

Pfizer's Tilrekimig Shows Significant Skin Clearance in Phase 2 Atopic Dermatitis Study

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Study met primary endpoint, showing a statistically significant increase in the percentage of participants achieving EASI-75 versus placebo at Week 16, for the potentially first-in-class trispecific antibody

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today presented detailed results from an ongoing Phase 2 study investigating tilrekimig (PF-07275315) in adults with moderate-to-severe atopic dermatitis (AD). The study met its primary endpoint, demonstrating a statistically significant increase in the percentage of participants achieving EASI-75* (75% reduction in the Eczema Area and Severity Index) at Week 16 across all evaluated doses compared to placebo. The findings were shared today in an oral presentation at the 35th European Academy of Dermatology and Venereology (EADV) Annual Congress in Vienna, Austria.

Tilrekimig is an investigational, potential first-in-class trispecific antibody that simultaneously inhibits upstream and downstream drivers of type 2 inflammation through concurrent high-affinity binding to interleukin-4 (IL-4), interleukin-13 (IL-13), and thymic stromal lymphopoietin (TSLP). By directly blocking TSLP together with its downstream effectors, tilrekimig is designed to provide broader cytokine pathway coverage and potentially more durable clinical responses. Tilrekimig is also designed to have an extended half-life of about 37 days, which is anticipated to support monthly administration.

“Tilrekimig is a promising investigational medicine in Pfizer’s inflammation and immunology pipeline as we seek to pursue next-generation biologics that address persistent unmet medical needs. The compelling efficacy and tolerability demonstrated in this Phase 2 study validate this multi-pathway, trispecific approach and suggest that tilrekimig has the potential to raise the bar beyond current standard-of-care biologics. Building on these promising findings, we have initiated Phase 3 trials of tilrekimig in atopic dermatitis and asthma, and we are advancing a Phase 2b/3 study in COPD.”

- Michael Vincent, M.D., Ph.D., Chief Inflammation & Immunology Officer, Pfizer

“Systemic treatment in moderate-to-severe atopic dermatitis has moved from broad immunosuppression to targeted therapy, and that shift has meaningfully changed what we can offer patients. But atopic dermatitis is driven by several inflammatory signals, and a substantial proportion of patients still live with persistent itch and extensive skin involvement. The Week 16 results presented today are meaningful at this stage of development, with tilrekimig’s tolerability profile supporting continued study in a larger patient population.”

- Eric Simpson, M.D., M.C.R., Department of Dermatology, Oregon Health & Science University

Detailed Phase 2 Study Results at Week 16

- The ongoing Phase 2 trial is evaluating adult patients with moderate-to-severe AD. Data presented at EADV reflect the first two stages of the study, which evaluated biologic-naïve patients:

- Stage 1 evaluated subcutaneous tilrekimig 450 mg every two weeks (Q2W) versus placebo.
- Stage 2 was a dose-ranging evaluation of tilrekimig 400 mg, 200 mg, or 50 mg every four weeks (Q4W) versus placebo.
- The results presented at EADV build upon previously announced topline results.
- **Primary Endpoint (EASI-75 at Week 16):**
 - In Stage 1, 62.5% of patients receiving tilrekimig 450 mg Q2W achieved EASI-75, compared to 19.9% in the placebo group ($p=0.0008$).
 - In Stage 2, 58.5% (400 mg Q4W), 61.0% (200 mg Q4W), and 47.8% (50 mg Q4W) of patients receiving tilrekimig achieved EASI-75, an absolute improvement of 49.4%, 51.9%, and 38.7%, respectively, compared to 9.1% for placebo (all $p<0.003$).
- **Key Secondary Endpoint:**
 - vIGA 0/1 (Clear/Almost Clear skin with ?2-point improvement):
 - In Stage 1, 30.3% of patients in the 450 mg Q2W group achieved vIGA 0/1 (vs 11.8% for placebo; $p=0.0251$)
 - In Stage 2, 26%–27% of patients across the Q4W groups achieved vIGA 0/1 (vs 0% for placebo; all $p<0.006$).
- **Exploratory Endpoint:**
 - Itch Reduction (PP-NRS4): In an exploratory analysis, greater proportions of patients receiving tilrekimig achieved a ?4-point reduction in weekly average Peak Pruritus Numerical Rating Scale compared to placebo, with treatment differences of 35.3% (42.5% vs 7.2%) in the 400 mg Q4W group and 43.6% (50.8% vs 7.2%) in the 200 mg Q4W group.
- **Safety:**
 - Tilrekimig was well-tolerated, with no dose-dependent safety signals, with treatment-emergent adverse event (TEAE) rates comparable between treatment and placebo groups.
 - In Stage 1, TEAEs were reported in 46.7% of patients receiving tilrekimig 450 mg Q2W versus 28.9% of patients receiving placebo. In Stage 2, TEAEs were reported in 42.2%, 47.7%, and 47.8% of patients receiving tilrekimig 400 mg, 200 mg, and 50 mg Q4W, respectively, versus 52.2% of patients receiving placebo.
 - In doses up to 400 mg of tilrekimig Q4W, the observed frequency of conjunctivitis and injection-site reactions in this study was lower than rates reported with IL-4 receptor alpha inhibitors and comparable to placebo.
 - There were no serious adverse events related to tilrekimig in both stages 1 and 2.

