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FDA Approves Pfizer's LITFULO™ (Ritlecitinib) for Adults and Adolescents With Severe Alopecia Areata

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- *LITFULO is the first and only treatment for severe alopecia areata approved for patients as young as 12*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has approved LITFULO™ (ritlecitinib), a once-daily oral treatment, for individuals 12 years of age and older with severe alopecia areata. The approved recommended dose for LITFULO is 50 mg. It is the first and only treatment approved by the FDA for adolescents (12+) with severe alopecia areata.

"While patients may start to develop symptoms of alopecia areata at any age, most people start showing signs in their teens, twenties, or thirties," said Dr. Brittany Craiglow, Associate Professor Adjunct – Dermatology at Yale School of Medicine. "LITFULO is a particularly important treatment option for younger patients with substantial hair loss, who often struggle with such a visible disease."

LITFULO is a kinase inhibitor which inhibits Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) family of kinases.

"LITFULO is an important treatment advancement for alopecia areata, an autoimmune disease that previously had no FDA-approved options for adolescents and limited options available for adults," said Angela Hwang, Chief Commercial Officer, President, Global Biopharmaceuticals Business, Pfizer. "With today's approval, adolescents and adults who struggle with substantial hair loss have an opportunity to achieve significant scalp hair regrowth."

The FDA approval was based on results of clinical trials in alopecia areata. The ALLEGRO Phase 2b/3 trial, which enrolled 718 patients with 50% or more scalp hair loss as measured by the Severity of Alopecia Tool (SALT), evaluated the efficacy and safety of LITFULO at 118 sites in 18 countries. In this pivotal study, 23% of patients treated with LITFULO 50 mg had 80% or more scalp hair coverage (SALT?20) after six months compared to 1.6% with placebo. The efficacy and safety of LITFULO were consistent between adolescents (12 through 17 years of age) and adults (18 years of age and older). The most common adverse events (AEs) reported in at least 4% of patients with LITFULO include headache (10.8%), diarrhea (10%), acne (6.2%), rash (5.4%), and urticaria (4.6%). Full results from the ALLEGRO Phase 2b/3 study were published by *The Lancet* in April 2023.

"People living with alopecia areata are often misunderstood, and their experience is frequently trivialized as 'just hair.' However, it is a serious autoimmune disease that can have considerable negative impact beyond the physical symptoms," said Nicole Friedland, President and Chief Executive Officer of the National Alopecia Areata Foundation (NAAF). "We believe the approval of LITFULO is a significant advancement for the treatment of alopecia areata, particularly for teens. It's exciting to see more FDA-approved treatments becoming available for this community."

View the full Prescribing Information. If it is not currently available via this link, it will be visible as soon as possible as we work to finalize the document. Please check back for the full information shortly.

LITFULO will be available in the coming weeks.

About Alopecia Areata

Alopecia areata is an autoimmune disease characterized by patchy or complete hair loss on the scalp, face, or body.[1,2] It has an underlying immuno-inflammatory pathogenesis and develops when the immune system attacks the body's hair follicles, causing hair to fall out.[1,2,3] This hair loss often occurs on the scalp, but it can also affect eyebrows, eyelashes, facial hair, and other areas of the body.[1,2] Alopecia totalis (total scalp hair loss) and alopecia universalis (total body hair loss) are types of alopecia areata.[1]

Impacting nearly 7 million people in the U.S. and approximately 147 million people globally, alopecia areata can affect people of any age, gender, race, or ethnicity and can cause considerable burden beyond hair loss.[1,2,3,4] Nearly 20% of people with alopecia areata are diagnosed before the age of 18.[5]

Additional Details on the ALLEGRO Clinical Trial Program

The randomized, placebo-controlled, double-blind ALLEGRO Phase 2b/3 trial (NCT03732807) investigated LITFULO in patients 12 years of age and older with alopecia areata. Patients included in the study had 50% or more scalp hair loss as measured by the Severity of Alopecia Tool (SALT), including patients with alopecia totalis and alopecia universalis, who were experiencing a current episode of alopecia areata that had lasted between six months and 10 years.

Patients were randomized to receive once-daily LITFULO (50 mg, 30 mg, 10 mg) with or without one month of initial treatment with once-daily LITFULO 200 mg, or placebo once-daily for 24 weeks. At Week 24, LITFULO groups continued their assigned doses and patients initially assigned to placebo switched to LITFULO (50 mg or 200 mg loading dose + 50 mg) for an additional 24 weeks.

In this pivotal study, a statistically significantly greater proportion of patients treated with LITFULO 50 mg had 80% or more scalp hair coverage (SALT?20) after six months of treatment versus placebo (23% treated with LITFULO 50 mg compared to 1.6% with placebo).

The most common AEs occurring in at least 1% of patients through 24 weeks were headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood creatinine phosphokinase increase, herpes zoster, red blood cell count decrease, and stomatitis. Cases of serious infection, malignancies, thromboembolic events, and lab abnormalities were also reported.

More information about the ALLEGRO Phase 2b/3 trial can be found at https://www.clinicaltrials.gov.

ALLEGRO-LT is an ongoing Phase 3, open-label, long-term study to investigate the safety and efficacy of LITFULO in adults with alopecia areata with 25% or greater hair loss and adolescents from 12 years of age with alopecia areata with 50% or greater hair loss.

About LITFULO™ (Ritlecitinib)

LITFULO is an inhibitor of JAK3 and the TEC family kinases. Inhibition of JAK3 and TEC kinase family members by LITFULO may block signaling of cytokines and cytolytic activity of T cells, which is implicated in the pathogenesis of alopecia areata.[6,7,8,9]

Regulatory applications for LITFULO in alopecia areata have been submitted to countries around the world for review, including China, the European Union, Japan, and the United Kingdom. The European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for ritlecitinib with a decision anticipated in the third quarter of 2023.

LITFULO is also being evaluated for vitiligo, Crohn's disease, and ulcerative colitis.

INDICATION

LITFULO is a kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

US IMPORTANT SAFETY INFORMATION

LITFULO may cause serious side effects, including:

Serious infections. LITFULO can lower the ability of your immune system to fight infections. Do not start LITFULO if you have any kind of infection unless your healthcare provider tells you it is okay. Some people have had serious infections while taking LITFULO or other similar medicines, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body, and have been hospitalized. Some people taking similar medicines to LITFULO have died from these infections. You may be at a higher risk of developing shingles (herpes zoster).

Your healthcare provider should test you for TB before starting treatment with LITFULO and should watch you closely for signs and symptoms of TB during treatment with LITFULO.

Before and after starting LITFULO, tell your doctor right away if you have an infection, are being treated for one, or have symptoms of an infection, including:

- fever, sweating, or chills
- muscle aches
- cough or shortness of breath
- blood in your phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinating more often than usual
- feeling very tired

LITFULO can make you more likely to get infections or worsen infections you have. If you get a serious infection, your healthcare provider may stop treatment with LITFULO until your infection is controlled.

There is an increased risk of death in people 50 years and older who have at least one heart disease (cardiovascular) risk factor and are taking a Janus kinase (JAK) inhibitor. LITFULO is a kinase inhibitor.

Cancer and immune system problems. LITFULO may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers, can happen. People,

especially current or past smokers, have a higher risk of certain cancers, including lymphoma and lung cancers, while taking a JAK inhibitor. Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment. Tell your healthcare provider if you have ever had any type of cancer.

There is an increased risk of major cardiovascular events such as heart attack, stroke, or death in people 50 years and older who have at least one heart disease (cardiovascular) risk factor and are taking a JAK inhibitor, especially for current or past smokers.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking LITFULO, 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. Blood clots in the veins of your legs (deep vein thrombosis, DVT), lungs (pulmonary embolism, PE), or eyes can happen in some people taking LITFULO. This may be life-threatening. Blood clots in the veins of the legs and lungs have happened more often in people 50 years and older, with at least one heart disease (cardiovascular) risk factor, taking a JAK inhibitor. Tell your healthcare provider if you have had blood clots in the past.

Stop taking LITFULO and get medical help right away if you have any signs and symptoms of blood clots, including swelling, pain, or tenderness in one or both legs; sudden, unexplained chest or upper back pain; shortness of breath or difficulty breathing; or changes in vision, especially in one eye only.

Allergic reactions. Symptoms that may mean you are having an allergic reaction have been seen during treatment with LITFULO. Some of these reactions were serious. Stop taking LITFULO and get emergency medical help right away if you have symptoms of allergic reaction, including hives; rash; trouble breathing; feeling faint or dizzy; or swelling of your lips, tongue, or throat.

Changes in certain laboratory test results. Your healthcare provider should do blood tests before you start taking LITFULO and during treatment to check your lymphocyte and platelet counts and liver enzyme and creatine phosphokinase (CPK) levels. You should not take LITFULO if your lymphocyte counts or platelet counts are too low or your liver tests are too high. Increased CPK levels in the blood are common with LITFULO and can also be severe.Your healthcare provider may stop treatment for a period of time if there are changes in these blood test results.

