Incyte Announces 24-Week Long-Term Data from Phase 3 TRuE-AD4 Trial of Opzelura® (ruxolitinib) Cream in Adults with Moderate Atopic Dermatitis

May 7, 2026

- *First presentation of Week 24 results from TRuE-AD4 study in adults with moderate atopic dermatitis (AD) who had an inadequate response, intolerance or contraindication to topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) at the 2026 EADV Symposium*
- *The vast majority of patients achieving EASI50 at Week 8 and continuing double-blind, as needed treatment with Opzelura® (ruxolitinib) cream through Week 24 demonstrated disease control, with 84.3% achieving EASI75 (a ≥75% improvement in the Eczema Area and Severity Index score from baseline) and 70.6% achieving IGA-TS (Investigator's Global Assessment Treatment Success)*
- *Data support Type-II variation application submitted for ruxolitinib cream 1.5% for the treatment of adults with moderate AD in the European Union (EU), feedback expected in 1H 2026*

WILMINGTON, Del.--(BUSINESS WIRE)--May 7, 2026-- Incyte (Nasdaq:INCY) today announced final 24-week data from the Phase 3 TRuE-AD4 study evaluating the efficacy and safety of Opzelura® (ruxolitinib) cream in adults with moderate atopic dermatitis (AD) who had an inadequate response, intolerance or contraindication to topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs). These data were presented (Abstract ID: P0851) today at the 2026 European Academy of Dermatology and Venereology (EADV) Symposium, being held May 7–9, 2026, in Athens, Greece.

As previously reported, the TRuE-AD4 study met both of its co-primary endpoints at Week 8, with a statistically significantly higher proportion of patients on Opzelura versus vehicle cream achieving EASI75 (≥75% improvement in Eczema Area and Severity Index score from baseline) and, separately, IGA-TS (Investigator's Global Assessment Treatment Success, defined as an IGA score of 0 [clear] or 1 [almost clear] with at least a two-point improvement from baseline).[1]

Patients who achieved an EASI50 response at Week 8 continued double-blind treatment, as needed, through Week 24. Most patients (84.3%) in the Opzelura treatment group completed treatment through Week 24. Among those patients, 84.3% achieved EASI75 and 70.6% achieved IGA-TS at Week 24, similar to the frequencies at Week 8 (83.5% and 74.4%, respectively). Mean affected body surface area (BSA) remained low (2.5% at Weeks 8 and 24) and itch relief (NRS4; ≥4-point improvement in Itch Numeric Rating Scale) remained high (74.3% at Week 8 and 64.7% at Week 24) with Opzelura treatment.

As-needed treatment with Opzelura was well tolerated, with few application site reactions (1.7%) and no new safety signals up to 24 weeks. The most common treatment-emergent adverse events were upper respiratory tract infection (10.6%) and nasopharyngitis (6.3%).

“We are pleased to share these results, which demonstrate sustained disease control over 24 weeks in adults with moderate AD and further reinforce the well-tolerated safety profile of Opzelura,” said Pablo J. Cagnoni, M.D., President and Global Head of Research and Development, Incyte. “We look forward to continuing to work with EU regulatory authorities to bring this differentiated, nonsteroidal treatment option to European adults with moderate AD who have progressed on standard topical therapies.”

More information regarding the EADV Symposium can be found at: https://eadv.org/symposium/.

About TRuE-AD4

TRuE-AD4 (NCT06238817) is a randomized, double-blind, vehicle-controlled Phase 3b study designed to evaluate the efficacy and safety of Opzelura® (ruxolitinib) cream in adults with moderate atopic dermatitis (AD). The study enrolled 241 patients (≥18 years old) who met the specific inclusion criteria, including an IGA (Investigator's Global Assessment) score of 3 and an EASI (Eczema Area and Severity Index) score greater than 7 at both screening and Day 1, and who have AD on 10% to 20% of their Body Surface Area (BSA; excluding scalp). Patients also had to have a documented history of inadequate response, intolerance or contraindication to topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) within the 12 months prior to the screening visit.

Patients were randomized 2:1 to receive Opzelura applied twice daily (BID) or vehicle (non-medicated cream) BID. At Week 8, patients who achieved EASI50 continued double-blind, BID treatment, applied as needed for an additional 16 weeks. Patients for whom EASI50 was not achieved at two consecutive visits ≥1 week apart were eligible to enter the escape arm at Week 8 or later, in which open-label Opzelura cream was applied as needed.

