Incyte Announces New Data from Phase 3b TRuE-AD4 Trial of Opzelura® (Ruxolitinib Cream) in Adults with Moderate Atopic Dermatitis

October 25, 2025

- *Eight-week results from the TRuE-AD4 trial demonstrate treatment with Opzelura® (ruxolitinib cream) significantly improved the clinical signs of atopic dermatitis (AD), including improved itch as early as Day 2, and was well tolerated in adults with moderate AD who had an inadequate response, intolerance or contraindication to topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs)*

- *At Week 8, 70% of patients treated with Opzelura achieved a ≥75% improvement in the Eczema Area and Severity Index (EASI75) and 61.3% achieved Investigator's Global Assessment Treatment Success (IGA-TS), co-primary endpoints of the study*

- *Based on these results, Incyte expects to file a Type-II variation application for ruxolitinib cream 1.5% for the treatment of adults with moderate AD in the European Union (EU) by end of year*

WILMINGTON, Del. --(BUSINESS WIRE)--Oct. 25, 2025-- Incyte (Nasdaq:INCY) today announced new data from the Phase 3b 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 will be presented during the Systemic and New Therapies for Atopic Dermatitis session on Sunday, October 26 at 10:55 a.m.> AEDT (Saturday, October 25 at 7:55 p.m. ET) (Abstract #1177) at the 15th Georg Rajka International Symposium on Atopic Dermatitis (ISAD), held from October 24 – 26, 2025, in Melbourne.

Data from TRuE-AD4, which build on previously announced topline results, show the study met its co-primary endpoints at Week 8, with a statistically significant proportion of patients achieving both a ≥75% improvement in Eczema Area and Severity Index (EASI75) score from baseline (70.0% with Opzelura vs. 18.5% with vehicle, *P*<0.0001) and Investigator's Global Assessment Treatment Success (IGA-TS; 61.3% vs. 13.6%; *P*<0.0001). Patients treated with Opzelura demonstrated improvement in EASI75 (43.8% vs. 3.7%, nominal *P*<0.0001) and IGA-TS (29.4% vs. 2.5%, nominal *P*<0.0001) at Week 2. More patients treated with Opzelura achieved both EASI75 and IGA-TS at Week 8 than vehicle (59.4% vs. 13.6%; nominal *P*<0.0001).

"The TRuE-AD4 data further reinforce the safety and efficacy profile of Opzelura and its ability to control key signs and symptoms of moderate AD, including improvement in bothersome symptoms like itch," said Jim Lee, M.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "These data will support the filing of a Type-II variation application for ruxolitinib cream 1.5% (Opzelura) in Europe, as we seek to meet the needs of more patients around the world who require nonsteroidal topical treatments for moderate AD."

Additional key findings from the TRuE-AD4 study include:

- Improvement in itch as measured by a ≥4-point improvement in Itch Numeric Rating Scale (NRS4) score.
  - Nearly two-thirds (62.5%) of patients treated with Opzelura achieved Itch NRS4 by Week 8 (vs. 19.8% with vehicle, *P*<0.0001).
  - There was significant improvement in worst daily itch at Day 2 with 29.1% of patients treated with Opzelura achieving Itch NRS4 vs. 14.3% with vehicle (*P*=0.0072; by multiple imputation).
  - Current Itch NRS4 was also measured at 15 minutes (16.4% with Opzelura vs. 7.7% with vehicle).
- Improved Patient-Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI) scores:
  - More patients treated with Opzelura vs. vehicle achieved a POEM score 0–2 (clear or almost clear) at Week 8 (39.7% vs. 8.6%).
  - Patients treated with Opzelura showed a mean DLQI score improvement at Week 8 (from 19.3 to 4.3 with Opzelura vs. 19.1 to 10.7 with vehicle).
- Opzelura was well tolerated with no serious infections, major adverse cardiovascular events (MACE), malignancies or thromboses reported during the 8-week vehicle-controlled period. The most common treatment-related adverse event observed in the Opzelura arm was application site acne (4.4% vs 0% in vehicle arm).

