



19.3% Weight Loss at Week 48: Phase 3 Data of Olatorepatide, Hansoh's Dual-Biased GLP-1/GIP Agonist, Presented at EASD

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

MILAN, Oct. 2, 2026 /PRNewswire/ - From September 28 to October 2, 2026, the Annual Meeting of the European Association for the Study of Diabetes (EASD) is being held in Milan, Italy. Hansoh Pharma's self-developed dual-biased glucagon-like peptide-1/glucose-dependent insulintropic polypeptide (GLP-1/GIP) receptor agonist, Olatorepatide (HS-20094), was presented as a Late-breaking Abstract (LBA) oral presentation, reporting the results from the Chinese Phase 3 weight management study (LIGHTEN).

The findings show that Olatorepatide exhibits substantial weight-loss efficacy and favorable gastrointestinal tolerability: Weight-loss Efficacy: Mean weight loss of 19.3% was achieved at Week 48 in the olatorepatide 15 mg group, with no weight-loss plateau observed; Waist-circumference Reduction: Mean waist-circumference reduction of 16.0 cm was observed in the olatorepatide 15 mg group; Low Incidence of Gastrointestinal Adverse Events: Nausea 7.8%; vomiting 4.9%. [1]

LIGHTEN is a multicenter, randomized, double-blind, placebo-controlled Phase III study conducted in Chinese adults with overweight or obesity, enrolling a total of 604 participants. Eligible participants had a BMI (Body Mass Index) $\geq 28 \text{ kg/m}^2$, or a BMI of $24 \leq \text{BMI} < 28 \text{ kg/m}^2$ accompanied by at least one weight-related comorbidity. Participants were randomized 1:1:1:1 to receive once-weekly subcutaneous injections of Olatorepatide 5mg, 10mg, 15mg, or placebo for 48 weeks. The co-primary endpoints were the percentage change in body weight from baseline at 48 weeks and the proportion of participants achieving $\geq 5\%$ weight loss. Overall, 90.1% of participants completed the full 48-week treatment period.

Study results showed that under the efficacy estimand, mean body weight reductions at week 48 were $\sim 12.5\%$, $\sim 17.5\%$ and $\sim 19.3\%$ in the Olatorepatide 5 mg, 10 mg and 15 mg groups, respectively, versus $\sim 2.7\%$ in the placebo group. Under the treatment-regimen estimand, mean body weight reductions were $\sim 11.8\%$, $\sim 17.0\%$ and $\sim 18.7\%$ across the three Olatorepatide dose groups,

respectively, versus -2.5% in the placebo group. All between-group differences were statistically significant ($P < 0.0001$).

In terms of weight loss goal achievement rates, under the efficacy estimand, the proportions for the Olatorepatide 5mg, 10mg, 15mg and placebo groups were as follows: $\geq 5\%$ weight loss: 87.3%, 97.2%, 95.2% and 28.6%; $\geq 10\%$ weight loss: 61.7%, 89.3%, 88.9% and 14.6%; $\geq 15\%$ weight loss: 32.6%, 60.2%, 71.7% and 3.2%.

Notably, the weight loss curve showed a continued downward trend at Week 48, without reaching a plateau, suggesting that a longer treatment duration may yield further weight-loss benefits.

Under the efficacy estimand, mean reductions in waist circumference from baseline were 10.5cm, 14.4cm, and 16.0cm in the Olatorepatide 5mg, 10mg and 15mg groups, respectively, versus 3.6cm in the placebo group, with statistically significant differences ($P < 0.0001$).

In addition, Olatorepatide brought improvements in metabolic parameters including blood pressure, lipid profiles, glycated hemoglobin (HbA1c), homeostatic model assessment for insulin resistance (HOMA-IR), urine albumin-to-creatinine ratio (UACR) and uric acid, demonstrating comprehensive metabolic benefits.

The overall safety profile of Olatorepatide was similar to that of incretin-based therapies approved for weight management. Its incidence of gastrointestinal adverse events was notably lower than published data for currently available agents of the same class. The mean incidence of nausea, vomiting, diarrhea, and constipation in the Olatorepatide treatment groups was 7.8%, 4.9%, 16.9%, and 5.1%, respectively, versus 2.6%, 2.0%, 7.8%, and 1.3% in the placebo group. No participants discontinued treatment or withdrew early due to Olatorepatide treatment-related adverse events.

A dual-biased GLP-1/GIP receptor agonist, Olatorepatide offers a novel signaling pathway approach to overcoming the challenge of achieving both weight loss efficacy and tolerability. This Phase III weight-management study conducted in Chinese adults with overweight or obesity demonstrated significant weight loss efficacy along with favorable safety and tolerability, supporting its potential as a novel weight management therapy.

The EASD Annual Meeting is one of the most influential academic conferences in the global diabetes and metabolism field. The LBA sessions are dedicated to the latest research of high innovation and major scientific significance. The selection of the Phase III study of Olatorepatide for this LBA oral presentation reflects international peers' high recognition of its data quality and clinical value.

Olatorepatide Injection is a once-weekly subcutaneous dual-biased GLP-1/GIP receptor agonist. It functions by modulating metabolic pathways governing appetite regulation, glucose metabolism, and energy balance. Olatorepatide is also currently in Phase III clinical development in China for the treatment of type 2 diabetes mellitus. In June 2025, Hansoh Pharmaceutical entered into a strategic collaboration with Regeneron, granting Regeneron exclusive overseas development and commercialization rights for the asset. In June 2026, the New Drug Application (NDA) for Olatorepatide Injection for long-term weight management in adults with overweight or obesity was accepted for review by the National Medical Products Administration (NMPA) of China.

Hansoh Pharma is a leading innovation-driven pharmaceutical company in China, with the mission of "Continuous innovation for better life". The Company focuses on major disease therapeutic areas such as oncology, metabolism, immunology, central nervous system (CNS) and anti-infectives.

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