

**EKOS EkoSonic® Endovascular System****Study Drug Name: Activase® (Genentech)**

**Primary Efficacy Objective:** Determine the optimum dose of thrombolytic and duration of the Acoustic Pulse Thrombolysis™ as a treatment for acute submassive pulmonary embolism (PE). The primary efficacy objective is a change in the RV to LV diameter ratio.

**Primary Safety Objective:** Determine the frequency of major bleeding within 72 hours after the initiation of Acoustic Pulse Thrombolysis™ treatment in patients with submassive PE.

**Study Patient Treatment:** OPTALYSE Acoustic Pulse Thrombolysis™ treatment groups are listed below. A repeat CTA was obtained to measure RV/LV at 48 hours after the start of treatment.

Cohort 1: 2hr ultrasound; 2mg r-tPA/hr/catheter

Cohort 2: 4hr ultrasound; 1mg r-tPA/hr/catheter

Cohort 3: 6hr ultrasound; 1mg r-tPA/hr/catheter

Cohort 4: 6hr ultrasound; 2mg r-tPA/hr/catheter\*

**Inclusion Criteria:** Age 18-75 inclusive; CTA evidence of proximal submassive PE (RV/LV diameter ratio  $\geq 0.9$  on CTA and hemodynamically stable); Symptom duration  $\leq 14$  days; Treated within 48 hours of diagnosis of PE by CTA.

**Exclusion Criteria:**

1. Stroke or transient ischemic attack (TIA), head trauma, or other active intracranial or intraspinal disease within one year
2. Recent (within one month) or active bleeding from a major organ
3. Major surgery within seven days
4. Clinician deems high-risk for catastrophic bleeding
5. History of heparin-induced thrombocytopenia (HIT) or any hematologic disease potentially involving abnormal platelet number or function
6. Catheter-based pharmacomechanical treatment for pulmonary embolism within 3 days of study enrollment
7. Systolic blood pressure less than 90 mm Hg and/or use of vasopressors
8. Cardiac arrest (including pulseless electrical activity and asystole) requiring active cardiopulmonary resuscitation (CPR)
9. Evidence of irreversible neurological compromise
10. Life expectancy < 1 year
11. Use of thrombolytics or glycoprotein IIb/IIIa antagonists within 3 days prior to inclusion in the study
12. Out-of-Range Laboratory Values: Hematocrit < 30%, Platelets < 100 thousand/ $\mu$ L, INR > 3
13. Creatinine outside the normal range for the treating institution
14. Pregnancy
15. Active cancer (metastatic, progressive, or treated within the last 6 months). Exception: non-melanoma primary skin cancers
16. Known allergy, hypersensitivity, or thrombocytopenia from heparin, r-tPA, or iodinated contrast except for mild-moderate contrast allergies for which steroid pre-medication can be used

\*Note: The steering committee closed Cohort 4 early.

US FDA CLEARED INDICATIONS: The EkoSonic® Endovascular System is indicated for the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism; the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; and the infusion of solutions into the pulmonary arteries. Instructions for Use, including warnings, precautions, potential complications, and contraindications can be found at [www.ekoscorp.com](http://www.ekoscorp.com). Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. EKOS and EkoSonic are registered trademarks of EKOS Corporation, a BTG International group company. BTG and the BTG roundel logo are registered trademarks of BTG International Ltd. NA-EKO-2017-0435



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