# Abbott Advances Heart Failure Management With Aspirin Free Regimen For Patients Receiving The HeartMate 3™ Heart Pump

- Aspirin has long been a routine regimen for patients receiving heart pumps for preventing the formation of blood clots; the change in patient management comes following data from the ARIES-HM3 trial that showed reductions in bleeding and days in the hospital for patients who did not receive aspirin as part of their medication regimen
- Abbott's life-saving HeartMate 3 device has helped more than 30,000 people with heart failure worldwide pump blood through their bodies, many who have no other option

ABBOTT PARK, Ill., Aug. 21, 2024 — Abbott today announced that the U.S. Food and Drug Administration (FDA) has approved a change to its label that will help patients who receive a HeartMate 3™ left ventricular assist device (LVAD, or heart pump) experience superior clinical outcomes by eliminating aspirin as part of routine patient management. The labeling update is exclusively for patients with an Abbott HeartMate 3 heart pump and has also been approved by regulatory agencies in Canada and the European Union.

Blood thinners have historically been used by patients receiving LVADs as a means to reduce the risk of blood clots associated with the use of a blood pump implant. The ARIES-HM3 study was designed to help clinicians understand whether aspirin is needed as part of a blood thinning regimen for HeartMate 3 patients. The ARIES-HM3 trial showed that patients who received an Abbott HeartMate 3 heart pump but didn't take aspirin as part of their blood-thinning medication regimen had nearly 40% fewer complications from bleeding without increasing the risk of forming a blood clot compared to patients who also received a HeartMate 3 but did take aspirin. As a result of reduced bleeding risk, the ARIES-HM3 trial also found patients avoiding aspirin post-implant experienced reduced days in the hospital compared to patients who took aspirin daily.

"Aspirin, along with warfarin, has traditionally been mandated for advanced heart failure patients living with an LVAD, but whether it contributes to excessive bleeding has been uncertain. The ARIES-HM3 trial, in which aspirin was removed from the medication regimen, provided important data challenging the assumption that patients with a heart pump must take aspirin daily," said Mandeep R. Mehra, M.D., executive director of the Center for Advanced Heart Disease and the William Harvey Distinguished Chair at Brigham and Women’s Hospital in Boston, MA and the principal investigator of the ARIES-HM3 trial. "With this labeling change, physicians can avoid using aspirin in patients receiving the HeartMate 3 LVAD, a decision that is safe, and decreases bleeding and its associated hospital visits."

Abbott's HeartMate 3 heart pump is an implantable device that pumps blood through the body in people whose heart is too weak to do so on its own. It is the only commercially approved heart pump with Full MagLev™ technology, which allows the device's rotor to be "suspended" by magnetic forces, a unique design that has been proven to reduce trauma to blood passing through the pump, improving patient survival and quality of life. These factors have led to HeartMate 3 offering the lowest rate of pump-related complications of any other blood pump.

**Advanced Heart Failure Patients Benefit From Going Aspirin-Free**

Approximately 6.7 million Americans have heart failure, and that number is expected to rise to 8.5 million by 2030[1]. Heart failure is a progressive condition that occurs when the heart can't circulate blood efficiently, resulting in symptoms such as fatigue, breathlessness and swollen ankles. If not managed and treated, it can lead to poor quality of life, hospitalizations and death.

"Removing aspirin from the medication regimen for the HeartMate 3 is a simple change that means people with an Abbott LVAD can focus on the things they love and spend less time worrying about and tending to bleeding events," said Keith Boettiger, vice president, Abbott's heart failure business. "Through research such as the ARIES-HM3 trial, we continue to rewrite the book on the management of patients with advanced heart failure and focus on bringing lifeenhancing benefits to people who rely on our devices to survive."

**About the ARIES-HM3 Trial**

The ARIES-HM3 trial was an international, randomized study of either aspirin (100mg/day) or placebo with vitamin-K antagonist (VKA) therapy in advanced heart failure patients newly implanted with Abbott's HeartMate 3 LVAD (ages 18 and older). The study found that HeartMate 3 patients who didn’t receive aspirin but continued using the standard post-implant VKA treatment regimen met the primary endpoint by showing non-inferiority of no aspirin to aspirin. The HeartMate 3 patients who did not take aspirin spent 47% fewer days in the hospital due to a nearly 40% decrease in bleeding events compared to patients who continued to take aspirin daily. The data also found this same group had no elevated risk in developing thrombosis (a blood clot that increases the risk of stroke).

**Indications and Important Safety Information**

Decisions regarding the pharmacological management of HeartMate 3 patients should be individualized by clinicians after fully considering potential risks and benefits.

For U.S. important safety information for the Abbott HeartMate 3, visit: HeartMate 3 LVAD Indications, Safety and Warnings | Abbott (cardiovascular.abbott).

**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 114,000 colleagues serve people in more than 160 countries.

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[1]Bozkurt, et. al. Heart Failure Epidemiology and Outcomes Statistics: A Report of the Heart Failure Society of America. J Card Fail. 2023; 29(10): 1412–1451

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