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TherOx Completes Next-Generation SuperSaturated Oxygen Therapy IDE Pilot Study for AMI

First Treatment Option Beyond PCI to Salvage Heart Muscle

IRVINE, Calif. (Sept. 11, 2013) – TherOx, Inc. a privately held medical device company focused on the treatment of Acute Myocardial Infarction (AMI), announced it completed enrollment in its multicenter Investigational Device Exemption (IDE) pilot study of a second generation system that delivers SuperSaturated Oxygen (SSO_2) Therapy for reduction of infarct size after an AMI. SSO_2 Therapy is intended to provide interventional cardiologists with the first treatment option beyond percutaneous coronary intervention (PCI) to salvage heart muscle in heart attack patients.

"We value the efforts of the investigators and research coordinators, and we believe the positive response we received is due to our investigators' eagerness for a new treatment option for further reducing infarct size in heart attack patients," said Gregg W. Stone, MD, principal investigator of the SSO_2 Therapy IDE trial and professor of medicine at Columbia University Medical Center. "Final infarct size correlates with improved cardiac function and mortality in heart attack patients, as demonstrated by several randomized clinical studies. Additional reduction of infarct size is an unmet clinical need that SSO_2 Therapy may help address."

"The new system is user-friendly and allows for rapid and seamless set up by the cath lab staff immediately after PCI of the infarct-related artery," commented Shukri David, MD, FACC, Section Chief of the Division of Cardiology at Providence Hospital near Detroit and an investigator for this study.

"We're pleased to be part of an industry-wide search for better options for treating heart attack patients," said Kevin T. Larkin, president and chief executive officer of TherOx. The pilot phase of the IDE study enrolled 20 patients at three prominent cardiac centers in the U.S. "We appreciate the cardiology community's enthusiasm to evaluate the potential benefits of the next generation system to deliver SSO_2 Therapy."

About SSO_2 Therapy

According to the American Heart Association, nearly one million people in the U.S. have heart attacks each year. Although PCI is the standard of care in treating AMI, for many patients it doesn't do enough to reduce infarct size and achieve maximum clinical benefit. SSO_2 Therapy is adjunctive to PCI and is intended to salvage the jeopardized myocardium and thus reduce infarct size.

A heart attack is typically caused when blood and oxygen flow to the heart is blocked or reduced. If not quickly restored, irreversible damage to the heart muscle, or infarction, will occur. SSO_2 Therapy is designed to reduce infarct size by boosting oxygen delivery to the heart muscle immediately after the coronary artery has been opened by PCI. The TherOx system creates SSO_2 Therapy by mixing highly oxygenated saline with the patient's blood and delivers it through a catheter directly to the targeted ischemic area of the heart.

The first generation system to deliver SSO_2 Therapy received the CE Mark and was successful in meeting the safety and effectiveness endpoints in the AMIHOT II trial. Statistical results from the AMIHOT II trial of SSO_2 Therapy, together with PCI and stenting, demonstrated a relative reduction of 26% in infarct size compared to PCI and stenting alone. In addition, the finding of device effectiveness was supported by additional analyses that showed a 53% increased likelihood of having a small (less than 5% damage of the left ventricle) infarct among SSO_2 Therapy patients. The results were published in Circulation: Cardiovascular Interventions.*

This second generation system being studied builds on the success of AMIHOT II and includes the additional benefits of shortening the treatment time to 60 minutes and broadening the treatment area to the entire left coronary system so that no ischemic area goes untreated. SSO_2 Therapy is consistent with the 90-minute "door to balloon" initiative and supports the current guidelines for interventional cardiology procedures.

About TherOx

TherOx is a privately held medical device company based in Irvine, Calif., focused on developing and commercializing SSO_2 Therapy for this sizeable patient population to save hearts, and ultimately save lives. The major investors in TherOx include Kleiner Perkins Caufield & Byers, New Science Ventures, Integral Capital Partners, Aperture Venture Partners, DAG Ventures, and Cross Creek Capital. For more information, visit www.therox.com.

In the United States, SSO_2 Therapy is delivered by an investigational device. It is limited by United States law to investigational use. It is not for sale or distribution in the United States.

* Stone GW, Martin JL, Boer MJ, et al. Effect of SuperSaturated Oxygen Delivery on Infarct Size After Percutaneous Coronary Intervention in Acute Myocardial Infarction. Cir Cardiovasc Interv 2009; 2:366-75.