Gubra announces positive GUBamy Phase 1 interim MAD results

- *GUBamy was well tolerated with adverse events being predominantly GI related, mild and consistent with data from the SAD study.*
- *Doses of 1 mg and 2 mg GUBamy administered once-weekly for six weeks led to a dose dependent mean weight loss. LS Mean weight loss in the 2 mg cohort was -7.77% on day 43. In the placebo group there was an LS Mean weight gain of +1.99% on day 43.*
- *The body weight loss was sustained in a manner consistent with the SAD study data.*
- *The study confirmed the favorable half-life of GUBamy of 11 days.*
- *This interim analysis of the first two cohorts was included in the original study protocol and is disclosed today to comply with Gubra's obligations under stock market rules.*

Henrik Blou, CEO of Gubra says:
"The interim topline results from the first part of the MAD study are very encouraging and builds upon and substantiates the results from the SAD study showing that GUBamy has potential to deliver significant body weight reduction with a favorable tolerability profile. We are very pleased with these results that have exceeded our expectations."

The multiple ascending dose (MAD) part A study was designed to assess safety and tolerability as primary objectives. Secondary and explorative endpoints included pharmacokinetic and pharmacodynamic effects of GUBamy. The study was conducted in healthy lean and overweight subjects, with a mean BMI of 27.63 (placebo) and 24.33 (2 mg cohort). Subjects were randomized (6: 2) within cohorts, treated with either GUBamy or placebo and dosed once-weekly with a fixed dose (1 mg or 2 mg) for 6 weeks and subsequently followed for 6 weeks.

GUBamy treatment was well tolerated. All related adverse events were mild. The most frequent adverse events were dose-dependent and GI related, corresponding well with data obtained during the SAD part of the trial.

Once-weekly administration for six weeks of 1 mg or 2 mg GUBamy led to a dose dependent mean weight loss compared to a weight gain in the placebo group. LS Mean weight loss in the 2 mg cohort was -7.77% compared to an LS Mean weight gain of +1.99% in the placebo arm on day 43.

The pharmacokinetic analysis confirmed a half-life of 270 hours (11 days).

The MAD part A results support further development of GUBamy for a weight management indication. The MAD study part B for testing higher doses is ongoing and is progressing as planned.

About GUBamy
GUBamy (GUB014295) is an investigational long-acting amylin analogue for 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.). GUBamy holds potential as both single agent and combination therapies for the treatment of obesity.

In March 2025, Gubra and AbbVie entered into a license agreement to develop and commercialize GUBamy for the treatment of obesity and overweight. All regulatory conditions were satisfied on March 28 2025 and the transaction effectiveness is subject to other customary closing conditions.

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About Gubra
Gubra, founded in 2008 in Denmark, listed on Nasdaq Copenhagen, 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. 260 employees and in 2024 revenue of DKK 266 million. See www.gubra.dk for more information.

This information is information that Gubra is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-04-01 08:45 CEST.

Attachments
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