25 January 2018
EMA/CHMP/811505/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lamzede

velmanase alfa

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lamzede, intended for the treatment of patients with non-neurological manifestations of mild to moderate alpha-mannosidosis. Lamzede was designated as an orphan medicinal product on 26 January 2005. The applicant for this medicinal product is Chiesi Farmaceutici S.p.A.

Lamzede will be available as 10 mg powder for solution for infusion. The active substance of Lamzede is velmanase alfa, a recombinant form of human alpha-mannosidase (ATC code: A16AB15). Lamzede is an enzyme replacement therapy intended to provide or supplement natural alpha-mannosidase, an enzyme that helps with the degradation of mannose–rich oligosaccharides and thus prevents their accumulation in various tissues in the body.

The benefits of Lamzede are its ability to restore serum oligosaccharides to normal levels and improve exercise capacity and lung function in some patients. The most common side effects are diarrhoea, fever and weight increase.

The full indication is:

“Enzyme replacement therapy for the treatment of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.” It is proposed that Lamzede be prescribed by physicians experienced in the management of patients with alpha-mannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact