Hengrui Pharma and Kailera Therapeutics Announce Additional Data from Phase 3 Obesity Trial in China of Dual GLP-1/GIP Receptor Agonist HRS9531

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- *Mean weight loss of 19.2%I at 6 mg with no plateau and favorable safety profile in 48-week Phase 3 clinical trial –*
- *Data builds on previously reported Phase 2 results that showed mean weight loss of 23.6%I at 8 mg at week 36 with no plateau –*
- *NDA submitted in China by Hengrui; Kailera plans to start global Phase 3 trials by year-end evaluating multiple maintenance doses including 8 mg –*

Shanghai, China and Waltham, Mass., USA, November 4, 2025 —Hengrui Pharma (Hengrui), a global pharmaceutical company focused on scientific and technological innovation, and Kailera Therapeutics, Inc. (Kailera), a clinical-stage biopharmaceutical company focused on advancing a differentiated, late-stage portfolio of next-generation therapies for the treatment of obesity, today announced the presentation of additional data from Hengrui's Phase 3 clinical trial [1] (GEMINI-1) of a once-weekly subcutaneous injection of HRS9531, a novel dual GLP-1/GIP receptor agonist, in individuals living with obesity or overweight in China (NCT06396429) at ObesityWeek® 2025, the annual meeting of The Obesity Society (TOS).

The trial met both co-primary endpoints, including superior weight loss with HRS9531 (2 mg, 4 mg, and 6 mg) and greater percentage of participants achieving body weight reductions of at least 5% compared to placebo at 48 weeks. Hengrui submitted a marketing authorization application to the National Medical Products Administration (NMPA) in China for chronic weight management of HRS9531 in adults, which has recently been accepted. Kailera plans to begin global Phase 3 trials of HRS9531 as KAI-9531 evaluating multiple doses, including 8 mg and 10 mg, and longer treatment durations by year-end 2025.

Efficacy Summary

- Hengrui's Phase 3 trial enrolled 567 participants with a mean baseline body weight of 93 kg (205 lb) and evaluated HRS9531 doses of 2 mg, 4 mg, and 6 mg compared to placebo.
- Based on the hypothetical strategy estimand[I], participants taking HRS9531 achieved a mean weight loss of 11.2% (2 mg), 17.4% (4 mg) and 19.2% (6 mg), compared to placebo (1.4%).
- Based on the treatment policy estimand[II], participants taking HRS9531 achieved a mean weight loss of 10.7% (2 mg), 16.4% (4 mg) and 17.7% (6 mg), compared to placebo (1.4%).
- Based on the treatment policy estimand[II], 68.1% (2 mg), 88.0% (4 mg) and 85.7% (6 mg) of HRS9531-treated participants achieved at least 5% weight loss.
- Based on the treatment policy estimand[II], 44.4% of participants taking HRS9531 (6 mg) achieved at least 20% weight loss.
- Treatment with HRS9531 resulted in robust improvement in cardiometabolic risk factors including blood pressure, lipids, measures of insulin resistance and hsCRP (high sensitivity C reactive protein).

Safety and Tolerability Summary

- The trial results demonstrated a safety and tolerability profile consistent with GLP-1-based treatments and the previously reported HRS9531 Phase 2 clinical data.
- Most treatment-emergent adverse events (TEAEs) were mild to moderate and were gastrointestinal-related.
- Permanent treatment discontinuation rates due to TEAEs were very low with 0.7% (1 participant, 2 mg), 0.7% (1 participant, 4 mg), 1.4% (2 participants, 6 mg) and 0% (placebo).

In previously reported Phase 2 clinical trial[2] (NCT06054698) results evaluating the 8 mg dose of HRS9531, participants taking HRS9531 achieved a mean weight loss of 23.6% (21.7% placebo-adjusted)[I] at week 36, with no plateau in weight loss and a favorable safety profile consistent with other GLP-1-based treatments. Kailera's global Phase 3 program is evaluating multiple maintenance doses, including 8 mg and 10 mg, and at least 52 weeks of maintenance dosing. The company plans to initiate this program by year-end 2025. The Phase 3 program is comprised of three trials evaluating KAI-9531: one in adults with a BMI greater than 30 kg/m^2 or greater than 27 kg/m^2 with at least one comorbidity and without type 2 diabetes, another in adults with BMI of greater than 27 kg/m^2 and type 2 diabetes, and a third in adults with a BMI of greater than 35 kg/m^2 and without type 2 diabetes.

