The Texas Heart Institute Provides BiVACOR® Total Artificial Heart Patient Update

Successful first-in-human bridge to heart transplant with revolutionary valveless artificial heart

Houston, Texas, July 26, 2024 – The Texas Heart Institute (THI), a globally renowned cardiovascular health center, and BiVACOR®, a leading clinical-stage medical device company, are pleased to provide an update on the condition of the first patient to receive the BiVACOR Total
Artificial Heart (TAH) implant on July 9, as part of the U.S. Food and Drug Administration (FDA) Early Feasibility Study (EFS). On July 17, eight days following the BiVACOR TAH implant, a donor heart became available and was transplanted into the patient, removing the BiVACOR TAH and meeting a goal of the EFS to evaluate the safety and performance of the BiVACOR TAH as a bridge-to-heart-transplant solution for patients living with severe biventricular heart failure or univentricular heart failure in which left ventricular assist device support is not recommended.

“It is rewarding to see this result and having the BiVACOR TAH perform as expected,” said Dr. Joseph Rogers, President and Chief Executive Officer of The Texas Heart Institute and National Principal Investigator of the research. “This successful outcome is a testament to the years of dedication and innovation invested in this project. The patient continues to do well through their recovery, demonstrating the potential impact of the BiVACOR TAH on the future of heart failure treatment.”

The successful implantation and bridge-to-heart transplant of BiVACOR’s TAH highlights the potential of this innovative technology to address critical challenges in cardiac care, such as long transplantation waitlists. BiVACOR and The Texas Heart Institute remain committed to advancing the field of cardiac medicine and improving outcomes for patients worldwide.

“This is an amazing advancement as the BiVACOR TAH may offer hope for countless patients who suffer from end-stage heart failure. This device may serve as a life-saving bridge to a heart transplant; future studies may prove its potential as a long-term pump that can effectively serve as a total replacement for a patient’s heart,” explained Dr. Alexis Shafii, Surgical Director of Heart Transplantation at Baylor St. Luke’s Medical Center and Associate Professor of Surgery, Cardiotoracic Transplant & Circulatory Support at Baylor College of Medicine. “We anticipate the BiVACOR TAH may eventually save numerous lives, as well as improve the quality of life for patients who otherwise have no alternative therapy available.”

Heart failure is a global epidemic affecting at least 26 million people worldwide, 6.2 million adults in the U.S., and its prevalence is increasing. Heart transplantations are reserved for those with severe heart failure and are limited to fewer than 6,000 procedures per year globally. Consequently, the U.S. National Institutes of Health estimated that up to 100,000 patients could immediately benefit from a ventricular assist device (VAD) or TAH, and the European market is similarly sized.

The successful implantation of the BiVACOR TAH marks a new era in cardiac care, offering hope to
thousands of patients awaiting heart transplants.

###

**About the BiVACOR Total Artificial Heart (TAH)**

The BiVACOR TAH, developed by founder Dr. Daniel Timms, represents a paradigm shift in artificial heart design. The size of the BiVACOR TAH is suitable for most men and women (body surface area >1.4 m$^2$). Despite its small size, the BiVACOR TAH is capable of providing enough cardiac output for an adult male undergoing exercise. Using magnetic levitation (MAGLEV) technology, the same principle used in high-speed trains, the BiVACOR TAH features a unique pump design with a single moving part: a magnetically suspended dual-sided rotor with left and right vanes positioned within two separate pump chambers, forming a double-sided centrifugal impeller that propels blood from the respective pump chambers to the pulmonary (lung) and systemic (body) circulations. The TAH has no valves or flexing ventricle chambers, with MAGLEV making pulsatile outflow possible by rapidly cycling the pump’s rotor. The non-contact suspension of the rotor via MAGLEV is designed to eliminate the potential for mechanical wear and provide large blood gaps that minimize blood trauma, offering a durable, reliable, and biocompatible heart replacement.

