Abbott's In-Development Fully Implantable Heart Pump System Earns FDA's Breakthrough Device Designation

ABBOTT PARK, Ill., Feb. 4, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the company has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) for its in-development Fully Implantable Left Ventricular Assist System (FILVAS). The FDA launched the Breakthrough Devices Program in 2018 to help expedite the development and review of submissions for technology that offers significant advantages over existing approved products.

Approximately 6.2 million people in the U.S. are living with heart failure. Because this is a progressive disease, more than 600,000 people each year reach an advanced stage where traditional therapies, such as medication and cardiac resynchronization therapies, no longer work.

"As the leader in heart failure management, a fully implantable heart pump has been our vision for the tens of thousands of people who progress into advanced heart failure each year," said Michael Pederson, senior vice president for Abbott's electrophysiology and heart failure division. "The potential for a fully implantable system would mean more freedom and a greater quality of life because there are no external components to be carried everywhere. These advances underscore Abbott's long-standing commitment to develop innovative devices that allow those with heart failure to live their best lives."

Heart pumps are small, implantable mechanical devices that pump blood throughout the body in people living with advanced heart failure. Those living with a heart pump are either waiting for a heart transplant or are not candidates for a heart transplant, and need the life-saving device to pump blood from their heart to the rest of their body. Currently, left ventricular assist devices are implanted into the body and then powered using an external battery pack or charging port.

Abbott's FILVAS is in research and development and is not available for sale anywhere in the world.

About Abbott's Heart Failure Portfolio
Abbott is pioneering heart failure disease management with innovative solutions like the CardioMEMS HF System, ground-breaking quadripolar pacing technology, our first-to-market MultiPoint™ pacing technology, and our HeartMate 3 LVAD. Abbott's HeartMate 3 heart pump is for advanced heart failure patients who are awaiting transplantation or are not candidates for heart transplantation. It is the first commercially approved (CE Mark and FDA approved) LVAD with Full MagLev™ 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. In the largest LVAD trial in the world, HeartMate 3 LVAD showed a survival rate of 79% at two years. Abbott collaborates with heart failure specialists, clinicians and advocacy partners to provide innovative, cost-effective solutions that help reduce hospitalizations and improve patient quality of life for heart failure patients around the world.

For important safety information, visit: abbott.com/isi.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

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For further information: Abbott Media: Kristi Warner (651) 756-2085; Abbott Financial: Mike Comilla (224) 668-1872

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