

Realheart® TAH Receives Humanitarian Use Device Designation by the U.S. Food and Drug Administration (FDA)

Västerås, Sweden, January 29, 2025 – Scandinavian Real Heart AB (publ) today announces that its total artificial heart, Realheart® TAH, has been granted Humanitarian Use Device (HUD) designation by the U.S. Food and Drug Administration (FDA). The HUD designation makes Realheart® TAH eligible to apply for Humanitarian Device Exemption (HDE), an expedited regulatory pathway that can grant the product limited marketing rights.

Realheart® TAH is a total artificial heart that mimics the structure and physiological function of the human heart. Following multiple rounds of communication with the FDA, the device has been granted Humanitarian Use Device status which paves the way for Realheart® TAH to treat patients with advanced biventricular heart failure who have few other options and need to be supported by a total artificial heart.

HDE is approved if the sponsor can demonstrate data indicating probable safety and benefit to the intended patient group.

Realheart will continue communications with the FDA to develop a clinical investigation strategy to support a Humanitarian Device Exemption premarket approval.

“We are extremely pleased that Realheart® TAH has been granted Humanitarian Use Device designation by the FDA. It is gratifying to look forward to our efforts culminating in such humanitarian benefit. We look forward to updating the market on further clinical and regulatory activities and meanwhile continue our preclinical development which will be important for a potential future full market approval,” says Ina Laura Perkins, CEO of Realheart.

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About Us

Scandinavian Real Heart AB (publ) is developing the first artificial heart that mimics the shape, function, and blood flow pattern of the human heart. These unique product features provide completely new opportunities to save lives and give patients a good quality of life while waiting for a heart transplant. In the future, artificial hearts may also become an alternative to transplantation for broader groups of patients with severe heart failure. Realheart® TAH (Total Artificial Heart) is now being evaluated in extensive preclinical trials ahead of a first clinical study in patients. The company's shares are traded on Nasdaq Stockholm First North Growth Market. For more information, visit www.realheart.se



PRESS RELEASE

29 January 2025 17:25:00 CET

This information is information that Scandinavian Real Heart is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-01-29 17:25 CET.