



## **Rivus Pharmaceuticals to Present Results from a Phase 2a Trial Evaluating its Controlled Metabolic Accelerator, HU6, at the American Association for the Study of Liver Diseases (AASLD) 2022 Meeting**

*Data demonstrate significant fat selective weight loss across all body compartments, including the liver, with no loss of skeletal muscle mass*

CHARLOTTESVILLE, Va., November 4, 2022 – Rivus Pharmaceuticals Inc., a clinical-stage biopharmaceutical company dedicated to improving cardio-metabolic health, today announced the company will present topline results from a Phase 2a trial evaluating the safety and efficacy of HU6, a first-in-class controlled metabolic accelerator (CMA), to address liver fat and total body fat in patients with Nonalcoholic fatty liver disease (NAFLD). Data will be presented Sunday, Nov. 6 at 11:30 am EST, in an oral presentation titled “HU6 Reduces Liver Fat in Subjects with High BMI NAFLD: Top-Line Results From a Phase 2a Trial.”

“Obesity is the underlying driver of a broad range of cardio-metabolic conditions including NAFLD,” said Shaharyar Khan, PhD, Chief Scientific Officer, Rivus Pharmaceuticals. “The Phase 2a trial results showed that HU6, a first-in-class controlled metabolic accelerator (CMA), stands alone in its mechanism for fat selective weight loss, meeting the primary endpoint for reducing liver fat, as well as reducing body fat in the treated population. These results setup the next phase of HU6 clinical development in cardio-metabolic disease, including a Phase 2a trial in obese patients with heart failure with preserved ejection fraction (HFpEF), which is currently enrolling, and a Phase 2b trial in obesity that will begin enrollment in 2023.”

### **Phase 2a Metabolic Trial Design and Results**

The Phase 2a metabolic trial was a 61-day randomized, double-blind, placebo-controlled trial (n=80) designed to evaluate the safety and efficacy of HU6 at three dose levels (150 mg, 300mg, and 450 mg) in NAFLD subjects with elevated liver fat (greater than 8%) and high BMI (body mass index 28 to 45 kg/m<sup>2</sup>). A subset of patients (40%) had elevated HbA1C levels.

The Phase 2a trial met primary (liver fat reduction by MRI-PDFF) and multiple secondary endpoints (including body weight and fat reduction by abdominal MRI). HU6 was associated with significant decreases in liver fat as well as total body fat in patients with Nonalcoholic fatty liver disease (NAFLD) while



preserving skeletal muscle mass. In addition, patients treated with HU6 demonstrated significant improvement in key cardiovascular and metabolic health indicators including glycemic control (glycated albumin) and inflammatory markers (hsCRP). This trial is the first clinical study with extended dosing of HU6 in subjects with high body mass index (BMI).

- A >30% absolute reduction in liver fat by MRI-PDFF was observed: 40%, 71%, and 72% for the HU6 150 mg, 300 mg, and 450 mg dose levels, respectively, and 43%, 75%, and 86% with HU6 doses in the HbA1c subset vs. 0-5% with placebo (P<0.05 for all).
- Relative reductions in liver fat were 33%, 43%, and 40% corresponding to responder rates (>30% relative reduction) of 40%, 71% and 72% at low, mid and high doses, respectively, compared to placebo relative reduction in liver fat of 2% and responder rate of 5%.

### **About HU6 and CMAs**

HU6 is a Controlled Metabolic Accelerator (CMA) that provides a novel, measured approach to activating mitochondrial uncoupling, a natural process in the body by which the body generates heat. 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 fat selective weight loss while preserving muscle mass.

### **About Rivus Pharmaceuticals**

Rivus Pharmaceuticals, Inc., a leader in mitochondrial biology, is dedicated to improving cardio-metabolic health by advancing a new class of medicines, Controlled Metabolic Accelerators (CMAs). Harnessing a natural metabolic process, CMAs target a significant risk factor for these diseases – obesity, the result of excess fat accumulation in the body. Rivus' first-in-class small molecule therapy, HU6, represents a tremendous opportunity to empower patients on their journey to better health when facing a broad range of conditions, including obesity, heart failure with preserved ejection fraction (HFpEF), type 2 diabetes, and Nonalcoholic fatty liver disease (NAFLD)/Nonalcoholic steatohepatitis (NASH). For more information, please visit [www.rivuspharma.com](http://www.rivuspharma.com).



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