



camurus®

# Company presentation

January 2024

# Forward looking statements

This presentation contains forward-looking statements that provide our expectations or forecasts of future events such as new product developments and regulatory approvals and financial performance.

Camurus is providing the following cautionary statement. Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include currency exchange rate fluctuations, delay or failure of development projects, loss or expiry of patents, production problems, unexpected contract, patent, breaches or terminations, government-mandated or market-driven price decreases, introduction of competing products, Camurus' ability to successfully market products, exposure to product liability claims and other lawsuits, changes in reimbursement rules and governmental laws and interpretation thereof, and unexpected cost increases.

Camurus undertakes no obligation to update forward-looking statements.

# Camurus snapshot



## Rapidly growing commercial stage company

Leader in opioid dependence treatment with Buvidal® weekly and monthly depots



## Advancing late-stage pipeline with blockbuster potential

Prospects for multiple new approvals in coming years in CNS and rare disease indications



## Strong financial performance

Entered profitability in 2022



## Unique FluidCrystal® technology platform

Commercially validated, with a broad range of applications

LISTED ON NASDAQ STOCKHOLM  
TICKER **CAMX**; EMPLOYEES: **210+**

# Significant recent progress



## Positive financial development

- ✓ High double-digit year-on-year revenue growth
- ✓ Sustained profitability
- ✓ Robust cash position SEK 1.15 B end Q3 2023 – no debt
- ✓ Raised Full Year 2023 guidance



## Commercial development

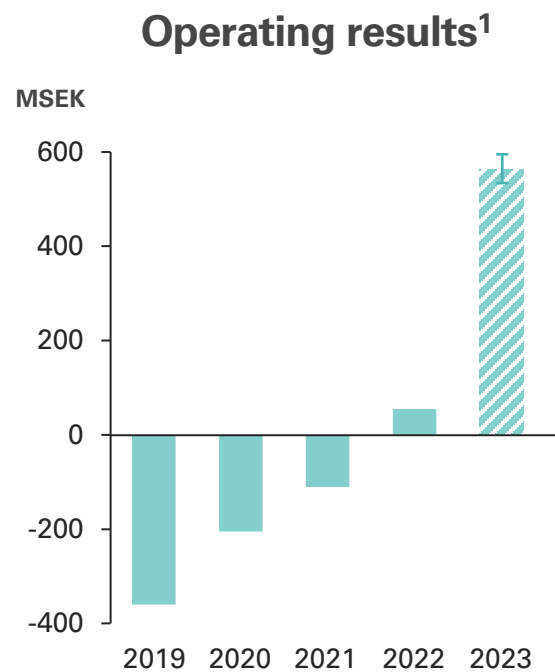
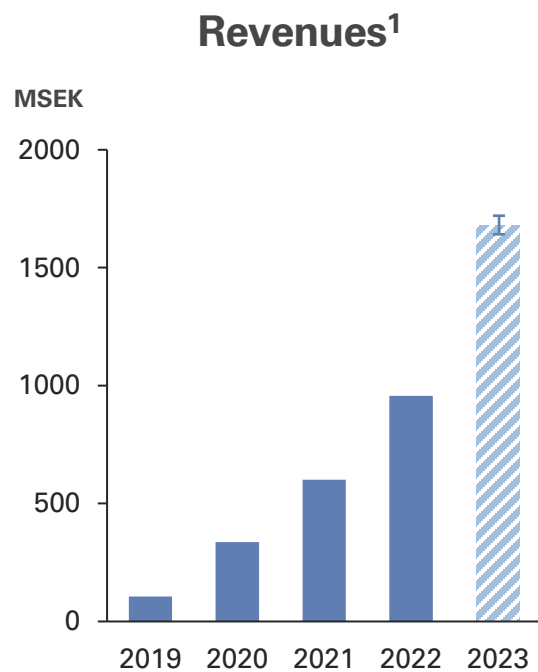
- ✓ Strengthened leadership in LAI treatment of opioid dependence
- ✓ High Buvidal sales growth, SEK 933 million Q3 YTD, +40%
- ✓ US launch of Brixadi™ for OUD by Camurus' licensee Braeburn



## Pipeline progress

- ✓ Positive ACROINNOVA 2 Phase 3 results for CAM2029 in acromegaly
- ✓ NDA submission of Oclaiz™ (CAM2029) in acromegaly
- ✓ Completed recruitment in SORENTO Phase 3 trial in GEP-NET

# Entered sustained profitability



## FY 2023 outlook

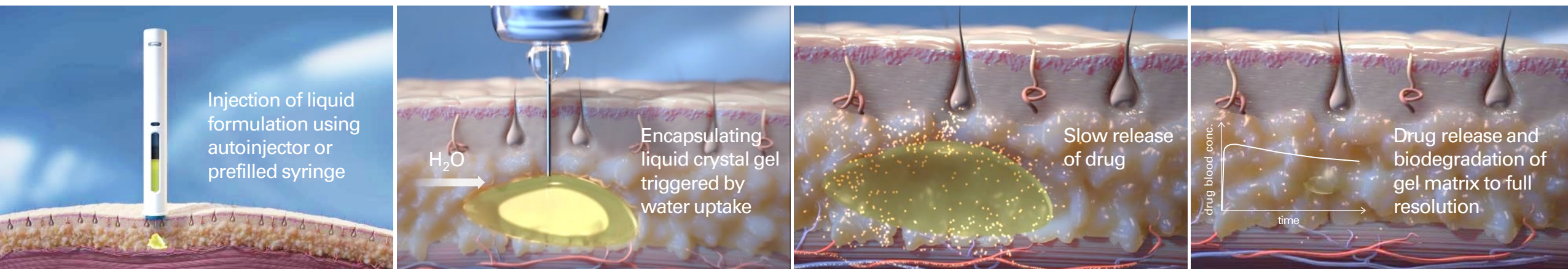
Total revenue  
**SEK 1,640 to 1,720 million**

Operating results  
**SEK 525 to 600 million**

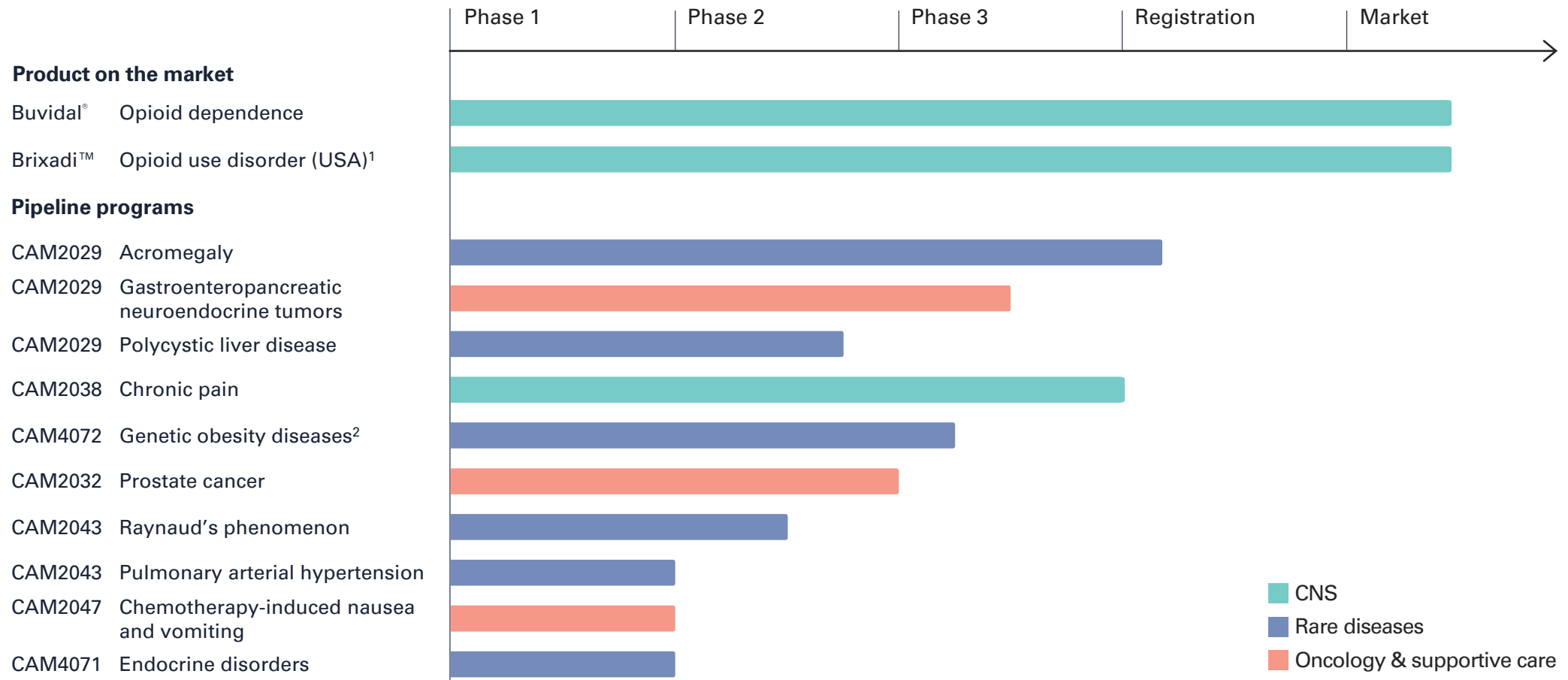
<sup>1</sup>Forecasted 2023 revenue and operating results

