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SuperSaturated Oxygen Therapy IDE Study Results in Smaller Infarct Size for Next-Generation System

TherOx Study Results Presented at TCT 2013

IRVINE, Calif. (Dec. 12, 2013) – TherOx, Inc. released results from the company's multicenter investigational device exemption (IDE) pilot study that showed a 9.6 percent smaller infarct size at 30 days in high-risk patients treated with its next-generation system for SuperSaturated Oxygen (SSO_2) Therapy. This new 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. The study results were presented at the 25th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

The next-generation SSO_2 system shows great potential in improving upon the earlier successful results of a first-generation system. Patients treated with the second-generation SSO_2 Therapy system had a 9.6 percent median infarct size measured at 30 days. In a previous prospective, multi-center, randomized IDE trial, AMIHOT II, patients treated with the first-generation SSO_2 system had a 20 percent infarct size, and control group patients treated with PCI alone had a 26.5 percent median infarct size. The pilot IDE study enrolled 20 patients at three prominent cardiac centers in the United States.

"In the successful AMIHOT II study performed with the prior system, SSO_2 Therapy was proven to reduce median infarct size by 26 percent, which is statistically significant. The new SSO_2 system shows promise in producing even better results," said Shukri David, MD, FACC, section chief of the division of cardiology at Providence Hospital near Detroit and the investigator for this study who presented the results at TCT.

The second-generation SSO_2 Therapy system was designed to improve therapeutic effectiveness by perfusing the entire left coronary system so that no ischemic area goes untreated. It also offers the additional benefit of shortening the treatment time to 60 minutes from 90 minutes. The original system only perfused the target artery treated with angioplasty and stenting.

According to the American Heart Association, every year approximately 1 million people in the United States 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, which correlates with improved cardiac function and mortality in heart attack patients

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.