Incyte Announces 52-Week Data From the Phase 3 TRuE-V Program Evaluating Ruxolitinib Cream (Opzelura™) in Patients With Vitiligo

March 26, 2022

- Use of ruxolitinib cream (Opzelura™) resulted in further improvement in facial and total body repigmentation at Week 52

- Results will be featured as an oral presentation in a late-breaking abstract session at the 2022 American Academy of Dermatology (AAD) Annual Meeting

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 26, 2022-- Incyte (Nasdaq:INCY) today announced new 52-week results from its pivotal Phase 3 TRuE-V clinical trial program evaluating ruxolitinib cream (Opzelura™), a topical JAK1/JAK2 inhibitor, in adolescent and adult patients (age ≥12 years) with nonsegmental vitiligo. These data were presented today as an oral presentation in a late-breaking abstract session (Session #S026 – Late-Breaking Research: Clinical Trials) at the 2022 American Academy of Dermatology (AAD) Annual Meeting, held from March 25-29 in Boston.

The 52-week results build on the previously announced positive 24-week results and include data from the 24-week double-blind and 28-week treatment extension periods of the Phase 3 TRuE-V1 and TRuE-V2 studies. Findings from the Week 52 analysis showed that patients applying 1.5% ruxolitinib cream twice daily (BID) had clinically meaningful facial and total body repigmentation as shown by greater proportions of patients reaching the facial and total body Vitiligo Area Scoring (F-VASI and T-VASI, respectively) endpoints at Week 52.

Specifically, efficacy results of patients who applied ruxolitinib cream from Day 1 showed:

- At Week 52, approximately 50% of patients achieved ≥75% improvement in the facial Vitiligo Area Scoring Index (F-VASI75) compared to the F-VASI75 improvement from baseline reported for these patients at Week 24 (the primary endpoint of the study) which was approximately 30%.
- At Week 52, approximately 75% of patients achieved ≥50% improvement in F-VASI (F-VASI50), and nearly one-third (approximately 30%) achieved ≥90% improvement in F-VASI (F-VASI90) compared to the Week 24 response rates for F-VASI50 and F-VASI90 which were approximately 51% and 15%, respectively.
- Additionally, a greater proportion of patients at Week 52 achieved ≥50% improvement in total body Vitiligo Area Scoring Index (T-VASI50), and over one-third of patients achieved a Vitiligo Noticeability Scale (VNS) response. Further improvement on percentage change from baseline in facial body surface area (F-BSA) with application of ruxolitinib cream was also observed.

Results at Week 52 in crossover patients (those who received 28 weeks of treatment with ruxolitinib cream after initial treatment with vehicle cream) were consistent with Week 24 data in patients who applied ruxolitinib cream from Day 1.

The overall safety profile of ruxolitinib cream in vitiligo was consistent with previous study data – there were no clinically significant application site reactions or serious treatment-related adverse events related to ruxolitinib cream.

“The positive 52 week results in facial and total body repigmentation seen with ruxolitinib cream in our pivotal Phase 3 TRuE-V program, which were presented today at the 2022 AAD meeting, add to the robust data showing ruxolitinib cream has the potential to be a meaningful treatment option for those with vitiligo,” said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte.

“Vitiligo is a serious and chronic autoimmune condition that can severely impact a person’s life and has very limited treatments,” said David Rosmarin, M.D., Vice Chair of Research and Education, Department of Dermatology at Tufts Medical Center. “These results are extremely encouraging and highlight the clinical potential of ruxolitinib cream for patients with vitiligo.”

As previously announced, based on the 24-week results, Incyte submitted marketing applications for ruxolitinib cream for the treatment of adolescent and adult patients with vitiligo (age ≥12 years) to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The FDA Prescription Drug User Fee Act (PDUFA) target action date is July 18, 2022.

About Vitiligo

Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results from the loss of pigment-producing cells known as melanocytes. Over-activity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. It affects approximately 1.9-2.8 million people in the United States[1] and can occur at any age, although many patients with vitiligo will experience initial symptoms before the age of 30.[2]

About TRuE-V

The TRuE-V clinical trial program includes two Phase 3 studies, TRuE-V1 (NCT04052425) and TRuE-V2 (NCT04057573), evaluating the safety and efficacy of ruxolitinib cream in patients with vitiligo.

