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Sentien Biotechnologies Announces Open IND in Phase 1/2 Trial of SBI-101 for Patients with COVID-19

Study to Focus on COVID-19 Patients Suffering from ARDS and AKI

LEXINGTON, MA, August 18, 2020 – Sentien Biotechnologies, Inc., a clinical-stage biotechnology company developing novel approaches to cell therapy, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational New Drug (IND) application for the evaluation of Sentien's lead asset, SBI-101, for the treatment of severe COVID-19. Approval of this IND allows Sentien to initiate a Phase 1/2 study with a focus on COVID-19 patients suffering from both acute respiratory distress syndrome (ARDS) and acute kidney injury (AKI) requiring renal replacement therapy (RRT).

SBI-101 is a combination product that integrates allogeneic mesenchymal stromal cells (MSCs) within an extracorporeal, blood-filtration 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-filtration 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.

"There is a compelling scientific rationale for studying SBI-101's effect on COVID-19. SBI-101 is designed to restore balance to a dysregulated immune system; we believe this design is well suited to calm the hyperinflammatory cytokine storm associated with severe COVID-19 patients," said Sentien Chief Medical Officer, Allen R. Nissenson, MD.

"COVID-19 is a very logical application for SBI-101," said Sentien CEO, Brian Miller. "Our previous study of SBI-101 in subjects with dialysis-requiring AKI showed preliminary evidence of anti-inflammatory effects consistent with the SBI-101 therapeutic hypothesis. We are fortunate to have been well-positioned to now focus our attention on COVID-19 patients, who obviously have an urgent need for therapeutics."

"We are excited to have clearance from FDA to initiate this study of SBI-101 in the COVID-19 patient population," said Sentien Executive Chairman, Richard Ganz. "Sentien's mission has always been to develop cell therapies to address diseases characterized by systemic inflammation. The emergence of COVID-19 has served to strengthen our mission even more."

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-filtration 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 investigated 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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