



International Society for Heart & Lung Transplantation
www.isHLT.org

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ROADMAP STUDY DEMONSTRATING BENEFITS OF HEARTMATE II® LEFT VENTRICULAR ASSIST DEVICE PRESENTED AT INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION

NICE, FR April, 17, 2015 – Today at the [35th Annual International Society for Heart and Lung Transplantation \(ISHLT\) Meeting & Scientific Sessions](#), researchers presented one-year results from the ROADMAP Study (Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients). The study evaluated the effects of Thoratec Corporation's (NASDAQ: THOR) HeartMate II® Left Ventricular Assist Device (LVAD) compared with optimal medical management patients. Results from the multi-center, non-randomized, controlled, observational study indicate that the HeartMate II enhanced the long-term outcomes of patients with advanced heart failure. One-year survival rate was 80 percent in the HeartMate II group, compared with 64 percent for medically managed patients on an as-treated basis.

The HeartMate II is aimed to restore blood flow, improve survival, functional status and quality of life, and the data gathered from the ROADMAP study revealed significant improvement using HeartMate II support as measured by changes in six minute walk distance, health related quality of life and [New York Heart Association](#) (NYHA) classification. At one year of follow up, 39 percent of patients in the HeartMate II group increased their walking distance by 75 meters in the six minute walk test, compared with 21 percent of patients on optimal medical management, demonstrating a statistically significant difference ($p=0.017$).

"LVADs continue to prove to be a viable treatment option for patients with heart failure," said Andreas Zuckermann, MD, ISHLT 2015 Scientific Program Committee Chair. "The ROADMAP trial is important to ISHLT as LVAD research and therapy continue to show positive results."

Within the LVAD group, 77 percent of patients at 12 months improved to NYHA Class I or II status compared with only 29 percent in NYHA Class II and no Class I patients in the optimal medical management group. Adverse events in total with HeartMate II remained similar to rates observed in the Destination Therapy clinical trial, with bleeding the most frequent adverse event. Additionally, 30-day mortality within the LVAD group was only one percent, equivalent to optimal medical management.

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HEART FAILURE

Heart failure is a widespread, chronic condition that develops when the heart muscle weakens and is unable to pump a sufficient amount of blood throughout the body. Heart failure worsens over time and is typically caused by persistent high blood pressure, heart attack, valve disease and other forms of heart disease or birth defects. Left untreated, the lack of adequate blood flow causes the organs to progressively fail, resulting in numerous medical complications that deteriorate a person's quality of life and often leads to death.

According to the American Heart Association (AHA) and the Heart Failure Society of American (HSFA), about six million Americans are living with Heart failure, and 670,000 new cases are diagnosed each year.

The International Society for Heart and Lung Transplantation (ISHLT) is a not-for-profit professional organization with more than 2,700 members from over 45 countries dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies via research, education and advocacy. For more information, visit www.isHLT.org.

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