

Thrombolex Announces the First Two Patients enrolled in the RAPID-PE Clinical Study evaluating an Advanced On-The-Table Protocol for the Treatment of Pulmonary Embolism

NEW BRITAIN, PA (October 23, 2024) Thrombolex, Inc. announced the enrollment of the first two patients in the RAPID-PE study using the BASHIR™ Endovascular Catheter for the treatment of acute pulmonary embolism by Dr. Ayman Iskander, interventional cardiologist at St. Joseph's Health Hospital in Syracuse, NY.

The RAPID-PE study is a single arm, multi-center post market study evaluating the safety and effectiveness of on-the-table pharmacomechanical lysis (PML) without post-procedural thrombolytic infusion using the new 0.035" guidewire compatible BASHIR™ Endovascular Catheter. This Next Gen platform technology is engineered for optimal resolution of thrombus in the treatment of pulmonary embolism (PE). Patients with acute intermediate-risk PE are treated with four 1 mg pulse sprays of r-tPA into each pulmonary artery without subsequent r-tPA infusion. The first two patients treated were discharged from the hospital in good health less than 24 hours post procedure.

Dr. Iskander commented, "It was exciting to see a dramatic improvement in hemodynamics on the table in both patients with very short treatment times (one bilateral; 38 minutes and one unilateral; 16 minutes) in the cath lab. This approach may eliminate the need for an ICU stay, which could be a boon to the overburdened health systems".

Dr. Wissam Jaber, Professor of Medicine and Director of the Cath Lab at Emory University and Co-National Principal Investigator of the RAPID-PE study, commented, "We are pleased to see the enrollment of the first two patients in the RAPID-PE study and are very encouraged by the clinical response with this novel PML approach. We believe this protocol will be as effective as traditional PE therapies and potentially safer, due to the ultra-low dose of lytics used. This is a logical next step in improving upon the excellent clinical results from the original RESCUE Study".

The RESCUE Study enrolled 109 patients with intermediate-risk PE at 18 US hospitals. It showed unsurpassed effectiveness and safety in this patient population. The data from a related single-center study from Temple University Hospital, the RESCUE-II study, that uses the on-the-table protocol will be presented at TCT on October 28th.

About Thrombolex, Inc.

Founded in 2016, Thrombolex is engaged in the design, development, and distribution of innovative endovascular catheters used in interventional procedures, particularly in pharmacomechanical lysis (PML) in patients who suffer from arterial and venous thromboembolic (A&VTE) conditions. The Company is currently marketing eight (8) different FDA-cleared devices based on the BASHIR™ Endovascular Catheter platform technology.

For More Information: Contact Thrombolex at info@thrombolex.com or visit our website www.thrombolex.com