"TRuE-AD4 offers compelling support for the utility of Opzelura for patients with moderate AD who have limited treatment options due to inadequate responses or intolerances to TCS and TCI-based topical therapies, who may otherwise be recommended for systemic therapy," said Dr. Andreas Wollenberg, Professor of Dermatology and Allergy, Augsburg University Hospital, Germany. "AD is a challenging, chronic condition and I believe that these data reinforce Opzelura as an important therapeutic option."

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 among adults of 5.5% across 27 European countries.[1,2,3,4,5,6,7] Signs and symptoms include irritated and itchy skin that can cause red lesions that may ooze and crust.

More information regarding the Georg RAJKA International Symposium on Atopic Dermatitis (ISAD) can be found at https://isad.org/rajka-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 meet the specific inclusion criteria, including an Investigator's Global Assessment (IGA) score of 3 and an Eczema Area and Severity Index (EASI) 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 corticosteroid (TCS)s and topical calcineurin inhibitor (TCI)s within the 12 months prior to the screening visit.

Patients were randomized 2:1 to receive Opzelura administered twice daily (BID) or vehicle (non-medicated cream) BID.

The co-primary endpoints of TRuE-AD4 are 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 EASI-75, defined as ≥75% improvement in EASI score, at Week 8. Key secondary endpoints include the proportion of patients with a ≥4-point improvement in Itch Numeric Rating Scale (NRS4) score at various time points. Other exploratory endpoints include the proportion of patients who achieved IGA-TS, NRS4, EASI-75, a decrease from baseline in the affected body surface area (%BSA), change from baseline in the skin pain NRS score, EASI90 and more, measured at various time points. The study also tracked the frequency, duration and severity of adverse events associated with the use of ruxolitinib cream.

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, approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients12 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 ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura and the Opzelura logo are registered trademarks of Incyte**.**

IMPORTANT SAFETY INFORMATION

OPZELURA is for use on the skin only. Do not use OPZELURA in your eyes, mouth, or vagina.

OPZELURA may cause serious side effects, including:

Serious Infections: OPZELURA contains ruxolitinib. Ruxolitinib belongs to a class of medicines called Janus kinase (JAK) inhibitors. JAK inhibitors are medicines that affect your immune system. JAK inhibitors can lower the ability of your immune system to fight infections. Some people have had serious infections while taking JAK inhibitors by mouth, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have been hospitalized or died from these infections. Some people have had serious infections of their lungs while taking OPZELURA. Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with OPZELURA.

OPZELURA should not be used in people with an active, serious infection, including localized infections. You should not start using OPZELURA if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster) while using OPZELURA.

Increased risk of death due to any reason (all causes): Increased risk of death has happened in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called JAK inhibitors by mouth.

Cancer and immune system problems: OPZELURA may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers have happened in people taking a medicine in the class of medicines called JAK inhibitors by mouth. People taking JAK inhibitors by mouth have a higher risk of certain cancers including lymphoma and lung cancer, especially if they are a current or past smoker. Some people have had skin cancers while using OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA. Limit the amount of time you spend in the sunlight. Wear protective clothing when you are in the sun and use a broad-spectrum sunscreen.

Increased risk of major cardiovascular events: Increased risk of major cardiovascular events such as heart attack, stroke, or death have happened in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors by mouth, especially in current or past smokers.

Blood clots: Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking OPZELURA. This may be life-threatening. Blood clots in the vein of the legs (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called JAK inhibitors by mouth.

Low blood cell counts: OPZELURA may cause low platelet counts (thrombocytopenia), low red blood cell counts (anemia), and low white blood cell counts (neutropenia). Your healthcare provider may do a blood test to check your blood cell counts during your treatment with OPZELURA and may stop your treatment if signs or symptoms of low blood cell counts happen.

