GUBamy

Once-weekly amylin analogue for the treatment of obesity

GUBamy

Significant potential as a novel treatment option for patients with obesity

GUBamy in short

- Long-acting amylin agonist suitable for once weekly subcutaneous administration
- Soluble at neutral pH making GUBamy chemically compatible in a formulation with other anti-obesity drugs (GLP-1 agonists etc.)

Results from preclinical studies

- Significant weight loss alone and additive weight loss in combination with other anti-obesity drugs
- No safety concerns

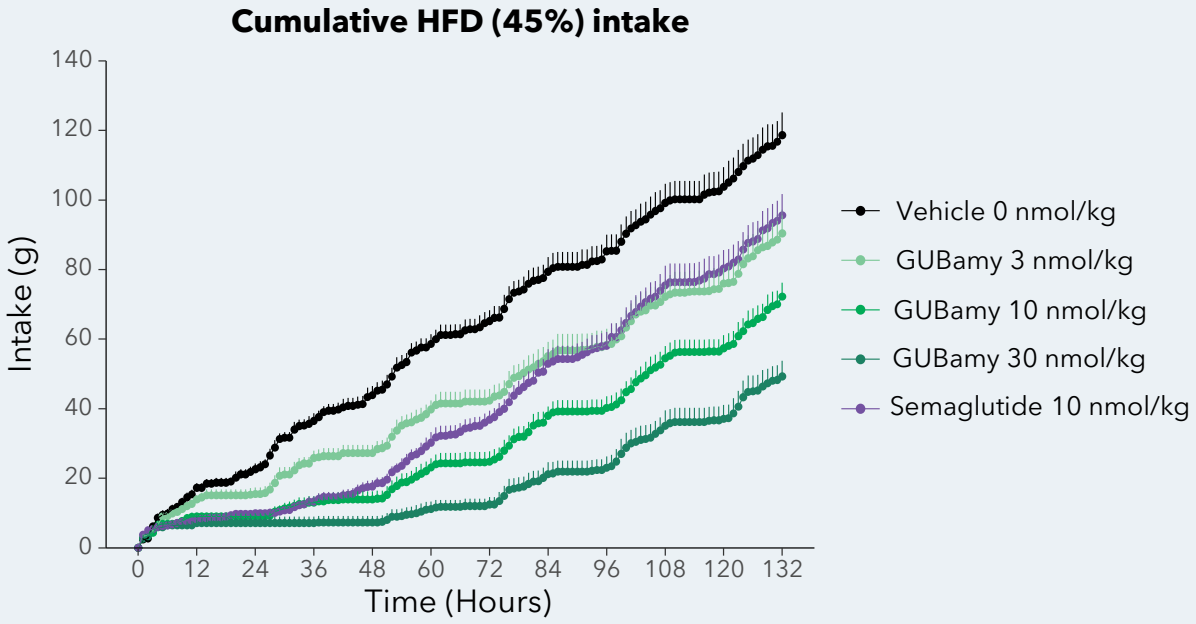
Phase 1 First-In-Human Study

- Study in up to 48 subjects to assess safety and pharmacokinetic properties and pharmacodynamic effects
- First human dosed 29 November 2023 and enrolment expected to be completed mid-2024