# FluidCrystal<sup>®</sup> extended-release technology

- ✓ Easy and convenient administration
- ✓ Rapid onset & long-acting release
- ✓ Controlled by composition, liquid crystal phase structure and biodegradation
- ✓ Applicable across substance classes
- ✓ Compatible with prefilled syringes, pen-injectors, and other advanced devices
- ✓ Manufacturing by standard processes



# Broad and diversified product portfolio and pipeline



<sup>1</sup>Licensed to Braeburn in North America; <sup>2</sup>Licensed to Rhythm Pharmaceuticals worldwide

# Buvidal – game changing opioid dependence treatment

*Weekly and monthly, subcutaneous buprenorphine for individualized treatment of opioid dependence within a framework of medical, social and psychological treatment in adults and adolescents 16 years or over<sup>1</sup>*

## Demonstrated benefits to patients and society

- Superior treatment outcome and patient satisfaction<sup>2-5</sup>
- Blockade of subjective opioid effects from first dose<sup>3</sup>
- Reduced treatment burden and improved quality of life<sup>5,6</sup>
- Decreased risk of diversion, misuse and pediatric exposure<sup>7,8</sup>
- Reduced treatment costs<sup>9</sup>

“Buvidal became my way out”

Justin, Buvidal patient in Australia

<sup>1</sup> SmPC Buvidal May 2021; <sup>2</sup>Lofwall et al. JAMA Int. Med. 2018;178(6): 764-773; <sup>3</sup>Walsh et al, JAMA Psychiatry 2017;74(9):894-902; <sup>4</sup>Frost, M., et al. Addiction. 2019;114(8):1416-1426. doi: 10.1111/add.14636; <sup>5</sup>Lintzeris, N., et al. JAMA Network Open. 2021;4(5):e219041. doi:10.1001/jamanetworkopen.2021.9041, <sup>6</sup>Barnett et al Drug and Alcohol Dependence 2021; <https://doi.org/10.1016/j.drugalcdep.2021.108959>; <sup>7</sup>EPAR for Buvidal; <sup>8</sup>Dunlop, A. J., et al. Addiction. 2021. <https://doi.org/10.1111/add.15627>; <sup>9</sup>Dunlop, A. Oral presentation at CPDD June 2020.



# Buvidal continuing to grow in Europe, Australia and MENA

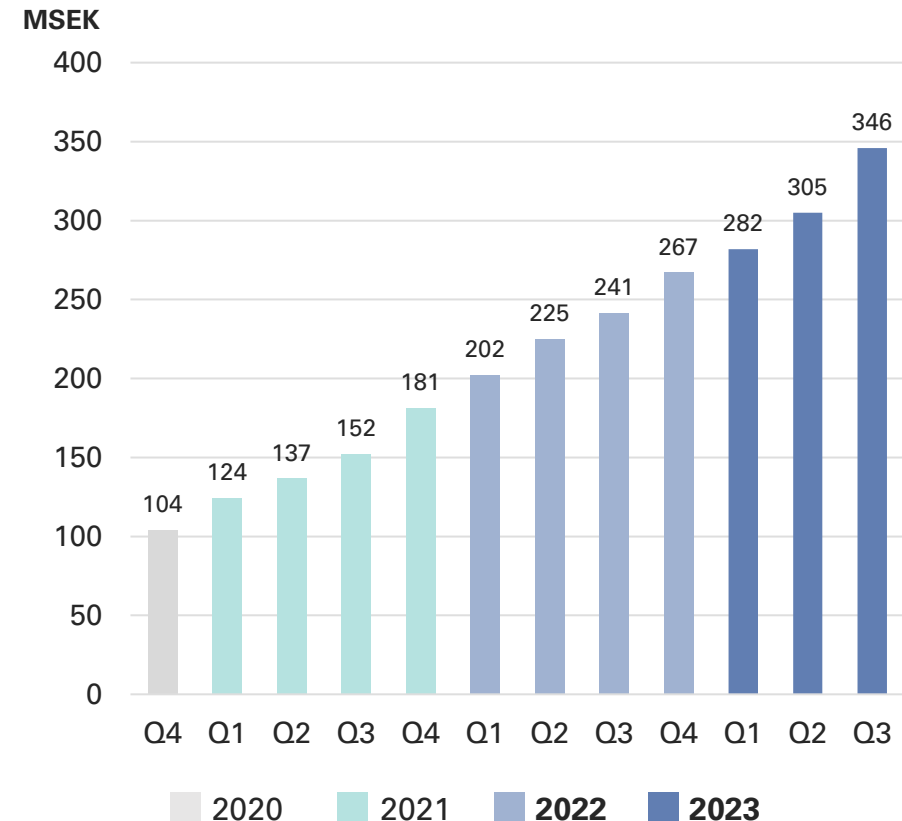
## Continued market penetration

- Robust double-digit YoY sales growth
  - Q3 net sales: SEK 346 million; +44% YoY, +13% QoQ
- Strong performance across markets including the UK, Nordics, Germany, Austria and Spain
- Est. 45,000 patients in treatment with Buvidal end Q3
- Target more than 100,000 in 2027

## Regulatory and market expansion processes

- Buvidal launched in Italy
- Four regulatory and four reimbursement submissions progressing
- New markets planned

## Quarterly product sales



# US launch of Brixadi in opioid use disorder

## Braeburn responsible for US commercialization

- Focused commercial organization of over 100 people

## Launch initiated 5 September 2023

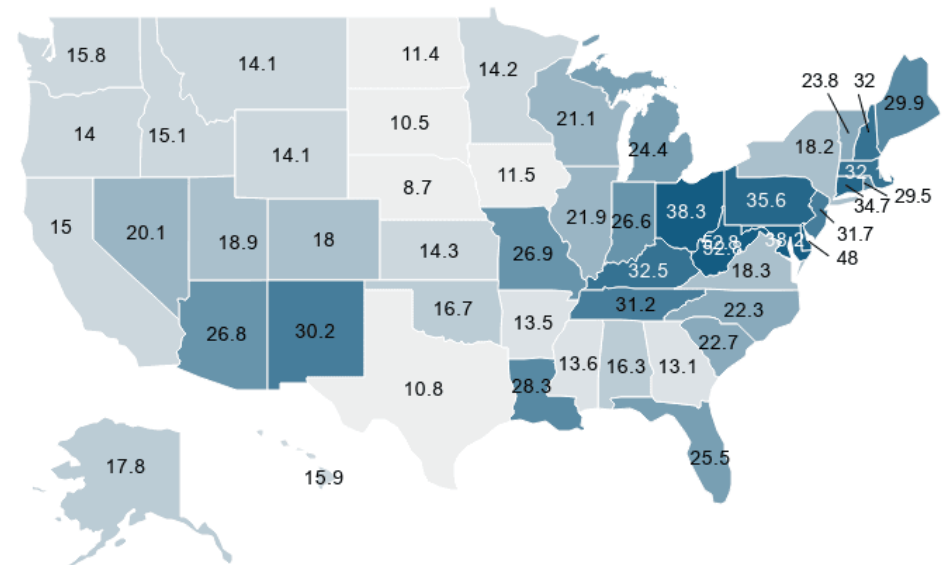
- Brixadi available in all 50 US states; in several cases with unrestricted access through Medicaid
- Increasing coverage by commercial payers
- Broad distribution network

