



Sentien Biotechnologies, Inc. Announces Open Enrollment in Phase 1/2 Trial of SBI-101 for Patients with Acute Kidney Injury

Trial is First-in-Human Study of Novel Blood-Conditioning Cell Therapy

CAMBRIDGE, MA, June 8, 2017 – Sentien Biotechnologies, Inc., a clinical-stage biotechnology company developing novel approaches to cell therapy, announced that it has opened enrollment in its Phase 1/2 trial of SBI-101 for adult patients with acute kidney injury (AKI). This trial is Sentien's first clinical program.

SBI-101 is a combination product that combines mesenchymal stromal cells (MSCs) within a blood-filtration device, allowing for controlled, dynamic interaction of MSCs with a patient's bloodstream. SBI-101 offers two major advantages over traditional, intravenous cell therapy: (1) The duration of cell therapeutic bioactivity is significantly extended by maintaining the MSCs outside the body, in an extracorporeal device; and (2) the MSC cell dose can be increased beyond intravenous limits because the cells are immobilized in the device.

To treat AKI, SBI-101 integrates seamlessly into a continuous renal replacement therapy (CRRT) circuit, thereby providing patients with both standard-of-care and MSC-mediated blood conditioning in a single session.

"Moving our lead product into the clinic marks a major milestone for our company," said Sentien CEO, Brian Miller. "We look forward to working with our clinical sites to advance development of SBI-101 for this significant unmet medical need."

The multi-center trial is a randomized, controlled Phase 1/2 study in patients with AKI receiving CRRT. The primary objective of the trial is to evaluate the safety and tolerability of SBI-101 in patients with AKI. Endpoints for efficacy and pharmacodynamic responses to SBI-101 therapy will also be evaluated. Patient recruitment is expected to continue into 2018, with an estimated enrollment of 24 patients.

Please visit www.clinicaltrials.gov/show/NCT03015623 for more information about the study.

About Acute Kidney Injury

Acute kidney injury is a sudden loss of kidney function, caused by conditions such as sepsis, heart surgery, or trauma. Patients diagnosed with severe AKI are placed on dialysis, require extensive stays in the ICU, and are at higher risk of progressing to chronic kidney disease, end-stage renal disease, or death.

About Sentien Biotechnologies

Sentien Biotechnologies, Inc. is a privately-owned, clinical-stage company pioneering new approaches to cell therapy. Sentien's technology harnesses the power of cell therapy with innovative drug delivery systems to treat a wide range of systemic inflammatory diseases. Sentien's lead product, SBI-101, is designed to allow for controlled, sustained delivery of mesenchymal stromal cell (MSC) secreted factors. This approach immobilizes the MSCs in an extracorporeal device, allowing for doses of therapeutic factors that are unattainable by direct injection.

SBI-101 is the first product application of Sentien's platform blood-conditioning technology that has the potential to restore balance to the immune system after acute vital organ injury, such as acute kidney injury.

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

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