16 October 2025
EMA/CHMP/310418/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Brinsupri

brensocatib

On 16 October 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Brinsupri, intended for the treatment of non-cystic fibrosis bronchiectasis in patients 12 years of age and older.

Brinsupri was reviewed under EMA's accelerated assessment programme.

Brinsupri will be available as 25 mg film-coated tablets. The active substance in Brinsurpi, brensocatib, is a competitive, reversible inhibitor of dipeptidyl peptidase 1 (DPP1). Brensocatib reduces the activity of neutrophil serine proteases (NSPs) involved in the pathogenesis of bronchiectasis, including neutrophil elastase, cathepsin G and proteinase 3.

The full indication for Brinsupri is:

> Brinsupri is indicated for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in patients 12 years of age and older with two or more exacerbations in the prior 12 months.

The main evidence of efficacy of Brinsupri was based on a Phase III randomised, double-blind, placebo controlled, clinical trial (ASPEN) involving 1,721 patients aged 12 years and older. At 52 weeks, the annualised rate of exacerbations was 1.04 with brensocatib 25 mg compared with 1.29 with placebo; the rate ratio was 0.81 (95% CI [0.69–0.94]), demonstrating a statistically significant reduction compared with placebo.

The most commonly reported adverse reactions were headache, hyperkeratosis, gingival and periodontal diseases, dermatitis, rash, upper respiratory tract infections, and dry skin. Use during pregnancy is not recommended; animal studies have shown reproductive (embryo-foetal) toxicity.

Detailed recommendations for the use of this product are described in the summary of product characteristics (SmPC), which will be published on the EMA website 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

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