Lilly's baricitinib delivered high rates of hair regrowth for adolescents with severe alopecia areata in Phase 3 BRAVE-AA-PEDS study

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Late-breaking results presented at AAD show 80% or more scalp hair coverage at Week 36 in 42.4% of adolescents receiving baricitinib 4 mg

Patients treated with baricitinib 4 mg saw significant regrowth of eyebrows and eyelashes at Week 36 compared to placebo

Positive data underscore Lilly's continued expansion across dermatologic conditions, with treatments that can improve outcomes for patients with the greatest need

INDIANAPOLIS, March 8, 2025 /PRNewswire/ -- Late-breaking results from Eli Lilly and Company (NYSE: LLY) and Incyte (NASDAQ: INCY) found adolescent patients (ages 12 to under 18) with severe alopecia areata (AA) treated with once-daily, oral baricitinib 4 mg and 2 mg saw clinically meaningful improvements in hair regrowth on the scalp, eyebrows and eyelashes at Week 36. Findings from the Phase 3 BRAVE-AA-PEDS study were presented in a late-breaker presentation at the American Academy of Dermatology (AAD) Annual Meeting taking place March 7-11 in Orlando.[1]

AA is an immune system condition that causes patchy hair loss on the scalp, face and sometimes on other areas of the body that can progress over time. Approximately 40% of patients with AA experience first onset by 20 years of age.[2]

"Early onset alopecia areata can be more severe, leading to extensive hair loss that frequently does not improve with topicals or corticosteroids often prescribed as first-line therapy," said Brittany Craiglow, M.D., Adjunct Associate Professor of Dermatology, Yale School of Medicine. "These initial results are exciting because they demonstrate that baricitinib can provide significant hair regrowth for adolescents at 36 weeks, a promising early signal of baricitinib's potential as an effective treatment for adolescents with severe disease."

In the BRAVE-AA-PEDS study, 257 patients were randomized to receive once-daily baricitinib 4 mg, baricitinib 2 mg or placebo. The primary endpoint of this study was a Severity of Alopecia Tool (SALT) score ≤20 (i.e., 80% or more scalp hair coverage) at Week 36. At the start of the study, patients had an average of 89% scalp hair loss (near total hair loss), 65% had minimal or no eyebrow hair (clinician-reported outcome [ClinRO] score of 2 or 3) and 57% had minimal or no eyelash hair (ClinRO score of 2 or 3).[1]

At Week 36:

- 60.0% of patients receiving baricitinib 4 mg and 36.9% of patients receiving baricitinib 2 mg saw at least a 50% improvement in their disease (as measured by SALT score) compared to 5.7% on placebo (p=0.001).
- 42.4% of patients receiving baricitinib 4 mg and 27.4% of patients receiving baricitinib 2 mg achieved 80% or more scalp hair coverage, compared to 4.5% on placebo (p=0.001).
- 36.5% of patients receiving baricitinib 4 mg and 21.4% of patients receiving baricitinib 2 mg had 90% or more scalp hair coverage (SALT ≤10), compared to 2.3% on placebo (p=0.001).
- 50.0% of patients receiving baricitinib 4 mg and 24.1% of patients receiving baricitinib 2 mg achieved significant eyebrow regrowth (ClinRO scores of 0 or 1 with a ≥2 point improvement from baseline) compared to 0% on placebo (p<0.01).
- 42.9% of patients receiving baricitinib 4 mg achieved significant eyelash regrowth, and 25.5% receiving baricitinib 2 mg saw improved eyelash regrowth, compared to 14.0% on placebo (p=0.002 for 4 mg, p=0.097 for 2 mg).[1]

Results achieved by adolescents at 36 weeks were comparable to results achieved by adults after 52 weeks of treatment, suggesting that hair regrowth may be faster in adolescents compared to adults.[1] In the BRAVE-AA1 and BRAVE-AA2 studies, 40.9% of adult patients treated with baricitinib 4 mg and 21.2% of patients treated with baricitinib 2 mg achieved 80% or more scalp hair coverage at Week 52.[3]

"With these data, baricitinib is the most well-studied JAK inhibitor in severe alopecia areata, a chronic immune system disorder that can have an especially devastating social and emotional impact on adolescent patients and their families," said Anabela Cardoso, senior vice president, Lilly Immunology Medical Affairs. "We are excited about these initial results, which show baricitinib can provide significant scalp hair regrowth in adolescents, potentially at an even faster rate compared to adults. We look forward to sharing longer-term data results at upcoming congresses and discussing findings with global regulators in the months ahead."

