

**For information contact:** Courtney Harris Feinstein Kean Healthcare 617-761-6744 courtney.harris@fkhealth.com

## RenaMed Biologics Reports Positive Phase II Data With Renal Bio-Replacement Therapy

--Phase II study results show improved survival rates in patients with Acute Renal Failure--

**Lincoln, RI, November 12<sup>th</sup>, 2005** – RenaMed Biologics, Inc. (RenaMed<sup>TM</sup>) reported today at the American Society of Nephrology preliminary positive findings from a Phase II, controlled randomized study of its Renal Bio-Replacement Therapy to treat patients with acute renal failure (ARF or acute kidney injury). The study of fifty-eight (58) patients found that RenaMed's therapy at 28 days increased survival rate by seventy two percent (72%). This trend in improved survival was sustained through 90 and 180-days.

"Despite improving methods for delivering dialysis, mortality rates for patients with ARF have remained unacceptably high for the past 30 years," said Dr. James Tumlin, associate professor of medicine at Emory University and a principal investigator in the RenaMed study. "Moreover the loss of tubule function often precedes the development of multi-organ dysfunction. The preliminary results of this study indicate that compared to conventional therapies, the use of the Bio-Replacement Therapy reduced 28-day all-cause mortality by 28%. If this difference is supported in subsequent studies, the use of "biologics" along side conventional forms of dialysis will be a major advance in the treatment of ARF."

RenaMed's Renal Bio-Replacement Therapy is designed to replace lost kidney functions in patients with ARF and bridge them to recovery. To meet this goal, the product uses physiologically active human renal epithelial cells incorporated in a hollow fiber cartridge and is administered outside of the body. While dialysis and hemofiltration replace the waste and fluid balance functions of the kidney, these processes do not replace the kidney's essential metabolic and endocrine functions. Bio-Replacement Therapy is designed to replace these additional, essential kidney functions during a critical phase of ARF and to work in conjunction with existing hemofiltration systems to provide comprehensive kidney function support.

"These Phase II results are extremely encouraging in terms of the potential survival benefit for our Renal Bio-Replacement Therapy in treating acute renal failure," said Greg Phelps, chairman and chief executive officer of RenaMed Biologics, Inc. "RenaMed is committed to developing life-saving products for critical disease states such as acute renal failure and we look forward to advancing this program to confirmatory trials. This is one of several important milestones for RenaMed this year. We recently announced a major collaboration with Genzyme Corporation for the development and commercialization of Renal Bio-Replacement Therapy for acute renal failure. We are also moving forward on additional applications for our core technology."

## The Study Design and Interim Results:

The controlled, randomized open-label study evaluated the effect of Renal Bio-Replacement Therapy in reducing all cause mortality associated with ARF. Fifty-eight ICU patients with acute oliguric or non-oliguric renal failure and multi-organ dysfunction were enrolled in the study. At the start of the study, patients were randomized (2:1) to receive either Renal Bio-Replacement Therapy with conventional therapy (hemofiltration) or conventional therapy alone. Treatment and control groups were comparable on all key measures including demographics and disease severity.

The primary efficacy endpoint of the trial was patient survival at 28 days. Secondary endpoints included the survival rates at 90 and 180 days, safety for up to 72 hours of use of Bio-Replacement Therapy, structural integrity of the delivery system and analysis of the therapy's cellular functions.

At twenty-eight days 39% of the control patients had survived and this is consistent with the expected result for these patients. Patients on Renal Bio-Replacement Therapy had a 67% survival rate. This translates to a 72% improvement in survival rate for patients treated with Renal Bio-Replacement Therapy. The long-term trend in efficacy was also demonstrated at 90 days with a 62 percent survival rate for the treatment group compared with 34 percent for the control group. The 180-day data remains consistent and will be complete in the near future.

Throughout the study duration, Renal Bio-Replacement Therapy was safe and well tolerated. The adverse event profile for the control and treatment groups was similar and consistent with expectations for this patient population.

The trial was conducted at 12 study centers across the United States. The principal investigators in the study were: J. Tumlin of Emory University, R. Wali of the University of Maryland, P. Murray of the University of Chicago A. Tolwani of the University of Alabama, Birmingham, W. Williams of Massachusetts General Hospital, A. Vinnikova of VCU/MCU, L. Dworkin of Rhode Island Hospital, E. Paganini of Cleveland Clinic, H. Szerlip of Medical College Georgia, J. Ye of Baystate Medical Center, M. Krause of the University of Indiana and K. Finkel of the University of Texas, Houston.

## About Acute Renal Failure (ARF):

ARF is the sudden loss of kidney function, which can lead to multi-organ failure, systemic inflammatory response syndrome (SIRS) and death. The most common causes of ARF are sepsis, blood loss during major surgery or injury, medications and contrast agents. ARF occurs in approximately 5 percent of all hospitalized patients (over 700,000 patients). Severe ARF, which represents approximately 20 percent of all ARF cases, is treated in the ICU with renal replacement therapy. These patients require extensive hospitalizations, and the mortality rate is 55-70 percent. Current therapy is limited to dialysis and hemofiltration; while these treatments address waste and fluid imbalances they do not treat all the consequences of kidney failure.

## About RenaMed Biologics:

RenaMed Biologics, Inc. is the leading clinical stage company focused on the development of proprietary Bio-Replacement Therapies for critical diseases involving severely compromised kidney function. The company's lead product is intended to replace the cellular biologic functions of the kidney that are lost in patients with acute renal failure. The product utilizes physiologically active human renal epithelial cells, administered *ex vivo* in a hollow fiber cartridge. Renal Bio-Replacement Therapy works in conjunction with existing hemofiltration systems and is designed to provide comprehensive kidney function support. Renal Bio-Replacement Therapy is intended to dramatically improve the clinical outcomes and cost of care for patients suffering from ARF. For more information, please visit www.renamedbio.com.

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