Jiangsu Hengrui Pharmaceuticals and Kailera Therapeutics Report Positive Topline Data from 8 mg Dose of Phase 2 Obesity Trial of GLP-1/GIP Receptor Dual Agonist HRS9531

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– Statistically significant mean weight loss of 22.8% (21.1% placebo adjusted) at 36 weeks; 59% of HRS9531-treated participants lost 20% or more of their baseline body weight

– Favorable safety profile with most adverse events being mild

– Hengrui's Phase 3 clinical trials in obesity and type 2 diabetes ongoing in China

Jiangsu, China and Boston, Mass., USA, January 13, 2025 — Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma), 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 and related conditions, today announced positive topline data from the 8 mg dose of Hengrui Pharma's Phase 2 clinical trial (HRS9531-203) of HRS9531, a GLP-1/GIP receptor dual agonist, in individuals living with obesity or overweight.

The clinical trial results showed that a once-weekly subcutaneous injection of the 8 mg dose of HRS9531 demonstrated a statistically significant 21.1% ($p<0.0001$) placebo-adjusted mean weight loss (22.8% mean change from baseline) at week 36, with no plateau in weight loss.[1] Additionally, 59% of HRS9531-treated participants achieved a weight loss of ≥20%.

The trial results demonstrated a favorable safety profile. Most adverse events (AEs) were mild and consistent with the profile reported for the injectable GLP-1/GIP receptor dual agonist class. The gastrointestinal-related AEs occurred primarily during dose titration.

"These compelling clinical results give us even greater confidence in the significant impact HRS9531 could have for the treatment of obesity and related conditions," said Ron Renaud, President & Chief Executive Officer, Kailera Therapeutics. "We are focused on building our clinical and manufacturing teams and infrastructure to advance HRS9531 as KAI-9531 into a global Phase 3 program. With our partner Hengrui, we believe that KAI-9531 is a leading next-generation treatment for chronic weight management with the potential to provide meaningful outcomes for many people."

These data build on the HRS9531 Phase 2 clinical results (HRS9531-201) presented in June 2024 at the American Diabetes Association (ADA) Scientific Sessions that showed HRS9531 was well-tolerated and demonstrated dose-dependent, placebo-adjusted mean weight loss across four doses administered weekly by subcutaneous injection, with maximum placebo-adjusted mean weight loss of 16.7% ($p<0.0001$) at the 6 mg dose at 24 weeks. In both clinical trials, patients receiving 6 mg or 8 mg of HRS9531 benefited from a dose titration schedule that included 12 weeks of treatment at the target dose.

Hengrui intends to share these Phase 2 clinical trial data evaluating the 8 mg dose of HRS9531 at an upcoming scientific conference.

About the HRS9531-203 Clinical Trial
The HRS9531-203 clinical trial is a multicenter, randomized, double-blind, placebo-parallel-controlled, Phase 2 trial (NCT06054698) conducted by Hengrui Pharma in China to evaluate the efficacy and safety of the 8 mg dose of HRS9531 injection in adults (ages 18-65) with overweight or obesity (BMI 24-40 kg/m^2) without type 2 diabetes. The study enrolled 61 participants with 49 participants receiving HRS9531. The primary endpoint of the trial is percentage change from baseline in body weight after 36 weeks of treatment. Participants were randomized (4:1) to receive once-weekly subcutaneous injections of HRS9531 or placebo titrating up to the target dose of 8 mg over a 24-week period and then maintaining that dose for 12 weeks.

About the HRS9531-201 Clinical Trial
The HRS9531-201 clinical trial was a multi-center, randomized, double-blind, placebo-parallel controlled Phase 2 clinical study (NCT05881837) conducted by Hengrui Pharma in China to evaluate the efficacy and safety of HRS9531 injection in adults (aged 18-65) with obesity (BMI of 28–40 kg/m2) without type 2 diabetes. The study enrolled 249 participants with 240 completing the 24-week double-blind treatment period. The primary objective was to evaluate the efficacy and dose-response relationship of HRS9531 injection vs. placebo in reducing body weight after 24 weeks of treatment, with a minimum of 12 weeks at top dose. Participants were randomized (4:1) to receive once-weekly subcutaneous injections of HRS9531 or placebo across four dose cohorts (1.0 mg, 3.0 mg, 4.5 mg, and 6.0 mg) for 24 weeks.

About HRS9531 (KAI-9531)
HRS9531 is a novel injectable GLP-1/GIP receptor dual agonist formulated as an injectable peptide in clinical development for the

treatment of obesity and type 2 diabetes. Over 650 patients to date were dosed with HRS9531 across several Phase 1 and Phase 2 clinical trials in obesity and type 2 diabetes in China. HRS9531 is being developed globally (ex-Greater China) by Kailera Therapeutics as KAI-9531.

About Hengrui Pharma
Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma) is an innovative global pharmaceutical company focused on unmet clinical needs, with a strong track record of scientific and technological innovation. Hengrui Pharma has set up 14 R&D centers in Lianyungang, Shanghai, the U.S., and Europe. It has 12 major manufacturing sites and a global R&D team of more than 5,500 professionals. Hengrui Pharma has independently established a number of leading technology platforms such as its ADC platform, proteolysis targeting chimera (PROTAC), bi/multi-specific antibodies, which provide a strong foundation for innovative R&D. Hengrui strives for continued innovation and collaboration with global partners to serve a healthy China and benefit patients around the world.

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 and related conditions. Kailera's most advanced program, KAI-9531 (being developed in China as HRS9531), is an injectable GLP-1/GIP receptor dual agonist that has demonstrated positive results in Phase 2 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.

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[1] Treatment-policy estimand.