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EMA accepts MMA for Hansa Biopharma’s IDEFIRIX

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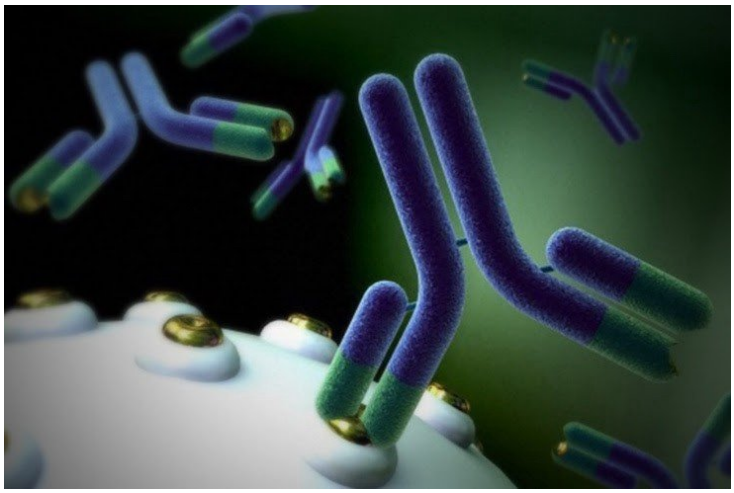
IDEFIRIX is a novel antibody-degrading enzyme that eliminates immunological barriers



Hansa Biopharma AB, the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases has declared that the European Medicines Agency (EMA) has accepted the Company's Marketing Authorization Application (MAA) for review of IDEFIRIX™ (INN: imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients.

IDEFIRIX is a novel antibody-degrading enzyme that eliminates immunological barriers. It is administered as a single intravenous infusion immediately prior to transplantation and rapidly inactivates donor specific antibodies (DSAs).

This acceptance follows Hansa's submission of the MAA on 5 February 2019 and marks the beginning of the regulatory review process for IDEFIRIX in the European Union (EU). IDEFIRIX has both EU Orphan Drug Designation and PRIority MEdicine (PRIME) designation, an EMA program to enhance support for the development of medicines that target an unmet medical need.

An opinion of the Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days (plus any clock-stops for the applicant to provide answers to questions which may arise during the review). After the adoption of a CHMP opinion, a final decision regarding the MAA for IDEFIRIX is made by the European Commission.

The MAA for IDEFIRIX is based upon the successful outcomes from five clinical studies demonstrating the efficacy and safety of IDEFIRIX to successfully enable kidney transplantation. In addition, the file includes evidence of the significant medical need for highly sensitized patients who today have extremely limited opportunity for transplantation.