



Kailera Therapeutics Announces Positive Topline Data from Two Hengrui Pharma Phase 3 Clinical Trials of Oral Small Molecule GLP-1 Receptor Agonist HRS-7535/KAI-7535

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- In Phase 3 trial in obesity/overweight in China, HRS-7535 achieved a mean weight loss of up to 10.9% at Week 44 and a mean weight loss of up to 11.1% at Week 50
- Kailera currently conducting global Phase 2 trial of KAI-7535 in obesity to further optimize KAI-7535's clinical profile for the treatment of obesity
- In second Phase 3 trial in type 2 diabetes in China, HRS-7535 lowered HbA1c by an average of 1.50% to 1.68% across doses
- Liver safety findings in both Phase 3 trials consistent with data generated to date; no liver safety signals observed

WALTHAM, Mass., July 07, 2026 (GLOBE NEWSWIRE) -- Kailera Therapeutics, Inc. (Kailera), a clinical-stage biotechnology company focused on elevating the next era of obesity care, today announced positive topline data from two additional Phase 3 clinical trials of oral small molecule GLP-1 receptor agonist HRS-7535 (also known as KAI-7535) conducted by Hengrui Pharma: the Phase 3 HARBOR-1 trial ([NCT06904105](#)) in adults living with obesity/overweight in China and the Phase 3 OUTSTAND-2 trial ([NCT06589765](#)) in adults with type 2 diabetes (T2D) in China.

Kailera is concurrently advancing KAI-7535 in a global Phase 2 clinical trial in people living with obesity or overweight. The trial initiated in April 2026, with data expected in 2027.

"The HRS-7535 Phase 3 results highlight the promise of oral small molecules as a treatment option for people living with obesity, with the potential to combine clinically meaningful weight loss with convenience, scalability, and accessibility," said Scott Wasserman, M.D., Chief Medical Officer, Kailera. "To optimize KAI-7535's overall clinical profile for the treatment of obesity in diverse patient populations, we are assessing a wide dose range, a lower starting dose, and a more gradual titration in our ongoing Phase 2 global clinical trial. Together with our other clinical stage programs, KAI-7535 reflects our strategy of advancing a differentiated portfolio across multiple mechanisms and modalities to meet the evolving and diverse needs of people living with obesity."

About HRS-7535 (KAI-7535)

HRS-7535 (being developed by Kailera as KAI-7535) is a small molecule GLP-1 receptor agonist, which was designed to improve upon the clinical profile of existing oral treatments. It was developed by Hengrui Pharma and licensed to Kailera outside of Greater China in 2024. Over 2,000 patients to date have been dosed with HRS-7535 in clinical trials in China. Kailera is conducting a global Phase 2 trial of KAI-7535 for the treatment of obesity, with data expected in 2027.

About the KAI-7535 Phase 2 Global Trial

The KAI-7535 Phase 2 global trial is a multicenter, randomized, double-blind, placebo-controlled conducted by Kailera in the U.S. and Australia. This trial is designed to further optimize KAI-7535's clinical profile for the treatment of obesity by evaluating a wide range of doses, starting at a lower dose of 15 mg, and following a more gradual titration schedule. The trial initiated in April 2026 and is expected to enroll approximately 320 adult participants with a BMI of 30 or greater, or a BMI of 27 or greater with at least one co-morbidity, which may include T2D. Participants are enrolled across four parallel cohorts (each N=80, randomized 4:1 active to placebo), including two dosing regimens (morning and evening). Participants receive escalating doses of KAI-7535 or placebo over a 44-week treatment period. The trial incorporates a stepwise titration schedule designed to improve tolerability and determine the optimal balance between weight loss and tolerability. All active-treatment participants initiate therapy at 15 mg and increase every four weeks, reaching a maximum dose of 180 mg. A higher-dose cohort follows an extended escalation schedule, with the option to further increase to 360 mg or remain at the maximum tolerated dose. The primary endpoint is percent change in body weight from baseline at Week 44.

HARBOR-1: HRS-7535 (KAI-7535) Phase 3 Trial in Obesity

HARBOR-1 met its primary endpoint, achievement of superior weight reduction at Week 44 with HRS-7535 compared to placebo.

- Based on the efficacy estimand¹, participants taking HRS-7535 120 mg and 180 mg achieved a mean weight loss of 9.5% and 10.9% from baseline at Week 44, respectively, compared to 2.5% with placebo.
- Based on the treatment policy estimand², participants taking HRS-7535 120 mg and 180 mg achieved a mean weight loss of 8.0% and 9.8% from baseline at Week 44, respectively, compared to 2.4% with placebo.
- Based on the treatment policy estimand², at Week 44, 58.6% (120 mg) and 68.2% (180 mg) of HRS-7535 treated participants achieved at least 5% weight loss; 39.6% (120 mg) and 46.6% (180 mg) achieved at least 10% weight loss;

and 18.5% (120 mg) and 26.0% (180 mg) achieved at least 15% weight loss.

- At Week 50, based on an ad hoc analysis, participants taking HRS-7535 120 mg and 180 mg achieved a mean weight loss of 9.5% and 11.1% from baseline, respectively, compared to 2.6% with placebo, based on the efficacy estimand.¹
- Improvements were also observed in HbA1c, systolic blood pressure, and lipid profiles.
- Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal-related.
- The most common TEAEs for participants treated with HRS-7535 (120 mg and 180 mg, respectively) were nausea (70.3% and 70.0% vs. 16.2% with placebo); vomiting (66.7% and 68.6% vs. 4.5% with placebo); and diarrhea (36.9% and 35.9% vs. 15.3% with placebo).
- Treatment discontinuation rates due to TEAEs were 4.1% (120 mg) and 3.1% (180 mg) for HRS-7535 vs. 2.7% with placebo.
- No liver safety signal was observed, consistent with prior HRS-7535 clinical trials.

