#### **TOPLINE RESULTS**

## **GUBamy Phase 1a SAD trial**

November 2024



### Henrik Blou Chief Executive Officer



### **Forward looking statements**



Matters discussed in this presentation may constitute forward-looking statements. Forward-looking statements are statements that are not historical facts and that can be identified by words such as "believe", "expect", "anticipate", "intends", "estimate", "will", "may", "continue", "should", and similar expressions. The absence of these words, however, does not mean that the statements are not forward-looking.

The forward-looking statements in this presentation are based upon various assumptions, many of which are based, in turn, upon further assumptions. Although the company believes that these assumptions were reasonable when made, these assumptions are inherently subject to significant known and unknown risks, uncertainties, contingencies and other important factors which are difficult or impossible to predict and are beyond its control. Such risks, uncertainties, contingencies and other important factors expressed or implied in this release by such forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties.

The information, opinions and forward-looking statements contained in this presentation speak only as at its date and are subject to change without notice.



### ~250

Employees September 2024

~50%

CRO revenue from the US (EUR 22 million CRO revenue 9M-2024)

### 30%

Yearly revenue growth (CAGR) since inception 2009 to 2023

Gubra has served 16 out of top 20

largest pharma companies

#### The Gubra Hybrid Business Model

**Discovery &** 

**Partnerships** 

Discovery, design and

development of peptidebased drug candidates

with the aim of entering

partnerships with pharma

or biotech companies

#### **CRO Services**

Specialized pre-clinical contract research and development services for the pharma and biotech companies

### **OPERATIONAL SYNERGIES**

### **R&D** pipeline



Disease area	Partner	Drug Discovery	Pre-Clinical Development	Phase 1	
Obesity (NPY2R agonist)*	Boehringer Ingelheim				
Obesity (triple agonist)	Boehringer Ingelheim				_
Obesity	Boehringer Ingelheim				
Obesity	Boehringer Ingelheim				
Bleeding disorders	Hemab				
Obesity (amylin)	Gubra				GUBamv
Obesity (UCN2)	Gubra				Phase 1a SAD trial
Obesity (GLP1R agonist)	Gubra				completed
Obesity	Gubra				
Narcolepsy (orexin)	Gubra				
Hypoparathyroidism (PTH)	Gubra				

\*Oct 31, 2024 discontinued by Boehringer Ingelheim

# GUBamy could be positioned as both an addition and an **Gubra** alternative to incretin-based therapies

Extensive need for <u>alternative</u> therapies

GUBamy as stand-alone therapy GUBamy as combination therapy



### "GUBamy was well tolerated, had a very long half-life and provided sustained body-weight loss.

This supports further development of GUBamy"

### Louise S. Dalbøge Chief Scientific Officer



### **Amylin: An important player in appetite regulation**



#### From pancreas to the brain

- Amylin is a 37 amino acid peptide hormone. It is produced in the pancreatic β-cells and co-secreted with insulin in response to meal ingestion
- + Regulates appetite by activating key areas in the brain (AP, NTS)
- + Plays an important role in maintaining glucose homeostasis
- + Potential for substantial weight loss alone or in combination with incretin-based therapies

Amylin Decreases food intake Reduces blood glucose Delays gastric emptying Decreases glucagon secretion



### GUBamy holds potential to become the next generation (gubra weight management therapy



### Mads Axelsen Chief Medical Officer





NCT06144684 (Phase 1, Part 1)



- + Randomized
- + Double-blind within cohorts
- + Placebo-controlled
- + Single subcutaneous administration
- + Single site (CRO in UK)
- + 8 subj. per cohort (2 placebo & 6 GUBamy)
- + 48 subjects
- + Men (18-55 years)
- + Lean to overweight or obese (22< BMI <32 kg/m<sup>2</sup>)
- + Healthy based on medical history, physical examination, ECG, and clinical laboratory tests





