Kailera Therapeutics Announces First Participants Randomized in KaiNETIC Global Phase 3 Clinical Program of GLP-1/GIP Receptor Dual Agonist Ribupatide (KAI-9531)

January 12, 2026

- *Ribupatide (KAI-9531) aims to address critical need for greater weight loss, especially for people living with a BMI of 35 kg/m^2 or greater*
- *KaiNETIC program includes three Phase 3 clinical trials in adults living with obesity or overweight*

Waltham, MA, January 12, 2026 —Kailera Therapeutics, Inc., an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care, today announced the randomization of the first participants in the KaiNETIC global Phase 3 clinical program of ribupatide (also known as KAI-9531), an investigational once-weekly injectable dual GLP-1/GIP receptor agonist peptide, for the treatment of people living with obesity or overweight.

The KaiNETIC global Phase 3 clinical program includes three global, double-blind, randomized, placebo-controlled Phase 3 trials (KaiNETIC-1, KaiNETIC-2, and KaiNETIC-3) to evaluate weekly ribupatide doses of up to 10 mg administered by subcutaneous injection over 76 weeks:

- KaiNETIC-1: target enrollment of 1,800 adults with a BMI of 30 kg/m^2 or greater, or a BMI of 27 kg/m^2 or greater with a comorbidity, excluding type 2 diabetes
- KaiNETIC-2: target enrollment of 1,700 adults with a BMI of 27 kg/m^2 or greater with type 2 diabetes
- KaiNETIC-3: target enrollment of 1,200 adults with a BMI of 35 kg/m^2 or greater and without type 2 diabetes. This trial will include an arm that will be randomized to open-label semaglutide 2.4 mg subcutaneous weekly injection.

“Obesity is the driving factor for more than 200 comorbidities and represents a significant contributor to increased morbidity and mortality. There remains a critical need for therapies offering greater weight loss, especially for the most severely impacted patient population – those living with a BMI greater than 35, which is projected to be half of U.S. adults with obesity by 2030,” said Scott Wasserman, M.D., Chief Medical Officer, Kailera. “Building on the significant weight loss seen in ribupatide clinical trials to date, we initiated the KaiNETIC global Phase 3 program to evaluate doses up to 10 mg to potentially help participants who need greater weight loss than today’s therapies provide, while also evaluating a range of doses to meet patients where they are in their treatment journey.”

“We believe ribupatide has the potential to have a category-leading profile for the treatment of obesity and we are proud to begin our KaiNETIC Phase 3 clinical program to further evaluate its potential in a global population. Reaching this milestone reflects the dedicated and focused effort of our team and underscores our commitment to leading the next era of obesity care,” added Ron Renaud, President and Chief Executive Officer, Kailera.

Ribupatide (also known as KAI-9531 and being developed as HRS9531 by Hengrui Pharma in Greater China) produced favorable data in several clinical trials to date. In a previously reported clinical trial conducted by Hengrui in China, after 36 weeks, including only 12 weeks of treatment at the 8 mg dose, ribupatide reduced body weight by 23.6% from baseline, compared to a 1.8% reduction with placebo, based on the efficacy estimand , with no observed plateau in weight loss and a favorable safety profile consistent with other GLP-1-based treatments.

About the KaiNETIC Phase 3 Program
KaiNETIC is a global Phase 3 program consisting of three double-blind, randomized, placebo-controlled Phase 3 clinical trials designed to evaluate the efficacy and safety of ribupatide for the treatment of obesity or overweight. The trial will evaluate ribupatide doses up to 10 mg administered by weekly subcutaneous injection over a period of 76 weeks with dose titration for up to 24 weeks and a maintenance dose of at least 52 weeks. The trials will enroll participants in North America, Europe, UK, Oceania, and South America.

The first trial, KaiNETIC-1, targets enrollment of approximately 1,800 participants with a BMI of 30 kg/m^2 or greater or a BMI of 27 kg/m^2 or greater with a comorbidity, excluding type 2 diabetes. The primary endpoint of the trial is the percentage change in body weight from baseline at Week 76. The second trial, KaiNETIC-2, targets enrollment of approximately 1,700 participants with a BMI of 27 kg/m^2 or greater and type 2 diabetes. The co-primary endpoints of this trial are percentage change in body weight from baseline and change in hemoglobin A1c from baseline at Week 76. In KaiNETIC-1 and KaiNETIC-2, participants will be randomized to a ribupatide dose of 4 mg, 6 mg, 8 mg, and 10 mg, or placebo. Both trials will also evaluate ribupatide in a pre-defined subgroup of participants with BMI 35 kg/m^2 or greater.

The third trial, KaiNETIC-3, targets enrollment of approximately 1,200 adults with a BMI of 35 kg/m^2 or greater and without type 2 diabetes. Participants will be randomized to ribupatide doses of 8 mg or 10 mg, placebo, or open-label semaglutide 2.4 mg. The co-primary endpoints of this trial are percentage change in body weight from baseline compared to placebo at Week 76 and percentage change in body weight from baseline compared to semaglutide 2.4 mg at Week 76.

About Ribupatide
Ribupatide (also known as KAI-9531 and being developed as HRS9531 by Hengrui Pharma in Greater China) is a once-weekly injectable GLP-1 (glucagon-like peptide-1)/GIP (glucose-dependent insulinotropic polypeptide) receptor dual agonist peptide. Over 2,500 clinical trial participants have been dosed with ribupatide with treatment out to 52 weeks, including in multiple late-stage clinical trials conducted by Hengrui in China. Hengrui submitted a marketing authorization application to the National Medical Products Administration (NMPA) in China for long-term weight management of HRS9531 in adults. Ribupatide is currently being evaluated in the KaiNETIC global Phase 3 clinical program comprised of three Phase 3 trials.

1. Based on the efficacy estimand: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other weight-loss therapies from the analysis.

About Kailera Therapeutics
Kailera Therapeutics (Kailera) is an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by progressing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. With an obesity-first focus, Kailera is advancing four clinical-stage product candidates leveraging multiple GLP-1-based mechanisms of action and routes of administration specifically designed to address critical needs in the current therapeutic landscape. The lead product candidate, ribupatide (also known as KAI-9531), is advancing in global Phase 3 trials as a once-weekly injectable GLP-1/GIP receptor dual agonist. Kailera is expanding the ribupatide franchise by developing a once-daily oral tablet formulation with the goal of providing an oral option with the potential for compelling weight loss and highly differentiated tolerability. Additionally, Kailera is advancing the development of KAI-7535, a once-daily oral small molecule GLP-1 receptor agonist with the potential to improve upon the clinical profile of existing oral treatments, and KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist that leverages an incremental mechanism to potentially deliver compelling weight loss, a differentiated tolerability profile, and improved liver fat reduction. Kailera's vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. Kailera is based in Waltham, MA. For more information, visit www.kailera.com and follow us on LinkedIn and X.

Contact Information for Kailera
Maura Gavaghan
Vice President, Corporate Communications and Investor Relations
maura.gavaghan@kailera.com