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TherOx Completes Enrollment in Study of Next-Generation Therapy System Designed to Improve AMI Outcomes

Brings FDA Submission for Supersaturated Oxygen Treatment One Step Closer

IRVINE, Calif. (May 3, 2017) – TherOx, Inc. a privately held medical device company focused on improved treatment of Acute Myocardial Infarction (AMI), announced that it completed enrollment in the IC-HOT (Evaluation of Intracoronary Hyperoxemic Oxygen Therapy) study. IC-HOT is a confirmatory study of the second-generation TherOx system that delivers SuperSaturated Oxygen (SSO_2) Therapy for reduction of infarct size after an AMI.

The IC-HOT study enrolled 100 patients and is being conducted to support a PreMarket Approval submission to the U.S. Food and Drug Administration (FDA). The primary study objective is to collect confirmatory data supporting the safety and effectiveness of SSO_2 Therapy in treatment of anterior AMI patients who have undergone successful percutaneous coronary intervention (PCI) with stenting within six hours of experiencing AMI symptoms.

"Since the advent of angioplasty and stenting to treat heart attack we haven't seen any new treatment options to reduce infarct size in this vulnerable population, and SSO_2 Therapy appears to fulfill this unmet need," said Nainesh Patel, MD, interventional cardiologist at Lehigh Valley Health Network and an investigator for the study.

According to the American Heart Association, every year nearly one million people in the U.S. have heart attacks. 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 treats patients who have experienced the most serious large anterior wall heart attacks - patients who often have poor outcomes even after successful intervention," said Frances Wood, MD, interventional cardiologist at WakeMed Heart and Vascular - Structural Heart and study investigator. "This therapy is a promising new tool to reduce infarct size and thus improve outcomes for these higher risk patients."

SSO_2 Therapy is intended to provide interventional cardiologists with the first treatment option beyond PCI to salvage heart muscle in heart attack patients. In SSO_2 Therapy, the patient's blood is supersaturated with oxygen and then returned directly to the targeted ischemic area of the heart through a small catheter. Adjunctive to PCI, SSO_2 Therapy is intended to salvage the jeopardized myocardium and thus reduce infarct size. Multiple peer-reviewed studies have demonstrated the infarct size reduction achieved by SSO_2 Therapy was clinically significant compared to PCI alone.

"Completing enrollment in our IC-HOT study significantly advances us closer to our goal of improving treatment options in the U.S. for physicians and their heart attack patients," said Kevin T. Larkin, president and chief executive officer of TherOx.

About SSO_2 Therapy

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.

This second-generation system being studied in IC-HOT builds on the success of AMIHOT II and includes the additional benefits of shortening the treatment time to 60 minutes and expanding the myocardial treatment area to the entire left coronary system so that no ischemic area goes untreated. (Clinicaltrials.gov identifier #NCT02603835)

SSO_2 Therapy supports the current guidelines for interventional cardiology procedures.

About TherOx, Inc.

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, improving and ultimately saving lives. For more information about TherOx, 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.