Clinical Trial Report: Once-Daily, Dual-Action Diabetes Drug (AG-200) Trial

Introduction:
This clinical trial evaluates the efficacy and safety of a novel, once-daily, dual-action diabetes drug, AG-200, in managing type 2 diabetes mellitus. Type 2 diabetes is a chronic metabolic disorder characterized by inadequate glycemic control, which can lead to serious health complications. AG-200 is a unique combination therapy that simultaneously targets both glucose absorption and insulin sensitivity. This randomized, controlled trial aims to assess the impact of AG-200 on glycemic control, insulin resistance, and other related cardiovascular risk factors.

Methods:
Study Design:
The study was a 16-week, randomized, double-blind, placebo-controlled trial. A total of 180 participants with type 2 diabetes inadequately controlled by diet and exercise alone were enrolled. Participants were randomized equally into three groups: the AG-200 low dose group, the AG-200 high dose group, and the placebo group. All participants continued their current diet and exercise regimen throughout the trial.

Inclusion Criteria:
• Age between 30 and 70 years
• Diagnosis of type 2 diabetes mellitus
• HbA1c level between 7.0% and 10.0%
• Body Mass Index (BMI) ranging from 25 to 40 kg/m²

Exclusion Criteria:
• History of gastrointestinal disorders or pancreatitis
• Renal or hepatic impairment
• Uncontrolled hypertension or cardiovascular disease
• Pregnancy or breastfeeding

Outcome Measures:
The primary outcome measure was the change in hemoglobin A1c (HbA1c) levels from baseline to Week 16. Secondary outcome measures included fasting plasma glucose (FPG) levels, insulin resistance as assessed by the Homeostasis Model Assessment for Insulin Resistance (HOMA-IR), body weight, and lipid profiles. Safety assessments included adverse event monitoring, vital sign measurements, and clinical laboratory tests.

Results:
Primary Outcome:
Both doses of AG-200 significantly reduced HbA1c levels compared to the placebo group. The low dose of AG-200 resulted in a mean change of -0.5% in HbA1c, while the high dose showed a -0.8% change, both achieving statistical significance compared to the placebo group's change of -0.1% ($p<0.001$ for both).

Secondary Outcomes:
• Fasting plasma glucose levels significantly decreased with AG-200 treatment, demonstrating a dose-dependent response ($p<0.001$).
• HOMA-IR scores improved significantly in the AG-200 groups, indicating reduced insulin resistance ($p<0.01$).
• Body weight was significantly reduced in both AG-200 groups, with a mean loss of 2.6 kg in the low dose group and 3.1 kg in the high dose group ($p<0.001$).
• Total cholesterol, LDL cholesterol, and triglyceride levels also demonstrated significant reductions with AG-200 treatment ($p<0.05$), while HDL cholesterol levels increased moderately ($p<0.01$).

Safety:
AG-200 was generally well-tolerated, with a low incidence of adverse events. Mild gastrointestinal symptoms, such as nausea and diarrhea, were reported in some participants but resolved spontaneously without drug discontinuation. No serious adverse events related to the study drug occurred. Clinical laboratory evaluations did not reveal any safety concerns or abnormalities.

Conclusion:
AG-200 administration resulted in significant improvements in glycemic control, insulin resistance, body weight, and lipid profiles in patients with type 2 diabetes. The dual-action mechanism of AG-200 appears to provide a promising approach in managing the

complex pathophysiology of diabetes. The drug's safety profile was favorable, making it a potential new option for the treatment of type 2 diabetes.

However, further investigations with larger sample sizes and diverse populations are warranted to validate these findings and establish the long-term efficacy and safety of AG-200.

Clinical Trial Registration Number: NCT04451656