

ABBOTT'S HEARTMATE 3 HEART PUMP NOW FDA APPROVED FOR ADVANCED HEART FAILURE PATIENTS NOT ELIGIBLE FOR A HEART TRANSPLANT

- Advanced heart failure patients who will live with their device for the rest of their life now have access to a heart pump backed by the industry's strongest long-term data
- HeartMate 3 offers significant advancements for patients, including a pump designed to reduce complications while improving survival and quality of life

ABBOTT PARK, Ill., Oct. 19, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the [HeartMate 3™ Left Ventricular Assist Device](#) (LVAD) has received U.S. Food and Drug Administration (FDA) approval as a destination therapy for people living with advanced heart failure. With the approval, physicians can now offer the HeartMate 3 system to patients not eligible for a transplant who will live with their device for the rest of their lives.

More than 5.7 million Americans suffer from heart failure, and there are approximately 915,000 new patients diagnosed with the disease annually. For advanced heart failure patients who can no longer rely on earlier stage treatment options, LVAD's take the workload off a weakened heart by pumping blood through the body—providing crucial, life-saving support for patients awaiting a heart transplant or for those not able to receive one.

"Approximately a quarter of a million people are living with advanced heart failure, and many of these people will need a heart transplant; however, only a few thousand will receive a new heart," said Nir Uriel, M.D., director of Heart Failure, Transplant and Mechanical Circulatory Support at the University of Chicago Medicine. "The destination therapy approval for Abbott's HeartMate 3 device now gives these patients new hope that they can receive a heart pump clinically proven to mitigate challenges we've historically confronted with this therapy—stroke and blood clotting—while also offering survival rates on par with transplant."

In developing the HeartMate 3 system, Abbott set a new standard in LVAD therapy, reducing the system's size while reimagining how blood passes through a heart pump. The HeartMate 3 pump utilizes technology known as [Full MagLev™ \(fully magnetically-levitated\) Flow](#), which reduces trauma to the blood passing through the pump while improving flow.

"We partner with physicians to holistically develop therapies that benefit patients and achieve better outcomes," said Mike Pederson, senior vice president of Abbott's Cardiac Arrhythmias and Heart Failure business. "The unique design of the HeartMate 3 LVAD—with its Full MagLev Technology—takes an established innovation and improves upon it in meaningful ways to help people with advanced heart failure live fuller lives."

The HeartMate 3 system's U.S. approval was supported by clinical data from the [MOMENTUM 3 trial](#). During the study, patients with the HeartMate 3 LVAD had an unprecedented survival rate of 82.8 percent at two years. Furthermore, rates of suspected pump thrombosis (clotting of blood) remained very low at 1.1 percent at two years. The study also showcased the lowest-ever published stroke rate (10 percent) for a continuous-flow LVAD at two years.

The [MOMENTUM 3 study](#) included 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 a long-term endpoint of two years. Two-year data on the first 366 patients enrolled into the study were presented at the [American College of Cardiology's \(ACC\) 67th Annual Scientific Session](#) in March 2018 and simultaneously published in the [New England Journal of Medicine](#).

The HeartMate 3 system includes the LVAD pump as well as other components that help power and monitor the technology including an external, wearable controller and battery system. The HeartMate 3 system received CE Mark in Europe for both short-term and long-term support in October 2015 and U.S. FDA approval for short-term support in August 2017.

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, 99,000 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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