FDA approves Lilly's Olumiant (baricitinib) for pediatric patients 12 years of age and older with severe alopecia areata

September 25, 2026

FDA approval supported by data from BRAVE-AA-PEDS, the first and largest Phase 3 study specifically designed to evaluate pediatric patients with severe alopecia areata (AA)

Treatment with Olumiant resulted in substantial scalp hair regrowth, as well as improvements in eyebrows and eyelashes

Severe AA can result in extensive hair loss during adolescence, a formative stage of life

INDIANAPOLIS, Sept. 25, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) approved Olumiant (baricitinib), a once-daily pill, for the treatment of pediatric patients 12 years of age and older with severe alopecia areata (AA).[1] The approval expands Olumiant's U.S. label, building on its established use in adults with moderately to severely active rheumatoid arthritis and severe AA. AA is a chronic immune-mediated disease that causes unpredictable hair loss. As many as 2% of people develop AA at some point in their lives,[2] and nearly 40% of cases occur before the age of 20.[3] Early-onset AA can be more severe and lead to extensive hair loss.[3]

"Today's approval marks an important milestone for young people living with severe alopecia areata and their families, who have had limited treatment options to date," said Adrienne Brown, executive vice president and president, Lilly Immunology. "The visible and often extensive hair loss that comes with severe alopecia areata can have a profound impact on anyone, especially adolescents who are at a pivotal stage of life. Expanding Olumiant to patients as young as 12 provides them a much-needed treatment choice and reinforces our commitment to advancing care for people living with immune-mediated diseases."

The FDA approval is based on 36-week data from the adolescent cohort (ages 12 to under 18) of BRAVE-AA-PEDS, the first and largest Phase 3 study specifically designed to evaluate pediatric patients with severe AA.[4] At baseline, the median Severity of Alopecia Tool (SALT) score was 100, indicating complete scalp hair loss, and patients had been living with AA for a mean of 6.4 years.[1]

At Week 36, treatment with once-daily Olumiant delivered:[1]

- **80% or more scalp hair coverage, as measured by a SALT score ≤20,** in 42% of patients treated with Olumiant 4 mg and 27% treated with Olumiant 2 mg, compared with 5% receiving placebo.
- **90% or more scalp hair coverage, as measured by a SALT score ≤10,** in 37% of patients treated with Olumiant 4 mg and 21% treated with Olumiant 2 mg, compared with 2% receiving placebo.
- **Improved eyebrow and eyelash coverage** among patients with substantial eyebrow and eyelash hair loss at baseline treated with Olumiant 4 mg.

The overall safety profile observed in pediatric patients 12 years of age and older with severe AA is consistent with the safety profile in adults with severe AA.[1] The U.S. FDA-approved labeling for Olumiant includes a boxed warning for risk of serious infections, mortality, malignancy, major adverse cardiovascular events (MACE) and thrombosis.[1] See below for full Safety Summary.

"Severe alopecia areata that starts early in life can be more extensive and harder to treat over time, making it important to consider all available treatment options early in the course of disease," said Brittany Craiglow, M.D., adjunct associate professor of dermatology, Yale School of Medicine. "The evidence supporting Olumiant's approval is particularly meaningful because it comes from a Phase 3 study specifically designed for pediatric patients, helping clinicians and families make more informed decisions when considering advanced therapies."

Olumiant is available as 4 mg, 2 mg and 1 mg tablets.[1] The recommended dose is Olumiant 2 mg/day, with an increase to 4 mg/day if treatment response is inadequate.[1] For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4 mg/day. Once an adequate response is achieved on 4 mg/day, the dosage is to be decreased to 2 mg/day.[1]

"Alopecia areata can affect much more than hair, particularly during adolescence, when young people are navigating important personal and social milestones," said George Gondo, chief mission officer, National Alopecia Areata Foundation. "More treatment choices mean more families have the opportunity to find the option that's right for their child, together with their doctor."

Lilly is committed to ensuring patients have access to much-needed medicines. Today, Olumiant has coverage at three of the largest pharmacy benefit managers (PBMs) for adults with severe AA.[5] Through Lilly Support Services™ for Olumiant, Lilly offers a patient support program including co-pay assistance for eligible, commercially insured patients.

Learn more about Olumiant; view the 2 mg and 4 mg product photos and brand logo.

Since 2017, more than 33,000 patients have been prescribed Olumiant in the U.S.[6] Olumiant is a once-daily, oral JAK inhibitor discovered by Incyte and licensed to Lilly and is available through specialty pharmacies nationwide. In 2022, the FDA approved Olumiant for adult patients with severe AA, making it the first systemic treatment approved in the U.S. for this condition. In April 2026, the European Commission also approved Olumiant for the

treatment of adolescents (ages 12 to under 18) with severe AA.

About BRAVE-AA-PEDS
BRAVE-AA-PEDS (NCT05723198) is an ongoing, placebo-controlled, Phase 3 clinical trial involving pediatric patients ages 12 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 was randomized 1:1 to Olumiant 4 mg or Olumiant 2 mg to further accumulate safety data.[7]

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. Olumiant is also approved for adults and pediatric patients 12 years of age and older with severe AA in the US, European Union and Japan. Olumiant is also approved for the treatment of hospitalized adults with COVID-19 in the U.S.

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.[1]

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

- adults and adolescents 12 years and older 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.

It is not known if Olumiant is safe and effective in children with juvenile idiopathic arthritis or with severe alopecia areata who are younger than 12 years old.

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 get 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 get 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.
- **Low blood sugar (hypoglycemia) in people with diabetes.** Low blood sugar, including serious low blood sugar, has happened in people with diabetes after starting Olumiant and other JAK inhibitors. Your doctor may check your blood sugar more often. While taking Olumiant, tell your doctor if you have diabetes and you have signs or symptoms of low blood sugar.
- **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 or had shingles (herpes zoster).

❑ Have or 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 or 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.** There is a pregnancy exposure registry that monitors women exposed to Olumiant during pregnancy. If you become pregnant during treatment with Olumiant call 1-800-284-1695 or visit https://pregnancyregistry.lilly.com 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 for conditions other than alopecia areata or in children under 12 years of age.

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 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

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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.

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

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[5] Eli Lilly and Company. (2026, June 9). FDA approves Lilly's EBGLYSS® (lebrikizumab-lbkz) for one maintenance dose every eight weeks in patients with moderate-to-severe atopic dermatitis [Press release]. https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-ebglyssr-lebrikizumab-lbkz-one-maintenance

[6] Enterprise Longitudinal Access and Adjudication Dataset (ELAAD) - September 2026.

[7]Craiglow B, Piraccini BM, Ohyama M, et al. Impact of severity and disease course on baricitinib treatment response in adolescents with severe AA: updated data from the BRAVE-AA-PEDS trial. Presented at: Society for Pediatric Dermatology Annual Meeting; July 22-25, 2026; Minneapolis, MN.

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