Lilly's Olumiant (baricitinib) recommended by CHMP for approval of expanded use in the European Union for adolescents with severe alopecia areata

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The positive opinion is based on data from the Phase 3 BRAVE-AA-PEDS study, in which 42% of patients with severe alopecia areata (AA) reached 80% or more scalp hair coverage at 36 weeks

The study is the first and largest of its kind specifically designed to evaluate children and adolescents with severe AA, a disease that has devastating social and emotional impact

Lilly has also submitted Olumiant in the U.S. for approval to treat severe AA in adolescents, with a decision expected in the second half of 2026

INDIANAPOLIS, Feb. 27, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte (NASDAQ: INCY) announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Olumiant (baricitinib) for the treatment of adolescents (ages 12 to <18) with severe alopecia areata (AA). AA is a chronic immune disease that can have an especially devastating social and emotional impact on young patients and their families, as early onset AA can be more severe and lead to extensive and unpredictable hair loss.[1]

"The positive CHMP opinion supports the potential expansion of Olumiant as a new treatment option for adolescents living with the profound physical and emotional realities of severe alopecia areata," said Anabela Cardoso, senior vice president, Lilly Immunology Medical Affairs. "The depth and rigor of data from BRAVE-AA-PEDS – the first and largest trial designed specifically for these young patients – reflects Lilly's longstanding commitment to advancing care for people with chronic skin diseases who have had limited options for far too long."

Olumiant is a once-daily, oral JAK inhibitor discovered by Incyte and licensed to Lilly. In 2022, the European Commission (EC) and U.S. Food and Drug Administration (FDA) approved Olumiant for adult patients with severe AA, making it the first JAK inhibitor approved in these geographies for severe disease. This positive opinion marks the next step toward European regulatory approval of Olumiant for adolescents ages 12 to under 18 with severe AA, and it is now referred to the European Commission for final action. The European Commission's decision is expected in the next one to two months.

The positive CHMP opinion is supported by 36-week data from the Phase 3 BRAVE-AA-PEDS study evaluating the safety and efficacy of once-daily, oral Olumiant compared with placebo in the cohort of patients ages 12 to under 18. Treatment with Olumiant helped many adolescents achieve near-complete scalp hair regrowth. Additionally, many patients achieved successful eyebrow and eyelash regrowth.[2]

Efficacy results at 36 weeks[2]			
	Dose: 4 mg	Dose: 2 mg	Placebo
Successful (≥80%) scalp hair coverage*	42.4 %	27.4 %	4.5 %
Near-complete (≥90%) scalp hair coverage†	36.5 %	21.4 %	2.3 %
Significant eyebrow regrowth‡	50.0 %	24.1 %	0 %
Eyelash regrowth‡	42.9 %	25.5 %	14.0 %

** Severity of Alopecia Tool (SALT) score ≤20*

† SALT score ≤10

‡ Clinician-reported outcome (ClinRO) score of 0 or 1 with a ≥2-point improvement from baseline

The safety profile of Olumiant in adolescents with AA was consistent with the safety profile seen in clinical trials for children with juvenile idiopathic arthritis and moderate-to-severe atopic dermatitis.[2]

In addition, 52-week efficacy and safety data demonstrating successful hair regrowth on the scalp, eyebrows and eyelashes in adolescent patients were also recently presented at the Fall Clinical Dermatology (FCD) Conference in October 2025.

Olumiant is the most-researched JAK inhibitor in AA. In total for all indications, more than 14,600 patients have received Olumiant in completed and ongoing clinical trials. Of these, over 1,200 have been children and adolescents.

"Adolescents with severe alopecia areata represent a particularly vulnerable population, as the disease is difficult to manage and occurs at a time when appearance can have a significant impact on social identity and emotional well-being," said Thierry Passeron, M.D., PhD, professor and chair, Department of Dermatology, Université Côte d'Azur. "In clinical practice, families are frequently left with limited options that fall short. If approved in the European Union, Olumiant will represent an important evidence-based treatment option for these young patients — and with it, the hope that more adolescents living with severe alopecia areata can be helped."

Lilly has submitted Olumiant in the U.S. for approval to treat severe AA in adolescents, with a decision expected in the second half of 2026.

About BRAVE-AA-PEDS

BRAVE-AA-PEDS (NCT05723198) is an ongoing, placebo-controlled, Phase 3 clinical trial involving children and adolescents 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, Olumiant 4 mg or Olumiant 2 mg. The primary endpoint of this study was a SALT score ≤20 (i.e., 80% or more scalp hair coverage) at Week 36. The second cohort of 166 adolescents were randomized 1:1 to Olumiant 4 mg or Olumiant 2 mg to further accumulate safety data.

The third cohort consists of children ages 6 to under 12 years and will be randomized in a 1:1:1 ratio to receive once-daily placebo, Olumiant high dose or Olumiant low dose.[3]

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.

INDICATIONS AND SAFETY SUMMARY WITH WARNINGS (in the United States)
Olumiant® (O-loo-mē-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.

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)

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 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. Toussi, A., Barton, V. R., Le, S. T., Agbai, O. N., & Kiuru, M. (2021). Psychosocial and psychiatric comorbidities and health-related quality of life in alopecia areata: A systematic review. *Journal of the American Academy of Dermatology*, *85*(1), 162–175. https://doi.org/10.1016/j.jaad.2020.06.047
2. 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.
3. 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.
4. Olumiant. Prescribing Information. Lilly USA, LLC.

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