

## THROMBOLEX, INC. – BASHIR™ ENDOVASCULAR CATHETER SHOWS MARKED REDUCTION IN RV/LV RATIO AND THROMBUS BURDEN IN PATIENTS WITH ACUTE INTERMEDIATE RISK PE: INTERIM RESULTS OF NIH-FUNDED RESCUE TRIAL

New Britain, PA, October 5, 2021 – THROMBOLEX, INC. today announced the results of the RESCUE Trial's pre-specified interim analysis, of the first 62 evaluable patients, at a Late Breaking Clinical Trials session at the VIVA Conference in Las Vegas. This Pivotal trial is scheduled to enroll at least 100 evaluable patients with acute intermediate-risk pulmonary embolism (PE). This trial is evaluating the efficacy and safety of the BASHIR<sup>™</sup> and BASHIR<sup>™</sup> S-B Endovascular Catheters (BECs) in the treatment of acute PE under an Investigational Device Exemption (IDE) from the FDA. The goal of RESCUE is to achieve an additional indication for use of these devices in the treatment of acute PE. This pre-specified interim analysis was presented by Dr. Akhilesh Sista, Chief of Interventional Radiology, NYU Langone Health, New York, USA. The analysis included 44 males and 18 females with an average age of 58.5 years; 90.3% had high intermediate-risk PE with both right ventricular dysfunction and elevated biomarkers. Each patient was treated with 7mgs of r-tPA into each pulmonary artery over 5 hours (a total of 14 mg r-tPA in 58 patients with bilateral PEs and 7 mg in 4 patients with unilateral PEs) at 18 participating centers in the USA. CT scan at 48 hours after infusion showed that the right ventricular to left ventricular (RV/LV) diameter ratio decreased by 32.1% (0.52±0.38: 95% CI 0.42 – 0.62, P<0.0001), and the pulmonary clot burden by Refined Modified Miller Index had decreased by 36.3% (8.4±4.3: 95% CI 7.34 – 9.50, P<0.0001). The successful device placement rate was 100%, there were no device-related complications and the major bleed rate at 72 hours was zero.

"These interim results from the RESCUE trial are very exciting" said Dr. Sista. "The most notable finding is the Core Lab assessed reduction in pulmonary thrombus burden at 48 hours, which may translate to better short and long-term outcomes pending further research. The reduction in RV/LV ratio and the absence of device or drug-related adverse events are also salutary outcomes. The expandable infusion basket of the BASHIR™ Endovascular Catheters, with its pharmaco-mechanical mode of action, appears to restore blood flow promptly. I look forward to the final results of RESCUE and subsequent investigations that will determine the role of this promising novel technology in the treatment of acute pulmonary embolism." Dr. Brian Firth, Chief Scientific Officer of THROMBOLEX, INC. and Principal Investigator on the SBIR grant from the National Heart Lung and Blood Institute (NHLBI) stated "The strong support and encouragement that we have received from the NHLBI as we have conducted this trial, especially in the midst of the COVID-19 epidemic, has really made this trial possible. We would also like to acknowledge additional support from the Commonwealth of Pennsylvania, Department of Health." Mr. Marvin Woodall, Chairman and CEO of THROMBOLEX Inc. added "Dr. Sista's presentation today reminds me of the early clinical trial outcomes for the PALMAZ<sup>™</sup> 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<sup>™</sup> Endovascular Catheters in the treatment of patients with a wide range of blood clot disorders."

**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<sup>™</sup> Endovascular Catheter platform technology.

For more information, please contact our Chief Scientific Officer, Dr. Brian Firth, <u>brian@thrombolex.com</u> or visit our website THROMBOLEX.com.