FDA Approves First Treatment for Alopecia Areata Throughout the Body

Olumiant is the first FDA-approved systemic treatment for alopecia.

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The Food and Drug Administration (FDA) has approved Olumiant (baricitinib) oral tablets, the first systemic treatment for people with severe alopecia areata, an autoimmune disorder that an autoimmune disorder causes patchy baldness.

Alopecia areata, commonly known as just alopecia, causes the body to attack its own hair follicles and affects more than 300,000 people in the United States each year. Olumiant is the first treatment approved by the FDA to target the entire body rather than a specific location.

Actress Jada Pinkett Smith discussed her alopecia areata earlier this month on an episode of Red Table Talk, her Facebook Watch show. The conflict between her husband, Will Smith, and comedian Chris Rock at the Oscars last March over a joke about her baldness has sparked a wider conversation about the condition and its impact on about 147 million people worldwide, according to the National Alopecia Areata Foundation.

“Access to safe and effective treatment options is crucial for the significant number of Americans affected by severe alopecia,” Kendall Marcus, MD, director of the Division of Dermatology and Dentistry in the FDA’s Center for Drug Evaluation and Research, said in a news release. “Today’s approval will help fulfill a significant unmet need for patients with severe alopecia areata.”

Olumiant was tested in two randomized, double-blind, placebo-controlled trials (Trial AA-1 and Trial AA-2) in patients with at least 50% scalp hair loss for efficacy and safety in treating alopecia areata. Participants received a placebo or 2 or 4 milligrams of Olumiant, daily. In both trials, efficacy was measured according to the number of patients who experienced 80% scalp hair coverage at week 36.

In Trial AA-1, 22% of the 184 people who received 2 mg of Olumiant and 35% of the 281 people who received 4 mg of Olumiant experienced satisfactory scalp hair coverage, compared with 5% of the 189 people given a placebo. Trial AA-2 saw similar results: 17% of the 156 patients who received 2 mg and 32% of the 234 patients who received 4 mg achieved satisfactory scalp hair coverage, compared with 3% of the 156 patients who received a placebo.

Olumiant received priority review and breakthrough therapy designations to expedite the development and review of the drug. It was originally approved in 2018 and has been used to treat certain adults with moderately to severely active rheumatoid arthritis as well as COVID-19 in certain hospitalized adults.

To learn more about treating hair loss, read “Skin Health Resources.”

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