# Realheart has successfully established a novel test system to evaluate hemolysis of its total artificial heart

**Västerås, November 1, 2023 – Scandinavian Real Heart AB (publ.) today announces that the company has successfully established a closed-loop preclinical test system that replicates the body's circulatory system and enables more precise evaluations of hemolytic events. Initial test results show that the company's artificial heart, Realheart TAH, induces 80% less hemolysis compared to the current market leader. The company will shortly start the evaluation of hemolytic events using a clinical version of the product.**

Measurements of hemoglobin released from red blood cells (plasma free hemoglobin; pfHb) are performed to determine the risk of ruptured blood cells (hemolysis) during the use of total artificial hearts (TAH). Such analyses compose a cornerstone in the preclinical documentation required to obtain approval from regulatory authorities before conducting clinical trials. During the fall, Realheart successfully completed the construction of an exhaustive test system, which surpasses the regulatory standards of hemolysis testing in pulsating artificial hearts. The model has thereafter been used in initial tests to evaluate the impact of a Realheart TAH prototype on human blood.

The human circulatory system is composed of two halves. One that pumps blood from the heart to the lungs with low pressure, and the other that distributes blood to the organs using high pressure. To the company's knowledge, there are no similar test systems that combine both halves of the human circulatory system for pulsatile pump testing. Initial test results using the preclinical version of Realheart TAH in the test system show that it induces 80% less damage to red blood cells (hemolysis), compared to the current market-leading artificial heart. Furthermore, the tests have been performed using human blood, enabling the company to generate more clinically relevant data and optimize the product design, with the aim of avoiding side effects in future patients who receive treatment with Realheart TAH.

The new and more technically demanding test system was developed following a request from the U.S. Food and Drug Administration (FDA). The development has been time and resource consuming, but has created a positive setting for future regulatory interactions. The CEO of Realheart, Ina Laura Perkins, PhD, has been an active participant in the committee meetings arranged by the agency to develop the new standards for hemolysis testing.

Next, the company will evaluate its clinical product version of Realheart TAH in combination with the clinical control unit in development, to generate the preclinical documentation required in an application to initiate clinical studies in heart failure patients.

"We have succeeded in establishing a test system that opens completely new ways to replicating the function of the human circulatory system, thereby allowing us to compare the properties of our proprietary artificial heart with other cardiac pumps. The model strengthens us in our dialogues with heart specialists and investors who recognize its value in generating comparative performance data. Our initial results point toward a low grade of hemolysis originating from the use of Realheart TAH and we are now eager to test the clinical version of our unique artificial heart," comments Ina Laura Perkins, CEO of Realheart.

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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.*