Gubra announces first subject dosed in Phase 1 clinical trial of amylin agonist (GUBamy) for the treatment of obesity

Today, Gubra announces that the first human subject has been dosed with a new long-acting amylin agonist (GUBamy) as a potential treatment for obesity. This first clinical trial is a single ascending, dose-escalation, safety, and tolerability trial in healthy volunteers.

"GUBamy holds promising potential as a novel treatment option for patients with obesity both as a monotherapy and in combination with other anti-obesity drugs. Our preclinical studies have shown significant weight loss with GUBamy alone and additive weight loss in combination with other anti-obesity drugs," says Mads Axelsen, Chief Medical Officer at Gubra. "I am proud of our dedicated clinical team who has progressed GUBamy to this Phase 1 clinical trial, which marks a very important milestone for Gubra," he adds.

The Phase 1 study
The phase 1, First-In-Human, randomized, single ascending dose trial, will assess safety, tolerability, pharmacokinetics, and pharmacodynamics of GUBamy administered in lean to overweight but otherwise healthy subjects. The study will be conducted in up to 48 subjects divided in 6 cohorts at Quotient Sciences in Nottingham in the UK. The first cohort of subjects will be administered with a single dose of 0.5 mg GUBamy. After each dose cohort, a safety review will be performed and a decision about study progress and dose will be made for the next dose cohort. In addition to assessing the safety (primary objective), the trial will also evaluate the pharmacokinetic properties of GUBamy as well as the pharmacodynamic effects on gastric emptying and metabolic and hormonal changes. The trial is expected to complete enrollment mid-2024. Additional information about the Phase 1 trial is available via ClinicalTrials.gov (NCT06144684).

About GUBamy
GUBamy (GUB014295) is a long-acting amylin agonist for once weekly subcutaneous (s.c.) administration. GUBamy is in development for weight management in people living with obesity. The drug product is a sterile solution with a neutral pH. The physical and chemical properties of GUBamy solution is compatible with future co-formulation with other anti-obesity injectable drugs (e.g. GLP-1 agonists, dual and triple agonists etc.).

Additional information about GUBamy can be found in the enclosed presentation material.

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About Gubra

Gubra, founded in 2008 in Denmark, listed on NASDAQ Copenhagen in 2023, is specialized in pre-clinical contract research services and peptide-based drug discovery within metabolic and fibrotic diseases. Gubra's activities are focused on the early stages of drug development and are organised in two business areas – CRO Services and Discovery & Partnerships (D&P). The two business areas are highly synergistic and create a unique entity capable of generating a steady cash flow from the CRO business while at the same time enjoying biotechnology upside in the form of potential development milestone payments and potential royalties from the D&P business. Gubra has approx. 200 employees and had annual revenue of approx. DKK 200 million in 2022. See www.gubra.dk for more information.

Attachments

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231129 GUBamy Presentation