Gubra submits clinical trial application (CTA) for first-in-human amylin trial

Gubra announces that a clinical trial application (CTA) for the anti-obesity amylin project has been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The clinical trial is expected to receive approval from the MHRA later in 2023 and the first human dose is planned for end of 2023.

Niels Vrang, Chief Scientific Officer at Gubra A/S, is excited with the progress of the amylin project (GUC17):

"This is the first drug project Gubra has progressed on its own to the clinic and I am of course excited not only for reaching this milestone but also extremely proud that we stick tightly to our timelines. Adding the capability to progress promising peptide drugs into early clinical drug development is a significant addition to the Gubra discovery engine. Our GUC17 amylin analogue is a potent and long-acting amylin-receptor agonist designed for weekly dosing, and we look forward to moving this potential anti-obesity drug in to the clinic. Our aim is to partner this programme during or after early clinical development."

The planned phase 1 trial is a placebo-controlled dose escalation study testing single increasing subcutaneous doses of the novel long-acting amylin agonist GUC17. Participants in the trial will be healthy men with overweight/obesity. The primary objective of the trial is to investigate safety of GUC17. The trial will also evaluate the pharmacokinetic (absorption and distribution) profile of GUC17 and early signs of energy intake and metabolism of the test drug.

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 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

Gubra submits clinical trial application (CTA) for first-in-human amylin trial