



## Realheart initiates chronic animal trials today

*In accordance with Realheart's development plan for 2021, the chronic animal trials that were postponed due to the pandemic are starting today. This has been made possible thanks to new technology that allows Realheart to participate in the studies remotely.*

Animal study data is required to obtain approval to initiate clinical trials, and studies are conducted to identify any product design problems that cannot be detected by other test methods. Animal studies require ethical approval, which is usually given in two steps. Firstly, an approval to perform acute studies for up to 24 hours, followed by approval to perform chronic trials, the length of which is determined by the authorities. Realheart is in the second stage.

Due to the pandemic's travel restrictions and the severe shut down in Belgium - where the animal lab carrying out Realheart's operations is located - it was not possible to follow the company's original plan to carry out these trials in 2020. Now, a solution in collaboration with Belgian partner Medanex Clinic is in place, in which Realheart's staff and other clinical experts will be able to follow and participate in the operations digitally in real time.

Realheart has for a few months trained a veterinarian who will act as a TAH operator during the operations. Furthermore, software and technology have been developed so that Realheart's staff can control the heart from a distance if the need arises. To strengthen local expertise, another experienced cardiac surgeon has been recruited: Dr Dilek Gürsoy. She runs a heart pump clinic in Germany and has extensive experience from artificial hearts, both in the treatment of heart failure patients and in animal studies.

To prepare the studies on live animals, a number of training operations on deceased animals have already been carried out successfully.

Today, the first series of several chronic trials begins. Results will be analysed continuously. When the results are positive, the planned survival time will gradually be extended.

"I am very hopeful now when we start our first chronic trials, and it is exciting to use completely new digital technology. We are very grateful for the support from our partner Medanex in this transition. The plan has always been that local staff will sooner or later be able to perform operations without our presence. The pandemic only made us take this step earlier. If this turns out well, it will release a lot of resources, which means that we can move forward at a faster pace," says Ina Laura Perkins, CEO of Realheart.

### **For more information please contact:**

Ina Laura Perkins, CEO

Phone: +46(0)70 406 49 21

E-mail: [inalaura.perkins@realheart.se](mailto:inalaura.perkins@realheart.se)

*Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atriums and two chambers) which provides the opportunity to generate a physiologically adapted blood flow that mimics the body's natural circulation. A unique concept in the medical technology world.*