THROMBOLEX
INNOVATIVE ENDOVASCULAR CATHETERS

**RESCUE-II Trial Demonstrates the Feasibility of On-The-Table Pharmacomechanical Lysis without Post-Procedure Infusion in Treating Acute Pulmonary Embolism**

**NEW BRITAIN, PA (October 28, 2024).** Christian Bichard, MD presented the results of the RESCUE-II Trial during the Innovations in Endovascular Therapies session at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, DC. This trial enrolled 9 patients with acute intermediate high-risk pulmonary embolism (PE). The BASHIR™ Endovascular Catheter was used to deliver 4mg of recombinant tissue plasminogen activator (r-tPA) into each pulmonary artery (PA). The study showed that the independent core laboratory assessed primary endpoint of the right ventricular to left ventricular (RV/LV) diameter ratio at 48 hours was reduced by 22.3% (p=0.0001). The reduction in the secondary endpoint of PA obstruction, as measured by the Refined Modified Miller Index (RMMI), was reduced by 29.2% (p=0.0001). The reduction in segmental PA occlusion was 55% (p<0.0001). The total procedure time was 39 minutes, while the device placement and treatment time was 17 minutes. All catheters and sheaths were removed on the table (OTT). There were no device-related adverse events or major bleeds by ISTH criteria at 72 hours. These core laboratory assessed outcomes parallel those seen with other contemporary catheter-based PE therapies, without requiring infusion in the ICU.

Parth Rali, MD, the PI of the RESCUE-II Trial and Associate Professor of Thoracic Medicine and Surgery at Lewis Katz School of Medicine at Temple University, commented, “The trial represents a potentially major advance in treating acute PE. This unique OTT treatment protocol is safe and effective, maximizing clot lysis with small doses of a thrombolytic while helping healthcare systems manage their limited resources.” Vladimir Lakhter, DO, Associate Professor of Medicine, said, “This OTT treatment protocol without post-procedural thrombolytic infusion may obviate the need for an ICU stay and dramatically increase access to this life-saving treatment around the globe.”

The RESCUE-II Trial, conducted at Temple University Hospital in Philadelphia, PA, was funded by the Commonwealth of Pennsylvania, Department of Health. It is a successor study to the highly successful pivotal RESCUE Trial that used the BASHIR™ Endovascular Catheter to deliver 2mg of tPA into each pulmonary artery followed by a 5mg infusion over 5 hours into each pulmonary artery, for a total of 14mg for a bilateral PE. Thrombolex has also started enrollment in the RAPID-PE Trial, that plans to enroll up to 500 patients at up to 50 centers in the United States, using this single session protocol without post-procedure infusion.

**About Thrombolex, Inc.**
Thrombolex designs, develops, and distributes innovative endovascular catheters using Pharmacomechanical Lysis (PML) to treat patients who suffer from arterial and venous thromboembolic conditions. The Company is currently marketing eight (8) different FDA-cleared devices based on the BASHIR™ Endovascular Catheter platform technology. The company is committed to simplifying procedures, optimizing outcomes, improving safety, and validating our superior clinical efficacy by generating ongoing clinical evidence.

For More Information, Please contact Thrombolex at info@thrombolex.com or visit our website www.thrombolex.com