The co-primary endpoints of TRuE-AD4 were the proportion of patients achieving IGA Treatment Success (IGA-TS), defined as an IGA score of 0 (clear) or 1 (almost clear) with at least a two-point improvement from baseline, and EASI75, defined as ≥75% improvement in EASI score, at Week 8. Secondary endpoints included the proportion of patients with a ≥4-point improvement in NRS4 (≥4-point improvement in Itch Numeric Rating Scale) score at various time points. Other efficacy measures included the proportion of patients who achieved IGA-TS, NRS4, EASI75, a negative change from baseline in the affected body surface area (%BSA), change from baseline in the skin pain NRS score, EASI50 and more, measured at various time points. The study also tracked the frequency, duration and severity of adverse events associated with the use of Opzelura.

For more information on the study, visit https://www.clinicaltrials.gov/study/NCT06238817.

About Atopic Dermatitis

AD – the most common type of eczema – is a chronic, recurring, inflammatory and highly pruritic skin condition that affects up to 25% of children and

up to 12% of adults worldwide, with an estimated prevalence of 4.4% - 7.1% of adults in Europe.[2,3] Signs and symptoms include irritated and itchy skin that can cause red lesions that may ooze and crust.[4]

About Opzelura® (ruxolitinib) Cream

Opzelura® (ruxolitinib) cream, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, approved by the U.S. FDA for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, is the first and only treatment for repigmentation approved for use in the United States. Opzelura is also approved in the U.S. for the topical short-term and non-continuous chronic treatment of mild to moderate AD in non-immunocompromised patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In Europe, Opzelura (ruxolitinib) cream 15mg/g is approved for the treatment of nonsegmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Incyte has worldwide rights for the development and commercialization of Opzelura.

Opzelura is a registered trademark of Incyte.

For more information, see the Opzelura SmPC.

About Incyte®

Incyte is redefining what's possible in biopharmaceutical innovation. Through deep scientific expertise and a relentless focus on patients, we have built an established portfolio of first-in-class medicines and an extensive portfolio of next-generation medicines across our key franchises: Hematology, Oncology and Inflammation and Autoimmunity.

To learn more, visit Incyte.com and Investor.Incyte.com. Follow us on social media: LinkedIn, X and Instagram.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the TRuE-AD4 study, anticipated discussions between Incyte and EU regulatory authorities, whether and when Opzelura might be approved or commercially available in Europe for adults with moderate AD and the potential for Opzelura to offer an effective nonsteroidal topical treatment option that can help delay or prevent progression to systemic therapy in appropriate adult patients, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including risks and uncertainties regarding research and development of products and product candidates, the sufficiency of clinical trial data to meet applicable regulatory standards or warrant continued development, the ability to enroll sufficient numbers of subjects in clinical trials, determinations made by the FDA, EMA and other regulatory authorities, the efficacy or safety of Incyte's products, the acceptance of Incyte's products in the marketplace, market competition, sales, marketing, manufacturing and distribution requirements, and other risks detailed from time to time in our reports filed with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-Q for the quarter ended March 31, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Carrascosa JM, et al. Efficacy and safety of ruxolitinib cream in adults with moderate atopic dermatitis: results from TRuE-AD4, a phase 3b, randomized, double-blind, vehicle-controlled study. Presented at: 15th Georg RAJKA International Symposium on Atopic Dermatitis; October 24–26, 2025; Melbourne, Australia.

[2] Global Atopic Dermatitis Atlas. Global report on atopic dermatitis 2022. Available at: https://www.eczemacouncil.org/assets/docs/global-report-on-atopic-dermatitis-2022.pdf. Accessed April 2026

[3] Eckert L, Gupta S, Gadkari A, et al. Burden of illness in adults with atopic dermatitis: Analysis of national health and wellness survey data from France, Germany, Italy, Spain, and the United Kingdom. *J Am Acad Dermatol.*

[4] Boguniewicz M, Fonacier L, Guttman-Yassky E, et al. Atopic dermatitis yardstick: practical recommendations for an evolving therapeutic landscape. *Ann Allergy Asthma Immunol.* 2018;120(1):10-22.e2. Link to source (https://pubmed.ncbi.nlm.nih.gov/29273118/)

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