## High peak market potential est. >USD 1 billion<sup>1</sup>

- Royalty revenues and sales milestones to Camurus



## US drug overdose deaths per 100,000 residents<sup>2</sup>

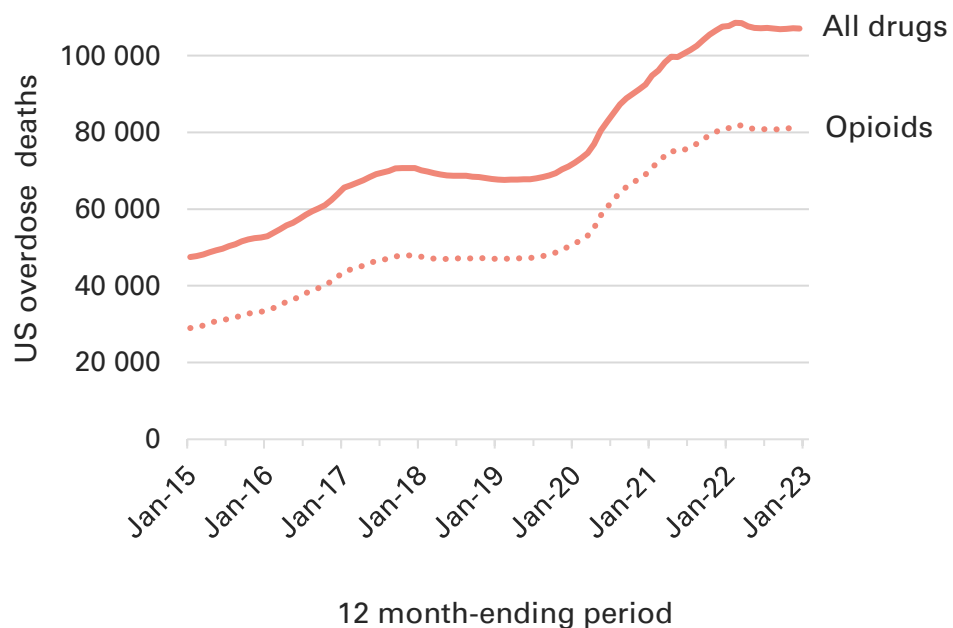


LAI – long acting injectable  
<sup>1</sup>Company estimate; <sup>2</sup>Drug Abuse Statistics 2023

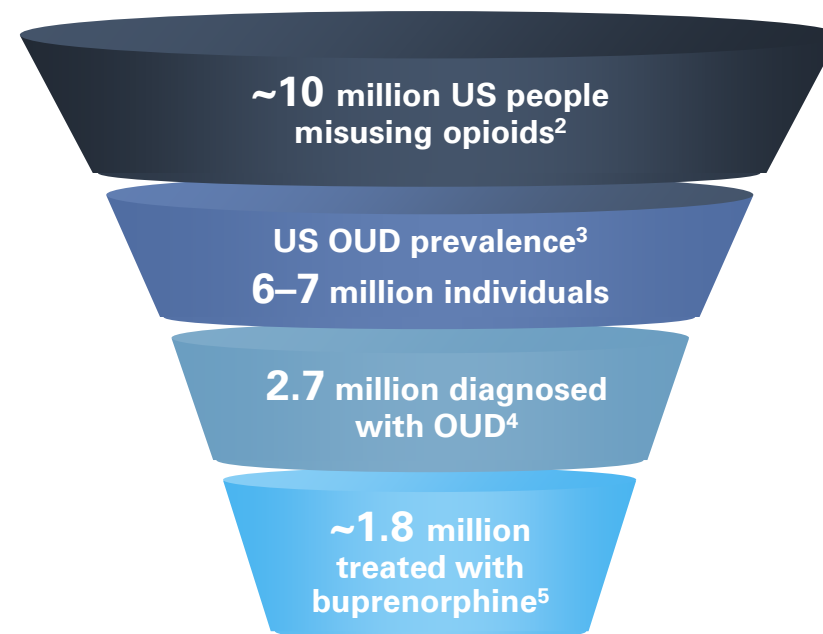
# Opioid crisis in the US continues

## High medical need in the US

~80,000 annual deaths in opioid overdoses<sup>1</sup>



## Significant treatment gap



<sup>1</sup>CDC Provisional Drug Overdose Death Counts; <sup>2</sup>2018 National Survey on Drug Use and Health; <sup>3</sup>Keyes KM, et al. Drug Alc. Dep. Reports 2022; <sup>4</sup>CDC 2023; <sup>5</sup>Symphony Health data

# Positive market dynamics in the US

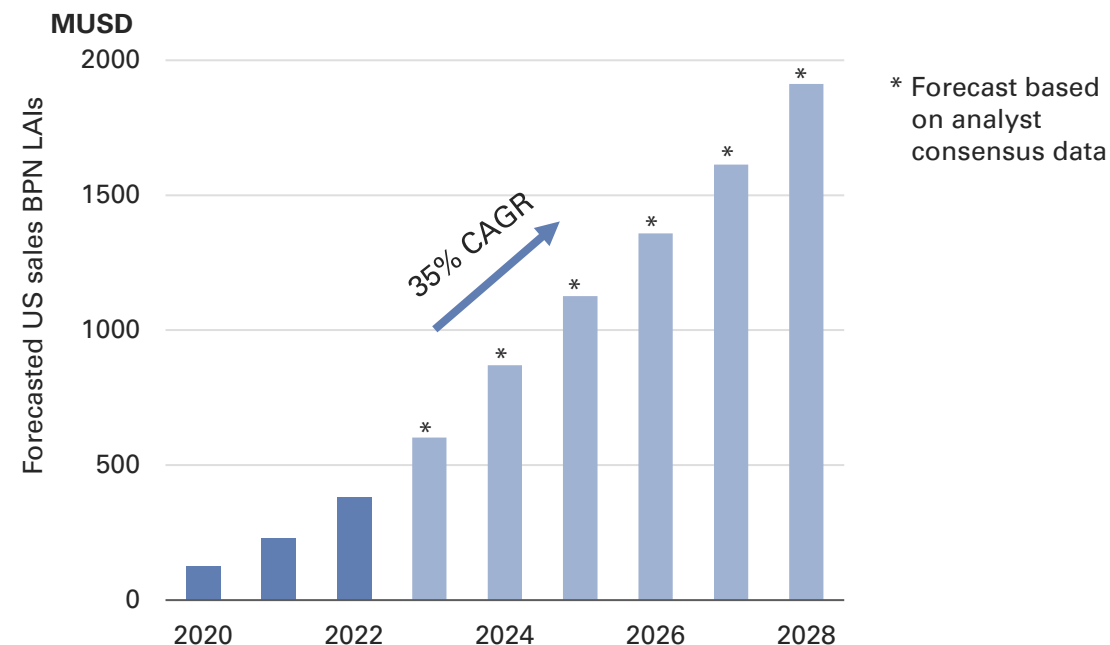
## Recent initiatives to address treatment hurdles

- President Biden’s Unity Agenda<sup>1</sup>
- Improved funding<sup>2</sup>
- Removal of DATA 2000 waiver and number of patients HCPs can treat<sup>3</sup>
- Expanded access to treatment in criminal justice system<sup>4</sup>
- Estimated 6-7 million people with opioid use disorder<sup>5</sup>

## Long-acting injectable buprenorphine growing

- Patient share (<5%<sup>6</sup>) rapidly growing
- Brixadi has competitive and well differentiated product profile

