

Realheart Reports Results From Another Successful Preclinical Trial With the Artificial Heart Realheart® TAH

Västerås, 15 April 2024 - Scandinavian Real Heart AB (publ) today announces that the company has successfully completed another implantation of the Realheart® TAH artificial heart within the framework of the preclinical programme that will form the basis for the first clinical study in humans. The results show that Realheart® TAH gives rise to good cardiac function and low levels of adverse blood effects, while the survival time of the implanted animal exceeded previous attempts. Overall, the results support that the Realheart® TAH has the potential to replace the human heart in the future.

Realheart is developing the world's first artificial heart that, like the human heart, consists of two atria and two ventricles and can thus imitate the function and blood flow pattern of the human heart. Before the first clinical study of Realheart® TAH, the authorities require a comprehensive preclinical data package based on safety studies, blood tests and reliability studies.

An important part of the preclinical programme is the trials where the artificial heart is implanted and evaluated in animals. Realheart has conducted a series of such trials since 2022 and can now report the results from the latest trial.

After the implantation, several positive results regarding the performance of the artificial heart were measured, including good cardiac output, proper blood pressure control and balance between the oxygen-rich and oxygen-poor side of the circulatory system. In accordance with the previously presented data, the hemolysis level was below the reference value, i.e. little harmful effect on red blood cells. Being able to document hemolysis below the reference value is an important regulatory requirement for conducting clinical studies in patients. Survival time was improved compared to previous trials and now exceeds well over four days. The surgical team included Realheart's medical partner, cardiac surgeon Dr Göran Dellgren, senior physician and professor at the Thorax Clinic and Transplantation Centre at Sahlgrenska University Hospital in Gothenburg.

Based on the results, Realheart continues to further optimise the surgical protocol for future trials. The latest trial used an updated version of Realheart® TAH with an improved anatomical design. This version follows an evaluation of in-depth anatomy studies by Dr Göran Dellgren and Dr Jan Schmitto, Professor of Cardiac Surgery at the Department of Cardiac, Thoracic, Transplantation and Vascular Surgery at Hannover Medical School in Germany. The updated design proved favorable and will be included in further implantation trials.

"We are very pleased with the results showing that Realheart® TAH has the ability to restore good systemic circulation without serious side effects. These types of complex trials are conducted under the strict ethical guidelines that surround animal experimentation, and each successful surgery provides invaluable new insights that will help us move forward. The surgeons



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in charge describe Realheart® TAH as very easy and efficient to work with and the results meet their and our high expectations. We are now working to further improve the surgical protocol and look forward to presenting new results as soon as possible", says cardiac surgeon Ulf Kjellman, Chief Medical Officer of Realheart.

About Realheart

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. Realheart® TAH (Total Artificial Heart) is now being evaluated in extensive preclinical trial models ahead of a first clinical study in patients expected to start in 2025. Realheart® TAH addresses a significant and urgent medical need - today 8,300 people around the world are waiting for a heart transplant and many patients unfortunately die during their time on the waiting list. In the future, artificial hearts may also become an alternative to transplantation for broader groups of patients with very severe heart failure. The company's shares are traded on Nasdaq Stockholm First North Growth Market. For more information, visit www.realheart.se

For more information, please contact:

Ina Laura Perkins, CEO

Phone: +46 (0) 70 406 49 21

E-mail: inalaura.perkins@realheart.se

Certified Adviser: Svensk Kapitalmarknadsgranskning AB, www.skmg.se

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