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Pfizer Announces Positive Topline Phase 3 Results for LITFULO in Patients with Nonsegmental Vitiligo

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- *Two pivotal studies of LITFULO™ (ritlecitinib) in nonsegmental vitiligo met their co-primary endpoints, showing significant improvement in facial and total repigmentation versus placebo at Week 52*
- *LITFULO was studied in the largest Phase 3 program to date evaluating an oral systemic therapy for nonsegmental vitiligo and has the potential to be a new treatment option for adults*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive topline results from two Phase 3 trials evaluating the efficacy and safety of LITFULO once daily in patients with both active and stable nonsegmental vitiligo (NSV) and who had a broad range of disease severity. The TRANQUILLO study included patients aged 12 years and older, while TRANQUILLO 2 enrolled adults only. Across the studies, both the 50 and 100 milligram doses of LITFULO delivered significant, clinically meaningful improvements over placebo on co-primary endpoints for the facial and total body Vitiligo Area Scoring Index, or VASI. Based on these results, Pfizer intends to submit global regulatory filings for LITFULO as a potential new oral systemic therapy for NSV for adults.

“LITFULO was internally discovered by Pfizer and has a unique mechanism of action targeting TEC family kinases and JAK3, giving rise to its distinct clinical profile,” said Michael Vincent, M.D., Ph.D., Chief Inflammation & Immunology Officer, Pfizer. “The positive results from the TRANQUILLO pivotal studies in nonsegmental vitiligo build on our deep expertise in dermatology and on our experience with LITFULO in severe alopecia areata, including its established efficacy and well-characterized safety profile. These findings give us confidence that, if approved, LITFULO could become a new oral systemic treatment option for adults living with NSV, significantly improving and potentially maintaining facial and total body repigmentation.”

NSV is a chronic autoimmune disease in which the immune system attacks melanin-producing cells, leading to a loss of pigment and resulting in white macules and patches on the skin/hair over time.[1] NSV can appear at any age and in all skin types, causing depigmentation anywhere on the skin, often affecting highly visible areas such as the face, neck, and hands.[2] While vitiligo is frequently treated as a cosmetic condition, it is a serious autoimmune disease that can have a considerable impact on patients’ lives well beyond the physical symptoms.[2,3] Because NSV is a chronic disease, systemic treatment options may be needed to help patients restore skin pigmentation and maintain repigmentation over time.[4]

Across both studies, significantly more patients treated with LITFULO achieved F-VASI75 (?75% improvement in Facial Vitiligo Area Scoring Index) and T-VASI50 (?50% improvement in Total Vitiligo Area Scoring Index) from baseline at Week 52 compared with placebo. In the U.S., the co-primary endpoints were the proportion of patients with F-VASI75 and the proportion of patients with T-VASI50 at Week 52. In countries outside of the U.S., F-VASI75 at Week 52 was the primary endpoint and T-VASI50 at Week 52 was a key secondary endpoint.

The safety profile of LITFULO in NSV was consistent with the established safety profile in alopecia areata. No new safety signals were observed. Overall, the proportion of patients with treatment?emergent adverse events (TEAEs) was similar across all treatment groups.

“Living with nonsegmental vitiligo can have a profound impact on patients’ daily lives. Many patients experience frustration due to the unpredictable nature of nonsegmental vitiligo as well as the limitations of currently available treatments and are seeking additional options that can address the underlying disease,”[2] said Iltefat Hamzavi, M.D., Senior Staff Physician, Department of Dermatology, Henry Ford Health and Hamzavi Dermatology Specialists. “In these trials, LITFULO (ritlecitinib) demonstrated significant improvements in both facial and total body repigmentation, with the findings reinforcing the potential of LITFULO to help support a new treatment paradigm with systemic therapies for patients for whom disease burden warrants more than localized treatment alone.”

Additional results from TRANQUILLO and TRANQUILLO 2 will be presented at a future medical meeting.

LITFULO was approved in 2023 by the U.S. Food and Drug Administration (FDA) for the treatment of severe alopecia areata in adults and adolescents 12 years and older. Pfizer plans to initiate a pivotal study evaluating LITFULO for the treatment of moderate alopecia areata in 2026.

