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

Media Contact: Stephen Chavez
Phone: +1 (210) 310-8215
E-mail: stephen.d.chavez@gmail.com

HeartMate 3 CE Mark Trial 1-Year Results Presented at ISHLT 36th Annual Meeting and Scientific Sessions in Washington, D.C.

Washington, D.C. (April, 28, 2016) – At today's opening plenary session at the 36th Annual International Society for Heart and Lung Transplantation (ISHLT) Meeting & Scientific Sessions, Thomas Krabatsch, MD, PhD of Deutsches Herzzentrum, Berlin, Germany presented data on the HeartMate3™ CE Mark Trial. The HeartMate3™ device is a left ventricular assist device for the treatment of advanced heart failure, and is the first in-man trial of the device. Using the Kaplan Meier Survival guidelines, HeartMate3™ demonstrated Destination Therapy (DT) and Bridge-to-Transplant (BTT) survival 80% at one year. Additionally, no pump malfunctions, hemolysis or pump thrombosis was demonstrated.

One year results show a decline in major complications including gastrointestinal bleeding, infection, strokes and right heart failure. Strokes were reduced by 50% (6 events, 3 procedural related, to only three in the second six months. GI bleed adverse events were reduced by 50% (four during first six months and two in the second) with the majority of the event occurring in destination therapy patients. HeartMate3™ CE Mark trial patients will continue to be followed through year two.

Andrew J Fisher, Program Chair for the 2016 ISHLT Annual Meeting said " This advancement in device technology in mechanical circulatory support is of huge potential benefit to patients with advanced heart failure. We are delighted to have the results of the groundbreaking HeartMate3™ trial presented at the ISHLT, the world's premier meeting for professionals involved in the management of patients with advanced heart failure, who require mechanical circulatory support."

Last September six month results of the HeartMate3™ CE Mark trial met the primary endpoint, a comparison of six-month survival to a performance goal resulting from the INTERMACS registry, with six-month survival of 92% surpassing the performance goal. Comparing to results from the previous version of the device, HeartMate II® INTERMACS derived performance goal of 88%. INTERMACS is the United States national registry for patients receiving mechanical circulatory support device therapy to treat advanced heart failure.

Further HeartMate3™ studies are on the horizon from the MOMENTUM 3 Study and ELEVATE Registry.

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.

-More-

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.

About ISHLT

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.

###