



## **Rivus Pharmaceuticals to Present Corporate Update at 2025 J.P. Morgan Healthcare Conference**

– Topline data readout from Phase 2 M-ACCEL study planned for Q2 2025 –

CHARLOTTESVILLE, Va., and SAN FRANCISCO, January 8, 2025 – Rivus Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company dedicated to treating cardiometabolic diseases driven by obesity, today announced that Jayson Dallas, M.D., chief executive officer, will provide a corporate update during a presentation at the 43<sup>rd</sup> Annual J.P. Morgan Healthcare Conference in San Francisco.

The corporate presentation will highlight Rivus' new class of investigational therapies, called Controlled Metabolic Accelerators (CMAs), and will include updates on the clinical development of its lead program, HU6, and preclinical pipeline progress. HU6 is a once-daily, oral investigational medicine that promotes sustained body fat loss while preserving muscle mass by increasing resting metabolic rate in a controlled manner. The company has completed the active six-month dosing phase of M-ACCEL, a Phase 2 study in 220 patients with metabolic dysfunction associated steatohepatitis (MASH), with topline data expected in the second quarter of 2025. M-ACCEL will be the third Phase 2 study of HU6 to be completed.

"Obesity is at the root of chronic diseases that kill more people every year than all cancers combined. We believe that HU6 and our portfolio of CMAs can potentially be important and transformative therapies for patients with diseases driven by obesity while preserving lean body mass," said Dr. Dallas. "We now have clinical experience with HU6 in more than 400 patients, across different patient populations."

### **J.P. Morgan Healthcare Conference Presentation Details**

Rivus Pharmaceuticals will present in the private company track at the 43<sup>rd</sup> Annual J.P. Morgan Healthcare Conference on Monday, January 13, at 8:30 a.m. Pacific Time (11:30 a.m. Eastern Time) at the Westin St. Francis Hotel.

### **About Controlled Metabolic Accelerators (CMAs)**

Rivus is advancing a new class of investigational therapies called Controlled Metabolic Accelerators (CMAs) that have the potential to improve metabolic health for people with obesity and associated metabolic diseases. Rivus' CMAs are oral small molecules in development to increase resting metabolic rate, which results in increased consumption of energy, primarily from fat. The loss in fat mass may address multiple cardiometabolic conditions driven by adiposity. CMAs increase metabolism in a manner that is consistent and imperceptible to the patient by leveraging the natural metabolic process of mitochondrial uncoupling. In preclinical studies, mitochondrial uncoupling was shown to account for a significant portion (20% to 50%) of daily energy expenditure. Caloric-restriction strategies, on the other hand, reduce energy

input and result in loss of muscle mass as well as fat. Initial data in humans has demonstrated that CMAs provided fat-selective weight loss, improved insulin sensitivity, and significantly reduced oxidative stress and inflammation.

### **About HU6**

HU6, a novel, oral, once-daily investigational therapy, is Rivus' lead CMA. It is a purposely designed investigational oral small molecule that is intended to be a foundational monotherapy for cardiac, liver, diabetes and obesity indications. HU6 has been demonstrated to promote sustained body fat loss by imperceptibly increasing resting metabolism, which results in fat burn, while preserving muscle mass. The current clinical development of HU6 is focused on metabolic diseases with the most morbidity and greatest treatment needs: obesity-related heart failure with preserved ejection fraction (HFpEF) and metabolic dysfunction-associated steatohepatitis (MASH)/metabolic dysfunction-associated steatotic liver disease (MASLD). To date, more than 400 patients have been treated with HU6 as part of the clinical development program.

Results of a Phase 2 metabolic study in patients with a high body mass index (BMI) and MASLD showed that once-daily HU6 significantly reduced liver fat content and body weight with no loss of lean muscle mass and improved key markers of systemic inflammation and metabolism.<sup>1</sup> HU6 was well tolerated in this trial; side effects were mainly mild or moderate in severity. Results from the Phase 2a HuMAIN study ([ClinicalTrials.gov: NCT05284617](https://clinicaltrials.gov/ct2/show/study/NCT05284617)) of HU6 in patients with obesity-related HFpEF showed the trial met its primary endpoint, demonstrating that treatment with HU6 resulted in statistically significant weight loss. The rationale for the use of HU6 in HFpEF and the design of the HuMAIN trial were published in the [European Journal of Heart Failure](#) in June 2024.<sup>2</sup>

The company is currently evaluating HU6 in the randomized, double-blind, placebo-controlled, parallel-group Phase 2 M-ACCEL trial ([ClinicalTrials.gov: NCT05979779](https://clinicaltrials.gov/ct2/show/study/NCT05979779)) in patients with MASH. The primary endpoint is percent change from baseline in liver fat as assessed by magnetic resonance imaging liver proton density fat fraction (MRI-Liver PDFF) at six months. The study is being conducted at approximately 20 clinical sites in the United States.

### **About Rivus Pharmaceuticals**

Rivus Pharmaceuticals, Inc., a leader in mitochondrial biology, is dedicated to improving metabolic health by advancing a new class of investigational therapies called Controlled Metabolic Accelerators (CMAs). Rivus' lead CMA is the investigational small molecule HU6 in clinical development to treat obesity-related heart failure with preserved ejection fraction (HFpEF), metabolic dysfunction associated steatohepatitis (MASH)/metabolic dysfunction-associated steatotic liver disease (MASLD) and Type 2 diabetes. For more information, please visit [www.rivuspharma.com](http://www.rivuspharma.com).

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## References

1. Nouredin M, Khan S, Portell F, et al. Safety and efficacy of once-daily HU6 versus placebo in people with non-alcoholic fatty liver disease and high BMI: a randomised, double-blind, placebo-controlled phase 2a trial. *Lancet Gastroenterol Hepatol*. 2023;8(12):1094-1105.
2. Kitzman DW, Lewis GD, Pandey A, et al. A novel controlled metabolic accelerator for the treatment of obesity-related heart failure with preserved ejection fraction: Rationale and design of the Phase 2a HuMAIN trial. *Eur J Heart Fail*. June 26, 2024.