Baseline characteristics

	Placebo	GUBamy	GUBamy	GUBamy	GUBamy	GUBamy	GUBamy
	(all)	0.5 mg	1.0 mg	2.0 mg	3.5 mg	4.75 mg	6.0 mg
n	12	6	6	6	6	6	6
Mean age, years (range)	35.7	34.8	38.0	43.5	48.8	40.2	32.0
	(23-53)	(22-51)	(24-50)	(28-53)	(33-55)	(34-46)	(21-43)
Sex, n (%) Male	12 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)	6 (100)
Mean Body Weight, kg	90.74	82.08	90.55	80.92	84.15	87.57	85.00
(range)	(79.5-105.7)	(71.8-93.6)	(82.0-103.1)	(72.7-91.6)	(71.4-98.5)	(76.9-109.9)	(78.1-88.4)
Mean BMI, kg/m²	28.61	24.85	27.97	26.50	27.03	26.98	26.58
(range)	(23.6-32.0)	(22.3-28.2)	(26.2-30.1)	(24.1-29.8)	(22.2-31.1)	(24.5-31.4)	(25.5-31.7)
Mean HbA1c, mmol/mol	33.4	35.7	34.0	34.3	35.5	34.7	34.0
(range)	(27-39)	(31-42)	(32-37)	(27-37)	(33-40)	(31-37)	(30-36)

Haemoglobin A1c reference range (20-42 mmol/mol)

### **GUBamy Phase 1a SAD key study endpoints**

## 

#### **Primary Endpoint**

Safety and tolerability incl. number of treatment-emergent adverse events (TEAEs)

#### **Secondary Endpoints (Pharmacokinetic)**

Pharmacokinetic (PK) evaluation incl. half-life (T<sup>1</sup>/<sub>2</sub>)

#### **Exploratory Endpoints (Pharmacodynamic)**

Change in body weight (%)

### **GUBamy was well tolerated**



Treatment Emergent Adverse Events (TEAEs)

Treatment group Dose (volume mL)	Placebo 0 mg (0.1-1.2 m	L)	GUBamy 0.5 mg (0.1 mL)		GUBamy 1 mg (0.2 mL)		GUBamy 2.0 mg (0.4 mL)		GUBamy 3.5 mg (0.7 mL)		GUBamy 4.75 mg (0.95 mL)		GUBamy 6.0 mg (1.2 mL)	
	n (%) E		n (%)	E	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е
TEAEs (all)	6 (50.0) 1	1 5 (8	83.3)	8	2 (33.3)	2	2 (33.3)	3	6 (100)	17	6 (100)	36	6 (100)	21
Severity of TEAEs Mild Moderate Severe	6 (50.0) 0 0	5 (8 0 0	83.3)		2 (33.3) 0 0		2 (33.3) 0 0		5 (83.3) 1 (16.7) 0		6 (100) 0 0		5 (83.3) 1 (16.7) 0	
Serious AEs	0	0			0		0		0		0		0	
Completed	12	6			6		6		6		6		6	

n = Counts are given for total number of subjects, not for events. If more events in one subject the most severe episode is counted.

Majority of AEs reported were mild and no severe or serious AEs. All study subjects completed the study.

### **Dose dependent GI adverse events**



Treatment Emergent Adverse Events (TEAEs)

Treatment group Dose (volume)	Placebo GUBamy   0 mg 0.5 mg   (0.1-1.2 mL) (0.1 mL)   n = 12 n=6		GUB 1.0 (0.2 n=	GUBamy 1.0 mg (0.2 mL) n=6		GUBamy 2.0 mg (0.4 mL) n=6		GUBamy 3.5 mg (0.7 mL) n=6		GUBamy 4.75 mg (0.95 mL) n=6		GUBamy 6.0 mg (1.2 mL) n=6		
-	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е	n (%)	Е
TEAEs (all)	6 (50.0)	11	5 (83.3)	8	2 (33.3)	2	2 (33.3)	3	6 (100)	17	6 (100)	36	6 (100)	21
GI AEs	1 (8.3)	1	0	0	0	0	1 (16.7)	1	4 (66.7)	7	4 (66.7)	9	6 (100)	8
Nausea	1 (8.3)	1	0	0	0	0	0	0	3 (50.0)	3	4 (66.7)	4	5 (83.3)	5
Vomiting	0	0	0	0	0	0	0	0	1 (16.7)	2	2 (33.3)	2	1 (16.7)	1
Other*	0	0	0	0	0	0	1 (16.7)	1	2 (33.3)	2	3 (50.0)	3	2 (33.3)	2
Metabolism AEs	0	0	1 (16.7)	1	0	0	0	0	4 (66.7)	4	5 (83.3)	5	6 (100)	7
Decreased appetite	0	0	1 (16.7)	1	0	0	0	0	4 (66.7)	4	5 (83.3)	5	6 (100)	7
Injection site AE**	2 (16.7)	2	2 (33.3)	2	0	0	0	0	1 (16.7)	1	2 (33.3)	2	2 (33.3)	2

