



US FDA Grants the BiVACOR Total Artificial Heart IDE Approval for First-in-Human Early Feasibility Study

Huntington Beach, CA/Gold Coast, Australia/Houston, TX [November 29, 2023] – BiVACOR, Inc., a clinical-stage medical device company developing a total artificial heart, today announced the United States Food and Drug Administration (FDA) has provided approval for The BiVACOR Total Artificial Heart (BTAH) to commence an investigational device exemption (IDE) for the first-in-human Early Feasibility Study (EFS).

The EFS will evaluate the safety and feasibility of BTAH as a bridge to a heart transplant in the treatment of subjects with biventricular heart failure. The EFS has ten hospital location options and will initially enroll three patients, one leading hospital being the Texas Heart Institute in Houston, TX. The study is anticipated to commence in 2024 and will pave the way for a subsequent pivotal study.

“I am eager to begin the BiVACOR Total Artificial Heart EFS to evaluate what I believe is a promising and potentially life-saving technology,” said Joseph Rogers, MD, National P.I. and CEO of the Texas Heart Institute. “The implantation of a TAH system is a potential treatment option for patients with heart failure who need support while on the heart transplant waiting list and for those who do not qualify for a transplant. The BTAH is designed to replace the function of the native heart completely. It is an impressive technology, and I am excited to see the potential of BTAH in treating patients with severe heart failure.”

The BiVACOR Total Artificial Heart is designed as the first long-term therapy dedicated for patients with severe biventricular heart failure as an implantable TAH based on rotary blood pump technology. Similar in size to an adult fist, it is designed to be small enough to be implanted in many women and some children yet capable of providing enough cardiac output to an adult male undergoing exercise. Using magnetic levitation technology, the same principle used in high-speed trains, the design includes left and right vanes positioned on a common rotor to form the only moving part, a magnetically suspended double-sided centrifugal impeller. Even though there are no valves or flexing ventricle chambers, the device is designed to create pulsatile outflow by rapidly cycling the rotational speed of the impeller. The non-contact suspension provides large blood gaps, which is expected to minimize blood trauma and eliminate mechanical wear to offer a durable, reliable, and biocompatible heart replacement.

“The FDA approval to begin The BiVACOR Total Artificial Heart EFS is a critical milestone for BiVACOR and is another validation of the remarkable work and accomplishments of the entire

BiVACOR team. This Device will provide a unique approach to help patients currently with limited clinical options”, said William Cohn, MD, Heart Surgeon at the Texas Heart Institute and BiVACOR Chief Medical Officer.

“We believe this study will build upon the already successful pre-clinical data we have and is expected to set up 2024 as a significant year of milestones for BiVACOR as we continue to build our database of evidence. I am incredibly proud of the unwavering hard work and dedication from our team and network around the globe for achieving this pivotal landmark in the clinical development of our TAH system,” said Daniel Timms, Ph.D., Founder and CTO of BiVACOR.

The BTAH is an investigational device limited by federal law for investigational use only. The initial focus of the EFS is planned to be for patients with biventricular heart failure who need a mechanical circulatory support device for a bridge to a transplant. It is envisioned that after the EFS, further studies will explore short-term and long-term destination therapy.

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About BiVACOR®

BiVACOR® is a clinical-stage medical device company developing the BiVACOR Total Artificial Heart, designed to be the first long-term therapy for patients with severe biventricular heart failure. The BTAH is designed to replace the native heart and address the global unmet need of patients with end-stage heart failure by providing a next-generation life-extending solution.

BiVACOR was founded in 2008 by a team of internationally renowned biomedical engineers and cardiac surgeons, including Founder and Chief Technical Officer Daniel Timms, Ph.D., and Chief Medical Officer William Cohn, MD, and is an international organization with operations in Huntington Beach, CA, Houston, TX, and Gold Coast, Australia.

Today, BiVACOR has a robust collaborative network that extends nationally and internationally and boasts a team of world-class engineers, medical specialists, and business executives fervently working to advance this ground-breaking technology. Core to BiVACOR and its culture is collaboration, working hard, and recognizing those around them.

Forward-looking statements

This press release contains forward-looking statements, including but not limited to statements related to the development, feasibility, efficacy, and performance of BTAH and its positive effects on potential patients. These forward-looking statements are based on BiVACOR’s current expectations and inherently involve significant risks and uncertainties. BiVACOR undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

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