HARBOR-1 (HRS-7535-303, [NCT06904105](#)) was a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial conducted by Hengrui in China to evaluate the efficacy and safety of HRS-7535 in adults with overweight or obesity. The trial enrolled 556 adults with obesity with a mean baseline body weight of 94.1 kg and mean baseline body mass index (BMI) of 34.0 kg/m². The participant population was 62% female. Participants were randomized (2:2:1) to receive once-daily HRS-7535 120 mg, 180 mg, or placebo. The primary objective was to evaluate the efficacy of HRS-7535 compared to placebo in the percentage change in body weight at Week 44. Following the primary endpoint assessment, participants continued treatment through Week 50, the end of the trial.

OUTSTAND-2: HRS-7535 (KAI-7535) Phase 3 Trial in Type 2 Diabetes (T2D)

OUTSTAND-2 met its primary endpoint, non-inferiority to dapagliflozin across all HRS-7535 dose levels (30 mg, 60 mg, and 90 mg) at Week 32, with the HRS-7535 90 mg group demonstrating significant HbA1c reduction compared to dapagliflozin. At Week 32:

- Based on the efficacy estimand³, the reductions in HbA1c from baseline for the HRS-7535 30 mg, 60 mg, and 90 mg groups and the dapagliflozin 10 mg group were 1.58%, 1.50%, 1.68%, and 1.28%, respectively.
- Improvements were observed in body weight, systolic blood pressure, lipid profiles, and the urinary albumin-to-creatinine ratio (UACR).
- Most TEAEs were mild to moderate and gastrointestinal-related.
- No Grade 3 hypoglycemic events were reported, and, consistent with prior HRS-7535 clinical trials, no liver safety signal was observed.

OUTSTAND-2 (HRS-7535-302, [NCT06589765](#)) was a multicenter, randomized, double-blind, dapagliflozin-controlled Phase 3 trial conducted by Hengrui Pharma in China. It aims to evaluate the efficacy and safety of HRS-7535 in adults with type 2 diabetes who have inadequate glycemic control despite metformin therapy. The trial enrolled 810 adults with type 2 diabetes with a mean baseline HbA1c of 8.60%, mean baseline body weight of 74.7 kg and mean baseline body mass index (BMI) of 27.1 kg/m². The participant population was 36% female. Participants were randomized in a 1:1:1:1 ratio to receive once-daily oral treatment with HRS-7535 (30 mg, 60 mg, or 90 mg) or dapagliflozin (10 mg). The core treatment period was 32 weeks, after which all participants entered an extended treatment period continuing through Week 52. The primary endpoint was change in HbA1c from baseline at Week 32.

Hengrui Pharma intends to share the full HARBOR-1 and OUTSTAND-2 clinical trial data at upcoming scientific conferences and plans to submit NDAs for HRS-7535 for the treatment of T2D and obesity in China.

About Kailera Therapeutics

Kailera Therapeutics (Kailera) is a 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 injection (also known as KAI-9531), that has the potential for the greatest weight loss. Ribupatide injection 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 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, and KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist. 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](#).

Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the profile of product candidates, the potential of Kailera's portfolio, the timing, design and outcome of research and development activities, including the potential to further optimize KAI-7535's clinical profile, market opportunities for product candidates, the competitive landscape, and timing and format of sharing of full clinical trial data. Forward-looking statements can be identified by terms such

as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "suggest," "plan," "designed," "goal," "vision," "potential," "predict," "project," "should," "target," "will," "would," or similar expressions and the negatives of those terms. Kailera cannot assure you that the forward-looking statements in this press release will prove to be accurate. Information in this press release may also include statements relating to past performance, which should not be regarded as a reliable indicator of future performance. Forward-looking statements are based on current expectations and assumptions together with projections of the future which are inherently uncertain, and involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied. These risks and uncertainties include, among others, uncertainties inherent in clinical development, regulatory review, manufacturing, competition, market opportunities, reliance on third parties, estimates of capital requirements, needs for additional financing, and other important factors, including those discussed under the caption "Risk Factors" in Kailera's filings with the Securities and Exchange Commission. These statements speak only as of the date of this press release, and Kailera undertakes no obligation to update or revise any forward-looking statements. Kailera may not actually achieve the plans, intentions, or expectations disclosed in its forward-looking statements, and you should not place undue reliance on these forward-looking statements.

¹ *Based on the efficacy estimand, which was pre-specified as a supplementary estimand in HRS-7535-303: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of medications or treatments with an obvious effect on body weight from the analysis.*

² *Based on the treatment policy estimand, which was pre-specified as the primary estimand in HRS-7535-303: treatment effect including the impact of premature discontinuations or use of medications or treatments with an obvious effect on body weight.*

³ *Based on the efficacy estimand, which was pre-specified as the primary estimand for non-inferiority in HRS-7535-302: treatment effect assuming participants adhered to protocol treatment and excludes data collected after premature treatment discontinuations or use of other glucose-lowering medications from the analysis.*

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