PROTECT II Interim Results Demonstrate That Impella Is Not Superior to the Intra-Aortic Balloon Pump in Reducing Major Adverse Events in High Risk Patients Receiving Percutane...

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MAHWAH, N.J., Dec. 9, 2010 /PRNewswire/ -- MAQUET Cardiovascular, the leading distributor of intra-aortic balloon pumps (IABP) worldwide, learned that the PROTECT II clinical trial, sponsored by Abiomed, that compared the safety and effectiveness of the Impella percutaneous ventricular assist device to intra-aortic balloon pumping in elective high-risk percutaneous coronary interventions (PCI) has been stopped. The Data Safety Monitoring Board determined, based on a review of the interim results, that Impella would likely not show a statistical difference in the rate of major adverse events compared to IABP at the completion of the trial.

The interim analysis of data from 305 patients, less than half of the 654 planned patients targeted for enrollment, showed no statistical difference in the rate of major adverse events, the primary endpoint of the trial, which included, but was not limited to, a difference in death, myocardial infarction and stroke between Impella and the IABP treatment groups. These results are consistent with an article published by Washington Hospital Center earlier this year, which questioned the clinical benefit of the PROTECT II study in this high-risk cohort of patients.

According to George W. Christy, MD, of Advocate Health System, Chicago, IL, "The trial did not meet the primary end-point and does not support use of a more expensive device with potentially higher complications over conventional and widely accepted IABP therapy."

"The trial speaks for itself – it did not meet the primary end-point," said Christian Keller, President and Chief Executive Officer of MAQUET Cardiovascular. "These results highlight what many cardiologists and hospital administrators have known for some time - IABP has been, and remains, the gold standard for delivering the critical cardiac support patients need in a way that also makes economic sense for the hospital."

About MAQUET IABP<
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