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TherOx Receives FDA IDE Approval for Study of Next-Generation SuperSaturated Oxygen Therapy for AMI

Important Milestone Toward Bringing SSO_2 Therapy 2 to the U.S. Market

IRVINE, Calif. (Nov. 05, 2015) – TherOx, Inc. a privately held medical device company focused on improved treatment of Acute Myocardial Infarction (AMI), announced it has received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval for a confirmatory safety study of a second generation system that delivers SuperSaturated Oxygen (SSO_2) Therapy for reduction of infarct size after an AMI. This 100-patient study is being conducted to support a PreMarket Approval submission to the FDA.

Simon Dixon, MBChB, chair of cardiovascular medicine at Beaumont Hospital Royal Oak and an investigator for this study, noted, "In multiple peer-reviewed studies, we have found the infarct size reduction achieved by SSO_2 Therapy was clinically significant compared to PCI. I am excited about the potential that SSO_2 therapy shows in improving outcomes for patients experiencing large anterior infarcts and treated within six hours of onset."

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. 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, adjunctive to PCI, is a solution of highly oxygenated saline mixed with the patient's blood delivered through a catheter to the targeted ischemic area of the heart. SSO_2 Therapy is intended to salvage the jeopardized myocardium and thus reduce infarct size.

"This IDE study is an important milestone toward bringing SSO_2 Therapy to the U.S. market," said Kevin T. Larkin, president and chief executive officer of TherOx. "Initiating this new study moves us another step closer to our goal of providing substantially better options for treating heart attack patients."

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 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. 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.