Hengrui Pharma and Kailera Therapeutics Present Ribupatide Clinical Data at ADA 2026

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- *Presentations will feature clinical results for ribupatide, a GLP-1/GIP receptor dual agonist being developed as a once-weekly injection and a once-daily oral pill for the treatment of obesity and overweight*
- *Additional data from Phase 2 obesity clinical trial of ribupatide oral demonstrating mean weight loss of up to 12.1% with no observed plateau and up to 38.6% of participants achieving at least 15% weight loss at 26 weeks; incidence of gastrointestinal adverse events was low, with vomiting reported in 11.4% and 7.5% of participants taking 25 mg and 50 mg ribupatide oral, respectively*
- *Phase 1 single ascending dose trial, the first ribupatide injection clinical data generated outside of China, demonstrated similar exposure, tolerability, and weight reduction in participants of Asian and non-Asian descent*

SHANGHAI and WALTHAM, Mass., June 05, 2026 (GLOBE NEWSWIRE) -- Hengrui Pharma (Hengrui), a global pharmaceutical company focused on scientific and technological innovation, and Kailera Therapeutics, Inc. (Kailera), a clinical-stage biotechnology company focused on elevating the next era of obesity care, today announced clinical results for ribupatide (also known as HRS9531 or KAI-9531), a GLP-1/GIP receptor dual agonist being developed as a once-weekly injection and a once-daily oral pill for the treatment of obesity and overweight, presented at the 86th Scientific Sessions of the American Diabetes Association (ADA).

“Building on our previously reported topline data, we are pleased to share additional results from our Phase 2 clinical trial of ribupatide oral in China. These findings further support its potential as a differentiated oral treatment option for people living with overweight or obesity,” said Su Zhang, Vice President and Head of Non-Oncology Clinical Development, Hengrui Pharma. “We are focused on rapidly advancing into Phase 3 in China this year with the goal of delivering this potential new option to patients. We also recognize the Kailera team for presenting the first ribupatide injection data generated outside of China, marking a meaningful step in establishing its role in the global obesity treatment landscape.”

“It is exciting to see clinical results for both ribupatide injection and ribupatide oral at ADA this year — highlighting the potential of ribupatide to deliver differentiated options for people living with obesity and overweight. We commend Hengrui on the ribupatide oral Phase 2 clinical results that demonstrate a potentially game-changing treatment option, and we look forward to starting global Phase 3 trials for ribupatide oral as early as the first half of 2027.” said Scott Wasserman, Chief Medical Officer, Kailera. “We are also pleased to present data from our Phase 1 bridging study of ribupatide injection — an important milestone as the first Kailera-sponsored study of ribupatide, as well as the first ribupatide injection data generated outside of China, which supported the initiation of our ongoing global Phase 3 KaiNETIC clinical program. We look forward to advancing ribupatide globally with the goal of broadening treatment options for people living with obesity—especially those with high BMIs and greater disease burden, where the unmet need remains substantial.”

Phase 2 Clinical Trial of Ribupatide Oral in Adults Living with Obesity

Hengrui’s Phase 2 clinical trial of once-daily ribupatide oral (also known as HRS9531 pill and KAI-9531-T) in China met its primary endpoint, achieving superior weight loss with ribupatide (10 mg, 25 mg, and 50 mg) compared to placebo at Week 26. The trial enrolled 166 participants of which 63% were female, with a mean baseline body weight and BMI of 92.6 kg and 33.3 kg/m^2, respectively.

Efficacy Summary at Week 26

- Based on the efficacy estimand[I], participants taking ribupatide oral 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 ribupatide oral 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.
- At week 26, ribupatide oral outperformed placebo in the proportion of participants achieving ≥5%, ≥10% and ≥15% body weight reduction. Based on the treatment estimand[II], 31.0% (10 mg), 59.1% (25 mg) and 52.5% (50 mg) of participants taking ribupatide oral achieved at least 10% weight loss; 4.8% (10 mg), 38.6% (25 mg) and 37.5% (50 mg) of ribupatide-treated participants achieved at least 15% weight loss.

Safety and Tolerability Summary

- The trial results demonstrated favorable safety and tolerability data, consistent with GLP-1-based treatments.
- Most treatment-emergent adverse events (TEAEs) were mild to moderate and gastrointestinal (GI)-related.
- Low GI TEAEs rates were observed with the most common being nausea (11.9% at 10 mg, 22.7% at 25 mg, 20.0% at 50 mg), diarrhea (4.8% at 10 mg, 20.5% at 25 mg, and 5% at 50 mg), and vomiting (2.4% at 10 mg, 11.4% at 25 mg, and 7.5% at 50 mg), generally consistent with the results of the Phase 1 trial of ribupatide oral conducted by Hengrui in China.
- No permanent treatment discontinuations or down-titrations due to GI AEs were reported in participants taking ribupatide oral.

