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## Incyte Announces New Data from Phase 2 Study Evaluating Ruxolitinib Cream (Opzelura®) in Patients with Mild-to-Moderate Hidradenitis Suppurativa

March 10, 2024

- *Randomized Phase 2 study met the primary endpoint in patients with hidradenitis suppurativa (HS), reinforcing efficacy and safety profile of ruxolitinib cream*
- *Results presented as a late-breaking oral presentation at the American Academy of Dermatology (AAD) Annual Meeting*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 10, 2024-- Incyte (Nasdaq:INCY) today announced new results from a Phase 2 study evaluating the efficacy and safety of twice-daily ruxolitinib cream 1.5% (Opzelura®) in adult patients with Hurley stage 1 or 2 (mild-to-moderate) hidradenitis suppurativa (HS). These data were presented as a late-breaking oral presentation (Session: S050 – Late-Breaking Research: Session 2) at the American Academy of Dermatology (AAD) Annual Meeting, held from March 8-12, 2024, in San Diego.

The study met its primary endpoint, demonstrating a significantly greater reduction in abscess and inflammatory nodule (AN) count in patients treated with ruxolitinib cream 1.5%, compared to those who applied the vehicle control (least squares mean change of -3.61 for ruxolitinib cream 1.5% vs. -2.42 for vehicle control;  $P < 0.05$ ) at Week 16.

"The results presented today reinforce the efficacy and safety profile of ruxolitinib cream, which shows great potential for people living with milder HS," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "Despite its daily impact on the lives of patients, there are currently no approved therapies for mild-to-moderate HS and the current standard of care is often inadequate. Today's data represent an important step in progressing research for HS with the goal of being able to provide patients with an effective option to better manage their condition."

Additional secondary endpoints of the study included:

- More than three quarters (79.2%) of on-treatment patients achieved at least a 50% reduction in AN count (AN50), 54.2% achieved a 75% reduction (AN75), 20.8% achieved 90% reduction (AN90), and 20.8% achieved complete clearance (100% reduction, AN100), surpassing the 56.3%, 25.0%, 12.5% and 12.5% reductions, respectively, in the vehicle control group.
- The majority (79.2%) of patients in the ruxolitinib cream 1.5% group met the criteria for Hidradenitis Suppurativa Clinical Response (HiSCR), which indicates a 50% or greater reduction in AN count without an increase in abscesses or draining fistulas, compared to 50.0% of patients in the vehicle control group.
- Patients treated with ruxolitinib cream 1.5% showed a greater mean reduction in the International Hidradenitis Suppurativa Severity Score System (IHS4) score compared to baseline at Week 16 (-4.46) compared to the vehicle group (-2.66).

Patients treated with ruxolitinib cream 1.5% showed a change -1.85 and -1.42 from baseline in the Skin Pain Numeric Rating Scale (NRS) and Itch NRS at Week 16, respectively, versus a -2.61 and -2.75 change from those in the vehicle control group. Due to patient eligibility criteria, patients studied did not have high itch or skin pain scores at baseline; however, additional research is needed to evaluate treatment impact on skin pain and itch scores.

The study results showed that ruxolitinib cream 1.5% was generally well-tolerated. Treatment-emergent adverse events (TEAEs) occurred in 38.2% of patients who applied ruxolitinib cream 1.5% versus 42.9% of patients who applied vehicle control. The most common TEAEs among patients receiving ruxolitinib cream 1.5% were COVID-19 (5.9%) and nasopharyngitis (5.9%). Discontinuation due to TEAEs were infrequent (ruxolitinib cream 1.5%,  $n=2$  [5.9%]; vehicle control,  $n=0$  [0%]), and no serious TEAEs were reported in the ruxolitinib cream 1.5% group.

"HS is a chronic, debilitating skin condition that unfortunately has no cure, so managing the signs and symptoms through an effective treatment is key to ensuring patients are able to live their lives with minimal impact from this disease," said Dr. Martina J. Porter, Beth Israel Deaconess Medical Center. "Better disease control can help manage the persistent symptoms of HS for these patients. There still remains a very large need for effective therapies for patients with HS, particularly for those with milder HS, and I'm encouraged by the results from this Phase 2 study of ruxolitinib cream for this patient population."

