

Realheart signs an important agreement with largest European heart pump manufacturer

Today Realheart signed a cooperative agreement with Berlin Heart, Europe's largest manufacturer for mid- to long-term ventricular assist devices, and thus reaches an important milestone for 2020. The agreement gives Realheart access to a large and experienced organization with cutting-edge expertise in development, production, and marketing of these complex products.

In accordance with the 2020 development plan, Realheart has actively searched for partners and suppliers who can assist with essential competence as the company now faces the most important development phase of its artificial heart. In the global search, the German-based company Berlin Heart stood out as an ideal partner.

Berlin Heart has succeeded in establishing world leadership in development, production, and commercialization of ventricular assist devices. The company has many years' experience in polyurethane processing to secure the path towards finished products and has more than 30 years of experience in clinical use of their own products approved for marketing in the EU, North America and Asia, for heart disease patients of all body sizes, from infants to adults for left, right or biventricular circulatory support. Berlin Heart was also one of the first companies in the world with a quality management system that was reviewed and approved under the new Medical Device Regulation (MDR). The latter can facilitate the future certification work for Realheart.

The collaboration agreement means that the companies will work side by side in a joint research and development project which will ensure that Realheart TAH's most critical parts - the parts through which blood flows and therefore needs to be durable - are developed in collaboration with a company with many years of relevant expertise.

"We are very satisfied with the collaboration, which also releases resources for us and make it possible to focus on other component parts and preparation for the upcoming preclinical and clinical trials," says Azad Najar, CEO and founder of Realheart.

"We look forward to sharing our knowledge and experience in this exciting research project, so closely aligned to our own mission to sustainably improve patients' lives," comments Sven-René Friedel, Managing Director of Berlin Heart.

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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 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.