company announcement

Monlunabant phase 2a trial in obesity successfully completed

Bagsværd, Denmark, 20 September 2024 – Novo Nordisk today announced headline results from a phase 2a clinical trial with monlunabant, a small molecule oral cannabinoid receptor 1 (CB1) inverse agonist. Monlunabant, formerly INV-202, was part of the acquisition of Inversago Pharmaceuticals Inc. announced in August 2023 [Link].

The trial investigated the efficacy and safety of a once-daily 10 mg, 20 mg and 50 mg dose of monlunabant compared to placebo on body weight after 16 weeks in 243 people with obesity and metabolic syndrome[1]. People were equally randomised among the four treatment arms.

From a baseline body weight of 110.1 kg, all doses of monlunabant achieved a statistically significant weight loss compared to placebo. After 16 weeks of treatment, people treated with a once-daily 10 mg dose of monlunabant achieved a weight loss of 7.1 kg compared to a reduction of 0.7 kg with placebo[2]. Limited additional weight loss was seen at higher doses of monlunabant.

In the trial, the most common adverse events were gastrointestinal, with the vast majority being mild to moderate and dose dependent. Reporting of mild to moderate neuropsychiatric side effects, primarily anxiety, irritability, and sleep disturbances, was more frequent and dose dependent with monlunabant compared to placebo. No serious adverse events were reported in relation to neuropsychiatric side effects.

"The phase 2a results indicate the weight-lowering potential of monlunabant and that further work is needed to determine the optimal dosing to balance safety and efficacy," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk. "Obesity is a complex disease with a significant unmet need, and as an oral small molecule having a new mechanism of action, monlunabant is one of the novel projects in our pipeline with the potential of treating obesity."

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[1] Metabolic syndrome defined as the presence of at least 3 of 5 key clinical features of abdominal obesity, elevated triglycerides and cholesterol, impaired glucose tolerance, and elevated blood pressure.

[2] Hypothetical estimand corresponding to if all people adhered to treatment

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Based on the results, Novo Nordisk expects to initiate a larger phase 2b trial in obesity to further investigate dosing and the safety profile of monlunabant over a longer duration in a global population. The phase 2b trial is expected to be initiated in 2025.

About monlunabant and CB1

Monlunabant is an inverse agonist of the CB1 receptor which plays an important role in metabolism and appetite regulation in the central nervous system as well as in peripheral tissues such as adipose tissues, the gastrointestinal tract, kidneys, liver, pancreas, muscles and lungs. CB1 plays an important role in appetite regulation and cardiometabolic pathways.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 69,000 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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