



# Gubra submits clinical trial application for First-in-Human study of lead asset GUB-UCN2

**Gubra today announces that a clinical trial application (CTA) for the first-in-human study of GUB-UCN2, the company's lead asset for high quality weight loss, has been submitted to the Competent Authority and associated Ethics Committee in Germany. The ambitious trial design sets the stage for exploring GUB-UCN2 across multiple indications and patient populations.**

"GUB-UCN2 entering the clinic marks a pivotal next step for Gubra as we advance a unique mechanism of action that enhances muscle mass and function. With currently approved drugs for obesity treatment, an estimated 20–45% of patients' weight loss may come from lean tissue, including muscle, bone, and vital organs. GUB-UCN2 aims to solve this problem. GUB-UCN2 is purpose-engineered to reduce fat mass while preserving — or potentially increasing — muscle mass to support a healthier more sustainable weight loss," said Chief Medical and Development Officer Thomas Langenickel.

## **Ambitious trial design**

The comprehensive Phase 1/2a clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of GUB-UCN2, with a particular focus on muscle volume and muscle function endpoints.

The trial will enroll approximately 188 participants, including both healthy volunteers and individuals living with obesity, with and without related co-morbidities. The study, with a treatment period of up to 16 weeks in selected cohorts, will investigate GUB-UCN2 as both a standalone therapy and in combination with incretin-based therapy for obesity.

The innovative trial design sets the stage for broad clinical exploration of GUB-UCN2 across multiple indications and patient populations. The trial is strategically designed to maximize asset value by generating multidimensional clinical data early in development and prepares the regulatory path for further development.

GUB-UCN2 is expected to enter clinical development in the first half of 2026.

## **Clinical trial supported by strong preclinical data**

GUB-UCN2 has delivered strong and comprehensive preclinical data. Results have shown that GUB-UCN2 selectively lowers fat mass and increases lean muscle mass when administered alone. In combination with GLP-1 receptor agonist, GUB-UCN2 completely prevented the lean mass loss typically seen with GLP-1 receptor agonists and enhanced fat mass reduction. Notably, GUB-UCN2 also reversed lean mass loss after prior GLP-1 exposure, positioning it as both protective and restorative therapy in treatment combination regimens.



Beyond body composition, UCN2 has delivered improvements of cardiac and renal function in preclinical models.

### **UCN2 mechanism of action**

UCN2 (Urocortin 2), is a 38 amino acid neuropeptide that binds the corticotropin-releasing hormone receptor 2 (CRHR2), essentially re-programming the muscle to an exercise-like phenotype which leads to increased muscle mass and decreased fat mass by:

- Stimulating muscle growth and enhancing muscle performance by acting directly on muscle CRHR2 receptors.
- Increasing protein synthesis in the muscle
- Improving lipid handling, reducing adipocyte size and fat mass
- Improving insulin sensitivity in skeletal muscle

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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 two main business units – Biotech (D&P) and CRO services. The two business areas are highly synergistic and 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 EUR 350 million) in the first 9 months of 2025. See [www.gubra.dk](http://www.gubra.dk) for more information.

### **Attachments**

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