## Positive outlook on BPN LAI market growth<sup>7</sup>



LAI – long-acting injectable; BPN – buprenorphine

<sup>1</sup>State of the Union 2023; <sup>2</sup>H.R.2471 - Consolidated Appropriations Act, 2022; <sup>3</sup>The White House – Consolidated Appropriations Act, 2023; <sup>4</sup>Justice Department Issues Guidance on Protections for People with Opioid Use Disorder, 5 Apr 2022; <sup>5</sup>Keyes KM, et al. Drug Alc. Dep. Reports 2022; <sup>6</sup>Patient share estimated based on average patient months calculated from dispensed Sublocade® units (Indivior FY22 report) and total treated patients from Symphony Health data; <sup>7</sup>GlobalData 2023, sales data and analyst consensus including expected Sublocade® and Brixadi™ sales

# Brixadi – well differentiated in the US market

## Convenient and flexible administration

- Weekly and monthly dosing
- Multiple dose strengths (four weekly, three monthly)
- Choice of multiple injection sites
- Thin needle and small dose volumes
- Room temperature stability (no cold chain required)




## Strong scientific evidence base

- Superior efficacy and patient reported treatment satisfaction vs daily standard of care

## Competitive label<sup>1</sup>

- Switch from daily sublingual buprenorphine using conversion table for dose equivalency
- Direct initiation of treatment following a single dose of transmucosal buprenorphine

### LAI features<sup>2</sup>

			
Weekly dosing	–	–	✓
Monthly dosing	✓	✓	✓
Multiple doses	–	–	✓
Choice of inj. sites	–	–	✓
Smallest needle	(19G)	(20G)	✓ (23G)
Lowest dose volume	0.5–1.5mL	3.4mL	✓ 0.16–0.64mL
Room temp. storage	–	–	✓
Day one initiation	–	–	✓
Clin. data vs active control	–	–	✓
Launched	US, CAN, AUS, SE, FI, IL	US	US, EU, UK, AUS

LAI – long acting injectable

<sup>1</sup>Brixadi US label; <sup>2</sup>See product information



# Octreotide SC depot

CAM2029 under development for three serious rare disease indications

- Acromegaly
- Gastroenteropancreatic neuroendocrine tumors (GEP-NET)
- Polycystic liver disease (PLD)

Designed for enhanced efficacy and patient convenience



# CAM2029 targeting USD 3-billion SRL market

## SRLs established treatment with limitations

- First-line treatment of acromegaly and neuroendocrine tumors (NET)
- Established safety and efficacy profile
- Potential for significant improvements of efficacy and patient convenience

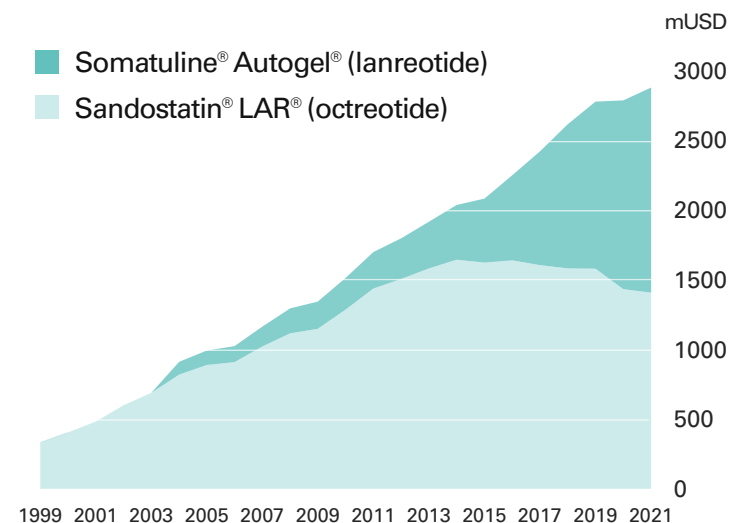
## CAM2029 best-in-class treatment potential

- Convenient self-administration with state-of-the-art pen device



- 5-fold increase of octreotide plasma exposure (dose adjusted)
- Potential for improved disease control and treatment outcomes

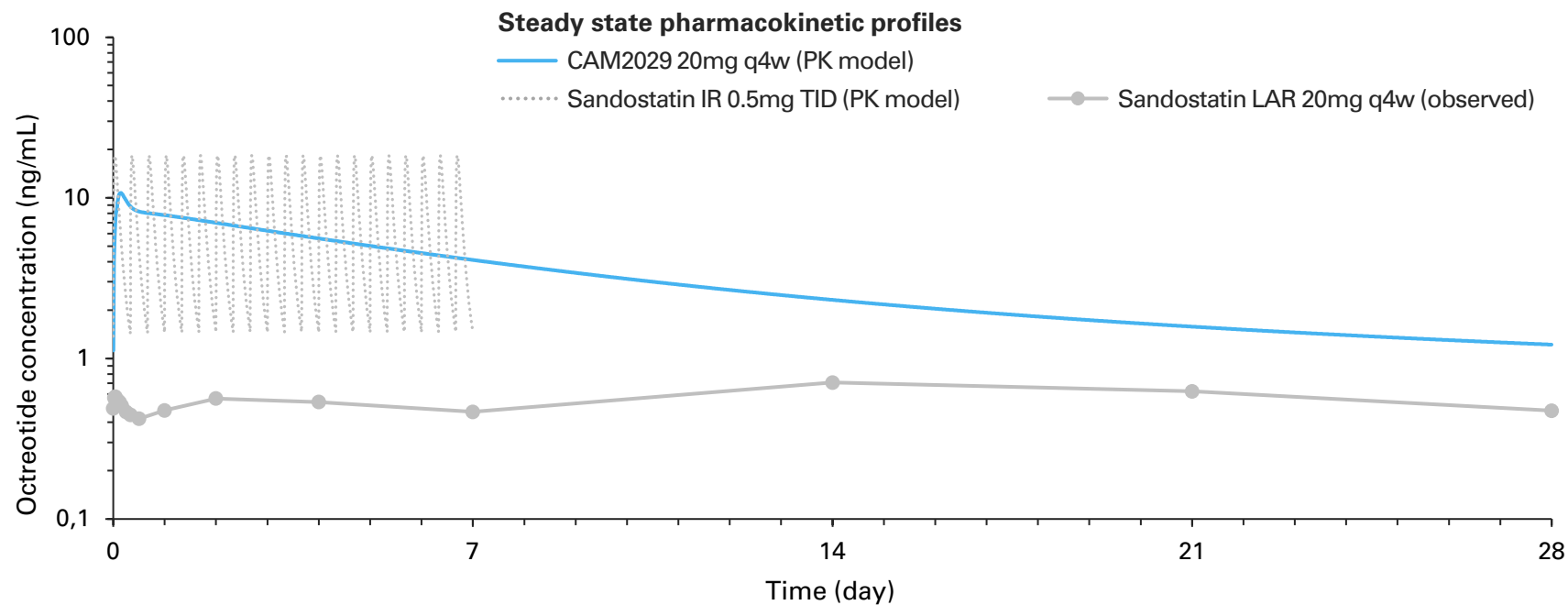
## Annual sales of first generation SRLs<sup>1</sup>



