

Pfizer's LITFULO Significantly Improved Facial and Total Body Repigmentation in Patients with Nonsegmental Vitiligo

Friday, October 02, 2026 - 11:15am

LITFULO significantly improved facial and total body repigmentation at Week 52 compared to placebo, with continuous improvement starting at Week 24, supporting planned regulatory filings for a potential new oral systemic therapy for adults with nonsegmental vitiligo

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today presented results from two Phase 3 trials evaluating the efficacy and safety of LITFULO® (ritlecitinib) as a once-daily oral treatment across a wide range of disease extent.

In the two studies, TRANQUILLO 2 and TRANQUILLO, LITFULO 100 mg and 50 mg, respectively, significantly improved facial and total body repigmentation compared to placebo. These improvements were supported by patient-reported outcomes indicating reduced disease severity and meaningful change in facial and total body vitiligo, as well as greater disease stabilization compared to placebo. These results from the largest Phase 3 program to date evaluating an oral systemic therapy for nonsegmental vitiligo (NSV) were presented today in a late-breaking oral presentation at the 35th European Academy of Dermatology and Venereology (EADV) Annual Congress in Vienna, Austria.

Pfizer intends to submit these data to regulatory authorities globally, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for review.

“LITFULO has dual selectivity for JAK3 and the TEC family kinases, signals that immune cells use to attack pigment-producing cells in the skin, so it addresses a root cause of nonsegmental vitiligo rather than its visible effects alone. Across the largest Phase 3 program to date evaluating an oral systemic therapy for nonsegmental vitiligo, both TRANQUILLO 2 and TRANQUILLO demonstrated strong and increasing improvements in facial and total body repigmentation over time and also improved patients’ own perception of facial and overall disease severity. We look forward to discussing these results with regulators to bring this potential option to patients as soon as possible.”

- Michael Vincent, M.D., Ph.D., Chief Inflammation & Immunology Officer, Pfizer

“Nonsegmental vitiligo is a disease that can have a substantial burden on patients’ lives beyond the visible symptoms on their skin. ^{1,2,3} It is a chronic autoimmune disease, yet patients often face stigma because it is trivialized as a condition that affects only skin appearance. ² It can progress unpredictably, often across highly visible areas, and for decades people living with vitiligo have relied on limited available treatment options. ^{2,3} Research has shown that LITFULO (ritlecitinib) not only significantly improved facial and total body

repigmentation, but also resulted in greater disease stabilization compared to the placebo. The results solidify the potential of LITFULO to support a new treatment paradigm rooted in systemic treatment that can address underlying disease drivers for people living with nonsegmental vitiligo.”

- Iltefat Hamzavi, M.D., Senior Staff Physician, Department of Dermatology, Henry Ford Health and Hamzavi Dermatology Specialists

Key Results from TRANQUILLO Studies

- **Co-primary Endpoints** – data presented from the TRANQUILLO 2 (100 mg LITFULO) and TRANQUILLO (50 mg LITFULO) studies, respectively :
 - **21.86%** and **12.47%** of patients taking LITFULO achieved F-VASI75 (≥75% improvement in Facial Vitiligo Area Scoring Index) compared to **2.40%** and **2.48%** on placebo, respectively.
 - **13.02%** and **8.98%** of patients taking LITFULO achieved T-VASI50 (≥50% improvement in Total Vitiligo Area Scoring Index) compared to **2.40%** and **1.98%** on placebo, respectively.
- **Key Secondary Endpoints:** LITFULO achieved statistically significant and clinically meaningful improvements compared to placebo across multiple measures of facial and total body repigmentation. Across both trials, significant improvements from baseline in F-VASI and T-VASI were seen as early as Week 24 and increased through Week 36 and Week 52 compared to placebo. Additionally, more patients on LITFULO achieved clinically meaningful improvements at earlier timepoints, as measured by F-VASI75 and T-VASI50 at Week 24 and Week 36 compared to placebo. LITFULO also significantly reduced patient-reported facial and overall disease severity compared to placebo at Week 52.
- **Other Selected Endpoints (not type I error controlled):** Patients on LITFULO also reported benefit over placebo based on meaningful change in patient global impression of change in face (PGIC-F) and overall vitiligo (PGIC-V) vs placebo. Noticeability (VNS) improved through Week 52 with more patients rating their vitiligo as “a lot less” or “no longer” noticeable compared to placebo. Treatment with ritlecitinib, at both dose levels, resulted in greater disease stabilization compared with placebo from Week 24 onward, with maintained stabilization through Week 52. In an assessment of 50 mg LITFULO in TRANQUILLO 2, clinically meaningful improvement over placebo was observed for both F-VASI75 and T-VASI50 at Week 52.
- **Safety:** 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.
 - In TRANQUILLO 2, a TEAE was reported in 67.7% or 62.0% of patients treated with LITFULO 100 mg or placebo, respectively. The most common TEAEs were upper respiratory tract infection (8.9% vs. 3.4%), nasopharyngitis (7.9% vs. 7.3%), and headache (4.0% vs. 5.4%).
 - In TRANQUILLO, a TEAE was reported in 81.0% or 77.1% of patients treated with LITFULO 50 mg or placebo, respectively. The most common TEAEs were upper respiratory tract infection (14.0% vs. 10.9%), increased blood creatine phosphokinase (11.0% vs. 8.0%), nasopharyngitis (10.5% vs. 9.5%), COVID-19 (6.0% vs. 5.0%), decreased lymphocyte count (6.3% vs. 1.5%), and headache (5.5% vs. 5.0%).
 - Treatment-emergent serious AEs (TESAEs) were reported in a low number of patients across both studies: 3.4% or 3.4% in TRANQUILLO 2 for those on LITFULO 100 mg or placebo, respectively; 2.0% or 2.5% in TRANQUILLO for those on LITFULO 50 mg or placebo, respectively.

