25 June 2015
EMA/CHMP/76738/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Respreeza

human alpha1-proteinase inhibitor

On 25 June 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Respreeza, intended for the treatment of alpha$_1$-proteinase inhibitor deficiency. The applicant for this medicinal product is CSL Behring GmbH. Respreeza will be available as 1000 mg powder and solvent for solution for infusion. The active substance of Respreeza is human alpha1-proteinase inhibitor, an alfa1 antitrypsin (B02AB02), derived from collected human blood. The administration of the human alpha1-proteinase inhibitor would reach the lungs where it would restore the level of alpha-1 antitrypsin in deficient patients. Alpha-1 antitrypsin has the role of inactivating some substances, such as elastase, normally produced by the body. In this way the human alpha1-proteinase inhibitor could oppose the effects of elastase. This action is expected to slow down the worsening of the lung disease such as the emphysema.

The benefit with Respreeza is its ability to slow down the annual rate of lung density decline, as measured by CT scan compared to placebo over 2 years, reflecting a 34% reduction. It has been evaluated in a randomised, double-blind, placebo-controlled, multi-centre study (RAPID).

The most common side effects are hypersensitivity or allergic reactions observed during the treatment. In the most serious cases, allergic reactions may progress to severe anaphylactic reactions even when the patient has shown no hypersensitivity to previous administrations.

The full indication is: "Respreeza is indicated for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha$_1$-proteinase inhibitor deficiency (*e.g.* genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ). Patients are to be under optimal pharmacologic and non-pharmacologic treatment and show evidence of progressive lung disease (*e.g.* lower forced expiratory volume per second (FEV$_1$) predicted, impaired walking capacity or increased number of exacerbations) as evaluated by a healthcare professional experienced in the treatment of alpha$_1$-proteinase inhibitor deficiency".

[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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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.