The most common treatment-emergent adverse events in BRAVE-AA-PEDS included acne, influenza and upper respiratory tract infection. A higher frequency of serious adverse events was seen in the placebo group compared to baricitinib groups. No deaths, opportunistic infections, major adverse cardiovascular events, venous thromboembolic events or malignancies were reported in the trial.[1]

The safety profile of baricitinib in adolescents with AA was consistent with the safety profile seen in clinical trials for adolescent patients with juvenile idiopathic arthritis and moderate-to-severe atopic dermatitis. Over 14,600 patients have received baricitinib in clinical trials; of these, 866 have been patients between the ages of >1 month to <18 years.

Lilly will present additional data from the BRAVE-AA-PEDS study at scientific meetings later this year and submit the results for peer-reviewed publication. Baricitinib is a once-daily, oral JAK inhibitor discovered by Incyte and licensed to Lilly. In 2022, the U.S. Food and Drug Administration (FDA) approved baricitinib (commercially available as Olumiant) for adult patients with severe AA, making it the first systemic treatment approved in

the U.S. for severe disease.

Baricitinib is also approved in the U.S. and more than 75 countries as a treatment for adults with moderately to severely active rheumatoid arthritis, in more than 40 countries for the treatment of patients down to the age of two with moderate-to-severe atopic dermatitis who are candidates for systemic therapy and in Europe and Japan for adult patients with severe AA. Marketing authorization for the treatment of hospitalized patients with COVID-19 has been granted for baricitinib in multiple countries.

About BRAVE-AA-PEDS Study
BRAVE-AA-PEDS (NCT05723198) is an ongoing, placebo-controlled, Phase 3 trial involving children ages 6 to under 18 years with severe AA, as measured by a Severity of Alopecia Tool (SALT) score of ≥50 (i.e., who had ≥ 50% scalp hair loss) and a current episode of severe AA lasting at least six months but no more than eight years. Adolescent participants were randomized in a 1:1:1 ratio to receive once-daily placebo, baricitinib 4 mg or baricitinib 2 mg. The first cohort of patients enrolled included adolescents (ages 12 to under 18 years, weighing ≥ 30 kg). The next cohort of children ages 6 to under 12 will begin enrollment in the next year. An additional cohort of adolescents were randomized 1:1 to baricitinib 4 mg or baricitinib 2 mg.

IMPORTANT SAFETY INFORMATION FOR OLUMIANT (BARICITINIB) TABLETS

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

The risks and benefits of treatment with Olumiant in COVID-19 patients with other concurrent infections should be considered.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, 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 Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another 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. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

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

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events 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 another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ANC <500 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ALC <200 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management. In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL. In patients with COVID-19, there is limited information regarding use of Olumiant in patients with hemoglobin less than 8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials.

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In RA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In COVID-19 trials, the most common adverse reactions (≥1%) reported with Olumiant were: ALT ≥3x ULN, AST ≥3x ULN, thrombocytosis (platelets >600,000 cells/mm^3), creatine phosphokinase >5x ULN, neutropenia (ANC <1000 cells/mm^3), DVT, PE, and urinary tract infection.

In AA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, headache, acne, hyperlipidemia, creatine phosphokinase increase, urinary tract infections, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant is not recommended in patients with RA or AA and severe hepatic impairment or severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m^2).

Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk. Olumiant is not recommended in patients with COVID-19 who are on dialysis, have end-stage renal disease, or with eGFR <15 mL/min/1.73m^2.

Please click to access full Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Medication Guide.

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About Olumiant
Olumiant, a once-daily, oral JAK inhibitor, was discovered by Incyte and licensed to Lilly. It is approved in the U.S. and more than 75 countries as a treatment for adults with moderately to severely active rheumatoid arthritis. FDA approval was granted for Olumiant for the treatment of certain hospitalized adult patients with COVD-19 in May 2022. Marketing authorization for Olumiant in COVID-19 has been granted in six other countries including Japan and Switzerland. The U.S. FDA-approved labeling for Olumiant includes a Boxed Warning for Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis. See the full Prescribing Information here.[4]

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of Olumiant and certain follow-on compounds for patients with inflammatory and autoimmune diseases.

About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

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.

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Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Olumiant (baricitinib) as a treatment for alopecia areata and reflects Lilly's and Incyte's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, and that Olumiant will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent respective Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly and Incyte undertake no duty to update forward-looking statements to reflect events after the date of this release.

References:

[1]Passeron T, et al. Baricitinib provides significant hair regrowth in adolescents with severe alopecia areata: 36-week efficacy and safety results from a Phase 3 randomized, controlled trial. American Academy of Dermatology Annual Meeting. March 7-11, 2025.

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