More information regarding the AAD Annual Meeting 2024 can be found at <https://www.aad.org/member/meetings-education/am24>.

### About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by painful nodules and abscesses that can lead to irreversible tissue destruction and scarring.<sup>1,2</sup> Over-activity of the JAK/STAT signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of HS.<sup>3</sup> More than 150,000 patients in the U.S. are estimated to have moderate-to-severe HS.<sup>4</sup> Given the debilitating nature of condition,

it can have a profoundly negative effect on patients' quality of life. <sup>5</sup>

### **About the Phase 2 Study (NCT05635838)**

This randomized, double-blind, vehicle-controlled Phase 2 clinical trial is designed to evaluate the safety and efficacy of ruxolitinib cream 1.5% (Opzelura<sup>®</sup>) in patients with mild-to-moderate hidradenitis suppurativa (HS). The study enrolled 69 adult patients (age ≥ 18 years) diagnosed with Hurley stage 1 or 2 HS who have a total abscess and inflammatory nodule (AN) count of 3 to ≤ 10, with no draining tunnels at screening and baseline visits.

The primary outcome measure of the study is change from baseline in AN count at Week 16. Secondary outcome measures include proportion of participants achieving reduction in AN count relative to baseline, change from baseline in the Skin Pain Numeric Rating Scale (NRS), change from baseline in the itch NRS score, proportion of participants who achieve Hidradenitis Suppurativa Clinical Response (HiSCR), change from baseline in the International Hidradenitis Suppurativa Severity Score System (IHS4) score and number of TEAEs.

For more information about the study, please visit <https://clinicaltrials.gov/study/NCT05635838>.

### **About Opzelura<sup>®</sup> (ruxolitinib) Cream 1.5%**

Opzelura, 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, and 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.

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.
- 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.

Our research and development efforts in dermatology are initially focused on leveraging our knowledge of the JAK-STAT pathway. We are exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including atopic dermatitis, vitiligo, hidradenitis suppurativa, lichen planus, 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 presentation of data from Incyte's clinical development pipeline, whether or when ruxolitinib cream might be approved in HS and/or offer patients with HS an effective treatment, and Incyte's goal of improving the lives of patients, 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 regulatory agencies outside of the United States; our dependence on relationships with and changes in the plans and expenditures of our collaboration partners; the efficacy or safety of our products and the products of our collaboration partners; the acceptance of our products and the products of our collaboration partners 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 and the products of our collaboration partners; sales, marketing, manufacturing, and distribution requirements, including our and our collaboration partners' 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 quarterly report on Form 10-Q for the quarter ended December 31, 2023. We disclaim any intent or obligation to update these forward-looking statements.

1 National Center for Advancing Translational Science Genetic and Rare Diseases Information Center. Hidradenitis suppurativa. <https://rarediseases.info.nih.gov/diseases/6658/hidradenitis-suppurativa>. Accessed February 7, 2024.

2 Kirby J, et al. Efficacy and Safety of the Janus Kinase 1 Inhibitor Povorocitinib (INCB054707) in Patients with Hidradenitis Suppurativa: Results from a Randomized, Placebo-Controlled, Phase 2 Dose-Ranging Study. Presented at the 31st European Academy of Dermatology and Venereology (EADV) Congress, September 7-10, 2022.

3 Solimani, F., Meier, K., & Ghoreschi, K. (2019). Emerging topical and systemic JAK inhibitors in dermatology. *Frontiers in immunology*, 10, 2847.

4 McMillan, K. Hidradenitis suppurativa: number of diagnosed patients, demographic characteristics, and treatment patterns in the United States. *Am J Epidemiol*. 2014 Jun 15;179(12):1477-83. doi: 10.1093/aje/kwu078. Epub 2014 May 8.

5 Sabat, R., Jemec, G. B., Matusiak, Ł., Kimball, A. B., Prens, E., & Wolk, K. (2020). Hidradenitis suppurativa. *Nature reviews Disease primers*, 6(1), 18.



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## Media

[media@incyte.com](mailto:media@incyte.com)

## Investors

[ir@incyte.com](mailto:ir@incyte.com)

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