# CAM2029 provides high SSA exposure

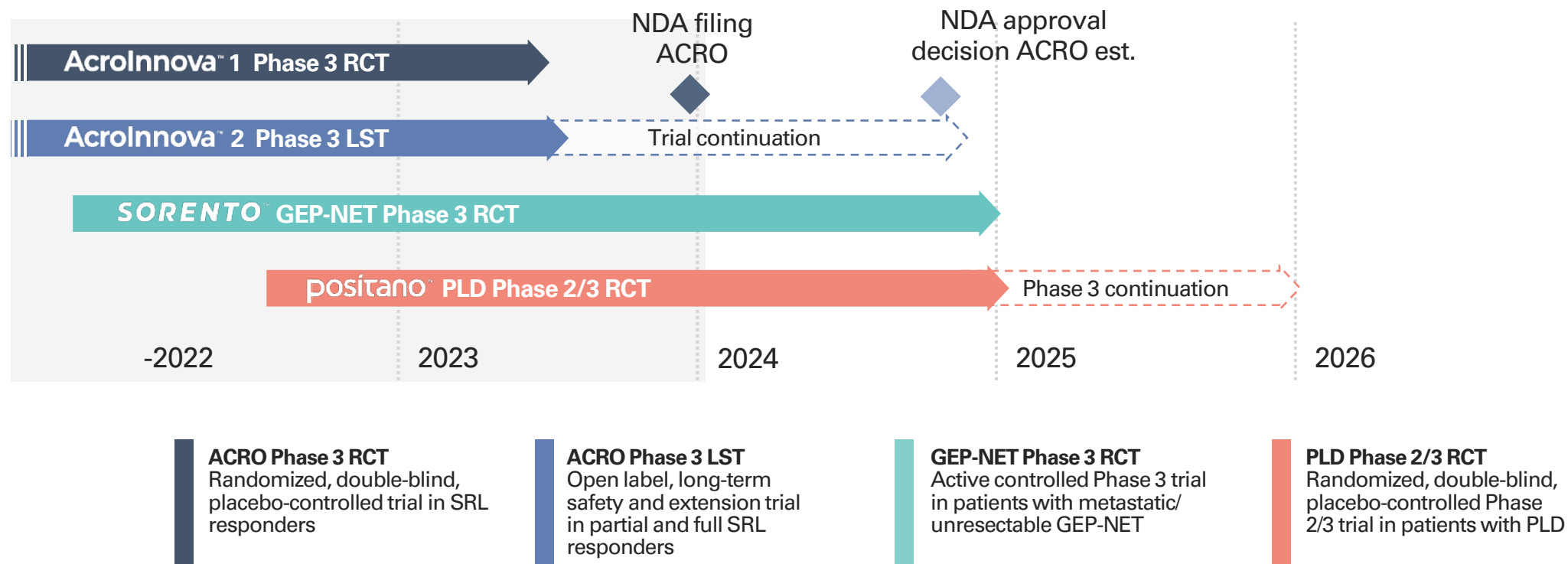
~5x higher octreotide plasma exposure for CAM2029 vs. Sandostatin LAR

CAM2029 octreotide plasma levels in the range of immediate release octreotide





# CAM2029 Phase 3 programs advancing



# ACROINNOVA 1

## Phase 3 RCT efficacy and safety trial

### ACROINNOVA 1 trial design

- 24-week, randomized, double blind, placebo-controlled trial

### Key eligibility criteria:

- Patients with acromegaly on treatment with a stable dose of octreotide LAR or lanreotide ATG for at least 3 months with
- IGF-1 levels  $\leq 1 \times \text{ULN}$  at screening

### Primary endpoint:

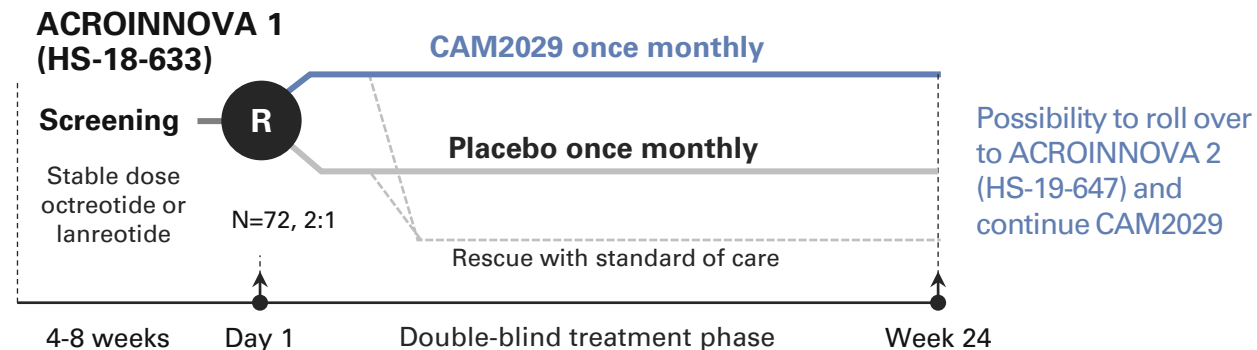
- Proportion of patients with mean IGF-1  $\leq 1 \times \text{ULN}$  (week 22 and 24)

### Key secondary endpoints:

- Proportion of patients with mean IGF-1 levels  $\leq 1 \times \text{ULN}$ , incl. patients with decreased dose
- Proportion of patients with mean IGF-1 levels  $\leq 1 \times \text{ULN}$  and GH cycle levels  $< 2.5 \mu\text{g/L}$

### Secondary endpoints, e.g.:

- Time to loss of IGF-1 response
- IGF-1 and GH over time and change from baseline
- Clinical signs and symptoms (AIS score)
- Patient satisfaction and treatment satisfaction (PSS and TSQM)
- Acromegaly quality of life (AcroQoL)
- Self-injection assessments (SiAQ)
- Plasma concentrations of octreotide
- Safety and tolerability

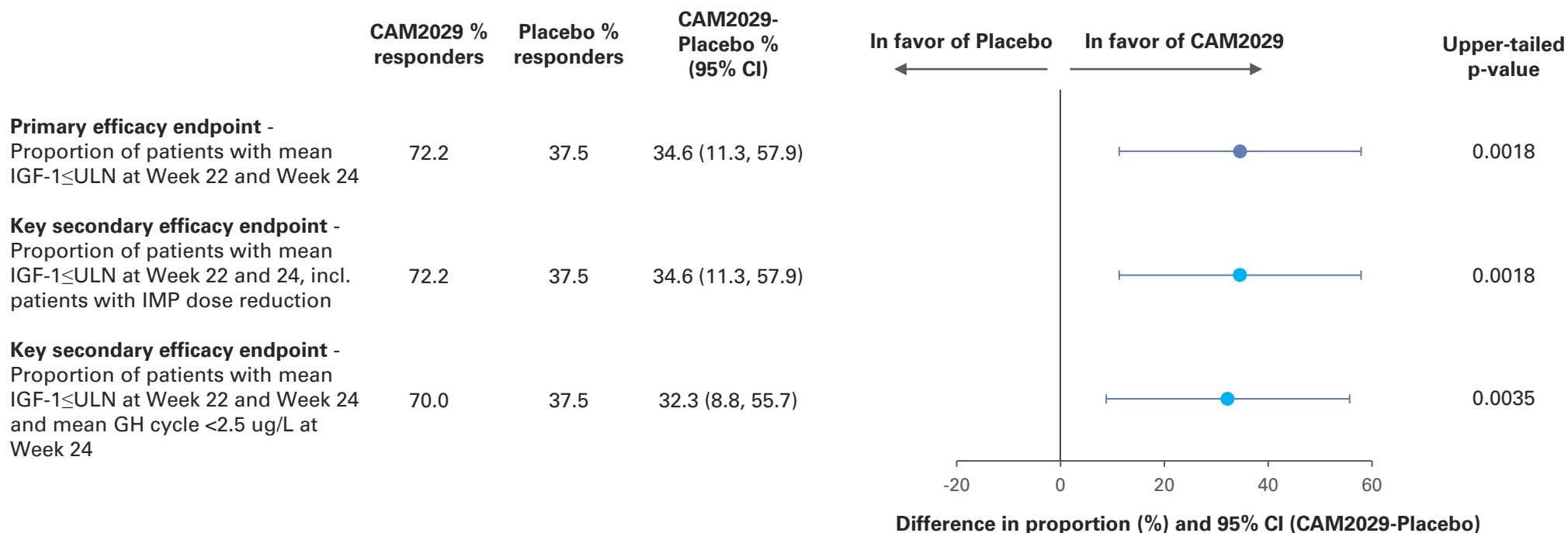


### Statistical assumption primary endpoint:

- 90% power to show treatment difference with 80% response for CAM2029 vs 40% response for placebo, based on Chi-squared test (with continuity correction)

# ACROINNOVA 1 – CAM2029 superior to placebo for IGF-1 and GH response

Primary and key secondary endpoints met with high statistical significance (ITT)



