Clinical Trial Results for Impella RP Right Ventricular Heart Failure Trial, RECOVER RIGHT, Released at TCT 2014

WASHINGTON, Sept. 16, 2014 (GLOBE NEWSWIRE) -- Abiomed Inc. (Nasdaq:ABMD), a leading provider of breakthrough heart support technologies, today announced clinical trial results from RECOVER RIGHT, an Investigational Device Exemption (IDE) study of the Impella RP™ (Right Percutaneous) System. The clinical trial results demonstrated a survival rate of 73% in the overall patient population.

RECOVER RIGHT was an FDA-approved, prospective, multicenter, single arm study designed to evaluate the safety and probable benefit of the Impella RP in patients with right ventricular failure (RVF) refractory to medical treatment and deemed to require hemodynamic support.

The 30 patients enrolled in the RECOVER RIGHT trial were categorized into two patient cohorts. Cohort A included patients who developed RVF within 48 hours after implantation of a left ventricular assist device (LVAD). Cohort B examined patients who developed RVF within 48 hours of post-cardiotomy shock or post-acute myocardial infarction (AMI) shock. The primary endpoint was patient survival at 30 days, hospital discharge, or bridge to the next therapy.

Overall, the survival rate was 73% in the entire population at 30 days. Cohort A showed a survival rate of 83.3% and Cohort B had a 58.3% survival rate at 30 days.

"Right-side heart failure carries a high risk of mortality, and historically has been difficult for physicians to treat minimally invasively. The data from this trial is encouraging, and demonstrates that the Impella RP may play a pivotal role in the treatment of RVF patients in need of hemodynamic support in the future here in the U.S.," said William O'Neill, M.D., co-principal investigator for the RECOVER RIGHT trial and medical director of structural heart disease at Henry Ford Hospital.

"The Impella RP is the first percutaneous, single vascular access pump designed for right heart support. The pump is designed to be used concurrently with other left ventricle pumps in the Impella platform, which in the future may offer physicians the option of percutaneous biventricular support for acute patients," said Michael R. Minogue, Chairman, President and Chief Executive Officer, Abiomed.

"The trial results were favorable and the 30-day outcomes appear promising compared with clinical data from surgical RV assist devices; however our study was not designed for a statistical comparison. Overall, the results show that the percutaneous approach with Impella RP potentially offers significant advantages to patients," said Mark Anderson, M.D., co-principal investigator for the RECOVER RIGHT trial and chair of the division of cardiothoracic surgery at Einstein Medical Center.

The trial results, "A Prospective, Multicenter Study to Evaluate a New Percutaneous Ventricular Assist Device for Right Ventricular Failure: The RECOVER Right Study," were presented today by Dr. O’Neill at the Cardiovascular Research Foundation's (CRF) annual Transcatheter Cardiovascular Therapeutics (TCT) 2014 scientific meeting in Washington, DC.

The Company also announced last week that it has completed its FDA submission of RECOVER RIGHT trial data for the Human Device Exemption (HDE) submission.

*The Impella RP is the subject of an investigational device exemption (IDE) clinical study and is limited by federal law to investigational use. The Impella RP currently is not available for sale in the United States.

ABOUT ABIOMED

Based in Danvers, Massachusetts, Abiomed, Inc., is a leading provider of medical devices that provide circulatory support. Our products are designed to enable the heart to rest by improving blood flow and/or performing the pumping of the heart. For additional information please visit: www.abiomed.com.

FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including statements regarding development of Abiomed's existing and new products, the Company's progress toward commercial growth, and future opportunities and expected regulatory approvals. The Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, including the
potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the Company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and quarterly report on Form 10-Q. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

CONTACT: For further information please contact:

Aimee Genzler
Director, Corporate Communications
978-646-1553
agenzler@abiomed.com