Press Release

November 29, 2016

Getinge Group's Intra-Aortic Balloon Counterpulsation Technology Validated as First-Line Mechanical Circulatory Support Device

-- Data Presented at TCT 2016 Showed Impella Heart Pump Failed to Demonstrate Superiority to Standard-of-Care Intra-Aortic Balloon Counterpulsation --

November 29 , 2016 - Wayne, N.J. – New results from a prospective, randomized, multi-center trial of the Impella CP heart pump (Abiomed) versus intra-aortic balloon (IAB) counterpulsation in patients with cardiogenic shock demonstrated no improvement in mortality with the Impella CP device and significantly more bleeding and hemolysis complications. The data were recently presented at the 28th Annual Transcatheter Cardiovascular Therapeutics (TCT) Scientific Symposium in a "Featured Clinical Research: Presentations to the Editors of the *European Heart Journal*" sub-session. The trial was designed and sponsored by the Academic Medical Center, Amsterdam.

"The use of circulatory assist devices for hemodynamic support has grown significantly over time and, for more than 40 years, IAB therapy has been the first-line strategy for patients requiring mechanical circulatory support. To date, no other percutaneous support device has proven superiority over IABPs," said Pierluca Lombardi M.D., Vice President Medical Affairs, Acute Care Therapies, Getinge Group. "Because these new trial results validate the safety and clinical benefits of IAB therapy, physicians should continue to turn to IAB counterpulsation as first-line hemodynamic support. This is encouraging for the thousands of interventional cardiologists treating these very sick patients, as well as for hospital decision makers, as IABPs are the most cost-effective option of any circulatory support device currently available."

The study presented at TCT 2016 was underpowered but did include an interim analysis to expand the number of patients enrolled. This turned out to be unnecessary because there was no signal that a larger trial would have yielded a

different result. This study is the third randomized trial that has failed to demonstrate an improvement in outcomes with Impella over IABPs. In 2008, the ISAR-SHOCK trial showed that, hemodynamic support increased at 30 minutes, but was similar at all other time points and 30-day mortality was the same in the Impella and IABP study groups but complication rates were higher with the Impella device. In 2010, Abiomed stopped its high-risk PCI PROTECT II trial after determining the study could not reach its primary endpoint of a difference in 30-day adverse events.

IAB pumps (IABPs) are circulatory assist devices that are inserted into the aorta and counterpulsate to help the heart pump blood in patients in need of cardiac support. Based on extensive literature supporting the hemodynamic effects and safety and effectiveness of IABPs, the U.S. Food and Drug Administration (FDA) has cleared them for use in patients with acute coronary syndrome (any condition in which blood flow to the heart is suddenly reduced or blocked), patients undergoing cardiac and non-cardiac surgery, and patients experiencing complications of heart failure. The FDA clearance for these indications was based on results from a comprehensive literature review of IAB therapies, which demonstrated low overall rates of complications with the device, despite the fact that patients in whom IABs were implanted had more severe comorbidities and underlying illnesses than patients without the device. Additionally, the literature shows trends to less device-related mortality over time, as balloon catheter sizes have decreased and procedural techniques have improved in recent years.

About Getinge Group

Getinge Group is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life, we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.

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Contact
Helena Swan
Sr. Manager, Marketing Communications
helena.swan@getinge.com
973-709-7967