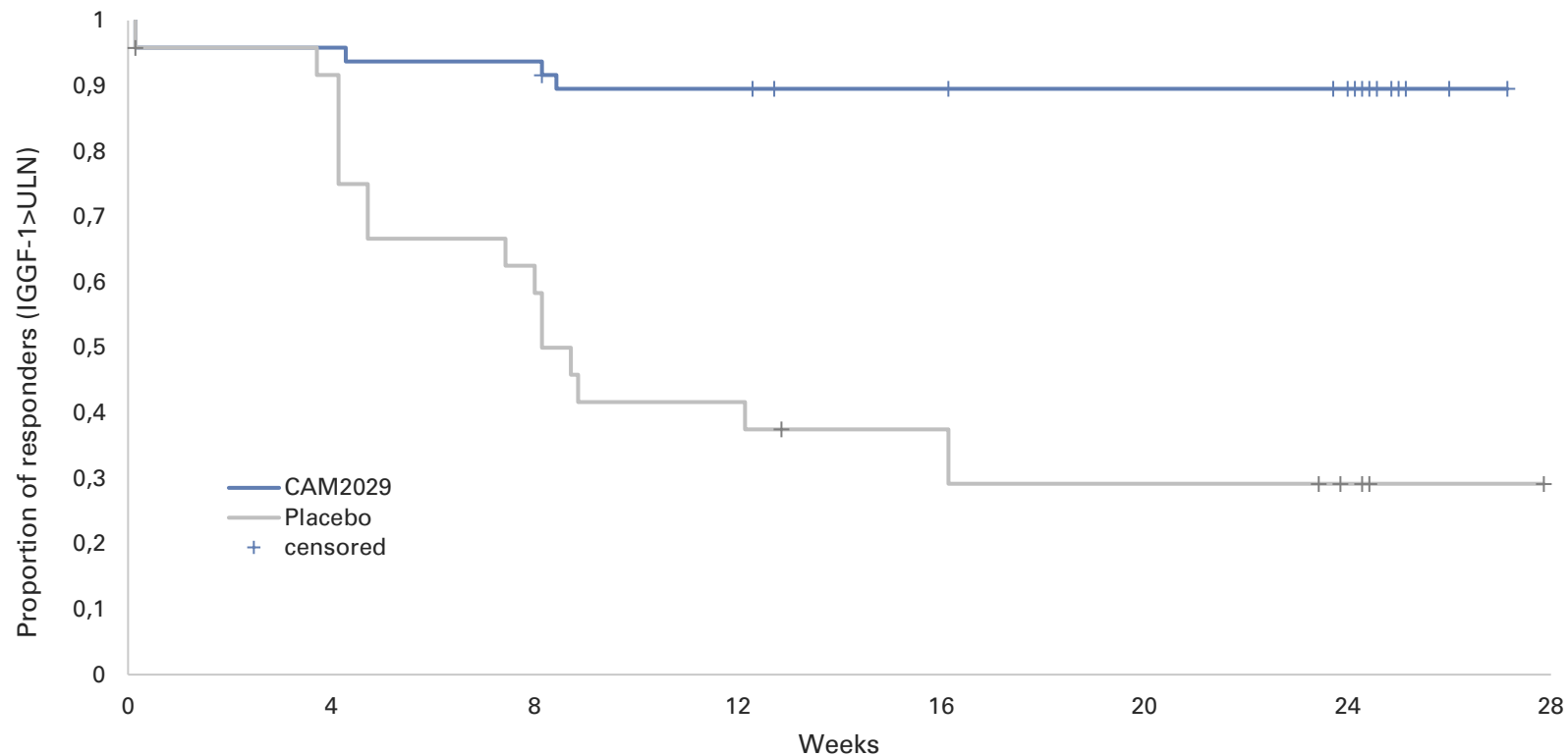
ITT – intention-to-treat analysis set.

Patients with intercurrent events were regarded as non-responders independently of their endpoint result; Mantel-Haenszel-type common difference in proportions across strata, stratified by prior treatment (octreotide LAR or lanreotide autogel). In the closed testing procedure, a comparison was eligible for superiority testing only if all previous comparisons, if any, had established superiority at the one-sided significance level of  $p < 0.025$

# ACROINNOVA 1

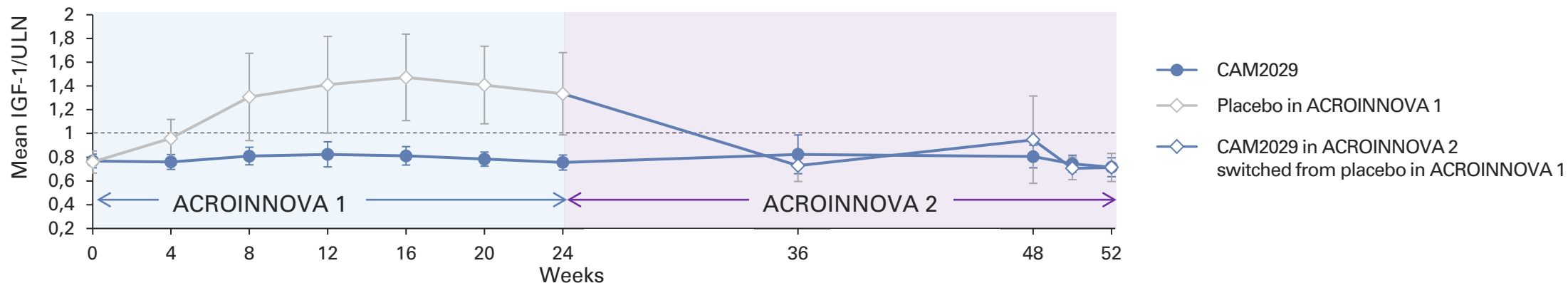
## High statistical difference in time to loss of response

