Gubra announces achievement of milestone from AbbVie following initiation of a Phase 2 clinical trial of ABBV-295, a long-acting amylin analog

- **ABBV-295 is a long-acting amylin analog that represents a mechanistically distinct class from incretin-based therapies such as GLP-1 and GIP receptor agonists.**
- **Under Gubra's license agreement with AbbVie, the initiation of the Phase 2 trial triggers a milestone payment of USD 50 million to Gubra.**

Markus Rohrwild, CEO of Gubra, says:
"The advancement of ABBV-295 into Phase 2 marks an important milestone for Gubra and brings the program another step closer to potentially expanding treatment options for people living with overweight or obesity. The Phase 1 data have demonstrated encouraging potential for differentiation, and we believe ABBV-295 has the potential to become an important part of the next generation of therapies for chronic weight management. We are very pleased to see the program progress into Phase 2 under AbbVie's leadership. This achievement also provides further validation of the strength of Gubra's drug discovery platform and our ability to discover and develop differentiated peptide therapeutics with the potential to address major unmet medical needs."

The Phase 2 trial is a randomized, double-blind, placebo-controlled, dose-finding trial designed to evaluate the efficacy, safety, and tolerability of ABBV-295 in approximately 360 adults who are obese (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2) with at least one weight-related comorbidity. Participants will be randomized to one of six active treatment arms or placebo, evaluating different dosing paradigms over a 52-week treatment period. The primary endpoint is the percentage change in body weight from baseline at week 32. Additional details are available at ClinicalTrials.gov (Identifier: NCT07752979).

The Phase 2 initiation of ABBV-295 is supported by data from a comprehensive Phase 1 program, including single ascending dose (SAD) and multiple ascending dose (MAD) studies. The 12/13-week Phase 1 MAD study in adults (88% male) with a mean BMI below 30 kg/m^2 at baseline demonstrated dose-dependent weight reduction of up to 9.8% with weekly dosing after 12 weeks, with comparable weight reduction observed after 13 weeks with every-other-week and monthly dosing after week 5. ABBV-295 demonstrated a favorable safety and tolerability profile at all evaluated dose levels. An ongoing Phase 1b MAD study in the U.S. (ClinicalTrials.gov ID: NCT07291232) is evaluating ABBV-295 in participants with obesity, with a higher baseline BMI (30–45 kg/m^2) and a greater proportion of female participants compared with the prior Phase 1 MAD studies.

About ABBV-295

ABBV-295 is an investigational, long-acting amylin analog being developed for chronic weight management and other potential indications. ABBV-295 was discovered by Gubra using Gubra´s streaMLine platform. ABBV-295 has not been approved by any health regulatory authority worldwide. The safety and efficacy of ABBV-295 have not been established.

About the AbbVie and Gubra partnership

In March 2025, Gubra and AbbVie entered into a license agreement for ABBV-295. Under the terms of the agreement, AbbVie will lead development and commercialization activities of ABBV-295 globally. Gubra is eligible to receive up to USD 1.875 billion in potential development, commercial, and sales-based milestone payments, as well as tiered royalties on global net sales.

Contacts at Gubra

Media: Marianne Thomas (mho@gubra.dk, +45 2483 2663)
Investors: Kristian Borbos (kbo@gubra.dk, +45 3080 8035) and Adam Lange (adl@gubra.dk, +45 6646 1589)

About Gubra

Gubra, founded in 2008 in Denmark and listed on NASDAQ Copenhagen, is a disease-agnostic techbio company specialized in peptide-based drug discovery and preclinical contract research services. Gubra's activities are focused on the early stages of drug development and are organized in three main business units – Biotech, CRO, and Ventures. The business areas create a unique entity capable of generating a steady cash flow from the CRO business while investing in high-impact biotech R&D projects with significant value inflection potential through partnerships. Gubra has around 300 employees and had revenue of DKK 2.6 billion (around $400 million) in 2025.

See www.gubra.dk for more information.

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Attachments

Phase 2 initiation milestone ABBV-295