THROMBOLEX™ Inc. First Patient Enrolled in the RESCUE Trial for Treatment of Acute Submassive Pulmonary Embolism

New Britain, PA. August 6, 2020 - THROMBOLEX™ Inc. has announced that it has enrolled the first patient in its pivotal RESCUE trial for the treatment of patients with acute submassive pulmonary embolism (PE) using the BASHIR® Endovascular Catheter, under an Investigational Device Exemption (IDE) from the FDA. RESCUE is a prospective, single-arm, multicenter trial of pharmaco-mechanical catheter-directed thrombolysis (CDT) and will enroll up to 125 patients at up to 20 sites in the USA. The first patient was a 50-year old man with a high-risk submassive pulmonary embolus affecting both lungs, treated at Charleston Area Medical Center, Vascular Center of Excellence, Clinical Trials Center and WVU Vascular Surgery Center, Charleston, WV by Dr. Aravinda Nanjundappa. He said "the patient had an excellent result with no complications following treatment with two BASHIR® Endovascular Catheters, 5 hours of infusion and a total of 14 mg of r-tPA being administered. We were privileged to enroll the first patient in this important PE trial using the BASHIR® Endovascular Catheter."

The RESCUE study follows on the very successful First-in-Human (FIH) trial completed by THROMBOLEX™ at the end of last year. The FIH trial met its primary safety and feasibility endpoints, and showed large and rapid reduction in right heart strain as evidenced by a reduction in RV/LV ratio of 37% (P<0.0009), as well as a 37.1% mean reduction (P< 0.0005) in pulmonary clot burden, as measured by the Modified Miller Index (MMI) following infusion of 14 mg of r-tPA over 8 hours. There were no major bleeding or other adverse events. "Based on the impressive early results of the FIH study I am excited to see a larger set of real world data using the BASHIR® Endovascular Catheter", said Dr. Akhilesh Sista, Section Chief of Vascular & Interventional Radiology at NYU Langone Health and member of the Steering Committee for RESCUE.

The BASHIR® Endovascular Catheter is a pharmaco-mechanical CDT device that received 510(k) pre-market regulatory clearance for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The goal of RESCUE is to achieve an additional indication for its use in the treatment of pulmonary embolism. This unique device comprises an array of six expandable mini-infusion catheters at the distal end of the catheter. When expanded, the infusion basket creates a channel for immediate blood flow through the culprit clot and rapid reperfusion to the lungs. This novel mode of action promotes delivery of the body's own endogenous fibrinolytics, combined with the administration of exogenous fibrinolytics, throughout multiple cross-sectional areas of the clot. It also allows for the measurement of PA pressure and oxygen saturations from the catheter tip during infusion, that in turn allows for the therapy to be customized by the physician based on the degree of clot lysis assessed physiologically.

About THROMBOLEX™, Inc.
Founded in 2016, THROMBOLEX™, Inc. is engaged in the design, development, manufacture and distribution of innovative endovascular catheters used in interventional procedures, particularly in

catheter-directed thrombolysis (CDT) of thrombus in patients who suffer from arterial, venous and arteriovenous thromboembolic conditions. Our innovative technology platform is easy to use, requires no capital equipment and helps physicians customize therapy plans for their patients. We are also focused on improving hospital economics as patients treated with our devices typically receive lower doses of thrombolytic while demonstrating short ICU and overall length of hospital stay. The company is currently selling seven (7) different FDA-cleared devices that are all based on the BASHIR® Endovascular Catheter platform technology.

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BASHIR™
endovascular catheter