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HeartMate II® Pivotal Clinical Trial Fact Sheet

Pivotal Clinical Trial Overview:

The Thoratec® HeartMate II Left Ventricular Assist System (LVAS) pivotal clinical trial incorporates a number of unique elements, including the use of the device for both Bridge-to-Transplantation (BTT) and Destination Therapy (DT). This is the first time the FDA has approved a clinical trial with both indications in one protocol.

BTT Study

The BTT pivotal clinical trial was a non-randomized trial in which all subjects received the HeartMate II LVAS and were compared to an objective performance criterion (OPC). Study enrollment ended with FDA approval in April 2008.

DT Study*

The DT pivotal clinical trial is a prospective, randomized evaluation of the HeartMate II LVAS. Patients will be randomly assigned to treatment with the HeartMate® XVE LVAS (control group) or to treatment with the HeartMate II LVAS. The DT arm of the study involves 200 total patients at up to 40 sites in its primary cohort, randomizing the HeartMate II LVAS to the HeartMate XVE LVAS on a 2-1 basis, respectively.

Primary Study Objectives:

- To determine the safety and efficacy of the HeartMate II LVAS as a BTT in advanced heart failure patients who are cardiac transplant listed but at imminent risk of dying.
- To determine the safety and efficacy of the HeartMate II LVAS as DT in advanced heart failure patients who do not qualify for cardiac transplantation.

Study Population:

BTT Patients–Enrollment for BTT was limited to transplant-listed, advanced heart failure patients. The patients also had to meet specific inclusion and exclusion criteria.

DT Patients–The HeartMate II LVAS will be implanted in patients who were not candidates for cardiac transplantation and met specific inclusion and exclusion criteria. The criteria of the trial allow the DT arm to enroll patients who are not yet as ill as those in the original REMATCH trial, even providing for inclusion of some late New York Heart Association (NYHA) Class IIIB heart failure patients.

Both the BTT and DT arms allow for hospital discharge, based on the patient's condition.

Primary Endpoints:

- The primary outcome measure for the HeartMate II BTT trial was the rate of survival to transplantation or 180 days.
- The primary endpoint of the HeartMate II DT* trial will be two-years, which includes patient survival, rate of neurological events and device reliability.

Special Considerations:

- The DT protocol also includes a separate study group of small patients who, because of their body size, could not be randomized to the larger HeartMate XVE LVAS. These patients may receive the HeartMate II device without randomization.
- Cross-over patients will be allowed in the trial, enabling those DT patients currently being supported by Thoratec's HeartMate XVE LVAS to be implanted with the HeartMate II device on an elective basis in the event of the need for device replacement.

Trial Timeline:

- Pilot Trial: The pilot trial for the HeartMate II LVAS began in November 2003 and consisted of 46 study patients at 15 centers. The pilot trial featured encouraging early results, including 11 patients supported for more than one year and three patients supported for more than two years.
- Pivotal Trial: The HeartMate II LVAS pivotal clinical trial was approved by FDA on Feb. 18, 2005, and successfully enrolled patients at a record pace. The trial continues to enroll additional patients under a Continued Access Protocol (CAP) approval for the Destination Therapy arm.
- Conformité Européenne (CE) Mark: The HeartMate II LVAS received European CE Mark in November 2005, allowing for commercial sale of the device in Europe.
- Pre-Market Approval: In December 2006, Thoratec completed the submission of a Pre-Market Approval (PMA) seeking approval for a bridge-to-transplantation (BTT) indication.
- As of early 2008, there were more than 365 pilot and pivotal trial patients who had been supported for a year or longer, with 50 of

them supported for two years or more.

- FDA Approval: In April 2008, Thoratec received FDA approval for the commercialization of HeartMate II in the U.S. as Bridge-to-Transplantation.
- In April 2009, Thoratec filed a PMA Supplement to provide data on adjunctive cohorts totaling an additional 409 patients, including those who had originally been supported by an XVE who elected to receive a HeartMate II based on the need for device replacement.
- In May 2009, Thoratec received FDA approval for a new 30-patient CAP.
- As of July 24, 2009, enrollment in the DT arm reached 795 patients. In total, 1,149 patients have been enrolled in the pivotal trial, by far the largest VAD study ever conducted.

Product: The HeartMate II is a mechanical circulatory support (MCS) device intended for a broad range of advanced-stage heart failure patients. An axial flow device, the HeartMate II can pump up to 10 liters of blood per minute, the full output of a healthy heart, and is designed to provide long-term cardiac support. The device is implanted alongside a patient's native heart and takes over the pumping ability of the weakened heart's left ventricle. It is easier to implant than prior devices, and with only one moving part, the HeartMate II is designed to provide exceptional reliability and improved patient quality of life. The device is designed to have a much longer functional life than the previous generation of devices and to operate more simply and quietly.

DEVICE	INDICATION	STATUS
HeartMate II LVAS	• Bridge-to-Transplantation	• Received Conformité Européenne (CE) Mark in November 2005. • Completed the submission of a Pre-Market Approval (PMA) seeking approval for bridge-to-transplantation (BTT) in December 2006. • Received FDA approval in April 2008.
	• Destination Therapy*	• Received Conformité Européenne (CE) Mark authorization in November 2005. • Currently in clinical trials in the U.S. FDA. Approval anticipated in the first half of 2010.

** CAUTION: For Destination Therapy, the HeartMate II is an investigational device limited by federal (U.S.A.) law to investigational use.*

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