Hansa Biopharma
Scheelevägen 22
SE-223 63 Lund, Sweden
Phone: +46 46 16 56 70

www.hansabiopharma.com

PRESS RELEASE

SERB Pharmaceuticals and Hansa Biopharma announce submission to EMA for conversion to standard marketing authorization of Idefirix in the EU

- **SERB has submitted a request to the European Medicines Agency (EMA) to convert the conditional marketing authorization for Idefirix (imlifidase) to standard marketing authorization.**
- **The submission for conversion is based on data from the European Post-Authorization Efficacy and Safety (PAES) study.**
- **Idefirix is the only treatment approved in Europe to enable kidney transplantation in highly sensitized patients with an incompatible organ from a deceased donor.**

Lund, Sweden, November 26, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA) and SERB S.A. ("SERB"), today announced the submission of an application to the European Medicines Agency (EMA) to convert the conditional marketing authorization for Idefirix®, a first-in-class treatment that specifically targets and cleaves all classes of immunoglobulin G (IgG) antibodies within 2 to 6 hours, to standard, or "full", marketing authorization.

Renée Aguiar-Lucander, CEO of Hansa Biopharma, said: "*The EMA submission for standard marketing authorization is an important milestone for Idefirix and reflects the body of clinical evidence generated since its conditional approval in Europe. The results from the PAES study further strengthen our understanding of Idefirix in highly sensitized kidney transplant patients and we look forward to supporting SERB in its interactions with the regulatory agency regarding potential full approval of Idefirix*"

Idefirix is currently conditionally approved by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Highly sensitized patients have limited access to kidney transplantation because compatible donors are difficult to find.[2,3] These patients often wait longer for a transplant, and longer waits are associated with a higher risk of death.[4,5]

The submission to the EMA for conversion to standard marketing authorization is based on the European PAES study (PAES; 20-HMedIdeS-19). This open-label,confirmatory study assessed one-year graft failure-free survival and patient survival in highly sensitized patients who received HLA-incompatible kidney transplants after desensitization with Idefirix. The study met its primary objective with 90% of patients achieving one-year graft failure-free survival, reflecting 98% survival and 92% graft survival. Idefirix was generally well tolerated, and its safety profile was consistent with previous clinical trial experience. The results were presented at ASN Kidney Week in October.

Hansa granted SERB Pharmaceuticals an exclusive license for Idefirix in transplantation in the EU, UK, Switzerland, Norway, Liechtenstein, Iceland and Middle East and North Africa (MENA) on July 1, 2026.

--- ENDS ---

Contacts for more information:

Adam Cutler, CFO
IR@hansabiopharma.com

Kerstin Falck, VP Global Corporate Affairs
media@hansabiopharma.com

Notes to editors

About highly sensitized patients

Highly sensitized patients have pre-formed antibodies called donor specific antibodies (DSAs) with a broad reactivity against human leukocyte antigens (HLAs), which can cause tissue damage and potentially transplant rejection.[1] The presence of DSAs means that highly sensitized patients tend to have limited or no access to transplant, as finding a compatible donor organ can be particularly challenging.[2,3] The complexity of their immunological profile means that highly sensitized patients spend longer time than average on transplant waiting lists, with evidence showing that this longer time waiting for a suitable donor relates to an increased mortality risk.[4,5] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[6,7]

About imlifidase

Imlifidase is conditionally approved in the European Union, Norway, Liechtenstein, Iceland and the UK under the tradename Idefirix® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Idefirix® is also approved in Australia, Israel and Switzerland.

About Idefirix® (imlifidase)

Imlifidase is an antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets and cleaves immunoglobulin G (IgG) antibodies and inhibits IgG-mediated immune response.[8] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration.

Imlifidase has conditional marketing approval in Europe and is marketed under the trade name Idefirix for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. The use of Idefirix should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[8] Idefirix was reviewed as part of the European Medicines Agency's (EMA) PRIority Medicines (PRIME) program, which supports medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.[8]

The efficacy and safety of imlifidase as a pre-transplant treatment to reduce donor-specific IgG antibodies was studied in four phase 2 single-arm, studies in EU and US, a controlled Phase 3 study in US and in this European Post-Authorization Efficacy and Safety (PAES) study.[5,7,10-11]

In the US, the Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for imlifidase in February of 2026 and assigned a Prescription Drug User Fee Act (PDUFA) action date of December 19, 2026.

