THROMBOLEX, INC. – BASHIR™ ENDOVASCULAR CATHETER SHOWS DRAMATIC REDUCTION IN THROMBOEMBOLIC OCCLUSIONS IN SEGMENTAL PULMONARY ARTERIES OF PATIENTS WITH ACUTE INTERMEDIATE RISK PE: INTERIM RESULTS OF NIH-FUNDED RESCUE TRIAL

New Britain, PA, January 17, 2022 – THROMBOLEX, INC. announced positive results from the pre-specified interim analysis of the first 62 evaluable pulmonary embolism (PE) patients enrolled in the investigational RESCUE Trial. RESCUE is a prospective multicenter, single-arm pivotal trial evaluating patient outcomes after treatment of acute intermediate risk PE. This pivotal trial is scheduled to enroll at least 100 evaluable patients. The trial is evaluating the efficacy and safety of the BASHIR™ and BASHIR™ S-B Endovascular Catheters in the treatment of acute PE under an Investigational Device Exemption (IDE) from the FDA. An analysis of the interim data was presented today at the Late Breaking Clinical Trials session at the ISET Conference in Miami by Dr. Ripal Gandhi, of the Miami Cardiac and Vascular Institute, on behalf of the RESCUE investigators.

During this session, Dr. Gandhi reported new detailed data on the reduction of clot burden in segmental pulmonary arteries. According to THROMBOLEX, these initial data have not been reported in any of the previous clinical trials of acute PE. The data demonstrated a 90% reduction in the number of totally occluded segmental pulmonary arteries ($p<0.0001$) and a 72% reduction in subtotal and total occlusions of segmental arteries ($p<0.0001$) at 48 hours post procedure compared to baseline by CT Angiogram. Each of the 20 segmental arteries showed a reduction in the degree of obstruction. The trial met its primary endpoint for reduction in right heart strain, and at 72 hours post procedure there were no major bleeds, no major adverse events and a zero-mortality rate. Collectively these patients experienced substantial improvement in hemodynamics and symptoms, which translated to improvements in right heart strain, cardiac function and functional status.

"These interim results from the RESCUE trial are very exciting," said Dr. Gandhi, a RESCUE trial investigator. "The reduction in thrombus burden at 48 hours after treatment, as assessed by the independent Core Lab, is remarkable especially with no bleeding complications. Complete resolution of thrombus burden should be an important goal of treatment. This represents a promising novel technology for the treatment of acute pulmonary embolism and other forms of large vessel Venous Thrombo-Embolic (VTE) disease."

Dr. Brian Firth, Chief Scientific Officer of THROMBOLEX stated "The strong support that THROMBOLEX has received from the National Heart Lung and Blood Institute as we have conducted this trial in the midst of the COVID-19 epidemic, has helped to make this trial possible. We would also like to acknowledge additional support for RESCUE from the Commonwealth of Pennsylvania, Department of Health." Marvin Woodall, THROMBOLEX Chairman and CEO added "Dr. Gandhi's presentation today reminds me of the clinical trial outcomes for the PALMAZ™ Stents in the early 1990's, whose development and commercialization I led at Johnson & Johnson Interventional Systems. This proved to be the start of the worldwide adoption of implantable balloon-expandable stents for the treatment of severely narrowed arteries. I feel that the very positive clinical outcomes presented today will similarly mark the beginning of the worldwide adoption of the unique and innovative BASHIR™ Endovascular Catheters in the treatment of patients with a wide range of blood clot disorders."

THROMBOLEX's BASHIR™ and BASHIR™ S-B Endovascular Catheters have received FDA 510(k) clearance for the localized infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The goal of the RESCUE IDE study is to achieve an additional indication for use of these devices in the treatment of acute PE.

About THROMBOLEX, INC. Founded in 2016, THROMBOLEX is engaged in the design, development, manufacturing and distribution of innovative endovascular catheters used in interventional procedures, particularly in pharmaco-mechanical catheter- directed thrombolysis (PCDT) of thrombus in patients who suffer from arterial, venous and arteriovenous thromboembolic conditions. The company is currently marketing seven (7) different FDA-cleared devices that are all based on the BASHIR™ Endovascular Catheter platform technology.

For more information, please contact our Chief Scientific Officer, Dr. Brian Firth, brian@thrombolex.com
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