

Hansa Biopharma Reports Positive European Post-Authorisation Data for Idefirix

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The kidney transplant study showed 90 percent one-year graft failure-free survival, supporting Hansa's planned EMA submission to convert Idefirix to full marketing authorisation.



Hansa Biopharma has reported positive topline results from a European post-authorisation efficacy study of Idefirix in highly sensitised kidney transplant patients.

The study addresses a major unmet need in transplantation. Highly sensitised patients have pre-formed donor-specific antibodies that can make it difficult to find a compatible donor organ, leaving some patients on transplant waiting lists for extended periods.

Idefirix, or imlifidase, is conditionally approved in the European Union as a desensitisation treatment for highly sensitised adult patients prior to kidney transplantation from deceased donors. As part of the conditional marketing authorisation, the European Medicines Agency required a post-authorisation efficacy study.

The open-label confirmatory study enrolled 51 patients across 22 transplant centres in 11 countries in the EU and the UK. The primary objective was met, with 90 percent of treated patients achieving one-year graft failure-free survival after Idefirix pre-treatment to convert a positive crossmatch to negative before transplantation.

At one year, graft survival was 92 percent and patient survival was 98 percent, while mean estimated glomerular filtration rate was 52.4 mL/min/1.73 m². Patient retention was above 94 percent, and Idefirix was generally well tolerated with a safety profile consistent with prior clinical experience.

Hansa plans to submit an application to the EMA by the end of 2026 to convert Idefirix from conditional to full marketing authorisation. If successful, the data could strengthen clinical confidence and reimbursement discussions for a therapy used in a highly specialised transplant setting.