Lilly's baricitinib delivered near-complete scalp hair regrowth at one year for adolescents with severe alopecia areata in Phase 3 BRAVE-AA-PEDS trial

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This trial is the first and largest study specifically designed to evaluate children and adolescents with severe alopecia areata, a population often underrepresented in clinical trials

New data show 71% of adolescents with severe disease treated with baricitinib 4 mg achieved successful scalp hair regrowth at one year, with continuous improvements observed throughout those 52 weeks

Lilly intends to submit the BRAVE-AA-PEDS data to global regulators for a potential label update for baricitinib (commercially available as Olumiant)

INDIANAPOLIS, Oct. 24, 2025 /PRNewswire/ -- New results from Eli Lilly and Company (NYSE: LLY) and Incyte (NASDAQ: INCY) showed once-daily, oral baricitinib 4 mg helped the majority of adolescent patients (ages 12 to <18) with severe alopecia areata (AA) achieve successful hair regrowth on the scalp, eyebrows and eyelashes at one year. These 52-week results from the BRAVE-AA-PEDS trial – the largest Phase 3 study of its kind – will be presented at the 2025 Fall Clinical Dermatology (FCD) Conference, taking place Oct. 23-26 in Las Vegas.[1]

These data build on 36-week results from the BRAVE-AA-PEDS trial previously presented at the 2025 American Academy of Dermatology (AAD) annual meeting in March.

"For nearly half of the people with severe alopecia areata, the disease starts before adulthood and can progress quickly, significantly impacting patients' lives," said Nicole Friedland, President and CEO, National Alopecia Areata Foundation (NAAF). "Given the profound burden of this disease, new treatment options are needed for children and adolescents, populations that have been underrepresented for far too long."

At the start of the study, patients had an average of 89% scalp hair loss, with 63.8% of them having very severe AA at baseline (Severity of Alopecia Tool [SALT] score 95-100).[1] In addition, 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 one year:

- 54.1% of patients receiving baricitinib 4 mg and 31% receiving baricitinib 2 mg achieved successful hair regrowth (defined as 80% or more scalp hair coverage, SALT ≤20)[1]
- 41.2% of patients receiving baricitinib 4 mg and 26.2% of patients receiving baricitinib 2 mg achieved near-complete scalp hair regrowth (defined as 90% or more scalp hair coverage, SALT ≤10)[1]
- 64.8% of patients receiving baricitinib 4 mg and 27.8% of patients receiving baricitinib 2 mg achieved significant eyebrow regrowth (ClinRO scores of 0 or 1 with a ≥2 point improvement from baseline)[1]
- 63.3% of patients receiving baricitinib 4 mg and 34% receiving baricitinib 2 mg achieved eyelash regrowth[1]
- Among patients with severe disease (baseline SALT score 50-94), 71% receiving baricitinib 4 mg and 58.6% receiving baricitinib 2 mg achieved successful hair regrowth[1]

In a separate, post-hoc analysis of adolescent patients who had been diagnosed with severe AA less than two years before starting treatment, 80% of those receiving baricitinib 4 mg and 64.3% receiving baricitinib 2 mg achieved successful hair regrowth at one year.[2]

The safety profile of baricitinib in adolescents with AA was consistent with the safety profile seen in clinical trials for adult and adolescent patients, and no new safety signals were observed after one year of treatment. The most common treatment-emergent adverse events included acne, upper respiratory tract infection and influenza. No deaths, opportunistic infections, major adverse cardiovascular events or venous thromboembolic events were reported in the trial.[1]

"These promising results for adolescents reinforce what we see in clinical practice with adults, which is that starting treatment with baricitinib early can lead to higher rates of scalp hair regrowth, including near-complete regrowth for many patients," said Brittany Craiglow, M.D., Adjunct Associate Professor of Dermatology, Yale School of Medicine. "Systemic treatments for adolescents shouldn't be the last resort, but part of the treatment conversation among doctors, caregivers and patients from the beginning."

Lilly will also present final, long-term results at FCD from the BRAVE-AA1/BRAVE-AA2 studies. Among adults with severe AA who responded to baricitinib at 52 weeks, 86.5% of patients receiving baricitinib 4 mg and 84.7% of patients receiving baricitinib 2 mg achieved sustained scalp hair regrowth through approximately four years of treatment. These data build on previous results from BRAVE-AA1/BRAVE-AA2, reinforcing that high rates of scalp hair regrowth can be maintained with baricitinib over multiple years. The safety profile of baricitinib in this study was consistent up to five years, with no new safety signals observed.[3]

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. Lilly intends to submit the adolescent data to global regulators for a potential label update for Olumiant, and plans to enroll the next cohort of

children ages 6 to under 12 in the U.S. to BRAVE-AA-PEDS in the next year.