**About The Texas Heart Institute**®

The Texas Heart Institute (THI) is an independent, nonprofit organization with the mission of improving cardiovascular health today through trailblazing research, thought leadership, education, and patient care. Located within the Texas Medical Center in Houston, Texas, and founded in 1962 by renowned cardiac surgeon Dr. Denton Cooley, THI performed the first successful heart transplant and total artificial heart implant in the United States. Since then, its physicians and surgeons have remained recognized as worldwide leaders in diagnosing and treating even the most complex cardiovascular conditions. Research programs at THI continue pushing cardiovascular science’s boundaries by translating laboratory discovery into patient care. THI has been ranked among the top cardiovascular centers in the United States by US News & World Report for over 30 years. THI has an equity ownership interest in BiVACOR. [www.texasheart.org](http://www.texasheart.org) [@texasheartinstitute](http://@texasheartinstitute)
About BiVACOR®

BiVACOR® is a clinical-stage medical device company pioneering the development of a long-term therapy for patients with biventricular heart failure. At the heart of this innovation is the BiVACOR TAH, a titanium implantable biventricular rotary blood pump. This patented device utilizes revolutionary MAGLEV technology to replace both ventricles of a failing heart. Under the expert direction of its founder and TAH inventor, Daniel Timms, PhD, CEO, Jim Dillon and the guidance of two luminaries in cardiovascular surgery, William E. Cohn, MD, and O.H. (Bud) Frazier, MD, the BiVACOR TAH is currently undergoing an FDA-approved first-in-human EFS. Headquartered in Huntington Beach, California, with clinical offices in Houston, Texas, and international offices in Gold Coast, Australia, BiVACOR is committed to addressing the global unmet need of patients with end-stage heart failure awaiting transplant by providing the next generation of life-extending solutions. For more information, visit bivacor.com.

About Baylor College of Medicine

Baylor College of Medicine (www.bcm.edu) in Houston is recognized as a health sciences university and is known for excellence in education, research and patient care. Baylor is a top-ranked medical school and listed 20th among all U.S. medical schools for National Institutes of Health funding and No. 1 in Texas. Located in the Texas Medical Center, Baylor has affiliations with seven teaching hospitals and jointly owns and operates Baylor St. Luke’s Medical Center, part of St. Luke’s Health. Currently, Baylor has more than 3,000 trainees in medical, graduate, nurse anesthesia, physician assistant, orthotics and genetic counseling as well as residents and postdoctoral fellows. Follow Baylor College of Medicine on Facebook (http://www.facebook.com/BaylorCollegeOfMedicine) and Twitter (http://twitter.com/BCMHouston).

About Baylor St. Luke’s Medical Center

Baylor St. Luke’s Medical Center is an 881-bed quaternary care academic medical center that is a joint venture between Baylor College of Medicine and St. Luke’s Health. Located in the Texas Medical Center, the hospital is the home of the Texas Heart Institute, a cardiovascular research and
education institution founded in 1962 by Denton A. Cooley, MD. The hospital was the first facility in Texas and the Southwest designated a Magnet hospital for Nursing Excellence by the American Nurses Credentialing Center, receiving the award four consecutive times. Baylor St. Luke’s also has three community emergency centers offering adult and pediatric care for the Greater Houston area.

**About Texas Medical Center**

**Texas Medical Center** — the largest medical city globally—is at the forefront of advancing life sciences. Home to the brightest minds in medicine, TMC nurtures cross-institutional collaboration, creativity, and innovation among its 106,000-plus employees. With a campus of more than 50 million square feet, TMC annually hosts 10 million patients, performs over 180,000 surgeries, conducts over 750,000 ER visits, serves close to 14,000 heart surgeries, and delivers over 25,000 babies. Beyond patient care, TMC is pushing the boundaries of clinical research across its extensive network of partner institutions daily, pioneering effective health policy solutions to address today’s complex health care issues, and cultivating cutting-edge digital health applications and medical devices.
The Texas Heart Institute Implants BiVACOR® Total Artificial Heart