Thoratec Announces FDA Approval To Commence REVIVE-IT Study Utilizing HeartMate II@

The Associated Press

Thoratec Corporation (NASDAQ: THOR), a world leader in device-based mechanical circulatory support (MCS) therapies to save, support and restore failing hearts, today announced that the U.S. Food and Drug Administration (FDA) has granted an Investigational Device Exemption (IDE) to commence the REVIVE-IT study utilizing the HeartMate II@ Left Ventricular Assist System.

REVIVE-IT (Randomized Evaluation of VAD InterVEntion before Inotropic Therapy) is a prospective, randomized, controlled trial designed to compare the use of the HeartMate II LVAD with optimal medical management (OMM) in patients with New York Heart Association (NYHA) Class III heart failure. This feasibility study is intended to provide initial scientific evidence regarding the potential advantages of MCS therapy in treating earlier-stage, less ill heart failure patients who are currently not indicated for LVAD support.

"IDE approval represents a significant milestone for REVIVE-IT, and we are excited to move forward with this important study, which will allow us to examine the use of LVAD technology earlier in the spectrum of heart failure," said Keith Aaronson, M.D., M.S., medical director of the heart transplant program and Center for Circulatory Support at the University of Michigan Cardiovascular Center (UM-CVC). Aaronson is serving as a co-principal investigator for REVIVE-IT, along with Francis D. Pagani, M.D., Ph.D., surgical director of the heart transplant program and Center for Circulatory Support at the UM-CVC, to whom the REVIVE-IT IDE was issued, and Robert Kormos, M.D., director of the University of Pittsburgh Medical Center (UPMC) Artificial Heart Program and co-director of the UPMC Heart Transplantation Program.

The REVIVE-IT pilot study is designed to enroll up to 100 patients in NYHA Class III heart failure from leading heart failure programs across the U.S. Patients will receive either the HeartMate II LVAD or OMM (drug therapy). The primary endpoint for the study is a composite measure of survival, freedom from disabling stroke, and improvement in functional outcomes, as measured by the six-minute walk test.

"REVIVE-IT will evaluate the use of the HeartMate II in heart failure patients currently not indicated for LVAD support. These patients suffer from highly impaired quality of life and functional capacity, but their disease has not yet advanced to the point of more serious consequences, such as organ damage or immobility," stated Dr. Kormos from UPMC.

The National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health and Thoratec are sponsoring the REVIVE-IT study, through a $5 million contract from the NHLBI and a funding commitment of up to $11 million from Thoratec. The NHLBI is providing executive and scientific guidance on the conduct

of the study.

"We appreciate the leadership demonstrated by the NHLBI in this pioneering study, as well as our partnership with Thoratec," said Dr.

Pagani. "The HeartMate II device has been extensively studied for long-term support of advanced heart failure patients and has a very well-defined efficacy and safety profile. We look forward to exploring its utilization and potential benefits, including extended survival and improved functional status, in earlier-stage patients." In addition to REVIVE-IT, Thoratec maintains a firm commitment to the completion of the ongoing ROADMAP (Risk Assessment and Comparative Effectiveness Of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients) study. "ROADMAP and REVIVE-IT are complementary studies which together should advance the field's understanding of LVAD therapy in Class III and earlier-stage Class IV heart failure patients," stated David Farrar, Ph.D., Vice President, Research and Scientific Affairs at Thoratec. ROADMAP is a post-market study of the HeartMate II, involving ambulatory advanced heart failure patients who are not yet dependent on intravenous inotropic support and are typically categorized as INTERMACS profiles 4-6, within the existing FDA-approved indication for Destination Therapy, whereas REVIVE-IT will include Class III patients currently not approved for LVAD support. As of the end of 2012, 90 patients have been enrolled in ROADMAP, and Thoratec expects the full cohort of 200 patients to be enrolled by the end of 2013.

"Thoratec's mission is to advance the treatment of heart failure and the field of mechanical circulatory support. To that end, we are pleased to partner with preeminent VAD programs across the U.S., under the leadership of the UM-CVC and UPMC, in the REVIVE-IT study," commented Gary F. Burbach, President and Chief Executive Officer of Thoratec.

For more information regarding the REVIVE-IT study, visit http://clinicaltrials.gov ID# NCT01369407. Given the change in sponsorship of the study, however, some information on this website is subject to change, including information about the study device as well as the investigational sites that will be participating in the study. For more information regarding the ROADMAP study, visit http://clinicaltrials.gov ID# NCT01452802.

About HeartMate II The HeartMate II is intended for a broad range of advanced heart failure patients and is the only continuous-flow left ventricular assist device (LVAD) approved by the FDA for both Bridge to Transplantation and Destination Therapy. The device is designed to provide long-term cardiac support, pumping up to 10 liters of blood per minute for full support of the circulation, or to supplement the native function of the patient's left ventricle. The HeartMate II is placed just below the diaphragm and is connected to the left ventricle, returning blood flow to the aorta, the main artery that carries oxygenated blood to the entire body. With only one moving part, a continuously spinning rotor, HeartMate II is designed to provide exceptional reliability. An external, wearable system that includes a small controller and two batteries is attached by a percutaneous driveline. More than 200 peer-reviewed publications have featured studies regarding the HeartMate II, far

exceeding the volume of published data on all other LVADs combined. To date, over 13,000 patients have been implanted with the HeartMate II, including over 5,500 currently on support.

About Thoratec Thoratec is the world leader in mechanical circulatory support with the broadest product portfolio to treat the full range of clinical needs for patients suffering from advanced heart failure. The company's products include the HeartMate LVAS and Thoratec VAD, with more than 20,000 devices implanted in patients suffering from heart failure. Thoratec also manufactures and distributes the CentriMag and PediMag / PediVAS product lines. Thoratec is headquartered in Pleasanton, California. For more information, visit www.thoratec.com.

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Many of the preceding paragraphs, particularly but not exclusively those addressing guidance for fiscal 2012 financial results or future performance contain forward-looking statements within the meaning of Sections 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements can be identified by the words, "believes," "views," "expects," "plans," "projects," "hopes," "could," "will," and other similar words. Actual results, events or performance could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond Thoratec's control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to regulatory approvals, the development of new products and new markets including Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of Thoratec products, the effects of FDA regulatory requirements, our ability to address issues raised by FDA inspections adequately and on a timely basis without a resulting recall of products or interruption of manufacturing or shipment of products, the effects of healthcare reimbursement and coverage policies, and the effects of competition.

Forward-looking statements contained in this press release should be considered in light these factors and those factors discussed from time to time in Thoratec's public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, "Risk Factors," in Thoratec's most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other SEC filings. These forward-looking statements speak only as of the date hereof. Thoratec undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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