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Results of TherOx AMI Study for Improved Patient Outcomes Meets Primary Endpoint**TherOx IC-HOT Study Results Presented at TCT 2017**

DENVER (November 1, 2017) – [TherOx, Inc.](#), a privately held medical device company focused on improving treatment of Acute Myocardial Infarction (AMI), announced that results of its IC-HOT (Evaluation of Intracoronary Hyperoxemic Oxygen Therapy) study successfully met its primary endpoint. The purpose of this study was to confirm the safety and effectiveness of Supersaturated Oxygen (SSO₂) Therapy in treatment of anterior AMI patients who have undergone successful percutaneous coronary intervention (PCI) with stenting within six hours of experiencing AMI symptoms. These results are included in the Premarket Approval (PMA) application for the SSO₂ Therapy system that has been accepted for filing by the U.S. Food and Drug Administration (FDA). The study results were presented at the 29th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

“Supersaturated oxygen is the only therapy shown in a pivotal randomized trial to reduce the important endpoint of infarct size in patients with large myocardial infarction,” said Gregg W. Stone, MD, principal investigator of the IC-HOT study and professor of medicine at Columbia University Medical Center. “The IC-HOT study, using a simpler delivery method than previously tested, demonstrated that use of supersaturated oxygen is safe after successful primary stenting in high-risk patients with anterior myocardial infarction.”

IC-HOT is a confirmatory study of the second-generation TherOx system that delivers SSO₂ Therapy for reduction of infarct size after an AMI. The study enrolled

100 patients at 15 investigational centers in the U.S. IC-HOT results build on the successful outcome of the AMIHOT II controlled, randomized pivotal trial that studied the first-generation SSO₂ Therapy system, and combined these study results provide the FDA with the basis for PMA approval.

“The IC-HOT study clearly met its endpoint with good margin, and with successful study completion and subsequent notice of the FDA’s acceptance for filing, TherOx’s PMA is now under final review,” said Kevin T. Larkin, president and chief executive officer of TherOx. “We continue to move closer to enabling physicians to provide this important new therapy to their patients who experience typically debilitating large anterior AMIs.”

SSO₂ Therapy is intended to provide interventional cardiologists with the first treatment option beyond PCI to salvage heart muscle in heart attack patients. 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 SSO₂ 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, SSO₂ Therapy is intended to salvage heart muscle and reduce infarct size.



About SSO₂ Therapy

SSO₂ 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 SSO₂ 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 SSO₂ 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, SSO₂ 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.