Results from preclinical studies

GUBamy reduces food intake

Food intake in Diet Induced Obese (DIO) rats after a single dose of GUBamy



Values expressed as mean of n = 6 + SEM

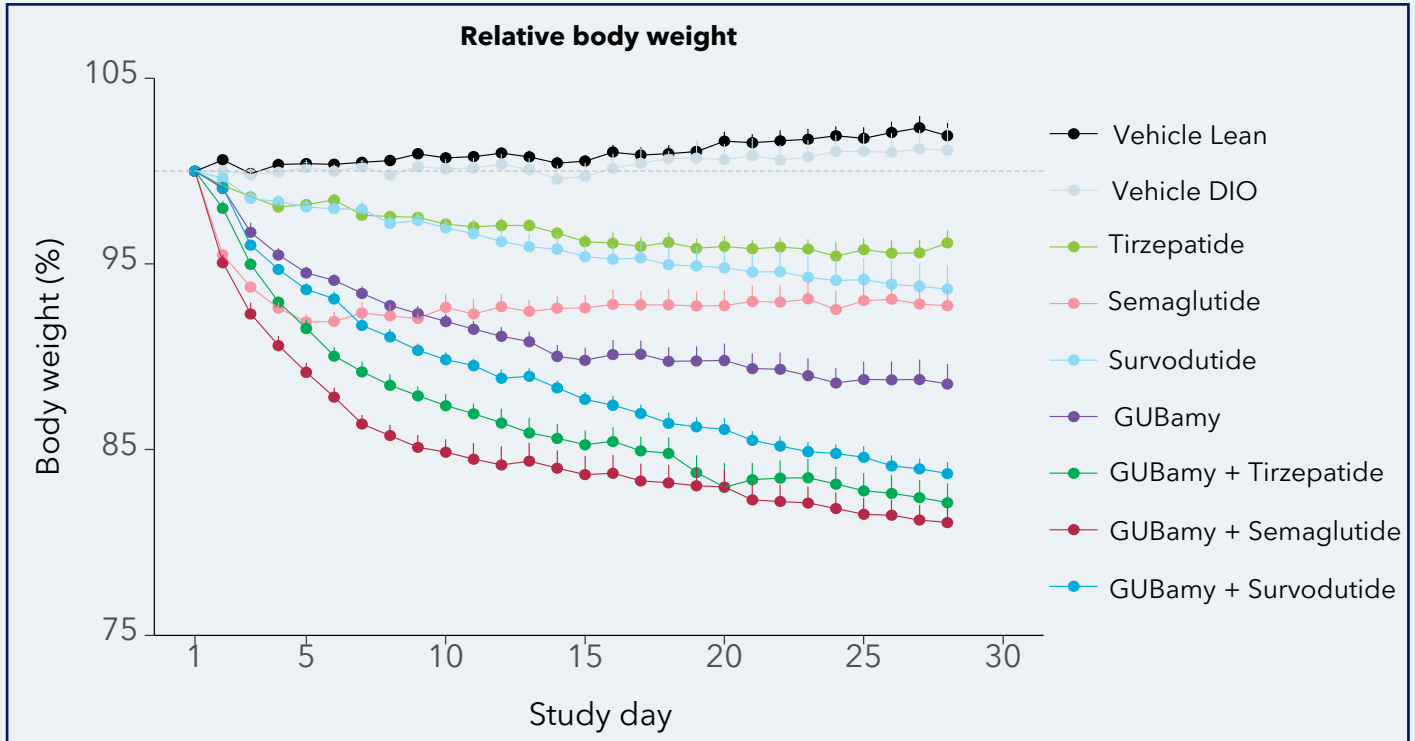
Key takeaways

- Dose dependent reduction of food intake seen after single dose administration of GUBamy
- Sustained reductions in food intake lasting more than 140 hours
- Half-life in rats and dogs support once weekly administration in humans

Additive effects of GUBamy in 4-week combination study

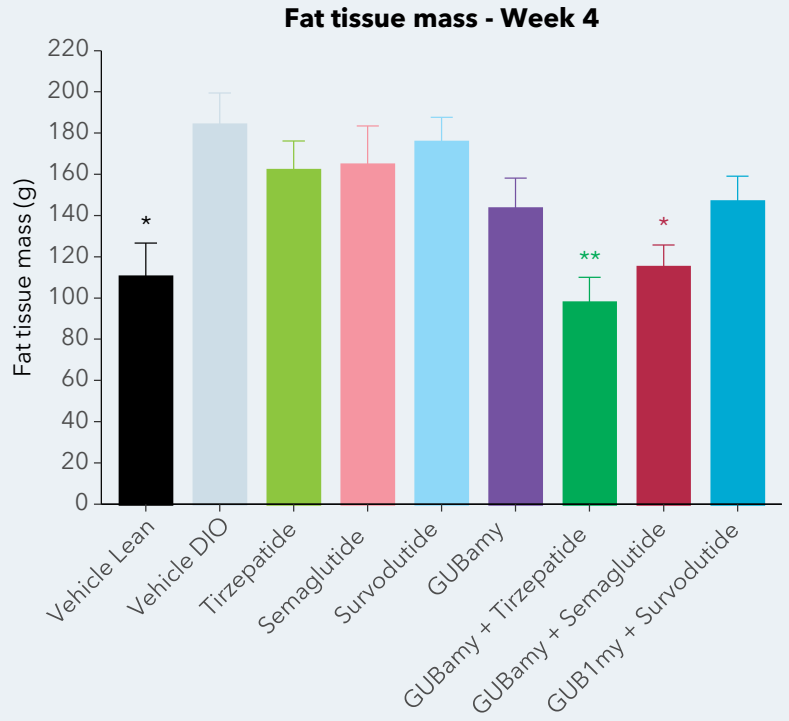
Co-dosing with other anti-obesity peptide drugs (with GLP-1 alone or GLP-1 + GIP/GCG agonism) leads to additive body-weight loss in obese DIO-rats

