Kailera Therapeutics and Hengrui Pharma Report Positive Topline Data from Phase 2 Obesity Trial of Oral Ribupatide

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- *Mean weight loss of up to 12.1% with no observed plateau at 26 weeks in Phase 2 trial in China with oral GLP-1/GIP receptor dual agonist ribupatide*
- *Up to 38.6% of participants taking oral ribupatide achieved at least 15% weight loss*
- *Vomiting reported in 11.4% and 7.5% of participants taking 25 mg and 50 mg oral ribupatide, respectively*
- *Hengrui to rapidly advance oral ribupatide to Phase 3 trial in China; Kailera plans to initiate a global Phase 2 clinical trial in 2026*

Shanghai, China and Waltham, Mass., USA, February 10, 2026 —Hengrui Pharma (Hengrui), a global pharmaceutical company focused on scientific and technological innovation, and Kailera Therapeutics, Inc. (Kailera), an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care, today announced positive topline data from Hengrui's Phase 2 clinical trial of once-daily oral ribupatide (also known as HRS9531 tablet and KAI-9531-T), a GLP-1/GIP receptor dual agonist peptide, in 166 adults living with obesity in China (NCT06841445). Participants receiving oral ribupatide demonstrated a mean weight reduction from baseline of up to 12.1% at 26 weeks based on the efficacy estimand[I] with no observed plateau in weight loss, and vomiting reported in no more than 11.4% of participants taking oral ribupatide.

Based on the efficacy estimand[I] at Week 26, participants taking oral ribupatide achieved a mean weight loss of 6.9% (10 mg), 12.1% (25 mg), and 12.1% (50 mg) from baseline, with no observed plateau in weight loss, compared to 2.3% with placebo. Based on the treatment policy estimand[II] at Week 26, participants taking oral ribupatide achieved a mean weight loss of 6.7% (10 mg), 11.9% (25 mg), and 11.4% (50 mg) from baseline, with no observed plateau in weight loss, compared to 2.1% with placebo. Additionally, at the 25 mg dose, 59.1% of participants achieved at least 10% weight loss, and 38.6% of participants achieved at least 15% weight loss at Week 26. At the 50 mg dose, 52.5% of participants achieved at least 10% weight loss, and 37.5% of participants achieved at least 15% weight loss at Week 26.

Oral ribupatide demonstrated a favorable safety and tolerability profile. Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal (GI)-related. Low GIAE rates were observed. Rates of vomiting were 2.4% at 10 mg, 11.4% at 25 mg, and 7.5% at 50 mg while nausea was 11.9% at 10 mg, 22.7% at 25 mg, and 20.0% at 50 mg, consistent with the results of the trials previously conducted by Hengrui in China. No permanent treatment discontinuations or down-titrations due to nausea, vomiting, diarrhea, or constipation were reported in participants taking oral ribupatide.

"We are pleased to share these positive topline Phase 2 results for oral ribupatide. These data highlight the potential to deliver a differentiated oral medication for the treatment of obesity," said Zi Ye, Senior Medical Director, Metabolic Diseases, Clinical Development, Hengrui Pharma. "We plan to rapidly advance to a Phase 3 clinical trial in China, bringing us a step closer to a potential new oral treatment option for people living with obesity."

"The Hengrui Phase 2 clinical trial results mark an important milestone in the expansion of our ribupatide franchise. We believe oral ribupatide could help to address the diverse needs of people living with obesity or overweight and meet patients wherever they are in their treatment journey," said Scott Wasserman, M.D., Chief Medical Officer, Kailera. "These positive data suggest a potentially game-changing clinical profile for an oral obesity therapy, and we look forward to initiating a Phase 2 trial later this year. Concurrently, we intend to build upon the comprehensive injectable ribupatide data with the Phase 3 KaiNETIC program with the goal of rapidly and efficiently bringing more options to patients."

Hengrui plans to advance oral ribupatide to a Phase 3 clinical trial for the treatment of obesity in China, and Kailera plans to initiate a global Phase 2 clinical trial in 2026.

Ribupatide is also being developed as an injectable therapy. In previously reported results[1] from a clinical trial conducted by Hengrui in China evaluating the 8 mg dose of injectable ribupatide, participants taking ribupatide achieved a mean weight loss of 23.6% from baseline at Week 36, with no observed plateau in weight loss, compared to 1.8% with placebo, and a favorable safety and tolerability profile consistent with other GLP-1-based treatments. Injectable ribupatide is currently being evaluated in the KaiNETIC global Phase 3 clinical program.

Hengrui intends to share the full oral ribupatide Phase 2 clinical trial data at an upcoming scientific conference.

About the Oral Ribupatide (HRS9531-T-201) Clinical Trial
The HRS9531-T-201 clinical trial is a multi-center, randomized, double-blind, placebo-controlled Phase 2 clinical trial

(NCT06841445) conducted by Hengrui in China to evaluate the efficacy and safety of oral ribupatide (HRS9531 tablet) in adults (≥18 years of age) living with obesity (BMI ≥ 28 kg/m^2) and without type 2 diabetes. The study enrolled 166 participants who were randomized in equal ratio to receive once-daily oral ribupatide 10 mg, 25 mg, 50 mg, or placebo. Participants followed a simple titration schedule, reaching the doses of 10 mg and 25 mg at Week 4, and 50 mg at Week 8. The primary objective was to evaluate the effect of oral ribupatide vs. placebo on body weight at 26 weeks.

About Ribupatide
Ribupatide is a GLP-1 (glucagon-like peptide-1)/GIP (glucose-dependent insulinotropic polypeptide) receptor dual agonist peptide being developed as a once-weekly subcutaneous injection and as a once-daily oral tablet for the treatment of obesity and overweight. Once-weekly injectable ribupatide has been studied in over 2,500 clinical trial participants who have been dosed 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 in adults. In May 2024, Hengrui granted Kailera exclusive global rights outside Greater China to develop, manufacture and commercialize its portfolio of innovative GLP-1 therapeutics, including ribupatide. Kailera is currently evaluating injectable ribupatide for the treatment of obesity in the KaiNETIC global Phase 3 clinical program. Based on compelling clinical data to date, Hengrui is advancing once-daily oral ribupatide to Phase 3 clinical trials in China, and Kailera plans to initiate a global Phase 2 trial in 2026.

About Hengrui Pharma
Hengrui Pharma is an innovative, global pharmaceutical company dedicated to the research, development and commercialization of high-quality medicines to address unmet clinical needs. Its therapeutic areas of focus include oncology, metabolic and cardiovascular diseases, immunological and respiratory diseases, and neuroscience. Driven by a patient-focused philosophy since its founding in 1970, Hengrui Pharma remains committed to advancing human health by striving to conquer diseases, improve health, and extend lives through the power of science and technology.

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 with a lead product candidate, ribupatide (also known as KAI-9531), that has the potential for the greatest weight loss. Ribupatide is 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.

[I] *Based on the efficacy estimand, which was pre-specified as the supplementary 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.*
[II] *Based on the treatment policy estimand: treatment effect including the impact of premature discontinuations or use of other weight-loss therapies.*

References
1. Efficacy and Safety of HRS9531, a Novel Dual GLP-1/GIP Receptor Agonist, in Chinese Adults with Overweight or Obesity Without Diabetes. J. Zhou et al. American Diabetes Association Scientific Sessions, Chicago, IL, June 2025.

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