# Realheart provides an update on the development and commercialization of its artificial heart

**Västerås, Sweden, November 13, 2023 – Scandinavian Real Heart AB (publ) today provides a strategy update on the development and commercialization of its artificial heart, the Realheart TAH, which in initial testing has been shown to induce 80% lower levels of hemolysis compared to today's market-dominant artificial heart. This update is based on a thorough analysis conducted under the guidance of the company's Board of Directors, including the new adjunct board members. Realheart will increase its focus on the use of the product as a bridging treatment ahead of organ transplantation and now deems that the product is eligible for reimbursement in the US already when used in upcoming clinical trials. Because of significant supply chain issues and delays with development partners, the scheduled start of the first clinical study has been postponed from 2024 to 2025. This is in turn likely to impact the timing of a future market introduction.**

"The Board and management, in consultation with external experts, have conducted a thorough review of the plans for the development and commercialization of the Realheart TAH. The updated plan includes a sharper focus on the use of the Realheart TAH as a bridging treatment for patients awaiting organ transplantation. Further, we have identified an opportunity to get the product reimbursed already for use in upcoming clinical trials in the US, which has the potential to generate early revenues for the company. The use of our artificial heart ahead of organ transplantation is the first important step towards our long-term vision – that no one should have to die from heart failure," says Realheart's CEO, Ina Laura Perkins.

### A more precisely defined commercialization strategy

In total, more than 8,300 patients with severe heart failure are currently listed for a heart transplant in Europe and the US. Many of these unfortunately die during their time on the waiting list. Realheart aims to significantly reduce this mortality and increase the quality of life for those waiting for a donor organ. The company aims to provide the first artificial heart that mimics the human heart, and thus, has the potential to minimize the risk of side effects.

Following decades of research and development, the Realheart TAH is now undergoing functional and safety testing ahead of the first clinical study in humans. Realheart deems that the product is eligible for reimbursement in the US already for use in the upcoming clinical trials, which has the potential to generate early revenue streams for the company.

Future market approvals will create significant commercial potential – each one percent of the patients currently on waiting lists in Europe and the US for heart transplantation corresponds to a potential sales revenue of SEK 150 million. The use of the Realheart TAH in this setting is an important first step towards the company's long-term vision – that broader patient groups will have access to the product so that no one must die of heart failure.

Since the global number of transplant centers is limited, it will be possible to market Realheart TAH with relatively limited resources. The company's business model is based on direct sales of the product in the US and Europe, with the addition of necessary services and support for clinical staff and patients.

**Updated timeline**

***Preparatory activities ahead of clinical studies***

An application to initiate the first clinical study of Realheart TAH is expected to be submitted to the relevant authorities at the turn of 2024/2025. This requires a comprehensive preclinical data package based on safety studies, blood tests and reliability studies.

Safety studies are being conducted in preclinical models to meet regulatory requirements for the first study in patients. This work is progressing with very positive results to date.

The blood tests are carried out in a laboratory setting and the company has recently established a preclinical test system that mimics the natural blood flow throughout the body, thereby enabling a more reliable evaluation of red blood cell damage (hemolysis). Initial test results show that the Realheart TAH induces 80% lower levels of hemolysis compared to today's market-dominant heart pump systems.

Reliability studies of the individual components of the Realheart TAH have already been carried out with good results, and corresponding tests of the artificial heart as a complete system will start shortly.

***First in human study***

As part of the preparations for the first clinical study of the Realheart TAH, the company has established a collaboration with Professor Göran Dellgren, Chief Physician at the Transplantation Center and Thorax Clinic at Sahlgrenska University Hospital in Gothenburg, Sweden. Several experimental and clinical preparatory studies are conducted within the framework of this collaboration, including further evaluation of alternative surgical methods, and definition of the suitable patient pool for the clinical study.

The initial clinical study, which is expected to be initiated in 2025, will be conducted in 2 to 4 patients awaiting heart transplantation. Assuming positive results, an additional study in 10-20 patients will follow to confirm the performance and safety of the Realheart TAH in clinical use, prior to market authorization applications.

***The process towards market authorization***

A process has been initiated in Europe with a Notified Body (an independent organization that ensures that manufacturers comply with EU regulations), to establish the requirements for Market Approval in the EU.

In parallel, Realheart has had meetings with the US regulatory authority (the FDA) to determine what documentation will be required for Market Approval, and further meetings are anticipated to establish the specific application process that is most appropriate in the US.

*This disclosure contains information that Real Heart is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information in this press release has been published through the agency of the contact persons set out below, at the time stated by Scandinavian Real Heart AB's news distributor Cision upon publication of this press release.*

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*Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart® TAH has a patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atria and two ventricles) designed to generate a physiological blood flow pattern that mimics the body's natural circulation. A unique concept in the medical technology world.*