



THROMBOLEX™ Inc. Receives \$3 million Small Business Innovation Research (SBIR) grant from the NIH to fund the RESCUE trial.

New Britain, PA, July 5, 2020

Thrombolex™ Inc. has announced that it was awarded a \$3 million Small Business Innovation Research (SBIR) grant from the National Heart, Lung and Blood Institute (NHLBI) section of the NIH to fund their pivotal RESCUE trial under an IDE for the treatment of up to 125 patients with acute, submassive, pulmonary embolism at up to 20 centers in the USA. Dr. Brian Firth serves as the Principal Investigator on this SBIR grant and is being assisted in this capacity by Dr. Riyaz Bashir of Temple University, the co-inventor of the Bashir™ Endovascular Catheter. The SBIR grant application by Thrombolex was awarded as a Direct-to-Phase II SBIR grant on the first application and received high commendation from the external reviewers for NHLBI. The Steering Committee for RESCUE includes eminent leaders of all the major specialties who treat this condition, namely, Drs. Anthony Comerota, Kenneth Rosenfield, Akhilesh Sista, and Victor Tapson.

“With the strong support of the NHLBI, we have an opportunity to advance the treatment of patients with acute PE and have the potential to reduce bleeding complications, enhance clot resolution and improve hospital economics”, said Dr. Brian Firth, Chief Scientific Officer, Thrombolex™.

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 mean infusion of 13.7 mg of r-tPA over 8 hours. There were no 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.

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. The company is currently selling seven (7) different FDA cleared devices that are all based on the Bashir™ Endovascular Catheter platform technology.

Contact

Brian G. Firth, MD, PhD, FACC, MBA
Chief Scientific Officer

brian@thrombolex.com

BASHIR™
endovascular catheter