Incyte Announces Positive CHMP Opinion for Opzelura® (ruxolitinib) Cream for the Treatment of Adults with Moderate Atopic Dermatitis

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- *If approved, Opzelura® (ruxolitinib) cream will be the first steroid-free, topical JAK treatment option in the European Union (EU) for adults with moderate atopic dermatitis (AD) for whom standard topical therapies have failed*
- *AD, the most common type of eczema which affects 230 million people globally,[1] is a chronic, recurring, inflammatory and highly pruritic (itchy) skin condition that can have a significant impact on daily life[2]*
- *Phase 3 TRuE-AD4 data supporting the positive CHMP opinion demonstrated that ruxolitinib cream met both co-primary endpoints at Week 8, maintained disease control with as-needed treatment through Week 24 and was well tolerated[3,4,5]*

MORGES, Switzerland--(BUSINESS WIRE)--Jun. 26, 2026-- Incyte (Nasdaq: INCY) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of 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.

“AD is a chronic skin condition that can have a significant impact on daily life. The positive CHMP opinion for Opzelura marks meaningful progress toward bringing the first non-steroidal topical JAK treatment option to adults in Europe with moderate AD for whom standard topical therapies have failed,” said Lee Heeson, Executive Vice President and Head of Incyte International. “If approved by the European Commission, Opzelura could help address an important gap for patients who have limited treatment options when TCSs and TCIs are inadequate or inappropriate.”

The positive CHMP opinion is based on results from the pivotal Phase 3 TRuE-AD4 study (NCT06238817), supported by the Phase 3 TRuE-AD1 (NCT03745638) and TRuE-AD2 (NCT03745651) studies, evaluating the safety and efficacy of ruxolitinib cream in adults with AD.[4,6,7]

In TRuE-AD4, ruxolitinib cream significantly improved the clinical signs and symptoms of moderate AD, including itch, as early as Day 2 and was well tolerated in adults who had an inadequate response, intolerance or contraindication to both TCSs and TCIs.[3] The TRuE-AD4 study met its co-primary endpoints at Week 8, with a statistically significantly higher proportion of patients on ruxolitinib cream versus vehicle cream achieving a ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI75), 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).[3]

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.[5] 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 ruxolitinib cream treatment.[3,5]

Additionally, patients treated with ruxolitinib cream 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).[3]

Ruxolitinib cream was well tolerated, with no serious infections, major adverse cardiovascular events, malignancies or thromboses reported during the 24-week treatment period.[4] The most common treatment-emergent adverse events were upper respiratory tract infection (10.6%) and nasopharyngitis (6.3%).[3]

“In clinical practice, many adults with moderate AD do not achieve the level of disease control they need, despite available topical therapies, and the impact on quality of life can be considerable,” said Dr. Andreas Wollenberg, Professor of Dermatology and Allergy, University Hospital Augsburg, Germany. “The data supporting this positive CHMP opinion suggest that ruxolitinib cream may offer an effective new topical treatment option for appropriate adult patients in Europe and may help delay or prevent progression to systemic therapy, potentially helping to address an important gap for those who have struggled to achieve lasting relief.”

AD, the most common type of eczema, 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.2,[8,9,10] Signs and symptoms include irritated and itchy skin that can cause red lesions that may ooze and crust.[2]

The CHMP opinion is now being reviewed by the European Commission (EC), which has the authority to grant approval for all centrally authorized products in the European Union (EU). If approved, this would be the second indication for Opzelura in the EU, which was previously approved by the EC for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

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.

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 & Autoimmunity.

To learn more, visit Incyte.com and 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 whether and when ruxolitinib cream might become a new treatment option for patients in the EU with moderate AD; ruxolitinib cream's potential to delay or prevent progression to systemic therapy; 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 March 31, 2026. Incyte disclaims any intent or obligation to update these forward-looking statements.

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Incyte Contacts:
Media
media@incyte.com

Investors
ir@incyte.com

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