NEWS RELEASE

# The Scottish Medicines Consortium (SMC) recommends use of Hansa Biopharma's Idefirix[®] (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

9/12/2022

- Idefirix® becomes the first and only product recommended by SMC for the desensitization of highly sensitized patients waiting for a kidney transplant[1]
- SMC considers Idefirix® to be a clinically effective and cost-effective treatment within current clinical practice [1]
- This is an important milestone for highly sensitized Scottish patients awaiting a kidney transplant, as NHS Scotland funding for Idefirix® will now be made available to hospitals in Scotland
- The SMC decision follows the recent positive NICE recommendation for Idefirix® in England, Wales and Northern Ireland,[2] expanding access for eligible patients across the UK

Lund, Sweden, September 12, 2022. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announce the recommendation by the Scottish Medicines Consortium (SMC) for its first-in-class treatment Idefirix® in the desensitization of highly sensitized adult patients prior to kidney transplant from a deceased donor. The SMC considers Idefirix® to be a clinically effective and cost-effective treatment and recognizes the significant unmet need of the licensed patient population it treats. [1]

The recommendation marks an important milestone for patients in Scotland, as specialized transplant centres will be

able to use Idefirix® to enable transplantation for highly sensitized patients, currently highly unlikely to receive a lifesaving compatible kidney transplant. Kidney transplant candidates are classified as highly sensitized if they have a broad and intense range of pre-formed antibodies against almost all donor organs. These anti-bodies are known as human leukocyte antigens (HLAs) Finding a match for these patients can be particularly difficult, leading to a longer average time on transplant waiting lists, and therefore have an increased risk of dying while waiting for a suitable donor.[6,7]

The approval of Idefirix® offers a new option to these highly sensitized patients in need of transplant to increase the chances of successful matching with a deceased donor organ.

Dr Adnan Sharif, trustee at Kidney Research UK welcomed the decision, saying ‘‘A lack of effective desensitization approaches has meant that until now, people who are classed as highly sensitized kidney patients have struggled to find a donor match, and have often had no alternative but to remain on long-term dialysis with a very poor quality of life. It is fantastic to see that the SMC has followed the direction of England and Wales to offer certain highly sensitized patients the opportunity of a life-altering transplant. The decision making around who has access to the treatment is key, and the lifespan of the transplanted kidneys will need to be carefully monitored. But success could see many patients gain freedom from gruelling dialysis treatments”.

“We are thrilled that the SMC has recommended Idefirix® as the first licensed therapy for highly sensitized kidney patients in Scotland. These patients have serious disease burden and unmet needs, and this recommendation is a significant milestone for them”, says Søren Tulstrup, President and CEO, Hansa Biopharma. “For Hansa, this recommendation is also encouraging as we continue to pursue our vision: A world where patients with rare immunologic diseases can lead long and healthy lives”.

Hansa will work closely with Scottish health boards to support the implementation of the service in line with the SMC’s recommendations.

--- ENDS ---

For more information:
Klaus Sindahl, Head of Investor Relations
M: +46 (0) 709 298 269
E: klaus.sindahl@hansabiopharma.com

Notes to editors

## About Idefirix® (imlifidase)

Idefirix® is an enzyme derived from the bacterium Streptococcus pyogenes and has the ability to specifically target and cleave all classes of immunoglobulin G (IgG) antibodies.[11]

Idefirix® is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[12] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[5] Once they are inactivated with Idefirix®, there is a window of opportunity for the transplant to take place. By the time the body starts to synthesize new IgG, the patient will be receiving immunosuppressive therapy to reduce the risk of organ rejection.

The efficacy and safety of Idefirix® as a pre-transplant treatment to reduce donor-specific IgG was studied in four phase 2, open-label, single-arm, six-month clinical trials.[10,13-14]

Hansa is now collecting further clinical evidence and will submit additional efficacy and safety data based on one observational follow-up study and one post-approval efficacy study. 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.[3]

Idefirix® was granted conditional European Marketing Authorization from the EMA in August 2020 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.[3] Conditional approval allows the Agency to recommend a medicine for marketing authorization in cases where the benefit of a medicine's immediate availability to patients outweighs the risk that not all data are yet available.

## 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%.[15] ESRD poses a significant global health burden, affecting nearly 2.5 million patients worldwide.[14] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits compared to long-term dialysis. There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.[16]

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

## About Hansa Biopharma

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and

commercialize innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. 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**.

References


1. Scottish Medicines Agency. Available at: **https://www.scottishmedicines.org.uk/medicines-advice/imlifidase-idefirix-full-smc2445/** accessed September 2022.
2. NICE. Available at: **https://www.nice.org.uk/guidance/ta809**. Last accessed September 2022.
3. European Medicines Agency. Available at: **https://www.ema.europa.eu/en/news/new-treatment-enable-kidney-transplant-highly-sensitised-patients**. Last accessed September 2022.
4. Mumford L, et al. Transpl Immunol. 2021; 64:101354.
5. Manook M, et al. Lancet. 2017; 389(10070):727–734.
6. Redfield R, et al. Nephrol Dial Transplant. 2016; 31:1746–1753.
7. Lonze BE, et al. Ann Surg. 2018; 268(3):488–496.
8. Database Global Observatory on Donation and Transplantation. Available at: **http://www.transplant-observatory.org/data-charts-and-tables/**.
9. Kuppachi S, et al. Transpl Int. 2020; 33(3):251–259.
10. Lorant T, et al. Am J Transplant 2018;18(11):2752–2762.
11. Hansa. Idefirix® Summary of Product Characteristics. Available from: **https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf**. Last accessed September 2022.
12. Winstedt L, et al. PLoS One 2015; 10(7): e0132011.
13. Jordan SC, et al. N Engl J Med 2017; 377(5):442–453.
14. Jordan SC, et al. Transplantation October 21, 2020 – volume online first issue.
15. NIH. What is kidney failure?, 2018. Available at: **https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/what-is-kidney-failure Last accessed September 2022**.
16. Newsletter Transplant 2020. pp 58–60