About the TRANQUILLO Clinical Trial Program
The Phase 3 TRANQUILLO clinical development program consists of two pivotal trials, TRANQUILLO and TRANQUILLO 2, as well as a long-term extension trial, TRANQUILLO LTE, for participants who completed treatment in the parent study, TRANQUILLO. TRANQUILLO and TRANQUILLO LTE included adults and adolescents, while TRANQUILLO 2 enrolled adults only. The program evaluated the efficacy and safety of LITFULO in people with active or stable NSV, with a broad range of disease severity and facial involvement:

- TRANQUILLO evaluated 50 mg LITFULO once-daily in 607 adults and adolescents.
- TRANQUILLO 2 evaluated 50 or 100 mg LITFULO once-daily in 1,567 adults; comparisons involving the 50 mg dose were exploratory and descriptive in nature.

The two trials evaluated 2,174 patients in total with NSV across 271 sites worldwide.

For both trials, the co-primary endpoints in the U.S. were:

- The proportion of patients with ?75% improvement in F-VASI from baseline (F-VASI75) at Week 52.
- The proportion of patients with ?50% improvement in T-VASI from baseline (T-VASI50) at Week 52.

In countries outside of the U.S., proportion of patients achieving F-VASI75 at Week 52 was the primary endpoint and proportion of patients achieving T-VASI50 at Week 52 was a key secondary endpoint. For more information on both trials, visit clinicaltrials.gov for Tranquillo and Tranquillo 2.

About LITFULO™ (ritlecitinib)
LITFULO is an oral inhibitor of Janus kinase 3 (JAK3) and the TEC family kinases which is being investigated for the treatment of nonsegmental vitiligo. By targeting key immune signaling pathways involved in the disease, LITFULO is thought to modulate the activity of immune cells that contribute to melanocyte destruction. LITFULO is currently approved for the treatment of severe alopecia areata in adults and adolescents 12 years and older, where it targets the underlying immune mechanisms that drive hair follicle damage and hair loss. Through its dual mechanism, LITFULO has demonstrated the potential to address immune-mediated pathology underlying both alopecia areata and nonsegmental vitiligo.

LITFULO is approved for the treatment of severe alopecia areata in adults and adolescents 12 years and older in the United States, European Union, Canada, Japan, China, and United Kingdom.

The LITFULO development program spans multiple immune?mediated dermatologic conditions, including alopecia areata, nonsegmental vitiligo, chronic spontaneous urticaria, and hidradenitis suppurativa, supporting a focused development approach in dermatology.

Important Safety Information & Use

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 healthcare provider if you think 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 of age 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 medicine.

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 taking 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 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 of age and older who have at least one heart disease (cardiovascular) risk factor and are taking a JAK inhibitor, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while using 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 of age 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.

Low blood sugar in people with diabetes.
If you have diabetes, your healthcare provider may instruct you to check your blood sugar levels more often during treatment with LITFULO. Call your healthcare provider if you have any problems with low blood sugar (hypoglycemia).

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
- have 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 parts of the country (such as the 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 low platelet counts or white blood cell counts
- 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 pregnant 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.

You are encouraged to report adverse events related to Pfizer products by calling **1-800-438-1985** (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit www.fda.gov/MedWatch or call **1-800-FDA-1088**.

Please see full Prescribing Information, including **BOXED WARNING**, and Medication Guide.

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

175 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 X at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Category: Prescription Medicines

Disclosure Notice
The information contained in this release is as of July 30, 2026. 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, the development program for LITFULO, topline results from two Phase 3 trials for LITFULO in patients with nonsegmental vitiligo, plans to submit global regulatory filings for LITFULO as a potential new oral systemic therapy for NSV, and plans to initiate a pivotal study evaluating LITFULO for the treatment of moderate alopecia areata in 2026, 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; 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; the risks associated with initial, preliminary or 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 applications for LITFULO may be filed in particular jurisdictions for any potential indications; whether and when any such applications for LITFULO that may be pending or filed 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 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; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on Pfizer's 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, 2025, 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.

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