n = the number of subjects reporting at least one event. E = Total number of events. GI: Gastrointestinal.

\*Other: Abdominal pain/discomfort (3 subjects), change in bowel habit, constipation, diarrhoea, gastroesophageal reflux disease, toothache (each event in 1 subject). \*\*Pain or bruising.

> Nausea and vomiting were mostly mild, transient and primarily reported at the higher doses. All TEAEs resolved during the study, the majority within a few days.

### **GUBamy Phase 1a SAD key study endpoints**



#### **Primary Endpoint**

Safety and tolerability incl. number of treatment-emergent adverse events (TEAEs)

#### Secondary Endpoints (Pharmacokinetic)

Pharmacokinetic (PK) evaluation incl. half-life (T<sup>1</sup>/<sub>2</sub>)

#### **Exploratory Endpoints (Pharmacodynamic)**

Change in body weight (%)

### Long half-life (11 days) supports weekly dosing



GUBamy shows a favourable pharmacokinetic profile



A long half-life of 11 days suitable for once weekly dosing. Cmax and AUC confirm dose proportionality.

### **GUBamy Phase 1a SAD key study endpoints**

#### **Primary Endpoint**

Safety and tolerability incl. number of treatment-emergent adverse events (TEAEs)

#### **Secondary Endpoints (Pharmacokinetic)**

Pharmacokinetic (PK) evaluation incl. half-life (T<sup>1</sup>/<sub>2</sub>)

#### **Exploratory Endpoints (Pharmacodynamic)**

Change in body weight (%)

### **Dose dependent body weight reduction**

![](_page_19_Picture_1.jpeg)

Relative weight change from baseline in percentage

![](_page_19_Figure_3.jpeg)

### Sustained body weight reduction for 6 weeks

![](_page_20_Picture_1.jpeg)

Relative weight change from baseline in percentage (SD)

![](_page_20_Figure_3.jpeg)

### Phase 1 Multiple Ascending Dose (MAD)

![](_page_21_Picture_1.jpeg)

NCT06144684 (Phase 1, Part 2)

![](_page_21_Picture_3.jpeg)

### **SAD study conclusions**

GUBamy dosed once in a dose range from 0.5 mg to 6.0 mg

![](_page_22_Picture_2.jpeg)

GUBamy was well tolerated with adverse events being predominantly GI related, mild and transient.

![](_page_22_Picture_4.jpeg)

GUBamy had a favourable pharmacokinetic profile with a half-life of 11 days supporting once weekly dosing.

A single dose of GUBamy reduced body-weight dose dependently - the effect was sustained for the duration of the trial (6 weeks).

![](_page_22_Picture_7.jpeg)

Mean body weight reduction in all high dose groups (3.5-6.0 mg) reached approx. 3% during the 6 weeks trial, whereas subjects in the placebo group gained approx. 1%.

![](_page_22_Picture_9.jpeg)

The results support further development of GUBamy for a weight management indication.

![](_page_22_Picture_11.jpeg)

MAD trial is ongoing with interim results expected to be released in 1st half of 2025.

![](_page_22_Picture_13.jpeg)

### Thank you for your attention

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#### Let's stay connected

![](_page_23_Picture_4.jpeg)

![](_page_23_Picture_5.jpeg)