20 July 2023
EMA/CHMP/328223/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Litfulo

ritlecitinib

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Litfulo, intended for the treatment of alopecia areata (AA). The applicant for this medicinal product is Pfizer Europe MA EEIG.

Litfulo will be available as a 50 mg hard capsule. The active substance of Litfulo is ritlecitinib, a Janus-associated kinase (JAK) inhibitor (ATC code: L04AF08). Ritlecitinib irreversibly and selectively inhibits JAK 3 and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) family by blocking γ-common cytokine signalling and reducing cytolytic activity of NK and CD8+ cells. Although the complete pathophysiology of AA is still not understood, JAK3 and TEC family mediated signalling pathways are both thought to be involved.

The benefit of Litfulo is its ability to regrow lost hair compared with placebo, as shown in a phase 2b/3 randomised, double-blind, dose-ranging study in patients with alopecia areata. The most common side effects are diarrhoea, acne, upper respiratory tract infections, urticaria, rash, folliculitis and dizziness.

The full indication is:

> Litfulo is indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older (see section 5.1).

Litfulo should be prescribed by physicians experienced in the diagnosis and treatment of alopecia areata.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union