

Renibus Therapeutics Initiates Phase 2 Study of RBT-1 for Prevention of Acute Kidney Injury

- The Phase 2 study will evaluate the efficacy of RBT-1 on acute kidney injury prevention in subjects undergoing cardiac surgery
- Renibus plans to enroll 126 subjects at up to 20 sites across the United States, Canada, Australia, and New Zealand

DALLAS, Texas, March 11, 2021 (GLOBE NEWSWIRE) -- Renibus Therapeutics® ("Renibus"), a clinical-stage biotech company focusing on the prevention, treatment, and diagnostic testing of kidney disease, announced today that the company has initiated a Phase 2 study evaluating the efficacy of RBT-1 on acute kidney injury (AKI) prevention in subjects undergoing coronary artery bypass graft (CABG) and/or cardiac valve surgery. The study plans to enroll 126 patients in up to 20 sites across the United States, Canada, Australia, and New Zealand

As the most common complication of a number of surgical procedures, AKI occurs in up to 30% of patients undergoing cardiac surgery and is associated with significantly increased in-hospital mortality¹. Administered prior to surgery, RBT-1 is a novel combination agent that preconditions organs via activation of an endogenous anti-inflammatory and antioxidant response, rendering organs resistant to stimuli that may cause injury. In a Phase 1 study in both healthy volunteers and patients with stage 3-4 chronic kidney disease (CKD), RBT-1 was shown to upregulate cytoprotective proteins, which were associated with AKI prevention in animal models.

"Each year, there are more than 13 million cases of AKI globally, and there are currently no approved therapies for the prevention or treatment of AKI," said Alvaro Guillem, PhD, chief executive officer at Renibus. "Initiating the Phase 2 Study of RBT-1 is a significant step forward in an area of critical unmet need and improving outcomes for patients at risk for AKI following cardiac surgery."

This Phase 2 study will evaluate the efficacy of RBT-1 in generating a preconditioning response as measured by a composite of biomarkers in subjects who are at risk for AKI following cardiac surgery. Prevention of AKI will be assessed as a key secondary endpoint.

The Montreal Health Innovations Coordinating Center (MHICC), is partnering with Renibus to conduct this study. Andreas Orfanos, MBCh, director of MHICC, said "We are excited to be part of this important trial that will help address pressing and unmet medical need in both the prevention and treatment of AKI."

Site selection is currently underway for this study. For more information on this study, please visit [ClinicalTrials.gov: NCT04564833](https://ClinicalTrials.gov/NCT04564833).

About Renibus Therapeutics, Inc.

Founded in 2015, Renibus is a clinical-stage biotech company dedicated to transforming the cardio-renal disease treatment paradigm by focusing on the prevention, treatment, and diagnostic testing of kidney disease. The company's portfolio includes RBT-1 for prevention of acute kidney injury, RBT-2 for treatment of chronic kidney disease, RBT-3 for treatment of iron deficiency anemia and platinum-based kidney toxicity, RBT-6 for pharmacologic stress testing in kidney diseases, and RBT-9 for treatment of COVID-19 and other viral diseases.

About Montreal Health Innovations Coordinating Center (MHICC).

The MHICC is a leading academic clinical research organization and an integral part of the Montreal Heart Institute (MHI) with an established network of research collaborators in over 4,500 clinical sites in more than 30 countries. It has specific expertise in a variety of drug, natural product, surgical and device trials in several therapeutic areas including cardiovascular diseases, and kidney disease.

Disclaimer

This article contains information regarding our future discovery, development efforts, business strategy, and market opportunities. This information constitutes a forward-looking statement. There are a number of risks and uncertainties that could cause our actual results to differ materially from those indicated by such forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research, such as adverse results in our drug discovery and clinical development processes, decisions made by the FDA and other regulatory authorities, market conditions, our ability to obtain, maintain and enforce proprietary rights and our ability to obtain any necessary financing to conduct our planned activities.

For more information, please visit the Company's website at www.renibus.com.

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¹ Rosner MH, Okusa MD. Acute kidney injury associated with cardiac surgery. Clin J Am Soc Nephrol. 2006;1(1):19-32. doi:10.2215/CJN.00240605