The studies each enrolled over 300 patients (age ≥12 years) who have been diagnosed with non-segmental vitiligo and have depigmented areas including at least 0.5% of the body surface area (BSA) on the face, ≥0.5 facial Vitiligo Area Scoring Index [F-VASI] score, at least 3% BSA on nonfacial

areas, ≥3 total body Vitiligo Area Scoring Index [T-VASI] score and total BSA involvement (facial and nonfacial) of up to 10%. Participants were randomized into two arms: 1.5% ruxolitinib cream twice daily (BID) and vehicle control for the 24-week double-blind period. Patients who successfully completed baseline and Week 24 assessments, including those that received vehicle control during the double-blind phase, were offered treatment extension with 1.5% ruxolitinib cream BID for an additional 28 weeks.

The primary endpoint of both studies in the TRuE-V program is the proportion of patients achieving F-VASI75, defined as at least a 75% improvement from baseline in the F-VASI score at Week 24. Key secondary endpoints include: the percentage change from baseline in facial BSA (F-BSA) at Week 24, the proportion of patients achieving F-VASI50 (at least 50% improvement from baseline in the F-VASI), F-VASI90 (at least 90% improvement from baseline in the F-VASI) and T-VASI50 (at least 50% improvement from baseline in the T-VASI) at Week 24 and the proportion of patients achieving a Vitiligo Noticeability Scale (VNS) score of 4 (a lot less noticeable) or 5 (no longer noticeable) at Week 24. Additional secondary endpoints included the proportion of patients achieving F-VASI75, F-VASI90, T-VASI50 and T-VASI75 (at least 75% improvement from baseline in the T-VASI) at Week 52.The studies also track the frequency, duration and severity of adverse events associated with the use of ruxolitinib cream.

For more information on the TRuE-V studies, please visit https://clinicaltrials.gov/ct2/show/NCT04052425 and https://clinicaltrials.gov/ct2/show/NCT04057573.

About Ruxolitinib Cream (Opzelura™)

Ruxolitinib cream (Opzelura) a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States 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.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura. On October 28, 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement.

Opzelura is a trademark of Incyte.

IMPORTANT SAFETY INFORMATION

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

OPZELURA may cause serious side effects, including:

Serious Infections: OPZELURA cream 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 from all causes, including sudden cardiac death, has happened in people taking 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. Some people have had lymphoma and other cancers while taking JAK inhibitors by mouth, especially if they are a current or past smoker. Some people have had skin cancers while taking OPZELURA. Your healthcare provider will regularly check your skin during your treatment with OPZELURA.

There is an increased risk of major cardiovascular events such as heart attack, stroke or cardiac death in people with cardiovascular risk factors and who are current or past smokers while using JAK inhibitors to treat inflammatory conditions.

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.

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 an infection that 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) or 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 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 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 include: pain or swelling in your nose or throat (nasopharyngitis), diarrhea, bronchitis, ear infection, increase in a type of white blood cell counts (eosinophil), hives, inflamed hair pores (folliculitis), swelling of the tonsils (tonsilitis), and runny nose (rhinorrhea).

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.

About Incyte Dermatology

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. In Dermatology, the Company's research and development efforts are focused on leveraging our knowledge of the JAK-STAT pathway to identify and develop topical and oral therapies with the potential to modulate immune pathways driving uncontrolled inflammation and help restore normal immune function.

Currently, Incyte is exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including vitiligo and hidradenitis suppurativa. To learn more, visit the Dermatology section of Incyte.com.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding Incyte's TRuE-V clinical program, whether and when ruxolitinib cream might be approved to treat patients with vitiligo, the potential for success of such treatment, and Incyte's Dermatology program generally, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on the Company'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; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of the Company's products; the acceptance of the Company's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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[1] Gandhi K, et al. Prevalence of vitiligo among adults in the United States. JAMA Dermatol. 2022;158(1):43-50.

[2] Frisoli M, et al. Vitiligo: mechanisms of pathogenesis and treatment. Annu. Rev. Immunol. 2020;38(1):621-648.

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