Rivus Pharmaceuticals Announces Positive Results from Phase 1 Trial of Lead Candidate HU6, Demonstrating Safety, Efficacy in Key Targets for Multiple Cardio-Metabolic Diseases

HU6 was well tolerated and increased resting energy expenditure

Dose dependent weight loss and an improvement in metabolic parameters were also observed, despite the study not being powered to demonstrate them

Enrollment for a Phase 2a Metabolic Trial of HU6 has completed with topline data expected in Q1 2022

HU6 leads a pipeline of first-in-class Controlled Metabolic Accelerators (CMAs), designed to harness the body's natural processes to improve cellular metabolism and treat underlying causes of poor metabolic health and cardiovascular disease

CHARLOTTESVILLE, Va., November 1, 2021 – Rivus Pharmaceuticals Inc., a biopharmaceutical company dedicated to improving cardio-metabolic health, today announced positive results from both single and multiple ascending dose portions of its Phase 1 clinical trial of HU6. HU6, a first-in-class, orally administered Controlled Metabolic Accelerator (CMA) therapy, demonstrated robust and sustained target engagement with no apparent safety signals. Additionally, sustained effects on key biological parameters relevant to cardio-metabolic diseases including type 2 diabetes, heart failure with preserved ejection fracture (HFpEF), non-alcoholic steatohepatitis (NASH), and severe hypertriglyceridemia (SHTG) were observed. HU6 was well-tolerated at all studied doses, and there were no serious adverse events. Participants dosed with HU6 demonstrated an increase in resting energy expenditure, dose dependent weight loss and improvements in metabolic parameters.

The HU6 Phase 1 program consisted of a double blind, placebo controlled, randomized single ascending dose (SAD) as well as a multiple ascending dose (MAD) trial. In the SAD portion of the program, 50 healthy volunteers received doses of HU6 ranging from 30 to 1400mg. In the MAD portion of the program, 24 subjects with high BMI (35-45) received doses of 200, 400, and 550 mg over 14 days of oral, once daily (QD) dosing. HU6 was well-tolerated at all dose levels. The limit to tolerability was not reached at any of the doses studied in the trial.

"We are highly encouraged by Phase 1 clinical trial results for HU6, which demonstrate a compelling, positive impact on multiple key indicators of cardio-metabolic disorders. The data overwhelmingly support the continued development of HU6 to deliver novel and effective treatment to the millions people who live with poor metabolic health and cardiovascular disease," said Allen Cunningham, President and CEO of Rivus Pharmaceuticals. "While many existing cardio-metabolic therapies address downstream effects of these diseases, we've designed CMAs to address the underlying cause."

CMAs provide a new, measured approach to activating proton leak and mitochondrial uncoupling, a natural process in the body that regulates and dissipates energy. By ferrying protons out of the mitochondrial intermembrane space, CMAs cue the increased oxidation of sugars and fats, while maintaining the same baseline production of adenosine triphosphate (ATP). Activating this process results in the reduction of accumulated fat and the prevention of additional fat accumulation throughout the body.

The company also announced it has completed enrollment for a double blind, placebo controlled, randomized Phase 2a clinical metabolic study of HU6 in cohorts of participants with high BMI (28-45 kg/m2). Topline data are expected in Q1 2022.

About Rivus Pharmaceuticals

Rivus Pharmaceuticals, Inc., is dedicated to transforming the treatment of cardio-metabolic disease. Rivus' first-in-class small molecule therapy, HU6, is a controlled metabolic accelerator (CMA) that addresses the underlying cause of cardio-metabolic disease by harnessing the body's natural processes to improve cellular metabolism. Rivus' therapy presents a tremendous opportunity to empower patients on their journey to better health when facing a broad range of cardio-metabolic conditions, including type 2 diabetes, hypertension, non-alcoholic steatohepatitis (NASH), dyslipidemia and obesity. For more information, please visit rivuspharmadev.wpengine.com.

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