NEWS

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Sentien Biotechnologies Completes Enrollment of First Cohort in Phase 1/2 Trial of Ex Vivo MSC Therapy for the Treatment of Severe COVID-19

Data Safety Monitoring Board Supports Dose Escalation

LEXINGTON, MA, March 30, 2021 – Sentien Biotechnologies, Inc., a clinical-stage biotechnology company developing novel approaches to cell therapy, today announced it has completed enrollment of the first cohort in its Phase 1/2 study of SBI-101 for the treatment of severe COVID-19. 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).

In addition, the independent Data Safety Monitoring Board has reviewed the safety data from the first cohort and supports continuation of the study and dose escalation.

"We are pleased to have reached this milestone in our evaluation of SBI-101 for the treatment of severe COVID-19," said Sentien CEO, Brian Miller. "We are grateful to the patients and clinical site investigators and staff for their participation in the study and we look forward to continued collaboration as we commence enrollment of the second cohort."

"There is increasing evidence that the serious clinical consequences of COVID-19 infection on the lungs and the kidneys is mediated by a dysregulated immune response" said Sentien Chief Medical Officer, Dr. Allen Nissenson. "We are encouraged by what we've observed in the first cohort and are eager to continue pursuing the therapeutic hypothesis that treatment with SBI-101 will restore a favorable immune response and result in improved clinical outcomes."

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.

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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