Thrasos Announces Promising Results for Phase 2 THR-184 Dose Ranging Clinical Study for the Prevention of Acute Kidney Injury (AKI)

MONTREAL Canada & Boston MA, February 29, 2016 – Thrasos Therapeutics, a biotherapeutics company focused on delivering new solutions for kidney disease, today announced it has successfully completed its Phase 2, first-in-patients, dose ranging, clinical study of THR-184 for the prevention of acute kidney injury (AKI) in at risk patients undergoing cardiac surgery (NCT01830920). In the study, there was a reduction in the incidence of AKI in patients treated with the highest dose and THR-184 was safe and well tolerated. The effect was observed across different definitions of AKI and was most prominent in patients with underlying chronic kidney disease (CKD), which is an important risk factor for AKI.

"This was the first study to assess the safety and efficacy of THR-184 in patients undergoing cardiac surgery, and the consistency of the results leads us to believe that we have identified the bottom of the therapeutic window," said Jerome Rossert M.D., Ph.D., CMO & CSO of Thrasos Therapeutics. "Given our excellent safety profile, we see an opportunity to increase our dosing regimen to achieve stronger efficacy and look forward to initiating the next study which may incorporate an adaptive Phase 2/3 design element. THR-184 could become the first drug approved by the FDA for the prevention of AKI associated with cardiac surgery and, based on these encouraging results, we are eager to move ahead rapidly either alone or with partner(s) into our next stage of clinical development."

According to Jonathan Himmelfarb, MD, Professor of Medicine, Director, Kidney Research Institute, at the University of Washington and a principal investigator in the study, "There is clearly a need for new methods for the prevention and treatment of AKI, as there are no current options and potential long-term consequences of the disease are significant. The results of this Phase 2 study were encouraging for future development. First, THR-184 appeared to be safe in all patient groups studied. Second, effects were seen in the highest dose arm among subjects in the CKD subset—suggesting the dosing for this trial may only have been at the beginning of the therapeutic window. Patients with CKD are known to be among the most sensitive to kidney injury and we are hopeful that future studies at higher doses with this group of patients will show substantial benefits."

The randomized, double-blind, placebo-controlled study was conducted in more than 40 sites in the United States and Canada and involved 452 patients undergoing cardiac surgery. These patients were selected for risk factors known to predispose them to AKI such as age, diabetes, underlying chronic kidney disease and heart failure. The primary endpoint was development of AKI within 7 days of surgery as measured by the Kidney Disease Improving Global Outcomes (KDIGO) criteria. Four different doses of THR-184, or placebo were administered both prior to surgery and after surgery.

The full results of this study will be submitted for presentation at an upcoming scientific conference.

About THR-184

THR-184 is a proprietary, first-in-class peptide that activates the BMP pathway. Results from a broad set of preclinical studies showed THR-184 had protective effects in animal models of AKI, and in two Phase 1 clinical trials THR-184 was found to be safe and well-tolerated. THR-184 has been granted Fast Track designation for the prevention of AKI following cardiac surgery by the U.S. Food and Drug Administration (FDA).

About Acute Kidney Injury (AKI)

AKI is the sudden loss of kidney function, and it affects more than 1.2 million people each year in the United States and an estimated 13.3 million worldwide. It occurs in different clinical situations and is particularly frequent in patients hospitalized for major surgery, including cardiac and/or vascular surgery, trauma, infection, cardiac disease or cancer. The prevention of AKI is estimated to have a market value in excess of $3.5B. AKI can lead to permanent reduction of kidney function and is also associated with an increased risk of death, extended hospitalization, and 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 with three products in development for kidney disease: THR-184 to prevent AKI associated with cardiac surgery, THR-204 to treat certain forms of CKD, and the THR-800 series to treat cast nephropathy, a form of AKI associated with multiple myeloma. The Company believes that its technology underlying THR-184 will be broadly applicable as well to other types of major surgery where AKI is also a significant complication. Thrasos is headquartered in Montreal, Canada, with a U.S. office in Boston, Massachusetts. www.thrasos.com

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