25 June 2020
EMA/178706/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Idefirix

imlifidase

On 25 June 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Idefirix[3], intended for the desensitisation of highly sensitised patients needing kidney transplantation, but unlikely to receive a compatible transplant. Idefirix benefited from the support of the PRIME scheme, EMA's platform for early and enhanced dialogue with developers of promising new medicines that address unmet medical needs. The applicant for this medicinal product is Hansa Biopharma AB.

Idefirix will be available as powder for concentrate for solution for infusion (11 mg). The active substance of Idefirix is imlifidase, an immunosuppressant (ATC code: L04AA). Imlifidase is a cysteine protease derived from the immunoglobulin G (IgG)-degrading enzyme of *Streptococcus pyogenes.* It cleaves the heavy chains of all human IgG subclasses (but no other immunoglobulins), eliminating Fc-dependent effector functions, including CDC and antibody-dependent cell-mediated cytotoxicity (ADCC). Thus, imlifidase reduces the level of donor specific antibodies, enabling transplantation.

The benefits with Idefirix are its ability to convert a positive crossmatch to a negative one in highly sensitised patients to allow renal transplantation. The most common side effects are infections and infusion related reactions.

The full indication is:

> Idefirix is indicated for desensitisation treatment of highly sensitised adult kidney transplant patients with positive crossmatch against an available deceased donor. The use of Idefirix should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritisation programmes for highly sensitised patients.

It is proposed that Idefirix be prescribed by physicians experienced in the management of

[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
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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immunosuppressive therapy and of sensitised renal transplant patients.

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.