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European Commission Approves Pfizer’s LITFULO™ for Adolescents and Adults With Severe Alopecia Areata

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has granted marketing authorization for LITFULO™ (ritlecitinib) to treat adults and adolescents 12 years of age and older with severe alopecia areata. LITFULO, a once-daily oral capsule, is the first medicine authorized by the EC to treat individuals as young as 12 years of age with severe alopecia areata. LITFULO is also the first and only treatment to selectively inhibit Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) family of kinases.

“Today’s approval of LITFULO in Europe is an important milestone for patients as young as 12 years of age with substantial hair loss from alopecia areata, as they now have an opportunity to achieve significant hair regrowth,” said Angela Hwang, Chief Commercial Officer, President, Global Biopharmaceuticals Business, Pfizer. “Previously, there were no treatment options approved by the EC for adolescents with severe alopecia areata, and Pfizer is proud to be bringing forward this new innovative medicine for patients living with the challenges brought by this autoimmune disease.”

The marketing authorization for LITFULO is valid in all 27 EU member states, and in Iceland, Liechtenstein, and Norway. This authorization follows the recommendation for approval by the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) in July 2023. It also follows approvals by the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare (MHLW) in June 2023.

The approval was based on the ALLEGRO clinical trial program, which included the ALLEGRO Phase 2b/3 study (NCT03732807) that investigated LITFULO in patients 12 years of age and older with alopecia areata with 50% or more scalp hair loss, including patients with alopecia totalis (total scalp hair loss) and alopecia universalis (total body hair loss). Results from this pivotal study showed that 13.4% of adults and adolescents saw 90% or more scalp hair coverage (SALT ?10) after 24 weeks of treatment with LITFULO 50 mg compared to 1.5% with placebo. Patient Global Impression of Change (PGI-C) response was also measured and was a key secondary outcome supporting the approval. At week 24, 49.2% of participants reported a response of “moderate” to “great” improvement in their alopecia areata compared to 9.2% with placebo.

ALLEGRO-LT (NCT04006457) is an ongoing Phase 3, open-label, long-term study, with safety and efficacy data being collected for adults with alopecia areata with 25% or greater scalp hair loss and adolescents from 12 years of age with alopecia areata with 50% or greater scalp hair loss. Long-term efficacy and safety data from this study were included in the submission to support the approval.

The most common adverse reactions reported with LITFULO included diarrhea (9.2%), acne (6.2%), upper respiratory tract infections (6.2%), urticaria (4.6%), rash (3.8%), folliculitis (3.1%), and dizziness (2.3%).

About Alopecia Areata

Alopecia areata is an autoimmune disease characterized by patchy or complete hair loss on the scalp, face, or body.[1,2] The disease 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] Impacting approximately 2% of the population at some point during their lifetime, alopecia areata can affect people of any age, gender, race, or ethnicity and can cause considerable burden beyond hair loss.[1,2,3,4]

About LITFULO™ (Ritlecitinib)

LITFULO is a first-of-its-kind treatment which irreversibly and selectively inhibits JAK3 and the TEC family of kinases by blocking ?-common cytokine signaling and reducing cytolytic activity of NK and CD8+ cells. This decreases the activity of parts of the immune system that are involved in the inflammation of hair follicles that causes hair loss in people with alopecia areata.

Ritlecitinib is also being evaluated for potential additional indications. The Tranquillo Phase 3 study (NCT05583526) is investigating the efficacy, safety, and tolerability of ritlecitinib in adults and adolescents with non-segmental vitiligo.

US 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, platelet counts, 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 September 18, 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 and an approval by the European Commission to treat adults and adolescents 12 years of age and older with severe alopecia areata, 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 description of these 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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