Idefirix is exclusively out-licensed for transplantation in EU, UK, Switzerland, Norway, Liechtenstein, Iceland and Middle East and North Africa (MENA) to SERB Pharmaceuticals since July 1, 2026.

Full EU product information can be accessed via the initial Summary of Product Characteristics found here.

About kidney failure

Kidney disease can progress to kidney failure or End-Stage Renal Disease (ESRD), identified when a patient's kidney function is less than 15%.[12] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[12] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits, and is cost savings compared to long-term dialysis. There are approximately 170,000 kidney patients in the U.S. and Europe waiting for a new kidney.[13]

About Hansa Biopharma

Hansa Biopharma AB is a pioneering commercial-stage biopharmaceutical company developing and commercializing novel immunomodulatory therapies to transform care for patients with acute or complex immune disorders. Hansa's proprietary IgG-cleaving enzyme technology platform addresses serious unmet medical needs in transplantation, gene therapy and autoimmune diseases. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients, and HNSA-5487, a next-generation IgG-cleaving molecule that is being developed for Guillain-Barré Syndrome (GBS). Hansa Biopharma is based in Lund, Sweden, and has operations in Europe and the U.S. The company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com and follow us on LinkedIn.

©2026 Hansa Biopharma AB. Hansa Biopharma, the beacon logo, Idefirix, and Idefirix flower logo are trademarks of Hansa Biopharma AB, Lund, Sweden. All rights reserved.

References

1. Eurostam Report (A Europe-wide strategy to enhance transplantation of highly sensitized patients on the basis of acceptable HLA mismatches.) Available at https://cordis.europa.eu/project/id/305385/reporting.
2. Redfield RR, et al. The mode of sensitization and its influence on allograft outcomes in highly sensitized kidney transplant recipients. *Nephrol Dial Transplant*. 2016 Oct;31(10):1746-53. doi: 10.1093/ndt/gfw099.
3. Lonze BE, et al. IdeS (Imlifidase): A Novel Agent That Cleaves Human IgG and Permits Successful Kidney Transplantation Across High-strength Donor-specific Antibody. Ann Surg. 2018 Sep;268(3):488-496. doi: 10.1097/
4. Alelign T, Ahmed MM, Bobosha K, Tadesse Y, Howe R, Petros B. Kidney Transplantation: The Challenge of Human Leukocyte Antigen and Its Therapeutic Strategies. J Immunol Res. 2018 Mar 5;2018:5986740. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859822/
5. Heidt S, et al. Highly Sensitized Patients are Well Serves by Recieving a Compatible Organ Offer Based on Acceptable Mismatches. Front Immunol. 2021;12:687254. Available at: https://pubmed.ncbi.nlm.nih.gov/34248971/
6. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Accessed [June 2024].
7. Jordan SC, et al. Imlifidase Desensitization in Crossmatch-positive, Highly Sensitized Kidney Transplant Recipients: Results of an International Phase 2 Trial (Highdes). Transplantation. 2021 Aug 1;105(8):1808-1817. doi: 10.1097/TP.0000000000003496.
8. European Medicines Agency. Idefirix® summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf.
9. Jordan SC, et al. IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation. *N Engl J Med* 2017;377:442-453. DOI: 10.1056/NEJMoa16125
10. 1Winstedt L, et al. Complete Removal of Extracellular IgG Antibodies in a Randomized Dose-Escalation Phase I Study with the Bacterial Enzyme IdeS--A Novel Therapeutic Opportunity. *PLoS One*. 2015 Jul 15;10(7):e0132011. doi: 10.1371/journal.pone.0132011. PMID: 26177518; PMCID: PMC4503742.
11. Lorant T, et al. Safety, immunogenicity, pharmacokinetics, and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients. *Am J Transplant*. 2018 Nov;18(11):2752-2762. doi: 10.1111/ajt.14733.
12. NIH (2018). What is kidney failure? Available at: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/what-is-kidney-failure.
13. Newsletter Transplant 2022. International figures on donation and transplantation. Available at: Newsletter Transplant - latest edition I Freepub (edgm.eu) Accessed: May 2024