Cox regression analysis (ITT): Hazard ratio=0.1;  $p<0.0001$

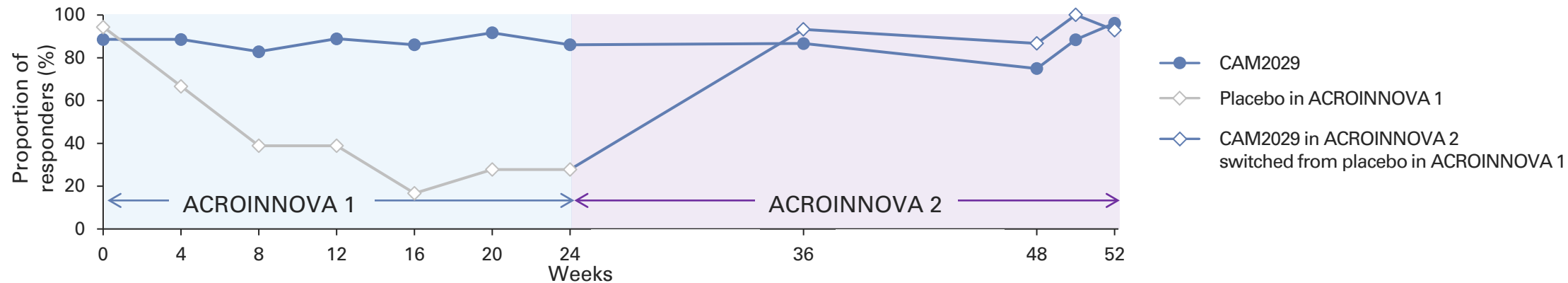


# Patients retained or regained IGF-1 control with CAM2029

## IGF-1 values over time (mean, 95% CI)



## Proportion of responders over time (IGF-1 ≤ ULN)

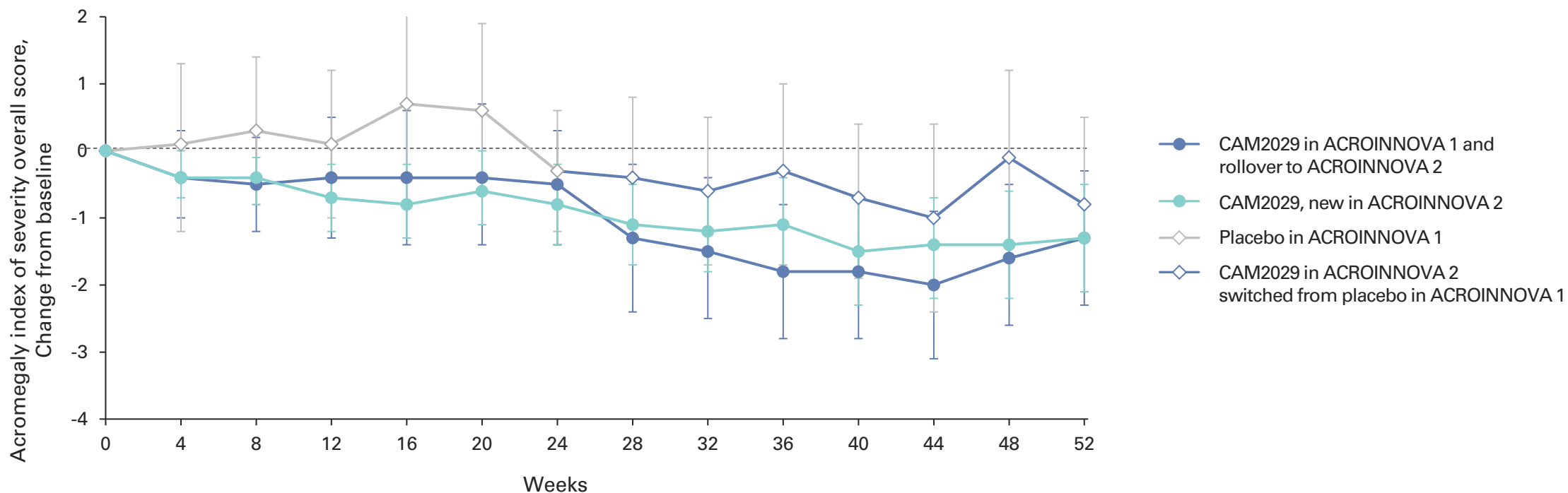


Patients with data at the cut-off timepoint for the interim analysis (N=54). All values are pre-dose and time points are nominal

# ACROINNOVA 2

## Decreasing acromegaly symptoms over time

Change from SoC treatment baseline in Acromegaly Index of Severity Score (6 symptoms)\*



\* The AIS overall score was calculated as the sum of the scores for the six symptoms of headache, sweating, fatigue, joint pain, paresthesia and soft tissue swelling. The AIS overall score ranges from 0 (no symptoms) to 18 (severe symptoms)

# Positive topline results from CAM2029 two Phase 3 trials<sup>1</sup>

## Key results from ACROINNOVA 1

- ✓ Met primary and key secondary endpoints of superior IGF-1 response rate versus placebo
  - Confirmed by sensitivity and supportive analyses

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- ✓ IGF-1 and GH well-controlled over time
  - Measured pre-dose, at trough octreotide conc.

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- ✓ Increased treatment satisfaction scores (TSQM) versus standard of care (SoC) at baseline

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- ✓ Increased quality of life (AcroQoL) scores versus SoC at baseline

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- ✓ Safety profile comparable to first-generation SRLs, octreotide LAR and lanreotide ATG

## Key interim results from ACROINNOVA 2

- ✓ Affirmative safety profile over 52-weeks
  - No new or unexpected safety findings

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- ✓ Improved IGF-1 response vs baseline in uncontrolled patients and treatment naïve patients after washout

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- ✓ Stable IGF-1 response in controlled roll-over patients

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- ✓ Decrease in symptom scores vs SoC at baseline

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- ✓ Increased treatment satisfaction (TSQM) and quality of life scores (AcroQoL, EQ-5D-5L) vs SoC at baseline

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- ✓ Improved injection experience by self-injection assessment questionnaire (SiAQ) scores

# SORENTO head-to-head Phase 3 superiority study: Largest clinical study of an SRL in NET

## Randomized, active-controlled Phase 3 trial

- Randomized, multi-center, open-label, active-controlled Phase 3 trial of CAM2029 vs. long-acting octreotide or lanreotide in patients with GEP-NET
- Single trial fulfilling regulatory requirements for safety and efficacy

## Patient population

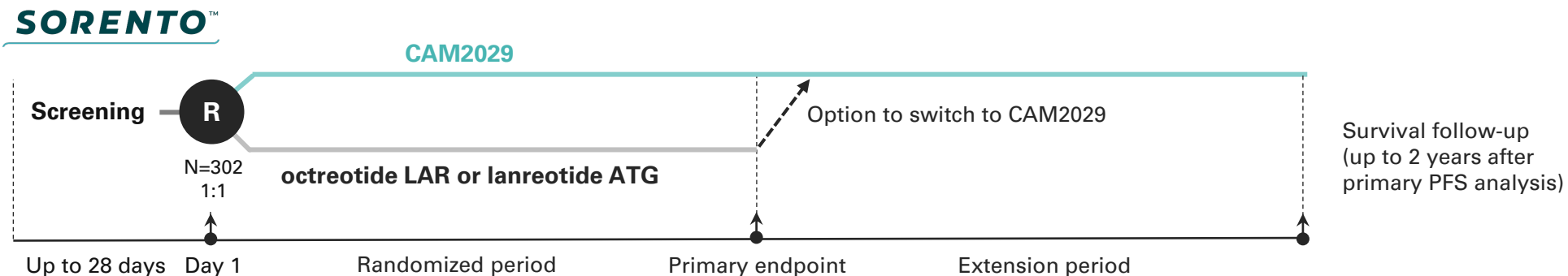
- Patients with confirmed, advanced (unresectable and/or metastatic), and well-differentiated GEP-NET (grade 1 to grade 3)

## Primary endpoint

- Superiority in progression free survival, PFS, vs. standard of care (first-line medical treatment)
- Assessed after 194 progression events

## Secondary endpoints include

- Overall survival
- PROs (e.g., treatment satisfaction, quality of life)
- Plasma concentrations of octreotide
- Safety





# Progress in three clinical programs

## AcroInnova™

Pivotal randomized placebo controlled and long-term safety trials in acromegaly

- ✓ Topline results reported from two Phase 3 trials
- ✓ Positive ACROINNOVA 1 results 20 Jun 2023
- ✓ Positive ACROINNOVA 2 results 17 Jul 2023
- ✓ Pre-NDA meeting
- ✓ **NDA submission acromegaly 21 Dec 2023**
- ☐ **MAA submission H1 2024**

## SORENTO™

Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors

- ✓ SORENTO Phase 3 trial progressing well
- ✓ **Completed enrollment 13 Dec 2023**
- ☐ **Primary endpoint readout after 194 PFS events**
- ☐ Est. NDA/MAA GEP-NET submissions in 2025

## positano™

Polycystic liver Safety and efficacy Trial with subcutaneous Octreotide

- ✓ Orphan drug designation (US)
- ✓ New PROs developed and aligned with FDA
- ✓ Phase 2/3 trial ongoing
- ☐ **Est. completion of enrollment around end of year 2023**
- ☐ Topline results end 2024/early 2025

# Preparing for commercialization of Oclaiz™ (CAM2029)

## Attractive specialty pharma opportunity

- Blockbuster potential in NET
- Highly concentrated target audiences
- Differentiated product features
- Switch from established first-line treatments

## US commercial infrastructure

- Camurus Inc. fully operational with core team in place
- Launch ready Q4 2024






## CAM2029 peak sales estimates from third party market research<sup>1-4</sup>

	TERRITORY	PATIENT POPULATION	EST. PEAK PATIENT SHARE	EST. PEAK SALES
ACRO	EU/AUS	16,500 <sup>4</sup>	20 – 35%	€30 – 65 million
	US	10,000	25 – 40%	\$150 – 280 million
NET <sup>1</sup>	EU/AUS	68,000 <sup>4</sup>	30%	€300 – 400 million
	US	37,000	40%	\$1,200 – 1,500 million
PLD <sup>1</sup>	EU/AUS	15-18,000 <sup>4</sup>	30 – 40%	€80 – 100 million
	US	12-13,000	30 – 40%	\$200 – 300 million

<sup>1</sup>Globe Life Science Aug 2022, data on file; <sup>2</sup>Globe Life Science 2020, data on file; <sup>3</sup>Assuming €10-12.5k (EU/AUS) and \$60-70K (US) per year net pricing in acromegaly, €15-20k (EU/AUS) and \$80-100K (US) per year net pricing in NET, and €17.5k (EU/AUS) and \$60K (US) per year net pricing in PLD; <sup>4</sup>Patient numbers extrapolated from 5EU estimates by assuming same prevalence across European countries and Australia



# Key takeaways

-  On track to deliver record full year revenues and result in 2023
-  High Buvidal growth in Europe and Australia
-  Accelerated Brixadi uptake following US launch in September 2023
-  NDA submission of Oclaiz™ (CAM2029) in acromegaly in December 2023
-  Commercial infrastructure being established in the US