"Our decade of firsts in dermatology has been driven by science that has advanced three novel medicines, redefined the standard of care and continues to expand possibilities for people with chronic skin diseases," said Anabela Cardoso, senior vice president, Lilly Immunology Medical Affairs. "We look forward to submitting these data to global regulators in the coming months. If approved, baricitinib could offer an important new option that raises treatment expectations for adolescents living with the profound burden of this disease."

Baricitinib is the most-researched JAK inhibitor in AA, with more than 1,300 adults and 423 adolescents enrolled in clinical trials. In total for all indications, more than 14,600 patients have received baricitinib in completed and ongoing clinical trials; of these, 866 have been patients between the ages of >1 month to <18 years (not including patients enrolled in BRAVE-AA-PEDS).

Lilly continues to raise the standard of care in dermatology and invest in our immunology pipeline, which includes big bets on next-generation modalities and the targeted expansion of small molecules. Lilly's investigational therapies include novel, oral IL-17 inhibitors such as DICE Therapeutics' DC-853, which is being studied for psoriasis, and eltrekibart, a novel monoclonal antibody that targets neutrophil-driven inflammation and is being assessed in hidradenitis suppurativa. Lilly is also advancing novel science to explore the potential of incretins in dermatology and has initiated the TOGETHER-PsO trial investigating the efficacy and safety of treating adults with moderate-to-severe plaque psoriasis and obesity with both ixekizumab and an incretin-based therapy.

About BRAVE-AA-PEDS
BRAVE-AA-PEDS (NCT05723198) is an ongoing, placebo-controlled, Phase 3 clinical trial involving children ages 6 to under 18 years with severe AA, as measured by a 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.

The first two cohorts of patients enrolled in BRAVE-AA-PEDS included adolescents (ages 12 to under 18 years, weighing ≥ 30 kg). The first cohort included 257 adolescent participants who were randomized in a 1:1:1 ratio to receive once-daily placebo, baricitinib 4 mg or baricitinib 2 mg. The primary endpoint of this study was a SALT score ≤20 (i.e., 80% or more scalp hair coverage) by Week 36. The second cohort of 166 adolescents were randomized 1:1 to baricitinib 4 mg or baricitinib 2 mg to further accumulate safety data.

The third cohort of children ages 6 to under 12 will be randomized in a 1:1:1 ratio to receive once-daily placebo, baricitinib high dose or baricitinib low dose. Enrollment for this cohort has started outside the U.S. and will begin enrollment in the U.S. in the next year.[1]

INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Olumiant® (O-loo-me‾ -ant) is a Janus kinase (JAK) inhibitor used to treat:

- adults with severe alopecia areata.
- adults with moderately to severely active rheumatoid arthritis after treatment with 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well enough or could not be tolerated.
- adult patients hospitalized with COVID-19 requiring oxygen or assistance with breathing.

Warnings - Olumiant may cause serious side effects, including:

- Serious infections, including tuberculosis (TB), shingles, and others caused by bacteria, fungi, or viruses. Some people have died from these infections. Olumiant can make you more likely to get infections or make any infections that you have worse. Your doctor should test for TB before starting Olumiant and watch for TB symptoms during treatment. You should not start Olumiant if you have any kind of infection unless your doctor tells you it is okay. While taking Olumiant, tell your doctor right away if you have symptoms of an infection, such as:
    - fever, sweating, or chills
    - muscle aches
    - cough
    - shortness of breath
    - blood in phlegm
    - weight loss warm, red, or painful skin or sores on your body
    - diarrhea or stomach pain
    - burning with urination or urinating more often than normal
    - feeling tired

  If you get a serious infection, your doctor may stop Olumiant until your infection is controlled.

- **Increased risk of death in people 50 years of age or older who have at least 1 heart disease risk factor and are taking a medicine in a class of medicines called JAK inhibitors.**
- **Cancer and immune system problems.** Olumiant may increase your risk of lymphoma and other cancers, including skin cancers. People taking a medicine in the class of medicines called JAK inhibitors have a higher risk of certain cancers, including lymphoma and lung cancer, especially if you are a current or past smoker. Follow your doctor's advice about having your skin checked for skin cancer while taking Olumiant.
- **Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.** Get emergency help right away if you have any symptoms of

a heart attack or stroke while taking Olumiant, 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
- **Blood clots** in the veins of your legs or lungs, and arteries. This may be life-threatening and cause death. Blood clots in the veins of legs and lungs have happened more often in people who are 50 years of age or older and with at least 1 heart disease risk factor taking a medicine in the class of medicines called JAK inhibitors. Stop taking Olumiant and tell your doctor or get emergency help right away if you have any signs and symptoms of blood clots, including swelling, pain or tenderness in the leg, sudden chest pain, or shortness of breath, while taking Olumiant.
- **Allergic reactions**. While taking Olumiant, if you have symptoms, such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, stop taking Olumiant and get emergency help right away. Some of these reactions seen in people taking Olumiant were serious.
- **Tears in the stomach or intestines.** This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. While taking Olumiant, tell your doctor right away if you have fever and stomach-area pain that does not go away, and a change in bowel habits.
- **Changes in laboratory test results.** Your doctor should do blood tests before and while taking Olumiant. You should not take Olumiant if your white or red blood cell count is too low or your liver tests are too high. Your doctor may pause your treatment with Olumiant because of changes in these test results. Your doctor should also check your cholesterol levels approximately 12 weeks after you start Olumiant and as needed.

