

Critical Biologics Commences Clinical Testing of Solinex

Lab Business Week, June 8, 2008 - Critical Biologics Corporation (CBC) announced the successful enrollment of the first four patients in its "first-in-man" clinical trial for Solinex(TM), an intravenous formulation of recombinant human plasma gelsolin (rhu-pGSN). The trial is designed to assess the safety and pharmacokinetics of a single intravenous infusion of rhu-pGSN in critically ill patients with profound hypogelsolinemia in cohorts receiving progressively larger doses of the drug. It is planned to enter a total of 40 patients into the double blind, placebo controlled trial being conducted at a leading medical institution in Hong Kong (see also Critical Biologics Corporation).

"This is an important and exciting development for CBC's Solinex(TM) program," said Richard Straube, MD, CBC's Chief Medical Officer. "The results of this trial will provide valuable insights into the mechanism of depletion of the naturally occurring plasma gelsolin. They will also help CBC determine the size and frequency of the Solinex(TM) dosing required to increase blood levels of this important protective protein above a critical threshold in hypogelsolinemic patients with a high mortality risk." Dr. Straube further commented, "We hope this is the first step to demonstrating that using rhu-pGSN replacement therapy to increase plasma gelsolin levels above a critical threshold will prevent critically ill patients from developing many of the life-threatening complications that appear to be strongly associated with hypogelsolinemia, including acute respiratory distress syndrome (ARDS), sepsis syndrome, multiple organ system failure (MOSF) and death."

CBC's Chief Executive Officer, Ashleigh Palmer, praised the efforts of CBC's collaborators in Hong Kong. "We are very pleased to be working with such a capable medical institution," he said. "We are especially grateful for the expertise and devotion of the lead investigator and the institution's team of dedicated clinical trial specialists. In CBC's previous 200 patient plasma gelsolin epidemiology study, this group proved themselves to be a highly competent team of clinical research professionals. Their world-class medical care, compliance to trial procedures, strict adherence to EU and FDA guidelines, and ability to rapidly accrue patients make them an ideal clinical research partner for a development stage company like CBC."

About Plasma Gelsolin

Gelsolin is a highly evolutionary conserved, naturally occurring protein found inside cells as well as in plasma. Circulating plasma gelsolin (pGSN) levels decrease shortly after a variety of tissue injuries such as trauma, major surgery, burns and sepsis. Severe depletion of pGSN has been found to correlate strongly with adverse clinical outcomes in critical care patients such as longer ventilator times, longer duration of ICU stays and death. Experiments in animal models have shown that disease progression and adverse outcomes can be averted by a timely replenishment of pGSN using rhu-pGSN. It is therefore anticipated that, in high-risk critical care patients, the early detection of reduced pGSN levels followed by replacement with rhu-pGSN could provide an efficacious and well tolerated therapeutic intervention.