"We are proud to present the data from this important clinical trial that showed impressive and sustained weight loss and optimization of multiple cardiometabolic risk factors, alongside a favorable safety and tolerability profile," said Hong Chen, Head of Metabolism Department I of Hengrui Pharma. "We believe HRS9531 has the potential to make a meaningful difference in the lives of people living with obesity."

"The HRS9531 6 mg results further validate the potential of KAI-9531 to be a transformative therapy for patients living with obesity and overweight, and we're excited to start our global Phase 3 program by year-end to evaluate both higher doses and longer treatment durations to unlock the full potential of KAI-9531," said Ron Renaud, President and Chief Executive Officer, Kailera. "We look forward to advancing our mission to deliver innovative therapies with the potential to meaningfully improve the lives of people around the world needing highly effective, sustainable weight loss."

The presentation is accessible on the Scientific Publications section of the Kailera website.

About the GEMINI-1 Clinical Trial
The GEMINI-1 clinical trial was a multi-center, randomized, double-blind, placebo-controlled Phase 3 clinical study (NCT06396429) conducted by Hengrui in China to evaluate the efficacy and safety of HRS9531 injection in adults (≥18 years of age) with obesity (BMI ≥ 28 kg/m^2) or overweight (BMI ≥ 24 kg/m^2) and at least one weight-related comorbidity without diabetes. The study enrolled 567 participants with 531 completing the trial. The primary objective was to evaluate the efficacy of HRS9531 injection vs. placebo in reducing body weight after 48 weeks of treatment. Participants were randomized (1:1:1:1) to receive once-weekly subcutaneous injections of HRS9531 2 mg, 4 mg, 6 mg or placebo for 48 weeks.

About HRS9531 (KAI-9531)
HRS9531 is a novel injectable dual GLP-1/GIP receptor agonist developed independently by Hengrui Pharma. It is formulated as an injectable peptide in clinical development for the treatment of type 2 diabetes, obesity and related conditions. Over 2,000 patients to date have been dosed with HRS9531 across several Phase 1, Phase 2, and Phase 3 clinical trials in China. HRS9531 is being developed globally (ex-Greater China) by Kailera Therapeutics as KAI-9531.

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. Founded in 1970 with the core principle of putting patients first, 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 developing a broad, advanced, and differentiated portfolio of clinical-stage injectable and oral therapies for the treatment of obesity. Kailera's most advanced program, KAI-9531 (being developed in China as HRS9531), is an injectable dual GLP-1/GIP receptor agonist that has demonstrated positive results in clinical trials in obesity and type 2 diabetes in China. The Company is also advancing a diversified pipeline leveraging several mechanisms and routes of delivery, including oral administration. Kailera's mission is to develop next-generation weight management therapies that give people the power to transform their lives and elevate their overall health. The Company is based in Waltham, MA and San Diego, CA. For more information, visit www.kailera.com and follow us on LinkedIn and X.

[I] Based on the hypothetical strategy estimand (supplementary estimand): treatment effect if the treatment is taken per protocol. Data collected after intercurrent events (ICEs) are excluded from the analysis. ICEs defined in the GEMINI-1 protocol are premature discontinuation of treatment and use of drugs or therapies with a substantial effect on body weight before reaching the primary endpoint.

[II] Based on the treatment policy estimand (primary estimand): treatment effect regardless of treatment adherence; Data collected after ICEs are included in the analysis.

References
1. Phase 3 Trial of HRS9531, a GLP-1/GIP Receptor Agonist, in Chinese Adults with Overweight or Obesity. X. Li et al. ObesityWeek® 2025, Annual Meeting of the Obesity Society, Atlanta, GA, November 2025.

2. 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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