Phase 1 Single Ascending Dose (SAD) Clinical Trial of Ribupatide Injection

Kailera's Phase 1 SAD trial of ribupatide injection enrolled participants of non-Asian and Asian descent to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of a single subcutaneous dose of ribupatide injection without titration. Participants were then followed through the end of the study at Day 29. The trial enrolled 49 participants of which 55% were female, with a mean baseline body weight and BMI of 80 kg (176 lbs.) and 27.6 kg/mg^2, respectively. Participants of non-Asian descent received a single 1 mg, 2 mg or 3 mg dose or placebo, and participants of Asian descent received a single 2 mg dose or placebo.

Primary Endpoints

- Ribupatide injection demonstrated a safety and tolerability profile similar in participants of both Asian and non-Asian descent.
- Most treatment-emergent adverse events (TEAEs) were mild and were GI-related.
- No serious TEAEs, TEAEs leading to study discontinuation or death, or severe TEAEs were reported.
- The most common TEAEs with ribupatide injection (no dose titration) were decreased appetite (62.5-81.8%), nausea (25.0-75.0%), and vomiting (0.0-50.0%).

Secondary and Exploratory Endpoints

- Systemic exposure (AUC) and peak exposure (Cmax) in Asian and non-Asian participants were similar when adjusted for baseline body weight.
- Ribupatide injection reduced body weight in a dose-dependent manner, with no differences observed in body weight reduction between non-Asian and Asian participants.
- Participants administered a single dose of ribupatide injection achieved a mean weight loss of 1.4 (1 mg) to 5.5 % (3 mg) from baseline at Day 29 compared to 0.4% with placebo.

All abstracts will be published online in the journal *Diabetes*® and presentations will be accessible on the Scientific Publications section of the Kailera website following the congress. Additional information can be found on the ADA website.

About the Ribupatide Oral Phase 2 Clinical Trial
The Phase 2 clinical trial (NCT06841445) was a multi-center, randomized, double-blind, placebo-controlled clinical trial conducted by Hengrui in China to evaluate the efficacy and safety of ribupatide oral (HRS9531 pill) in adults living with obesity (BMI ≥ 28 kg/m^2) and without type 2 diabetes. The trial enrolled 166 participants who were randomized in equal ratio to receive once-daily ribupatide oral 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 ribupatide oral vs. placebo on body weight at 26 weeks.

About the Ribupatide Injection Phase 1 SAD Trial
The Phase 1 clinical trial (NCT07044401) was a randomized, double-blind, placebo-controlled, single ascending dose trial conducted by Kailera at a single center in Australia to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of a single subcutaneous dose of ribupatide injection without titration. The trial enrolled 49 participants of non-Asian and Asian descent who were assigned to 5 cohorts, randomized to receive a single subcutaneous dose of ribupatide injection without titration (1 mg, 2 mg, or 3 mg) or placebo, and were followed for 29 days.

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 pill for the treatment of obesity and overweight. Once-weekly ribupatide injection 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 an NDA 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 injection and ribupatide oral. Kailera is currently evaluating ribupatide injection 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 ribupatide oral to Phase 3 clinical trials in China, and Kailera plans to initiate Phase 3 global trials as early as the first half of 2027, subject to discussions with the FDA and other regulatory agencies.

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. For more information, visit us at Hengrui.com and follow us on LinkedIn.

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 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 pill 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. Zi Ye, MD, PhD. (2026, June 7). *Efficacy and Safety of Oral Ribupatide (HRS9531) in Adults with Obesity: A Phase 2 Trial* [Poster presentation]. The American Diabetes Association's (ADA's) Scientific Sessions, New Orleans, LA. https://www.kailera.com/wp-content/uploads/2026/06/HRS9531-T-201_ADA-2026_poster_22May.pdf
2. Lloyd Klickstein, MD, PhD. (2026, June 8). *A Phase 1, Randomized, Double-Blind, Single-Ascending Dose Study of KAI-9531, a Novel Dual GLP-1/GIP Receptor Agonist in Development for People Living with Overweight/Obesity* [Poster presentation]. The American Diabetes Association's (ADA's) Scientific Sessions, New Orleans, LA. https://www.kailera.com/wp-content/uploads/2026/06/ADA_2026_KAI-9531-1701_pos_22May26_HR.pdf

Special Note Regarding Kailera 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, market opportunities for product candidates, the competitive landscape, and timing and outcome of regulatory interactions. Forward-looking statements can be identified by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "suggest," "plan," "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.

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