# Update on FDA Review of Ruxolitinib Cream (Opzelura®) for Children Ages 2-11 with Atopic Dermatitis

June 20, 2025

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 20, 2025-- Incyte (Nasdaq: INCY) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period for the supplemental New Drug Application (sNDA) for ruxolitinib cream (Opzelura®), a topical Janus kinase (JAK) inhibitor, for the treatment of children 2-11 years old with mild to moderate atopic dermatitis (AD). The Prescription Drug User Fee Act (PDUFA) action date has been extended by three months to September 19, 2025.

The FDA extended the PDUFA action date to allow time to review additional chemistry, manufacturing and controls (CMC) data on the 0.75% strength submitted by Incyte in response to a recent FDA information request.

“Atopic dermatitis (AD) is a chronic immune-mediated skin condition that can be difficult to manage, particularly for the millions of children in the U.S. affected by AD,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We are confident in the potential of ruxolitinib cream to become an important non-steroidal, topical treatment option for pediatric patients with atopic dermatitis and we will continue to work closely with the FDA to ensure the Agency has all of the information needed to complete its review.”

The sNDA submission for ruxolitinib cream in pediatric AD was based on data from the Phase 3 TRuE-AD3 study, which evaluated the safety and efficacy of ruxolitinib cream in children (age ≥2 to <12 years) with AD. The TRuE-AD3 study met its primary endpoint with significantly more patients treated with Opzelura achieving Investigator’s Global Assessment-treatment success (IGA-TS), a measure of treatment efficacy, than patients treated with vehicle control (non-medicated cream). In addition, a secondary endpoint of patients demonstrating at least a 75% improvement in the Eczema Area and Severity Index (EASI75) at Week 8 was also achieved.

The overall safety profile of Opzelura in the TRuE-AD3 trial was consistent with previous data, and no new safety signals were observed. No serious infections, major adverse cardiovascular events (MACE), malignancies or thromboses were reported during the 8-week vehicle-controlled period. The most common treatment-related adverse event among patients treated with Opzelura was application site pain (2.7% vs 0% in vehicle arm). These events were mild and did not lead to treatment interruption.

**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 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 12 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). If needed, your healthcare provider will 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 treated for atopic dermatitis include:** common cold (nasopharyngitis), diarrhea, bronchitis, ear infection, increase in a type of white blood cell (eosinophil) count, hives, inflamed hair pores (folliculitis), swelling of the tonsils (tonsillitis), and runny nose (rhinorrhea).

**The most common side effects of OPZELURA in people treated for nonsegmental vitiligo include:** acne at the application site, itching at the application site, common cold (nasopharyngitis), headache, urinary tract infection, redness at the application site, and fever.

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.**

**INDICATIONS AND USAGE**

OPZELURA is a prescription medicine used on the skin (topical) for:

- short-term and non-continuous chronic treatment of mild to moderate eczema (atopic dermatitis) in non-immunocompromised adults and children 12 years of age and older whose disease is not well controlled with topical prescription therapies or when those therapies are not recommended
- the treatment of a type of vitiligo called nonsegmental vitiligo in adults and children 12 years of age and older

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 12 years of age with atopic dermatitis or nonsegmental vitiligo.

**About Incyte Dermatology**

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. Today, we are building on this legacy as we discover and develop innovative dermatology treatments to bring solutions to patients in need.

We strive to identify and develop therapies to modulate immune pathways driving uncontrolled inflammation. Specifically, our efforts in dermatology are focused on a number of immune-mediated dermatologic conditions with a high unmet medical need, including atopic dermatitis, vitiligo, hidradenitis suppurativa, lichen sclerosus, and prurigo nodularis.

To learn more, visit the Dermatology section of Incyte.com.

**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 potential for ruxolitinib cream to provide a successful treatment option for pediatric patients with AD; Incyte's plans to work with FDA; and Incyte's expectations with regard to the PDUFA date for its sNDA and regulatory approval, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on our current expectations and are 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 and the ability to enroll subjects in accordance with planned schedules; determinations made by the FDA and other regulatory agencies; the efficacy or safety of our products; the acceptance of our products in the marketplace; market competition; unexpected variations in the demand for our products and the products of our collaboration partners; the effects of announced or unexpected price regulation or limitations on reimbursement or coverage for our products; sales, marketing, manufacturing, and distribution requirements, including our ability to successfully commercialize and build commercial infrastructure for newly approved products and any additional new products that become approved; 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, 2025. We disclaim any intent or obligation to update these forward-looking statements.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250620553806/en/

**Media**
media@incyte.com

**Investors**
ir@incyte.com

Source: Incyte