New Long-Term Data from Incyte Phase 3 TRuE-V Program Demonstrates Efficacy of Continued Treatment with Opzelura® (Ruxolitinib) Cream in Nonsegmental Vitiligo Patients

October 11, 2023

- Patients who initially experienced limited or no facial or total body repigmentation at six months achieved improved repigmentation after continued treatment with Opzelura for up to two years

- Results were presented in a late-breaking news session at the European Academy of Dermatology and Venereology (EADV) Congress 2023

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 11, 2023-- Incyte (Nasdaq:INCY) today announced new results of a pooled analysis of long-term extension (LTE) data from the pivotal Phase 3 TRuE-V program assessing Opzelura® (ruxolitinib) cream 1.5% in patients 12 years of age and older with nonsegmental vitiligo who previously experienced limited or no response to treatment at Week 24. These data were presented today in a late-breaking oral presentation (Abstract #6479; Session: D1T01.1I: Late Breaking News) at the European Academy of Dermatology and Venereology (EADV) Congress 2023, held from October 11-14 in Berlin.

"We are excited by the TRuE-V LTE study data presented today during a late-breaking session at EADV. These long-term data highlight encouraging updates for an important sub-group of patients with nonsegmental vitiligo, those who initially showed limited or no response to treatment," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & AutoImmunity, Incyte. "The pooled analysis builds on the positive LTE data previously presented at the 2023 American Academy of Dermatology (AAD) Annual Meeting earlier this year and underscores the long-term potential of this treatment for people with vitiligo who are seeking repigmentation."

The analysis assessed participants initially randomized to apply Opzelura twice-daily (BID) from the TRuE-V1 and TRuE-V2 studies who had <25% improvement from baseline in facial Vitiligo Area Scoring Index (F-VASI) or total body Vitiligo Area Scoring Index (T-VASI) at Week 24 and had non-missing VASI assessments at the evaluated time points.

Key findings from the pooled analysis include:

- More than half of patients (54.9%) who initially experienced limited or no facial repigmentation at Week 24 achieved ≥75% improvement in facial repigmentation from baseline (F-VASI75) with continued treatment with Opzelura at Week 104.
  - For patients with no initial facial repigmentation at Week 24, improvements in F-VASI were observed in 77.8% (49/63) and 97.1% (34/35) of patients at Weeks 52 and 104, respectively.
  - For patients with limited facial repigmentation at Week 24, F-VASI improvements were observed in 64.0% (32/50) and 83.3% (30/36) of patients at Weeks 52 and 104, respectively.
- Half of the patients (50.0%) who initially experienced limited or no body repigmentation at Week 24 achieved ≥50% improvement in body repigmentation from baseline (T-VASI50) with continued treatment with Opzelura at Week 104.
  - Among patients with no body repigmentation at Week 24, T-VASI improvements were observed in 79.6% (39/49) and 93.3% (28/30) of patients at Weeks 52 and 104, respectively.
  - Among patients with limited body repigmentation at Week 24, T-VASI improvements were observed in 64.5% (80/124) and 81.6% (62/76) of patients at Weeks 52 and 104, respectively.
- Opzelura was well-tolerated – no serious treatment-related adverse events (TEAEs) occurred among patients using Opzelura from Day 1; 6.3% (n=14/224) of these patients experienced ≥1 treatment-related TEAE. Application site pruritus was the only TEAE that occurred in >1 patient (n=2; 0.9%).

Opzelura is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

"With this analysis, we were able to more closely examine the impact of continued treatment with Opzelura in patients who showed limited to no improvements in facial or total body repigmentation following an initial six-month course of treatment," said Dr. Albert Wolkerstorfer, Netherlands Institute for Pigment Disorders, Department of Dermatology, University of Amsterdam. "These data highlight the importance of continuing treatment with Opzelura in patients with vitiligo, even when minimal or no repigmentation is achieved after six months of treatment."

Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results from the loss of pigment-producing cells known as melanocytes. Overactivity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. In the United States, more than 1.5 million people are diagnosed with vitiligo[1]. The overall prevalence of the condition is estimated to be approximately 2-3 million[2], with the majority of patients (approximately 85%) suffering from nonsegmental vitiligo[3]. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30[4].

More information regarding the EADV Congress 2023 can be found at https://eadvcongress2023.org/.

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 Opzelura in patients with vitiligo. Each study enrolled approximately 300 patients (age ≥12 years) who have been diagnosed with nonsegmental vitiligo.

About Opzelura® (ruxolitinib) Cream 1.5%

Opzelura, 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 is a registered trademark of Incyte.

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death. Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled. Carefully consider the benefits and risks of treatment prior to initiating OPZELURA in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with OPZELURA.

Serious lower respiratory tract infections were reported in the clinical development program with topical ruxolitinib.

No cases of active tuberculosis (TB) were reported in clinical trials with OPZELURA. Cases of active TB were reported in clinical trials of oral Janus kinase inhibitors used to treat inflammatory conditions. Consider evaluating patients for latent and active TB infection prior to administration of OPZELURA. During OPZELURA use, monitor patients for the development of signs and symptoms of TB.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical trials with Janus kinase inhibitors used to treat inflammatory conditions including OPZELURA. If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves.

Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib. OPZELURA initiation is not recommended in patients with active hepatitis B or hepatitis C.

MORTALITY

In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing an oral JAK inhibitor to tumor necrosis factor (TNF) blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA.

MALIGNANCIES

Malignancies were reported in patients treated with OPZELURA. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with an oral JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients with a known malignancy (other than successfully treated non-melanoma skin cancers), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

Non-melanoma skin cancers, including basal cell and squamous cell carcinoma, have occurred in patients treated with OPZELURA. Perform periodic skin examinations during OPZELURA treatment and following treatment as appropriate. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients who are

current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue OPZELURA in patients that have experienced a myocardial infarction or stroke.

THROMBOSIS

Thromboembolic events were observed in trials with OPZELURA. Thrombosis, including pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately.

Thrombocytopenia, Anemia, and Neutropenia

Thrombocytopenia, anemia, and neutropenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for individual patients who have a known history of these events prior to initiating therapy with OPZELURA. Perform CBC monitoring as clinically indicated. If signs and/or symptoms of clinically significant thrombocytopenia, anemia, and neutropenia occur, patients should discontinue OPZELURA.

Lipid Elevations

Treatment with oral ruxolitinib has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides.

Adverse Reactions

In nonsegmental vitiligo, the most common adverse reactions (incidence ≥1%) are application site acne (6%), application site pruritus (5%), nasopharyngitis (4%), headache (4%), urinary tract infection (2%), application site erythema (2%), and pyrexia (1%).

Pregnancy

There is a pregnancy registry that monitors pregnancy outcomes in pregnant persons exposed to OPZELURA during pregnancy. Pregnant persons exposed to OPZELURA and healthcare providers should report OPZELURA exposure by calling 1-855-463-3463.

Lactation

Advise women not to breastfeed during treatment with OPZELURA and for approximately four weeks after the last dose (approximately 5-6 elimination half-lives).

Please see Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

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

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 the presentation of data from Incyte's TRuE-V program, whether or when Opzelura will provide a successful treatment option for patients with vitiligo, and Incyte's dermatology program generally 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's products; the acceptance of Incyte's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Bergqvist C, Ezzedine K. Vitiligo: A Review. *Dermatology*. 2020;236:571-592.

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

[3] Ezzedine K, et al. Seminar: Vitiligo. *Lancet*. 2015;386:74–84.

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

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