NEWS

For Immediate Release

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Sentien Biotechnologies Announces First Subject Dosed in Phase 1/2 Trial of Ex Vivo MSC Therapy for the Treatment of Severe COVID-19

Subject was Enrolled at the University of New Mexico Hospital

LEXINGTON, MA, November 23, 2020 – Sentien Biotechnologies, Inc., a clinical-stage biotechnology company developing novel approaches to cell therapy, today announced that the first subject has been enrolled in its Phase 1/2 study of SBI-101 for the treatment of severe COVID-19 at the University of New Mexico (UNM) Hospital. SBI-101, Sentien's innovative cell-based therapy, is being evaluated in COVID-19 patients suffering from both acute respiratory distress syndrome (ARDS) and acute kidney injury (AKI) requiring renal replacement therapy (RRT).

"We are excited to have enrolled the first subject in Sentien's study of SBI-101 for the treatment of severe COVID-19," said Christos Argyropoulos, MD, Chief of Nephrology at UNM Hospital. "Patients with severe COVID-19 still have few therapeutic options; we are pleased to partner with Sentien to evaluate SBI-101, an investigational therapy which has the potential to significantly lessen the severity of this challenging disease."

J. Pedro Teixeira, MD, principal investigator for the study at UNM, added, "The scientific rationale for studying SBI-101's effect on COVID-19 is compelling. We are learning more and more that AKI is a systemic disease. COVID-19, especially in its most severe cases, is also very much a systemic disease. SBI-101 offers a cutting-edge systemic therapeutic approach to patients with AKI and COVID-19."

SBI-101 is a combination product that integrates allogeneic mesenchymal stromal cells (MSCs) within an extracorporeal, blood-contacting device. MSCs are a unique source of therapeutic secreted factors that modulate the immune-mediated inflammatory response to acute organ injury. By keeping the MSCs confined within a blood-contacting device, SBI-101 enables controlled, dynamic, and sustained delivery of MSC-secreted factors to the patient's blood, without the need for direct injection of the MSCs themselves. SBI-101 integrates into a standard blood circuit such as used with renal replacement therapy, thereby providing patients with both standard-of-care and MSC-mediated blood conditioning in a single session.

"Enrolling the first subject in this COVID-19 study is an important milestone for Sentien," said Sentien Chief Medical Officer, Allen R. Nissenson, MD. "SBI-101 is designed to restore balance to a dysregulated immune system. If SBI-101 can calm the hyperinflammatory cytokine storm associated with severe COVID-19, its therapeutic impact could be significant."

The multi-center trial is a randomized, controlled, ascending dose Phase 1/2 study in patients with COVID-19 requiring RRT. The primary objective of the trial is to evaluate the safety and tolerability of SBI-101; endpoints for efficacy and pharmacodynamic responses to SBI-101 therapy will also be evaluated.

Please visit https://clinicaltrials.gov/ct2/show/NCT04445220 for more information about the study.

About Sentien Biotechnologies

Sentien Biotechnologies, Inc. is a privately-held, clinical-stage company developing novel ex-vivo cell therapy applications to treat conditions caused by systemic, immune-mediated inflammation. Sentien's lead product, SBI-101, integrates allogeneic mesenchymal stromal cells (MSCs) within an extracorporeal, hollow-fiber device. By immobilizing MSCs within a blood-contacting device, SBI-101 enables controlled, dynamic, and sustained delivery of MSC-secreted factors to the patient's blood, without the need for direct injection of the MSCs themselves.

SBI-101 has been evaluated in a Phase 1b/2a study in subjects with dialysis-requiring acute kidney injury (AKI-D). An initial readout from the study provides preliminary evidence of anti-inflammatory and wound healing effects consistent with the SBI-101 therapeutic hypothesis. Building on this data, SBI-101 is being evaluated in COVID-19 patients suffering from severe systemic inflammation.

Sentien's technology can be applied to additional systemic inflammatory indications in both acute and chronic diseases, focusing on complex conditions where single-factor agents have not been effective.

For more information, please visit www.sentienbiotech.com.

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