Common side effects

The most common side effects of Olumiant in people treated for alopecia areata include:

- upper respiratory tract infections (cold or sinus infections)
- headache
- acne
- increased cholesterol levels
- increased muscle enzyme levels
- urinary tract infection
- increased liver enzyme levels
- inflammation of hair follicles (folliculitis)
- tiredness
- lower respiratory tract infections
- nausea
- genital yeast infection
- low red blood cell count (anemia)
- low white blood cell count (neutropenia)
- stomach-area (abdominal) pain
- shingles (herpes zoster)
- increased weight

The most common side effects of Olumiant in people treated for rheumatoid arthritis include:

- upper respiratory tract infections (cold or sinus infections)
- nausea
- herpes simplex virus infections, including cold sores
- shingles (herpes zoster)

The most common side effects of Olumiant in people treated for COVID-19 include:

- increased liver enzyme levels
- increased platelets in your blood (thrombocytosis)
- increased blood creatine phosphokinase
- low white blood cell count (neutropenia)
- blood clots in the veins of your legs (DVT)
- blood clot in your lungs (pulmonary embolism)

- urinary tract infection

These are not all the possible side effects of Olumiant. Tell your doctor if you have any side effects. **You can report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before using
Before you use Olumiant, tell your doctor if you:

❑ Are being treated for an infection, have an infection that won't go away or keeps coming back, or think you have symptoms of an infection.
❑ Have TB or have been in close contact with someone with TB.
❑ Have had shingles (herpes zoster).
❑ Have had hepatitis B or C, cancer, or blood clots in the veins of your legs or lungs.
❑ Live, have lived, or have visited parts of the country that increase your risk of fungal infections. These may include the Ohio and Mississippi River valleys and the Southwest. Ask your doctor if you do not know if you have lived in an area where these infections are common.
❑ Are a current or past smoker.
❑ Have had a heart attack, other heart problems or stroke.
❑ Have other medical conditions, including kidney or liver problems, low blood cell counts, diabetes, lung disease, HIV, or a weak immune system.
❑ Have any stomach-area pain or have been diagnosed with inflammation in the large intestine (diverticulitis) or ulcers in your stomach or intestines.
❑ Have recently received or plan to receive a vaccine. People taking Olumiant should not receive live vaccines.
❑ Are pregnant or plan to become pregnant. It is not known if Olumiant may harm your unborn baby. If you become pregnant while taking Olumiant, call Eli Lilly and Company at 1-800-545-5979 to report the pregnancy.
❑ Are breastfeeding or plan to breastfeed. You should not breastfeed while taking Olumiant and for 4 days after the last dose. Talk to your doctor about the best way to feed your baby while taking Olumiant.
❑ Are taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. It is especially important to tell your doctor, if you take:

- a medicine called probenecid
- medicines that affect your immune system, such as biologic medications, other JAK inhibitors, or strong immunosuppressants (such as azathioprine or cyclosporine) since these may increase your risk of infection.

❑ Are under age 18. It is not known if Olumiant is safe and effective in children.

How to take

- Take Olumiant exactly as your doctor says.
- Take Olumiant once a day by mouth with or without food.
- Talk to your doctor if you cannot swallow tablets whole.
- If you take too much Olumiant, call your doctor or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

Learn more
Olumiant is a prescription medicine. For more information, call 1-800-545-5979 [or go to **www.olumiant.com**]

This summary provides basic information about Olumiant but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other healthcare provider about Olumiant and how to take it. Your doctor is the best person to help you decide if Olumiant is right for you.

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About Olumiant
Olumiant, a once-daily, oral JAK inhibitor, was discovered by Incyte and licensed to Lilly. Baricitinib is 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 outside the U.S. 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 the U.S., 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.

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,

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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.

1. Craiglow B, et al. Baricitinib provides significant hair regrowth in adolescents with severe alopecia areata: 52-week efficacy and safety results from a Phase 3 randomized, controlled trial. 2025 Fall Clinical Dermatology Conference. October 24, 2025.
2. Craiglow B, et al. Impact of severity and disease course on baricitinib treatment response in adolescent patients with severe AA from the BRAVE-AA-PEDS trial. 2025 Fall Clinical Dermatology Conference. October 24, 2025.
3. Vleugels R, et al. Baricitinib provides sustained, long-term efficacy with consistent safety up to 5 years of treatment in adults with severe alopecia areata: final results from BRAVE-AA1 and BRAVE-AA2. 2025 Fall Clinical Dermatology Conference. October 24, 2025.
4. Olumiant. Prescribing Information. Lilly USA, LLC.

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