Abbott Introduces HeartMate 3 Left Ventricular Assist System - The Latest Milestone In Therapy For Advanced Heart Failure Patients

- Abbott pioneered the evolution of heart pumps; U.S. approval of the HeartMate 3™ system further broadens its market-leading heart failure portfolio

- The HeartMate 3™ system offers significant advancements, including a pump that is designed to reduce complications while improving survival and quality of life for patients with advanced heart failure

ABBOTT PARK, Ill., Aug. 28, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) announced today it has received U.S. Food and Drug Administration (FDA) approval for its Full MagLev™ HeartMate 3™ Left Ventricular Assist System (also known as an LVAD). The HeartMate 3 system provides a new option for physicians managing advanced heart failure patients in need of short-term hemodynamic support (bridge-to-transplant or bridge to myocardial recovery). The system also provides patients living with their device new benefits that embody the evolution of left ventricular assist device (LVAD) therapy, such as improved blood flow in a pump that uses full magnetic levitation to reduce trauma to blood passing through the system.

More than 5.7 million people in the U.S. suffer from heart failure and approximately 915,000 new patients are diagnosed with the disease each year. For advanced heart failure patients who can no longer rely on earlier stage treatment options, an LVAD can help their weakened heart pump blood through the body and provide crucial support as patients await further treatment, including heart transplants. For patients who are not candidates for heart transplants or who will live with their device long term, Abbott continues to offer HeartMate II™, the world's most widely used LVAD, which is indicated for long-term or "destination therapy."

As the pioneer and global leader in LVAD therapy, Abbott designed the HeartMate 3 system to take LVAD therapy further and provide physicians new benefits for their patients. In developing the HeartMate 3 system, Abbott reduced the system's size while reimagining how blood passes through an LVAD. The HeartMate 3 system deploys Full MagLev technology to reduce trauma to the blood passing through the pump while optimizing blood flow. Improved blood flow can help minimize complications – such as pump thrombosis – that can be associated with LVAD therapy, ultimately improving the patient's quality of life.

"Heart failure is a crippling and costly disease and the HeartMate 3 system is a big stride forward in giving patients the opportunity to return to better quality lives. Abbott is the pioneer and global leader in LVAD therapy and offers the broadest heart failure portfolio on the market to help physicians manage their patients from early to end-stage heart failure," said Mark D. Carlson M.D., divisional vice president and chief medical officer of Abbott's Cardiac Arrhythmias and Heart Failure business.

A System Proven Through Clinical Data
U.S. approval of the HeartMate 3 system was supported by the MOMENTUM 3 clinical study. In that study, patients who received a HeartMate 3 system had a significant improvement in their heart failure status, an 83 percent increase in their walk distance and a 68 percent improvement in quality of life at six months. Patients receiving HeartMate 3 also had an 86 percent survival rate with freedom from disabling stroke and reoperation to replace the pump at six months.

"In the MOMENTUM 3 study, the HeartMate 3 system had no instances of suspected or established blood clotting within the pump at six months, which is a major milestone for those of us working tirelessly to improve clinical outcomes for patients living with advanced heart failure," said Mandeep R. Mehra, M.D., medical director of Brigham and Women's Hospital Heart and Vascular Center in Boston.

The MOMENTUM 3 study includes more than 1,000 patients with New York Heart Association (NYHA) Class IIIB or IV heart failure. Patients were followed for a short-term endpoint of six months and continue to be followed for a long-term endpoint of two years.

Setting a New Standard in LVAD Therapy
In traditional LVAD pumps, plasma, white blood cells and oxygen-rich red blood cells passing through a mechanical pump can be damaged by the system's bearings. While Abbott's previous generation system – the HeartMate II – made great strides in offering patients a more reliable pump. The HeartMate 3 system builds on this reliability and was designed to further reduce damage to the patient's blood.

The HeartMate 3 system can pump up to 10 liters of blood per minute and is the only commercially-approved continuous flow implantable left ventricular assist system to utilize Full MagLev™ (fully magnetically-levitated) Flow technology, which allows the device's rotor to be "suspended" by magnetic forces—rather than bearings—with the goal of being able to more gently pass the blood cells through the pump. The magnets keep the rotor in place by calibrating tens of thousands of times per second to ensure it stays suspended and centered within the pump, no matter the speed settings used by a physician. This ensures the pump is performing effectively while continuing to deliver the best patient therapy possible.

The HeartMate 3 system also uses the industry's widest pump pathway, designed so the blood cells are not damaged when passing through. The system also relies on a built-in "pulse" programmed to help ensure the blood continues to move through without becoming static, therefore reducing the risk of blood clot formation.

The HeartMate 3 system includes the LVAD pump as well as the rest of the components that are crucial to making this technology work—an external, wearable controller, driveline and battery system that powers the pump. The HeartMate 3 System

was CE Mark approved in Europe for both short-term and long-term support in October 2015.

About Abbott:
At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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