About the Tilrekimig Clinical Trial Program

The Phase 2 study is an ongoing randomized, double-blind, placebo-controlled trial in adults with moderate-to-severe atopic dermatitis.

The Phase 3 pivotal program for tilrekimig is underway, with patients dosed in three Phase 3 studies: two in atopic dermatitis — including one with dupilumab as an active comparator — and one in asthma. Pfizer is also studying tilrekimig in an ongoing Phase 2b/3 study in chronic obstructive pulmonary disease (COPD).

Continuing Pfizer's Commitment to Inflammation and Immunology Conditions

These results build on Pfizer's ongoing commitment to advancing care for people living with immune-mediated skin conditions. Pfizer currently offers three approved medicines across atopic dermatitis and alopecia areata and continues to invest in a growing dermatology pipeline focused on addressing unmet needs for patients across these conditions.

Pfizer is presenting more than 30 accepted abstracts across its dermatology portfolio at the 35th EADV Congress, spanning atopic dermatitis, alopecia areata, and nonsegmental vitiligo.

- Also in atopic dermatitis, Pfizer will present a late-breaking exploratory analysis of serum protein biomarkers from the Phase 3 JADE COMPARE study of CIBINQO (abrocitinib), alongside a final integrated safety analysis of 3,850 patients with up to 6.5 years of exposure.
- In nonsegmental vitiligo (NSV), Pfizer will present Phase 3 results from the TRANQUILLO program evaluating LITFULO (ritlicitinib) as an investigational medicine in the largest Phase 3 program to date studying an oral systemic therapy in NSV.
- In alopecia areata, Pfizer plans to share long-term Phase 3 data showing clinically meaningful improvements in scalp hair regrowth with LITFULO through five years, with no new safety signals observed. Pfizer has also initiated a pivotal study evaluating LITFULO for the treatment of moderate alopecia areata.

For more information on Pfizer's Commitment to Immunology and Inflammation, please visit: [Inflammation & Immunology | Pfizer](#).

For more information on Tilrekimig and the trispecific program, please visit: [Pfizer's Phase 2 Study of Trispecific Antibody Positive in Moderate to Severe Atopic Dermatitis | Pfizer](#).

About Atopic Dermatitis

Atopic dermatitis is more than “just a rash.” It is a chronic Type 2 (Th2) inflammatory skin condition, affecting people of all ages and genders around the world.^{1,2} Atopic dermatitis is the most common form of eczema, and sometimes the terms are used interchangeably.³ The most frequent symptom of atopic dermatitis is itchy skin, which can lead to rashes, pain, and poor sleep.³ The condition can be debilitating, disrupting patients' daily lives, and negatively affecting their emotional well-being. Many patients do not experience a clinically meaningful response to currently available treatments, signaling a critical need for further innovation in this class of medicines.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on X at [@Pfizer](#) and [@Pfizer_News](#), [LinkedIn](#), [YouTube](#) and like us on Facebook at www.facebook.com/Pfizer/.

Disclosure Notice

The information contained in this release is as of October 1, 2026. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about tilrekimig (PF-07275315), including its potential benefits, the development program for tilrekimig, results from an ongoing Phase 2 trial for tilrekimig in patients with moderate-to-severe atopic dermatitis, the initiation of Phase 3 trials of tilrekimig in atopic dermatitis and asthma and the advancement of a Phase 2b/3 study in COPD, and Pfizer's ongoing commitment to advancing care for people living with immune-mediated skin conditions and continued investment in a growing

dermatology pipeline focused on addressing unmet needs for patients across these conditions, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risks associated with initial, preliminary or interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for tilrekimig may be filed in particular jurisdictions for any potential indications; whether and when any such applications for tilrekimig that may be filed may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether tilrekimig will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of tilrekimig; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

References

¹ Jeskey J, Kurien C, Blunk H, et al. Atopic dermatitis: A review of diagnosis and treatment. *J Pediatr Pharmacol Ther.* 2024 Dec;29(6):587-603. doi: 10.5863/1551-6776-29.6.587.

² Choragudi S, Yosipovitch G. Trends in the prevalence of eczema among US children by age, sex, race, and ethnicity from 1997 to 2018. *JAMA Dermatol.* 2023;159(4):454-456.

³ Chovatiya R. Atopic dermatitis (eczema). *JAMA.* 2023 Jan 17;329(3):268. doi: 10.1001/jama.2022.21457.

Category: Research and Pipeline

* EASI-75 is the industry standard for measuring how effectively a treatment candidate reduces atopic dermatitis (eczema) severity and extent from baseline.

Media Contact:

PfizerMediaRelations@Pfizer.com

Investor Contact:

IR@Pfizer.com

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