Phase 3 Clinical Trial Designs for TRANQUILLO 2 and TRANQUILLO

- The Phase 3 TRANQUILLO clinical development program consists of two pivotal trials — TRANQUILLO 2 and TRANQUILLO — and a long-term extension trial, TRANQUILLO LTE.

- TRANQUILLO 2 and TRANQUILLO evaluated 2,174 patients in total with NSV across 271 sites worldwide.
 - **TRANQUILLO 2:** Evaluated 100 mg LITFULO once daily in 1,567 adults. The study also included an assessment of 50 mg LITFULO that is exploratory and descriptive in nature.
 - **TRANQUILLO:** Evaluated 50 mg LITFULO once daily in 607 patients aged 12 years and older.
 - Patients enrolled in the TRANQUILLO LTE completed treatment in the parent study, TRANQUILLO.
- **Endpoints:** For both studies in the U.S., the co-primary endpoints were the proportion of patients who achieved F-VASI75 and the proportion of patients who achieved 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.

Advancing Pfizer's Commitment to Immune-Mediated Dermatologic Conditions

These results for LITFULO highlight the medicine's potential for people living with NSV and build on Pfizer's longstanding commitment to immune-mediated dermatologic conditions. LITFULO is currently approved by the FDA for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

The positive results for LITFULO in vitiligo further reinforce the potential value of inhibiting the JAK3 and TEC family kinases across multiple immune-mediated skin diseases and may position it to be a new oral systemic therapy option for adults with NSV.

Pfizer is presenting more than 30 accepted abstracts across its dermatology portfolio at the 35th EADV Congress, spanning nonsegmental vitiligo, alopecia areata, and atopic dermatitis.

- In alopecia areata, Pfizer presented long-term Phase 3 data showing clinically meaningful improvements in scalp hair regrowth with LITFULO (ritlecitinib) through five years, with no new safety signals observed. Pfizer has also initiated a pivotal study evaluating LITFULO for the treatment of moderate alopecia areata.
- In atopic dermatitis, Pfizer presented a late-breaking exploratory analysis of serum protein biomarkers from the Phase 3 JADE COMPARE study of CIBINQO (abrocitinib), alongside a final integrated safety analysis of 3,850 patients with up to 6.5 years of exposure. Pfizer also presented interim Phase 2 efficacy and safety results at Week 16 for tilrekimig (PF-07275315), an investigational, potential first-in-class trispecific antibody targeting IL-4, IL-13, and TSLP.

About Nonsegmental Vitiligo

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.⁴ 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.¹ 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.^{1,2} Because NSV is a chronic disease, systemic treatment options may be needed to help patients restore skin pigmentation and maintain repigmentation over time.³

For more information on Pfizer's Commitment to Immunology and Inflammation, please visit: [Inflammation & Immunology | Pfizer](#).

For more information on LITFULO and the Phase 3 results in NSV, please visit: [Pfizer Announces Positive Topline Phase 3 Results for LITFULO in Patients with Nonsegmental Vitiligo | Pfizer](#)

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.

U.S. Indication

LITFULO (ritlecitinib) is a prescription medicine used to treat severe alopecia areata in adults and adolescents 12 years and older.

It is not known if LITFULO is safe and effective in children under 12 years of age.

U.S. 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 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 www.facebook.com/Pfizer/.

Disclosure Notice

The information contained in this release is as of October 2, 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, results from two Phase 3 trials for LITFULO in patients with nonsegmental vitiligo, and plans to submit these data to regulatory authorities globally, including the U.S. Food and Drug Administration and European Medicines Agency, for review, 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.

References

1. Seneschal J, Bae JM, Ezzedine K, et al. Vitiligo. Nat Rev Dis Primers. 2025;11(1):85. doi:10.1038/s41572-025-00670-x
2. Ma S, Zieneldien T, Tan IJ, Jafferany M. Cross-cultural beliefs and stigmatization in vitiligo: A systematic review. J Cosmet Dermatol. 2026;25(4):e70725. doi:10.1111/jocd.70725
3. Ezzedine K, Eleftheriadou V, Whitton M, van Geel N. Vitiligo. Lancet. 2015;386(9988):74-84. doi:10.1016/S0140-6736(14)60763-7
4. Upadhya S, Andrade MJ, Shukla V, Rao R, Satyamoorthy K. Genetic and immune dysregulation in vitiligo: Insights into autoimmune mechanisms and disease pathogenesis. Autoimmun Rev. 2025;24(8):103841. doi:10.1016/j.autrev.2025.103841

Category: Prescription Medicines

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Source: Pfizer Inc