# Q&A

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# Strategy for growth and innovation

- 1. Grow Buvidal and expand to new markets
- 2. Advance the R&D pipeline to new approvals
- 3. Diversify through business development and partnerships
- 4. Strengthen our organization and sustainability agenda

**Camurus' vision 2027**

Sustainable value  
to all stakeholders through:

5x

Five-fold  
revenue growth



Establish-  
ment of US  
commercial  
infrastructure

4

Approvals  
for four R&D  
pipeline  
programs

~50%

Operating margin  
around 50 percent

# Reported Q3 profit and loss

MSEK	Jul – Sep 2023	Change vs. 2022	CER Change vs. 2022	YTD Jan – Sep 2023	Change YTD vs. 2022	CER Change YTD vs. 2022
Total revenues	384	+59%	+49%	1 342	+95%	+86%
<i>out of which CAM2038 milestones</i>	36			406		
Gross margin	352	+162bps	+165bps	1 253	+425bps	+473bps
<i>% GM Product Sales</i>	<i>90,8%</i>	<i>+75bps</i>	<i>+79bps</i>	<i>90,4%</i>	<i>+135bps</i>	<i>+97bps</i>
Marketing and distribution costs	-94	+41%	+34%	-264	+35%	+29%
Administrative expenses	-10	0%	-6%	-32	+22%	+17%
Research and development costs	-148	+39%	+32%	-408	+20%	+15%
Other operating expenses	5	–	–	5	–	–
Operating result	104	+63 MSEK	+46 MSEK	554	+501 MSEK	+453 MSEK

# Key milestones in 2023/2024

## Advancing the pipeline

- ✓ Positive ACROINNOVA 1 & 2 Phase 3 topline and interim results in acromegaly
- ✓ NDA submission of Oclaiz™ (CAM2029) in acromegaly
- ✓ Completed recruitment in SORENTO study in GEP-NET
- ❑ Completed recruitment in POSITANO study in PLD
- ❑ FDA acceptance for review of Oclaiz™ NDA
- ❑ MAA submission of CAM2029 in acromegaly to EMA
- ❑ FDA approval Oclaiz™ in acromegaly

## Commercial and corporate development

- ✓ US approval and launch of Brixadi in opioid use disorder
- ❑ Launch-ready US commercial infrastructure
- ❑ Business development and inorganic growth



# Shareholders and analyst coverage

Shareholders as of 30 November 2023	Number of shares	% of capital	% of votes
Sandberg Development AB	21,875,692	39.4	39.4
Fjärde AP-fonden	2,780,000	5.0	5.0
Avanza Pension	1,774,758	3.2	3.2
Fredrik Tiberg, CEO	1,600,000	2.9	2.9
Swedbank Robur Fonder	1,320,000	2.4	2.4
State Street Bank and Trust	1,248,353	2.2	2.2
JP Morgan Chase Bank	1,186,820	2.1	2.1
Handelsbankens fonder	1,159,300	2.1	2.1
The Bank of New York Mellon SA/NV	903,642	1.6	1.6
Afa Försäkring	794,993	1.4	1.4
The Bank of New York Mellon	625,783	1.1	1.1
Svenskt Näringsliv	610,000	1.1	1.1
Öhman Fonder	521,070	0.9	0.9
SEB AB, Luxembourg Branch	509,040	0.9	0.9
Camurus Lipid Research Foundation	486,350	0.9	0.9
Other shareholders	18,143,017	32.8	32.8
<b>In total</b>	<b>55,538,818</b>	<b>100.0</b>	<b>100.0</b>

## Analysts

### Carnegie

Erik Hultgård

### DNB

Patrik Ling

### Handelsbanken

Suzanna Queeckbörner

Mattias Häggblom

### Jefferies

James Vane-Tempest

### Nordea

Viktor Sundberg

### Pareto

Dan Akschuti

### Bryan Garnier

Alex Cogut



# Experienced and committed management team



**Fredrik Tiberg, PhD**  
*President & CEO, CSO*  
**In Company since 2002**  
**Holdings: 1,615,000 shares, 15,000 subscription warrants & 102,000 employee options**

**Education:** M.Sc. in Chem. Eng., Lund Institute of Technology, Ph.D. and Assoc. Prof. Physical Chemistry, Lund University.  
**Previous experience:** More than 20 years executive leadership experience from the pharmaceutical industry. Professor Physical Chemistry, Lund University; Visiting Professor at Oxford University; Section Head, Institute for Surface Chemistry.



**Jon Garay Alonso**  
*Chief Financial Officer*  
**In Company since: 2022**  
**Holdings: 1,450 shares & 57,750 employee options**

**Education:** Bachelor in Business Administration by Universidad Comercial de Deusto. Executive MBA by IESE Business School.  
**Previous experience:** More than 20 years experience from Finance within pharmaceutical and medtech companies, incl. Baxter, Gambro, Convatec, Bristol Myers Squibb.



**Maria Lundqvist**  
*Head of Global HR*  
**In Company since 2021**  
**Holdings: 1,000 shares and 38,500 employee options**

**Education:** B.Sc. in Business and Economics, Uppsala University  
**Previous experience:** More than 20 years of experience of leadership roles within Human Resources, including HR Director Nordics at Teva Pharmaceuticals and HR positions at Tetra Pak, Vestas and AstraZeneca.



**Richard Jameson**  
*Chief Commercial Officer*  
**In Company since: 2016**  
**Holdings: 37,193 shares and 57,750 employee options**

**Education:** B.Sc. in Applied Biological Sciences from University West of England  
**Previous experience:** General Manager, UK & Nordics for Reckitt Benckiser (2010 – 2013) and Area Director Europe, Middle East and Africa for Indivior (2013 – 2016).



**Fredrik Jobsson, PhD**  
*Chief Business Dev. Officer*  
**In Company since 2001**  
**Holdings: 50,170 shares & 38,500 employee options**

**Education:** M.Sc. in Chemistry, PhD in Physical Chemistry, Lund University  
**Previous experience:** More than 20 years of experience in pharmaceutical R&D, business development and alliance management.



**Markus Johansson**  
*Senior VP R&D*  
**In Company since: 2003-2017, 2019-**  
**Holdings: 21,000 shares & 23,500 employee options**

**Education:** Ph.D. in physical chemistry and M.Sc. in chemistry from Uppsala University.  
**Previous experience:** More than 20 years of experience from pharmaceutical development and project management



**Torsten Malmström, PhD**  
*Chief Technical Officer*  
**In Company since 2013**  
**Holdings: 46,858 shares & 38,500 employee options**

**Education:** M.Sc. in Chemistry, PhD in Inorganic Chemistry, Lund University  
**Previous experience:** More than 20 years of experience from pharmaceutical R&D including Director Pharmaceutical Development at Zealand Pharma, Director of Development at Polypeptide, Team Manager at AstraZeneca.



**Annette Mattsson**  
*VP Regulatory Affairs*  
**In Company since: 2017**  
**Holdings: 2,204 shares, 1,000 subscription warrants & 38,500 employee options**

**Education:** Bachelor of Pharmacy, Uppsala University and Business Economics, Lund University  
**Previous experience:** More than 25 years of experience within regulatory affairs, including European RA Director/Global RA Lead at AstraZeneca and Global RA Lead at LEO Pharma.



**Alberto M. Pedroncelli**  
*Chief Medical Officer*  
**In Company since 2023**  
**Holdings: 1,000 shares & 20,000 employee options**

**Education:** MD University of Milan. Ph. D. endocrinology post-graduate school University of London  
**Previous experience:** Head of Clinical Development and Medical Affairs Recordati, Senior Leadership positions Novartis, clinician and research fellow Dept. Endocrinology, University Hospital Bergamo, Italy



**Agneta Svedberg**  
*VP Clinical & Regulatory Dev.*  
**In Company since: 2015**  
**Holdings: 22,987 shares & 38,500 employee options**

**Education:** M.Sc. In Radiophysics and B.Sc. In Medicine from Lund University, Executive MBA from Executive Foundation Lund  
**Previous experience:** More than 25 years of experience in drug development, incl. as COO at Zealand Pharma, CEO of Cantargia, Senior VP Clinical Development at Genmab.

# ACROINNOVA 1

## