St. Jude Medical Announces CE Mark Approval for the HeartMate 3 Left Ventricular Assist System

With approval, the HeartMate 3 System offers physicians in Europe the most advanced ventricular assist technology available to support the management of patients with advanced stage heart failure.

ST. PAUL, Minn. – October 12, 2015 – St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the company has received CE Mark approval for the HeartMate 3™ Left Ventricular Assist System (LVAS), a cardiac support option for advanced heart failure patients who are awaiting transplantation, are not candidates for heart transplantation, or are in myocardial recovery.

“The advanced heart failure medical community has eagerly anticipated the expected clinical improvements with the HeartMate 3 system and looks forward to its broad adoption throughout Europe,” said Professor Friedhelm Beyersdorf, Medical Director, Department of Cardiovascular Surgery, Heart Center Freiburg University.

The HeartMate 3 system is the first commercially approved centrifugal-flow left ventricular assist device (LVAD) utilizing Full MagLev™ (fully magnetically-levitated) technology, which allows the device’s rotor to be “suspended” by magnetic forces. This design aims to reduce trauma to blood passing through the pump and improve outcomes for patients.

The device is implanted above the diaphragm, immediately next to the native heart, and is attached to the aorta leaving natural circulation in place while providing all of the energy necessary to propel blood throughout the body.

CE Mark approval for the HeartMate 3 system was based on data from the HeartMate 3 CE Mark clinical trial, which met its primary endpoint and demonstrated a 92 percent six month survival rate; the best six month survival rate to date to be documented in an LVAD CE Mark clinical study. St. Jude Medical expects a limited market release across Europe to begin immediately, with additional market releases taking place throughout 2016.

“We are pleased to announce CE Mark approval of the next-generation HeartMate 3 system, which has been proven through the HeartMate 3 CE Mark study to show high survival rates, material improvements in functional status, and very low adverse event rates highlighted by zero pump thrombosis events,” said
Eric Fain, M.D., group president at St. Jude Medical. “Heart failure remains one of the most costly epidemic diseases in the world, and the HeartMate 3 system is critical to supporting physicians managing the care of patients battling such a complex and challenging condition.”

Unlike artificial hearts, LVADs don’t replace the heart. Instead, the small implantable devices supplement the pumping function of the heart in patients whose hearts are too weak to pump blood adequately on their own. LVADs can benefit patients either awaiting transplant, known as bridge to transplant therapy, or can be used as a “destination therapy” for heart failure patients who need years of cardiac support but who are not candidates for transplantation.

The design of the HeartMate 3 LVAD includes large, consistent blood flow gaps over a wide range of device operation levels, designed to reduce blood trauma. The artificial pulse technology is designed to further reduce adverse patient events including combatting the formation of thrombus in the device.

The HeartMate 3 CE Mark clinical trial, which concluded in November 2014, enrolled 50 patients at 10 hospitals in six countries outside the U.S. Enrollment included both bridge-to-transplant and destination therapy patients in New York Hospital Association Class IIIb or IV heart failure. The study met its primary endpoint by demonstrating a six month survival rate of 92 percent with the HeartMate 3 LVAS, as well as overall adverse event rates that were either lower or consistent with expectations for severely ill and complex patients requiring LVAD support. In the U.S., the HeartMate 3 system is in an ongoing IDE trial. The MOMENTUM 3 IDE trial, the largest of its kind, remains ongoing and will enroll more than 1,000 patients.

About the HeartMate 3 Left Ventricular Assist System
The HeartMate 3 LVAS includes a centrifugal blood pump that is implanted directly onto a patient’s native heart and designed to take over the pumping ability of the weakened heart’s left ventricle, which is responsible for pumping oxygen-rich blood from the lungs throughout the body. The device is implanted above the diaphragm, immediately next to the native heart, and is attached to the aorta (the main artery that feeds blood into the entire body), leaving natural circulation in place while providing all of the energy necessary to propel blood throughout the body. The patient wears an external, wearable controller and battery system that powers the pump. The HeartMate 3 LVAS can pump up to 10 liters of blood per minute.

About St. Jude Medical
St. Jude Medical is a global medical device manufacturer dedicated to transforming the treatment of some of the world’s most expensive epidemic diseases. The company does this by developing cost-effective medical technologies that save and improve lives of patients around the world. Headquartered in St. Paul, Minn., St. Jude Medical has four major clinical focus areas that include cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com or follow us on Twitter @SJM_Media.

Forward-Looking Statements
This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management’s current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company’s control and the risk factors and other cautionary statements described in the Company’s filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company’s Annual Report on Form 10-K for the fiscal year ended January 3, 2015 and Quarterly Report on Form 10-Q for the fiscal quarter ended July 4, 2015. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.