



AbbVie reports Positive Phase 1 Multiple Ascending Dose Results for ABBV-295, a Long-Acting Amylin Analog

Gubra's partner AbbVie today announced positive topline results from the 12 and 13-weeks Phase 1 Multiple Ascending Dose (MAD) trial showing that ABBV-295 was well tolerated with a dose-dependent significant and clinically meaningful weight loss, compared to placebo.

- ABBV-295 treatment showed clinically meaningful body weight reduction from -7.75% to -9.79% (least-squares mean) at week 12 (weekly dosing), to -7.86% to -9.73% at week 13 (every other week and monthly dosing after week 5)¹
- ABBV-295 demonstrated a favorable tolerability profile at all evaluated dose levels. No serious adverse events were reported¹
- Data support continued development of ABBV-295 as a potentially differentiated treatment for chronic weight management, with a non-incretin-based mechanism of action

"We are very encouraged by these clinical results. Obesity continues to be a growing global health challenge, with a well-recognized need for novel treatment options. These data demonstrate the potential of ABBV-295 to deliver meaningful body weight reduction with a favorable tolerability profile, supporting its differentiated positioning within the evolving obesity treatment landscape. We are very pleased with these results and we look forward to seeing AbbVie continue the advancement of the asset," said Markus Rohrwild, CEO of Gubra.

Results from the trial

The multiple ascending dose (MAD) part of its Phase 1 study evaluated safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of subcutaneous ABBV-295, in adults with a mean body mass index (BMI) of less than 30 kg/m². 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.

Study enrollment mostly comprised male participants (88.3%). Different doses (2-14 mg), titrations and dose frequencies were tested in the study. ABBV-295 was generally well tolerated across all dose levels evaluated. The most commonly reported adverse events were gastrointestinal disorders, which were mostly mild, and predominantly occurred during the first 6 weeks of treatment.¹

ABBV-295 demonstrated clinically meaningful, dose-dependent reductions in body weight from baseline, over a 12-13-week treatment period. In the ABBV-295 treated groups dose-dependent least-squares (LS) mean percentage change in body weight ranged from -7.75% to -9.79% at week 12 (for weekly dosing groups), to -7.86% to -9.73% at week 13 (for every other week dosing group and monthly dosing group after week 5), compared to -0.26% and -0.25% in the placebo group at week 12 and week 13, respectively.¹



"Obesity is a complex, chronic disease that places a substantial burden on patients, healthcare systems and society, and there remains a critical need for therapies that combine efficacy with tolerability and support long-term adherence," said Primal Kaur, M.D., senior vice president, global development of immunology, neuroscience, eye care and specialty at AbbVie. "We are encouraged by these early results for ABBV-295, which demonstrate meaningful weight loss together with a well-tolerated safety profile. These initial results further reinforce the potential of ABBV-295 as a novel therapeutic option for people living with obesity."

Results from the [single ascending doses \(SAD\) part](#) and [other cohorts from the MAD part](#) of the study were announced previously. Full data from the study will be presented at a future scientific conference.

Summary of Phase 1 MAD Study Key Results¹ (Percent Change from Baseline in Body Weight at Week 12 and Week 13)

Cohort ^a	LS Mean (95% CI) at week 12 ^b	LS Mean (95% CI) at week 13 ^b
All Placebo	-0.26 (-1.89, 1.37)	-0.25 (-1.88, 1.38)
Cohort 3 (weekly dosing)	-7.75 (-9.89, -5.61)	-
Cohort 4 (weekly dosing)	-8.70 (-10.75, -6.65)	-
Cohort 5a (weekly dosing)	-9.79 (-11.99, -7.59)	-
Cohort 5b (every other week dosing)	-7.76 (-9.82, -5.70)	-9.73 (-11.79, -7.67)
Cohort 6 (monthly dosing after week 5)	-6.74 (-8.70, -4.79)	-7.86 (-9.80, -5.91)

^a Doses from 2mg to 14mg were tested using different dose escalations and dosing frequencies.

^b LS mean estimates were derived using a Mixed Model for Repeated Measures (MMRM). Participants were required to adhere to the dosing plan and those unable to continue treatment were withdrawn from the study with no further efficacy data collected.

About ABBV-295

ABBV-295 is an investigational, long-acting amylin analog being developed for the treatment of obesity. It is an agonist that specifically activates amylin and calcitonin receptors. Amylin, a satiety hormone, has been identified as a potential therapeutic target for the treatment of obesity given its role in activating signals to the brain that result in appetite suppression and the reduction of food intake, while also acting as an inhibitory signal to delay gastric emptying. 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 Phase 1 GUC17-01 Study

The Phase 1 clinical trial is a two-part, single center, double-blind (within cohorts), randomized, placebo-controlled, single (Part 1) and multiple (Part 2) ascending dose study of subcutaneous ABBV-295 (GUB014295). A total of 76 participants were enrolled in the MAD study. More information on this trial can be found at <https://www.clinicaltrials.gov/> (NCT06144684).

ABBV-295 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 \$1.875 billion in development, commercial and sales milestone payments with tiered royalties on global net sales.

1. AbbVie Data on File: ABVRRTI82837
2. A Two-Part First-In-Human Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of GUB014295. ClinicalTrials.gov. Available at: <https://clinicaltrials.gov/study/NCT06144684?intr=GUB014295&rank=1#participation-criteria>. Accessed March 3, 2026.

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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.

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 2026-03-09 13:23 CET.

Attachments

[AbbVie reports Positive Phase 1 Multiple Ascending Dose Results for ABBV-295, a Long-Acting Amylin Analog](#)