First Systemic Treatment for Severe Alopecia Is Approved

The more than 300,000 people in the US with alopecia areata now have a systemic treatment for the autoimmune disorder.

The FDA recently approved baricitinib (Olumiant) oral tablets for severe alopecia areata, an autoimmune disease that causes hair to fall out and often appears as patchy baldness. Baricitinib is a Janus kinase (JAK) inhibitor, a type of drug that blocks the activity of 1 or more of a family of enzymes, thereby interfering with the pathway that leads to inflammation. The drug had received priority review and breakthrough designations for treating severe alopecia.

In 2 recently published randomized, double-blind, placebo-controlled trials involving patients who had lost at least 50% of their scalp hair for more than 6 months, participants received 2 mg or 4 mg of baricitinib or placebo. The primary efficacy measure in both trials was the proportion of participants whose hair covered at least 80% of their scalp at week 36.

In one trial of 654 patients, that end point was met by 22.8% of patients who received 2 mg of baricitinib and 38.8% of patients who received 4 mg of the drug, compared with 6.2% of the 189 patients who received a placebo. In the other trial, which included 546 patients, 19.4% of participants who received 2 mg and 35.9% of those who received 4 mg achieved at least 80% hair coverage at week 36, compared with 3.3% of those who received a placebo.

The most common adverse effects associated with baricitinib included upper respiratory tract infections, headache, acne, hyperlipidemia, nasopharyngitis, and herpes zoster. Baricitinib isn’t recommended for use with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants.

Clinicians should monitor patients who take baricitinib for signs and symptoms of infection and evaluate them for active or latent tuberculosis before beginning treatment, according to the FDA. Patients also may develop hypersensitivity, gastrointestinal perforations, and laboratory abnormalities such as low white and red blood cell counts. Baricitinib carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis.

In May, the FDA approved baricitinib for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. In 2018, the FDA approved baricitinib for adults with moderate to severe rheumatoid arthritis who’ve had an inadequate response to 1 or more tumor necrosis factor blockers.

Campaign Against e-Cigarette Use Targets “Next Legends”

The FDA recently launched a campaign to prevent e-cigarette use among American Indian and Alaska Native youth.

In collaboration with the American Medical Association, publisher of JAMA, the FDA has developed a free continuing medical education program for physicians and other health care professionals about the regulation of dietary supplements, informing patients about their use, and reporting adverse events to the agency. The program includes 3 videos and accompanying educational materials. It is available on the FDA website and the AMA Ed Hub.

New Education Initiative on Dietary Supplements

A recently launched FDA initiative, “Supplement Your Knowledge,” aims to help inform health care professionals, consumers, and educators about dietary supplements.

“Dietary supplements can be valuable to your health but taking some supplements can also involve health risks,” Douglas Stearn, JD, deputy director for regulatory affairs in the FDA’s Center for Food Safety and Applied Nutrition, said in a statement. “These Supplement Your Knowledge resources will help provide consumers and health care professionals with facts to make informed decisions when determining if they want to use or recommend dietary supplements.”

More than half of the approximately 400,000 American Indian and Alaska Native teens in the US are at risk of using e-cigarettes and other tobacco products, and studies show that they are more susceptible to e-cigarette use according to the FDA, citing data from the US Centers for Disease Control and Prevention’s Youth Risk Behavior Surveillance System. For example, American Indian and Alaska Native high school students are nearly twice as likely to frequently use e-cigarettes than high school students overall.

The “Next Legends” campaign will reach out to teens via social media and streaming and gaming platforms as well as on billboards, radio, and television. Campaign advertisements will feature American Indian and Alaska Native community members to inform youths about the health dangers and addiction risks of e-cigarette use, the harmful chemicals and metals in e-cigarettes, and vaping’s detrimental effects on aspects of life important to the community.

“E-cigarettes are the most used tobacco product among youth, and they pose serious health risks if used during adolescence, when the brain is still developing,” Michele Mital, acting director of the FDA’s Center for Tobacco Products, said in a statement. “Next Legends builds on the success of previous youth e-cigarette prevention campaigns while also addressing health disparities among Native Americans and Alaska Natives associated with tobacco use.”

News From the Food and Drug Administration