# Rhythm Initiates Phase 2 Clinical Trial of RM-493 for Obesity

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*BOSTON, January 4, 2013*—Rhythm announced today the initiation of a Phase 2 clinical trial with RM-493, the company's novel melanocortin 4 receptor (MC4R) agonist, for the treatment of obesity.

"This Phase 2 study will greatly expand our understanding of RM-493's profile for the treatment of obesity," said Liz Stoner, MD, Chief Development Officer of Rhythm. "Based on the data from preclinical studies and early clinical trials, we believe RM-493 has substantial therapeutic potential for reducing body weight and insulin resistance in obese and diabetic patients."

The Phase 2 trial is designed to evaluate the effect of RM-493 on weight loss and safety in obese subjects treated for three months. The trial will also assess the drug's effects on glucose and insulin resistance. In 2012, Rhythm completed Phase 1 clinical trials with RM-493 in which obese subjects were treated for up to 28 days. These studies evaluated RM-493's safety, pharmacokinetics, and effect on body weight. Extensive preclinical studies in obese primates preceded these human clinical trials; primates treated for eight weeks lost an average of 13.5% of their body weight, with significant improvements in both insulin sensitivity and cardiovascular function.

"We have seen compelling preclinical and clinical results with RM-493 to date, "said Keith Gottesdiener, MD, CEO of Rhythm. "RM-493's potential for double-digit-percent weight loss, its promising initial cardiovascular safety profile, and the improving regulatory climate for obesity drug development present a unique and exciting opportunity to improve the treatment of obesity and diabetes."

## About RM-493

RM-493 is a small-peptide melanocortin 4 receptor (MC4R) agonist that is in clinical development for the treatment of obesity and diabetes. The MC4 receptor mediates a key pathway in humans that regulates energy homeostasis and food intake. The MC4 pathway is well validated in humans; mutations of MC4R are associated with obesity and are estimated to be responsible for 4%-6% of all severe obesity.

## **About Obesity and Diabetes**

Over 78 million U.S. adults and 12.5 million U.S. children and adolescents are obese. Obesity is also a risk factor for the development of diabetes and is likely the critical factor in the 25% increase in the prevalence of diabetes over the past 20 years. Of the 24 million people with diabetes in the U.S., two-thirds have a body mass index (BMI) exceeding 27. The World Health Organization forecasts the prevalence of both obesity and diabetes to double worldwide over the next 20 years, with substantial health and economic impact.

## **About Rhythm**

Rhythm is a biotechnology company developing peptide therapeutics that address unmet needs in metabolic diseases. Rhythm is developing the ghrelin peptide agonist, RM-131, for the treatment of diabetic gastroparesis and other GI functional disorders, and the MC4R peptide agonist, RM-493, for obesity and diabetes. Rhythm investors include MPM Capital, New Enterprise Associates, Third Rock Ventures, Ipsen, and Pfizer Ventures. The company is based in Boston, Massachusetts.