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TherOx Announces Its PMA Application for AMI Therapy System is Accepted for Filing by FDA

SSO_2 Therapy System is Designed to Improve Acute AMI Patient Outcomes

IRVINE, Calif. (September 26, 2017) – TherOx, Inc., a privately held medical device company focused on improving treatment of Acute Myocardial Infarction (AMI), announced that the U.S. Food and Drug Administration (FDA) has accepted the Premarket Approval (PMA) application for its SuperSaturated Oxygen (SSO_2) Therapy system. The second-generation SSO_2 Therapy system is designed to reduce infarct size and thereby improve outcomes in anterior AMI patients treated within six hours of symptom onset.

"The SSO_2 Therapy system has the potential to provide interventional cardiologists with the first treatment option beyond angioplasty and stenting to save substantially more heart muscle in heart attack patients than the current state-of-the-art treatment," said Kevin T. Larkin, president and chief executive officer of TherOx. "The FDA's acceptance for filing of our PMA brings us one step closer to providing a promising new tool to reduce infarct size and thus improve outcomes for heart attack patients, and we look forward to working with the FDA during the review process."

Although percutaneous coronary intervention (PCI) is the standard of care in treating AMI, for many patients it doesn't sufficiently reduce infarct size to achieve maximum clinical benefit. 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 heart muscle and reduce infarct size.

The PMA application includes data from the IC-HOT (Evaluation of Intracoronary Hyperoxemic Oxygen Therapy) study, a confirmatory study that enrolled 100 patients at 15 investigational centers in the U.S. The primary objective of the IC-HOT study was to collect confirmatory data supporting the safety and effectiveness of SSO_2 Therapy in the treatment of anterior ST-elevation AMI patients who have undergone successful PCI with stenting within six hours of experiencing AMI symptoms. (Clinicaltrials.gov identifier #NCT02603835)

About SSO_2 Therapy

SSO_2 Therapy is intended to reduce infarct size by boosting oxygen delivery to the heart muscle immediately after the coronary artery has been opened by PCI. The TherOx SSO_2 Therapy system delivers a one-time, 60-minute infusion of superoxygenated blood to the coronary arteries after standard-of-care treatment for heart attack has been completed.

About TherOx, Inc.

TherOx is a privately held medical device company based in Irvine, Calif., focused on developing and commercializing SSO_2 Therapy for the sizeable AMI 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.