Do not take LITFULO if you are allergic to ritlecitinib or any of the ingredients in LITFULO. See the Medication Guide for a complete list of ingredients.

Before taking LITFULO, tell your healthcare provider if you:

- have an infection, are being treated for one, or have one that won't go away or keeps returning

- have diabetes, chronic lung disease, HIV, or a weak immune system
- have TB or have been in close contact with someone with TB
- have had shingles (herpes zoster)
- have had hepatitis B or hepatitis C
- live, have lived, or traveled to certain areas (such as Ohio & Mississippi River Valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or worsen when taking LITFULO. Ask your healthcare provider if you're unsure if you have lived in an area where these infections are common
- have had any type of cancer
- have had blood clots
- are a current or past smoker
- have had a heart attack, other heart problems, or stroke
- have liver problems
- have abnormal blood tests (low platelet count or white blood cell count)
- have recently received or are scheduled to receive any vaccinations. People who take LITFULO should not receive live vaccines right before or during treatment
- are or plan to become pregnant. It is not known if LITFULO will harm your unborn baby. Tell your healthcare provider if you are pregnant or plan to become pregnant during treatment with LITFULO. There is a pregnancy registry for people who take LITFULO during pregnancy. Report pregnancies to Pfizer, Inc. at 1-877-390-2940
- are breastfeeding or plan to breastfeed. It is not known if LITFULO passes into your breast milk. Do not breastfeed during treatment with LITFULO and for 14 hours after your last dose of LITFULO. Talk to your healthcare provider about the best way to feed your baby during treatment with LITFULO

Tell your healthcare provider about all the medicines you take, including prescription and over?the?counter medicines, vitamins, and herbal supplements. LITFULO and other medicines may affect each other causing side effects.

The most common side effects of LITFULO include headache; diarrhea; acne; rash; hives; inflamed hair pores (folliculitis); fever; eczema; dizziness; shingles; decreased red blood cell counts; and mouth sores, redness and swelling of the lining of your mouth. These are not all of the possible side effects of LITFULO.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE:

The information contained in this release is as of June 23, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or

developments.

This release contains forward-looking information about LITFULO (ritlecitinib), including its potential benefits, an approval in the U.S. for individuals 12 years of age and older with severe alopecia areata, applications pending for LITFULO (ritlecitinib) in other jurisdictions and potential regulatory decision and launch timings, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of LITFULO (ritlecitinib); the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in particular jurisdictions for LITFULO (ritlecitinib) for any potential indications; whether and when any applications that may be pending or filed for LITFULO (ritlecitinib) may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether LITFULO (ritlecitinib) for any such indications will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of LITFULO (ritlecitinib); uncertainties regarding the regulatory, commercial or other impact of the results of Janus kinase (JAK) inhibitor studies and data or actions by regulatory authorities based on analysis of such studies and data, which will depend, in part, on benefit-risk assessments and labeling determinations; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

Category: Prescription Medicines

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[1] Pratt CH, King LE Jr, Messenger AG, Christiano AM, Sundberg JP. Alopecia areata. Nat Rev Dis Primers. 2017;3:17011.
[2] Islam N, Leung PSC, Huntley AC, et al. The autoimmune basis of alopecia areata: a comprehensive review. Autoimmun Rev. 2015:14(2):81-89.
[3] Food and Drug Administration. The voice of the patient: a series of reports from the U.S. Food and Drug Administration's (FDA's) patient-focused drug development initiative. Silver Spring, MD:FDA;2018. Available from: https://www.fda.gov/files/about%20fda/published/Alopecia-Areata--The-Voice-of-the-Patient.pdf. Accessed 14 Dec. 2022.
[4] Stefanaki C, Kontochristopoulos G, Hatzidimitrakib E, et al. A Retrospective Study on Alopecia Areata in Children: Clinical Characteristics and Treatment Choices. Skin Appen Dis. 2021.
[5] Caldwell CC, Saikaly SK, Dellavalle RP, et al. Prevalence of pediatric alopecia areata among 572,617 dermatology patients. J Am Acad of Dermatol. 2017;77(5):980-981.
[6] Xing L, Dai Z, Jabbari A, et al. Nat Med.
[7] Howell MD, et al. Front Immunol. 2019;10:2342-2356.
[8] Telliez JB, et al. ACS Chem Biol.

[9] Xu H, et al. ACS Chem Biol. 2019;14(6):1235-1242.

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