Gubra announces positive GUBamy Phase 1 SAD data (correction)

The correction in this announcement refers solely that that company announcement published today at 5.41pm CET should have been labelled as inside information and not company information. The content in the release is completely unchanged and provided again below.

Gubra announces positive results from the single ascending dose (SAD) phase 1 clinical trial with the long-acting amylin analogue GUBamy:

- *GUBamy was well tolerated with adverse events being predominantly GI related, mild and transient.*
- *GUBamy had a favourable pharmacokinetic profile with a half-life of 11 days supporting once weekly dosing.*
- *A single dose of GUBamy reduced body-weight dose dependently – an effect that was sustained for the duration of the trial (6 weeks).*
- *Mean body weight reduction in all high dose groups (3.5-6.0 mg) reached approx. 3% during the 6 weeks trial, whereas subjects in the placebo group gained approx. 1%.*
- *MAD trial is ongoing with interim results expected to be released in 1st half of 2025.*

Henrik Blou, CEO of Gubra says:
"We are very pleased to see that our data confirms the potential of GUBamy as an anti-obesity treatment. GUBamy was well tolerated, and the very long half-life supports a weekly dosing regimen. We are also excited to see that treatment with a single dose of GUBamy led to a sustained body-weight loss that lasted for the entire six-week trial period. We look forward to interim results from the ongoing Phase 1b study assessing multiple ascending doses of GUBamy during first half of next year."

This single ascending dose study was designed to assess safety and tolerability as primary objectives. Secondary and explorative endpoints included pharmacokinetic (PK) and pharmacodynamic effects of GUBamy. The study was conducted in healthy lean and overweight male subjects with a mean BMI of 26.65 that were randomized (6:2) into six cohorts treated with either GUBamy or placebo. GUBamy was well tolerated, with the vast majority of events being mild and transient. The most frequent adverse events were gastrointestinal and dose-dependent: Nausea (frequent), reduced appetite (frequent) and vomiting (occasional).

The pharmacokinetic analysis showed dose proportionality and confirmed a once weekly dosing schedule with a half-life of 270 hours (11 days). The data from this SAD trial also demonstrated that a single dose of GUBamy reduced body weight in a dose dependent manner. Effects on body weight were observed from 3 days after dosing and were sustained throughout the duration of the trial (6 weeks). Mean body weight reduction in the three highest dose groups (3.5-6.0 mg) reached approx. 3% during the 6 weeks (ranging from -1.81% to -3.25% for the various timepoints) compared to approx. +1% (+0.52% to +1.25%) in the placebo group.

Gubra expects to present the results from the SAD study at a future scientific conference. The

Phase 1 multiple ascending dose (MAD) study of GUBamy is ongoing and interim results from the first part of the MAD study is expected in the first half of 2025. For the second part of the MAD study, dosing is expected to be completed in Q4 2025. The SAD results support further development of GUBamy for a weight management indication.

Investor conference call
A presentation for analysts and investors will be held on 14 November at 2:00pm CET. The event will be hosted by the company's CEO Henrik Blou, CSO Louise S. Dalbøge, CMO Mads Axelsen and CFO Kristian Borbos. The presentation will be held in English.

To participate in the conference, please register here to receive the dial-in details: https://palvelu.flik.fi/teleconference/?id=5007181

The presentation can also be followed live via the link: https://hca.videosync.fi/2024-11-14-gubra-presentation/register

It will also be possible to take part of the webcast afterwards at the same above mentioned link.

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

Contacts at Gubra
Media: Sofia Pitt Boserup, sbo@gubra.dk, +45 4188 9586
Investors: Kristian Borbos, kbo@gubra.dk, +45 3080 8035

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. 250 employees and in 2023 revenue of DKK 205 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 2024-11-13 18:36 CET.

Attachments

Gubra announces positive GUBamy Phase 1 SAD data (correction)