



Hengrui Pharma and Kailera Therapeutics Report Positive Topline 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% at 6 mg with no plateau in 48-week Phase 3 trial
- Favorable safety profile consistent with other GLP-1-based treatments
- Hengrui to submit NDA in China; Kailera plans to evaluate both higher doses and longer duration of treatment in global clinical trials

Jiangsu, China and Waltham, Mass., USA, July 15, 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 broad pipeline of next-generation therapies for the treatment of obesity, today announced positive topline data from Hengrui's Phase 3 clinical trial (HRS9531-301) of once-weekly subcutaneous injection of HRS9531, a novel dual GLP-1/GIP receptor agonist, in individuals living with obesity or overweight in China ([NCT06396429](#)). The HRS9531-301 trial met both 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 plans to submit a New Drug Application (NDA) for chronic weight management in China, and Kailera is advancing HRS9531 as KAI-9531 to global clinical trials.

The trial enrolled 567 participants with a mean baseline body weight of 93 kg (205 lb). Based on the primary analysis (treatment policy estimand)¹, participants taking HRS9531 achieved a mean weight loss of up to 17.7% (16.3% placebo-adjusted). Additionally, up to 88.0% of HRS9531-treated participants achieved at least 5% weight loss, and 44.4% of participants achieved at least 20% weight loss. Based on the pre-specified supplementary analysis (hypothetical strategy estimand)², participants taking HRS9531 achieved a mean weight loss of up to 19.2% (17.7% placebo-adjusted).

The trial results demonstrated a favorable safety and tolerability profile consistent with GLP-1-based treatments and previously reported HRS9531 Phase 2 clinical data. Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal-related.

In previously reported Phase 2 clinical trial results (NCT06054698), based on the primary analysis (treatment policy estimand)¹, participants taking the 8 mg dose of HRS9531 achieved a mean weight loss of 22.8% (21.1% placebo-adjusted) at week 36, with no plateau in weight loss and a favorable safety profile consistent with other GLP-1-based treatments. Based on supplementary analysis (hypothetical strategy estimand)², mean weight loss with the 8 mg dose of HRS9531 was 23.6% (21.7% placebo-adjusted).

"We are delighted to share the data from this landmark study. This is a huge step forward in providing innovative solutions to meet the needs of people living with obesity," said Hong Chen, Head of Metabolism Department I of Hengrui Pharma. "The positive data from the HRS9531-301 study demonstrated meaningful, sustained weight loss. With an affirmed safety and tolerability profile, we strongly believe in its potential to help more people living with obesity reach their individual weight loss goals. Based on these robust and encouraging clinical results, we are accelerating our efforts to advance this highly promising candidate. We look forward to filing for market approval in China as soon as possible to bring HRS9531 to patients struggling with obesity and overweight."

"We commend our colleagues at Hengrui for these impressive Phase 3 clinical results, building on the strong momentum behind HRS9531 (KAI-9531). As Kailera prepares to advance KAI-9531 into a global clinical program, we look forward to evaluating both higher doses and longer duration of treatment to expand on KAI-9531's best-in-class potential," said Ron Renaud, President and Chief Executive Officer, Kailera. "Together with Hengrui, we believe KAI-9531 has tremendous potential to improve the lives of countless individuals worldwide, including those with higher BMIs who are seeking greater weight loss to achieve optimal health."

Hengrui intends to share the full HRS9531 Phase 3 clinical trial data at an upcoming scientific conference.

About the HRS9531-301 Clinical Trial

The HRS9531-301 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/m²) or overweight (BMI ≥ 24 kg/m²) 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 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 were 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. With a global R&D team that includes 14 R&D centers and more than 5,500 professionals, Hengrui Pharma's therapeutic areas of focus include oncology, metabolic and cardiovascular diseases, immunological and respiratory diseases, and neuroscience. To date, Hengrui has commercialized 23 new molecular entity drugs and 4 other innovative drugs in China. 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](#).

¹ Based on the treatment policy estimand (primary statistical analysis): treatment effect regardless of treatment adherence

² Based on the hypothetical strategy estimand (supplementary statistical analysis): treatment effect excluding the occurrence of intercurrent events

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