiligo, and being initiated in hidradenitis suppurativa (HS).[1-6] Zasocitinib is an investigational compound that has not been approved for use by any regulatory authority.

About the LATITUDE Psoriasis Phase 3 Studies

The Latitude Phase 3 psoriasis studies (NCT06088043 and NCT06108544) 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.[18,19] The studies were conducted in 21 countries and enrolled 693 and 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.[18,19] Ranked (key) secondary endpoints included comparisons versus placebo (week 16) and apremilast (week 16 and week 24).[18,19]

About Tyrosine Kinase 2 (TYK2) Inhibitors

TYK2 is an intracellular enzyme and member of the Janus kinase (JAK) protein family.[17,20,21] However, TYK2 is distinct from JAK1, 2 and 3 as it primarily regulates immune responses, whereas JAK1, 2 and 3 regulate broader biological processes. [17,20,21] TYK2 mediates IL-23 plus other immune and inflammatory signaling pathways that are fundamental to psoriasis, psoriatic arthritis and other immune-mediated inflammatory diseases.[22] Highly selective allosteric inhibition of TYK2, with minimal inhibition of JAK1, 2 and 3, may be a promising therapeutic approach to target immune-mediated inflammation while potentially avoiding risks associated with inhibition of other members of the JAK family. [23]

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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The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, "Takeda" is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words "we", "us" and "our" are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

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