

Opzelura® (ruxolitinib) Cream Becomes First Steroid-Free Topical JAK Inhibitor Approved in the European Union for Adults with Moderate Atopic Dermatitis

July 29, 2026

The European Commission approval is based on Phase 3b TRuE-AD4 data which demonstrated that Opzelura® (ruxolitinib) cream met both co-primary endpoints at Week 8, maintained disease control with as-needed treatment through Week 24, and was well tolerated ^{1,2,3}

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 29, 2026-- Incyte (Nasdaq:INCY) today announced that the European Commission (EC) has approved Opzelura® (ruxolitinib) cream for the treatment of moderate atopic dermatitis (AD) in adult patients for whom topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are inadequate or inappropriate.

"The European Commission's approval of Opzelura is an important milestone for adults in Europe living with moderate atopic dermatitis who need more treatment options," said Bill Meury, Chief Executive Officer, Incyte. "As the first steroid-free topical JAK inhibitor approved in the EU for atopic dermatitis, Opzelura offers an effective new treatment choice and reflects our commitment to advancing innovation for people with inflammatory and autoimmune diseases."

The EC decision follows the June 2026 positive opinion received from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). This marks the second indication in Europe for Opzelura, which was previously approved by the EC as a treatment for non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

This approval is based on data from the pivotal Phase 3b TRuE-AD4 study ([NCT06238817](#)) evaluating the safety and efficacy of Opzelura in adults with moderate AD, and is supported by the Phase 3 TRuE-AD1 ([NCT03745638](#)) and TRuE-AD2 ([NCT03745651](#)) studies.^{2,4,5}

In [TRuE-AD4](#), Opzelura significantly improved the clinical signs and symptoms of moderate AD, including itch as early as Day 2.¹ Opzelura was well tolerated in adults who had an inadequate response, intolerance or contraindication to both TCSs and TCIs.¹ In the TRuE-AD4 study the co-primary endpoints were met at Week 8, with a statistically significantly higher proportion of patients on Opzelura versus vehicle cream achieving a ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI-75), and, separately, Investigator's Global Assessment 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).¹

Efficacy was maintained following the initial treatment period with 84.3% of patients achieving EASI75 and 70.6% achieving IGA-TS with as needed therapy at Week 24.³ Mean affected body surface area (BSA) decreased markedly from 15.1% at baseline to 2.5% at Week 8 and remained low at Week 24 (2.5%), while 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.^{1,3}

Additionally, patients treated with Opzelura also showed improvements in quality of life, with mean Dermatology Life Quality Index (DLQI) scores improving from 19.3 at baseline to 4.3 at Week 8, compared with 19.1 to 10.7 with vehicle cream (control).¹

Opzelura was well tolerated, with no serious infections, major adverse cardiovascular events, malignancies or thromboses reported during the 24-week treatment period.² The most common treatment-emergent adverse events were upper respiratory tract infection (10.6%) and nasopharyngitis (6.3%).¹

"Despite advances in the treatment of moderate atopic dermatitis, many patients continue to face residual symptoms that can affect their everyday quality of life, underscoring the need for additional treatment options," said Prof. Andreas Wollenberg, Professor of Dermatology and Allergy, University Hospital Augsburg, Germany. "This approval represents an important new treatment option for patients who have not responded to topical corticosteroids or topical calcineurin inhibitors, offering the potential to improve disease management and reduce the burden of their condition on everyday life."

The most common type of eczema, AD, is a chronic recurring, inflammatory and highly pruritic skin condition that affects up to 4% of adults worldwide, with an estimated prevalence of 4.4-7.1% of adults in Europe.^{6,7,8,9} Signs and symptoms of AD include, but are not limited to, irritated and itchy skin that can cause red lesions that may ooze and crust.⁶

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 reduction 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 Opzelura® (ruxolitinib) cream

Opzelura (ruxolitinib) cream, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is approved by the U.S. Food & Drug Administration 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 atopic dermatitis (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 non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age and in adult patients with moderate atopic dermatitis (AD) for whom topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are inadequate or inappropriate.

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](https://www.incyte.com) and [Investor.Incyte.com](https://investor.incyte.com). Follow us on social media: [LinkedIn](#), [X](#) and [Instagram](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the potential for Opzelura to be a successful treatment option for patients in the EU with moderate AD, the potential benefits of Opzelura, Incyte's commitment to advancing innovation for people with inflammatory and autoimmune diseases and Incyte's aspirations and goals as set forth under the heading "About Incyte."

Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including 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 and the ability to enroll subjects in accordance with planned schedules; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; the efficacy or safety of Incyte's products; Incyte's ability to achieve commercial success for its marketed products and product candidates, if approved; Incyte's ability to obtain and maintain protection of intellectual property for its products and technology; Incyte's reliance on third parties and partners; the acceptance of Incyte's products in the marketplace; market competition, sales, marketing, manufacturing and distribution requirements; greater than expected expenses, including expenses relating to litigation or strategic activities; and those risks and uncertainties discussed in greater detail in Incyte's reports filed with the U.S. Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2025, and its quarterly report on Form 10-Q for the quarter ended June 30, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

¹ Carrascosa JM, Prajapati VH, and Hong HCH, et al. Ruxolitinib cream in adults with moderate atopic dermatitis after failure of other topicals: A randomized trial. *J Eur Acad Dermatol Venereol*. 2026;00:1-13. Available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/jdv.70595>.

² ClinicalTrials.Gov. A study to evaluate the efficacy, and safety study of ruxolitinib cream in adults with moderate atopic dermatitis (TRuE-AD4). Available at: <https://clinicaltrials.gov/study/NCT06238817>. Accessed June 2026

³ Wollenberg A, Hong HC, Agius E, et al. Long-term disease control and safety with ruxolitinib cream in adults with moderate atopic dermatitis following failure of prior topical therapies: results from the TRuE-AD4 phase 3b study. Results presented at the European Academy of Dermatology and Venereology (EADV) Symposium, Athens, Greece, 2026. Accessed May 2026. Available at: https://s3.eu-central-1.amazonaws.com/m-anage.com/storage/eadv/abstracts_symposium_2026/61731.pdf. Accessed June 2026

⁴ ClinicalTrials.Gov. Topical ruxolitinib evaluation in atopic dermatitis study 1 (TRuE AD1) - an efficacy and safety study of ruxolitinib cream in adolescents and adults with atopic dermatitis. Available at: <https://clinicaltrials.gov/study/NCT03745638>. Accessed June 2026

⁵ ClinicalTrials.Gov. TRuE AD2 - an efficacy and safety study of ruxolitinib cream in adolescents and adults with atopic dermatitis. Available at: <https://clinicaltrials.gov/study/NCT03745651>. Accessed June 2026

⁶ 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 June 2026

⁷ Barbarot S, Auziere S, Gadkari A, et al. Epidemiology of atopic dermatitis in adults: Results from an international survey. *Allergy*. 2018;73(6):1284-1293. Link to source (<https://pubmed.ncbi.nlm.nih.gov/29319189/>)

⁸ Silverberg JI, Barbarot S, Gadkari A, et al. Atopic dermatitis in the pediatric population: A cross-sectional, international epidemiologic study. *Ann Allergy Asthma Immunol*. 2021;126(4):417-428.e2. Link to source (<https://pubmed.ncbi.nlm.nih.gov/33421555/>)

⁹ 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*. 2019;81(1):187-195. Link to source (<https://pubmed.ncbi.nlm.nih.gov/30905805/>)

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