Cholesterol increases: Cholesterol increase has happened in people when ruxolitinib is taken by mouth. Tell your healthcare provider if you have high cholesterol or triglycerides.

Before starting OPZELURA, tell your healthcare provider if you:

- have an infection, are being treated for one, or have had an infection that does not go away or keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system
- have TB or have been in close contact with someone with TB
- have had shingles (herpes zoster)
- have or have had hepatitis B or C
- live, have lived in, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use OPZELURA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- think you have an infection or have symptoms of an infection such as: fever, sweating, or chills, muscle aches, cough or shortness of breath, blood in your phlegm, weight loss, warm, red, or painful skin or sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than usual, feeling very tired.
- have ever had any type of cancer, or are a current or past smoker
- have had a heart attack, other heart problems, or a stroke
- have had blood clots in the veins of your legs or lungs in the past
- have high cholesterol or triglycerides
- have or have had low white or red blood cell counts
- are pregnant or plan to become pregnant. It is not known if OPZELURA will harm your unborn baby. There is a pregnancy exposure registry for individuals who use OPZELURA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you become exposed to OPZELURA during pregnancy, you and your healthcare provider should report exposure to Incyte Corporation at 1-855-463-3463 or www.opzelura.pregnancy.incyte.com.
- are breastfeeding or plan to breastfeed. It is not known if OPZELURA passes into your breast milk. Do not breastfeed during treatment with OPZELURA and for about 4 weeks after the last dose.

After starting OPZELURA:

- Call your healthcare provider right away if you have any symptoms of an infection. OPZELURA can make you more likely to get infections or make worse any infections that you have.
- Get emergency help right away if you have any symptoms of a heart attack or stroke while using OPZELURA, including:
    - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
    - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
    - pain or discomfort in your arms, back, neck, jaw, or stomach
    - shortness of breath with or without chest discomfort
    - breaking out in a cold sweat
    - nausea or vomiting
    - feeling lightheaded
    - weakness in one part or on one side of your body
    - slurred speech

- Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with OPZELURA, including: swelling, pain, or tenderness in one or both legs, sudden, unexplained chest or upper back pain, or shortness of breath or difficulty breathing.
- Tell your healthcare provider right away if you develop or have worsening of any symptoms of low blood cell counts, such as: unusual bleeding, bruising, tiredness, shortness of breath, or fever.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

The most common side effects of OPZELURA in people 12 years of age and older treated for atopic dermatitis include: common cold (nasopharyngitis), bronchitis, ear infection, increase in a type of white blood cell (eosinophil) count, hives, diarrhea, inflamed hair pores (folliculitis), swelling of the tonsils (tonsillitis), and runny nose (rhinorrhea). For people 2-11 years: upper respiratory tract infection, COVID-19, application site reaction, fever, white blood cell count decreased.

These are not all of the possible side effects of OPZELURA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Incyte Corporation at 1-855-463-3463.

Please see the Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA at Opzelura.com.

INDICATION AND USAGE

OPZELURA is a prescription medicine used on the skin (topical) for the short-term and non-continuous chronic treatment of mild to moderate eczema (atopic dermatitis) in non-immunocompromised adults and children 2 years of age and older whose disease is not well controlled with topical

prescription therapies or when those therapies are not recommended.

The use of OPZELURA along with therapeutic biologics, other JAK inhibitors, or strong immunosuppressants such as azathioprine or cyclosporine is not recommended.

It is not known if OPZELURA is safe and effective in children less than 2 years of age with atopic dermatitis.

About Incyte
A global biopharmaceutical company on a mission to *Solve On.*, Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

Incyte Forward-Looking Statements
Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the presentation of data from the TRuE-AD4 study, Incyte's plans to file an application with regulators in Europe, and whether and when Opzelura might provide a successful treatment option to patients beyond its already-approved indications in specific regions, 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 unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient 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 and its partners' products; the acceptance of Incyte and its partners' 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-K for the quarter ended June 30, 2025. Incyte disclaims any intent or obligation to update these forward-looking statements.

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