

# NEW LONG-TERM DATA SHOW IMPROVED SURVIVAL AND LOWER RATES OF STROKE AND PUMP THROMBOSIS FOR ABBOTT'S HEARTMATE 3 HEART PUMP

-- HEARTMATE 3™ LVAD DEMONSTRATED IMPROVED CLINICAL OUTCOMES OVER THE MOST WIDELY USED LVAD IN THE WORLD

-- MOMENTUM 3 STUDY MET THE PRIMARY ENDPOINT AT TWO YEARS

-- RESULTS PRESENTED AT ACC AND SIMULTANEOUSLY PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE

ORLANDO, Fla., March 11, 2018 /[PRNewswire](#)/ -- Abbott (NYSE: ABT) announced new late-breaking clinical trial data from the MOMENTUM 3 clinical study, the largest left ventricular assist device (LVAD) trial in the world to evaluate patients in need of both short-term and long-term support in a single study. The data were published online in [The New England Journal of Medicine](#) (NEJM) and presented during a late-breaking session at the [American College of Cardiology's \(ACC\) 67<sup>th</sup> Annual Scientific Session](#).

"The long-term data for the pivotal MOMENTUM 3 trial demonstrate overall survival of 83 percent at 2-years and marked improvement in clinical outcomes for our patients suffering with advanced heart failure," said Mandeep R. Mehra, M.D., medical director of Brigham and Women's Hospital Heart and Vascular Center in Boston. "We have seen greater pump durability—mostly driven by an absence of confirmed pump thrombosis—as well as a significantly lowered stroke rate without an increase in other adverse events."

The MOMENTUM 3 study data—which will be submitted to the U.S. Food and Drug Administration (FDA) to support consideration of a long-term (destination therapy) indication for Abbott's HeartMate 3 LVAD—compared the HeartMate 3 LVAD to the HeartMate II LVAD in treating advanced heart failure. The HeartMate II is the most widely used LVAD in the world for long-term support. More than 1,000 patients with New York Heart Association (NYHA) Class IIIB or IV heart failure participated in the study. Patients were followed for a short-term endpoint of six months and a long-term endpoint of two years.

Patients who participated in the MOMENTUM 3 study received the following benefits from Abbott's HeartMate 3 system:

- **Superior Rates of Event-Free Survival.** The long-term cohort met its primary endpoint with 77.9 percent event free survival (survival free from disabling stroke and device removal due to malfunction), showing superiority over the HeartMate II LVAD at 56.4 percent.
- **Improved Survival.** Patients with the HeartMate 3 LVAD had a survival rate of 82.8 percent at two years compared to 76.2 percent for those with the HeartMate II LVAD.
- **Low Pump Thrombosis.** Rates remained very low at 1.2 percent suspected thrombosis for the HeartMate 3 LVAD, with no reoperations, pump replacements or urgent transplants occurring at two years.
- **Lower Stroke Rate.** Stroke rate was significantly lower (10 percent) for the HeartMate 3 LVAD compared to the HeartMate II LVAD (19 percent).

In addition, patients receiving HeartMate 3 LVAD had significant improvements compared to the HeartMate II LVAD in functional capacity and quality of life scores at two years compared to baseline. Rates of all other adverse events were similar between the HeartMate 3 LVAD and

historical rates seen in the HeartMate II LVAD, which is the most widely used and extensively studied LVAD commercially available.

"As the leader in LVAD therapy, our goal is to provide patients with life-changing health technology that minimizes risk and offers them an enhanced quality of life. Data from the MOMENTUM 3 study show Abbott's significant progress in LVAD innovation and how it's improving patient health outcomes," said John B. O'Connell, M.D., medical director for mechanical circulatory support at Abbott.

The MOMENTUM 3 Investigation Device Exemption (IDE) study is a prospective, multi-center, randomized, unblinded study evaluating the safety and effectiveness of the HeartMate 3 LVAD when used for the treatment of advanced, refractory, left ventricular heart failure. This study included all-comers, which means researchers evaluated the device regardless of whether the patient needed a short-term support option while awaiting transplantation or a long-term support option for those who are not candidates for cardiac transplantation.

The HeartMate 3 LVAD is CE Mark approved and FDA approved for short-term (bridge-to-transplant) use in the United States. The HeartMate 3 LVAD is limited by federal law to investigational use in the United States for long-term (destination therapy) support.

### **About Abbott's HeartMate 3 LVAD**

Abbott's HeartMate 3 LVAD is a small, implantable mechanical circulatory support (MCS) device for advanced heart failure patients who are awaiting transplantation or are not candidates for heart transplantation. It is the first commercially approved (CE mark approved and FDA approved for bridge-to-transplant) LVAD with Full MagLev™ technology, designed to minimize complications and restore blood flow. The HeartMate 3 system utilizes 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.

### **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, in select European markets and the U.S. (short-term support only), the HeartMate™ 3 left ventricular assist system. 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 more information about Abbott's focus on heart failure, visit <https://www.sjm.com/en/patients/heart-failure>.

### **About Abbott:**

At Abbott, we're committed to helping people live their 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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