Thrasos Announces Successful Formal Interim Analysis and Clinical Update

Clinical trial continues following dose selection; enrollment has reached 200

MONTREAL, September 16, 2014 – Thrasos Therapeutics, a biotherapeutics company focused on delivering new solutions for kidney disease, today announced that a pre-planned formal interim analysis of 140 subjects enrolled in its Phase 2 clinical study of THR-184 for Acute Kidney Injury (AKI) has been completed. The study will now continue and the dosing strategy will be adjusted based on recommendations of the Independent Data Monitoring Committee (IDMC). At this time 200 subjects have been enrolled in the ongoing clinical trial.

The interim analysis was conducted by an independent statistical team and reviewed with the IDMC. It focused on the safety and efficacy of three original doses of THR-184 compared to placebo. The IDMC recommended continuation of the study based on safety and further recommended that the study proceed using the original high dose arm, dropping the two lower dose arms. Thrasos will continue the study as recommended by the IDMC and will add a higher dose arm, expanding the study to a total of approximately 450 subjects.

"I am pleased that the IDMC was able to complete its assessment of the safety and potential efficacy of THR-184 in the Phase 2 trial, and particularly pleased that the Committee determined, based on the observed safety profile, that additional subjects could be enrolled," said Glenn Chertow, Professor of Medicine and Chief, Division of Nephrology, Stanford University School of Medicine.

THR-184 is a small proprietary peptide that acts on the BMP/Smad pathway. It is in development for the prevention and treatment of AKI. Results from a broad set of preclinical studies, as well as two, Phase 1 clinical trials in which THR-184 was found to be safe and well-tolerated, led to the design and initiation of this Phase 2 clinical trial. The trial is expected to enroll up to 450 patients at more than 40 sites in Canada and the United States. The trial is focused on the prevention of AKI in patients undergoing cardiac surgery. Earlier this year, THR-184 was granted Fast Track designation for this indication by the U.S. Food and Drug Administration (FDA).

"The incidence of acute kidney injury following cardiac surgery is a serious concern for patients and physicians; the potential of THR-184 to prevent this complication is very exciting," said Jean-Claude Tardiff, Director of the Montreal Heart Institute Research Centre, Université de Montréal and Co-Chair of the Study Committee. "The successful outcome of this interim analysis is an important step in moving this program forward to a more complete understanding of the potential of this therapy."

"We are very pleased with the progress of this Phase 2 study. The Company has worked closely with the experts on its Steering Committee to bring us to this stage. And, this trial has been carefully designed to evaluate the safety, tolerability and efficacy of different doses of THR-184," said Jens Eckstein, Ph.D., President, SR One and Chairman of the Board of Thrasos. "We are looking forward to the next stage of this Phase 2 program."

About Acute Kidney Injury (AKI)

Acute kidney injury (AKI) is the sudden loss of kidney function, and it affects more than 1.2 million people each year in the United States. It occurs in different situations and is particularly frequent in patients hospitalized for major surgery, including cardiac and/or vascular surgery, trauma, infection, cardiac disease or cancer. Acute kidney injury can lead to permanent reduction of kidney function and is also associated with an increased risk of death, extended hospitalization and significantly increased medical cost. There are currently no available therapies to prevent or treat AKI.

About Thrasos

Thrasos is a privately held, clinical-stage biotherapeutics company focused on delivering new solutions to individuals affected by kidney disease. The company’s lead compound, THR-184, is currently being evaluated in a Phase 2 clinical study for the prevention of acute kidney injury in patients undergoing cardiac surgery. Thrasos is also developing compounds for diabetic nephropathy, a major cause of chronic kidney disease.