

Litfulo™ (ritlecinib) – New drug approval

- On June 23, 2023, [Pfizer announced](#) the FDA approval of [Litfulo \(ritlecinib\)](#), for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
 - Litfulo is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
- Litfulo is the second JAK inhibitor approved for alopecia areata and the first approved in adolescents.
 - Eli Lilly's JAK inhibitor, [Olumiant® \(baricitinib\)](#), was [approved](#) in June 2022 for the treatment of adult patients with severe alopecia areata.
- The efficacy of Litfulo was established in a randomized, double-blind, placebo-controlled study in 718 patients 12 years of age and older with alopecia areata with $\geq 50\%$ scalp hair loss. Patients were randomized to several different treatment regimens of ritlecinib or placebo, but the results below are only for the recommended dose of Litfulo 50 mg once daily vs. placebo (N = 261). Assessment of scalp hair loss was based on the Severity of Alopecia Tool (SALT) score.
 - At week 24, 23.0% of patients in the Litfulo 50 mg arm achieved SALT ≤ 20 response (20% or less of scalp hair loss) vs. 1.6% with placebo (treatment difference 21.4, 95% CI: 13.4, 29.5). SALT ≤ 10 response (10% or less of scalp hair loss) was achieved in 13.4% of patients with Litfulo 50 mg vs. 1.5% with placebo (treatment difference 11.9, 95% CI: 5.4, 18.3).
- Litfulo carries a boxed warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.
- Additional warnings and precautions for Litfulo include hypersensitivity, laboratory abnormalities, and vaccinations.
- The most common adverse reactions ($\geq 1\%$) with Litfulo use were headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, increased blood creatine phosphokinase, herpes zoster, decreased red blood cell count, and stomatitis.
- The recommended dose of Litfulo is 50 mg orally once daily.
- Pfizer plans to launch Litfulo in the coming weeks. Litfulo will be available as a 50 mg capsule.