All compounds dosed at 10nmol/kg daily for 28 days



Key takeaways

- GUBamy exhibits additive weight loss in DIO rats when dosed once daily with a GLP-1 (Semaglutide), a GLP-1/GIP co-agonist (Tirzepatide) or a GLP-1/glucagon co-agonist (Survodutide)



Key takeaways

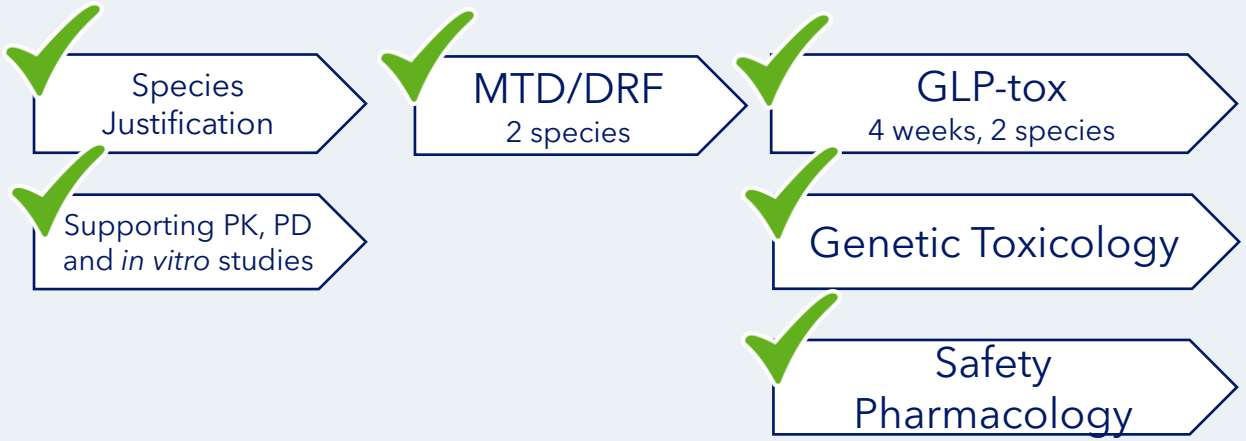
- GUBamy increases fat tissue mass loss in DIO rats when dosed once daily with GLP-1, GLP-1/GIP co-agonist or GLP-1/glucagon co-agonist

Non clinical
GLP toxicity studies

Studies included in Clinical Trial Application submitted and approved by the regulatory authority in UK (MHRA)

Non-clinical study summary

Human trial enabling studies (GLP toxicity studies)



Key takeaways

- All pivotal non-clinical studies have been conducted in accordance with Good Laboratory Practice (GLP) in countries that are members of the OECD Mutual Acceptance of Data (MAD) program
- Results and conclusion have been submitted and reviewed by the regulatory authority in UK (MHRA) which has led to approval for First Human Dose trial initiation.

Phase 1 study

First-In-Human

Phase 1 study First-In-Human

ClinicalTrials.gov NCT06144684

Study setup

- Randomized, placebo-controlled, single ascending dose trial
- Assess safety, tolerability, pharmacokinetics, and pharmacodynamics of GUBamy
- Lean to overweight, but otherwise healthy subjects

Participants and timeframe

- Up to 48 subjects in 6 cohorts at Quotient Sciences in Nottingham in the UK
- First cohort administered with a single dose of 0.5 mg GUBamy
- Completion of enrolment expected mid-2024

Objectives of the study

- Primary objective: Safety (Incidence of Adverse Events)
- Secondary objectives: Characterize the pharmacokinetics (PK) and investigate possible pharmacodynamic effects measured as weight changes and changes in gastric emptying and changes in glucose, insulin, C-peptide, and glucagon

Thank you for your attention

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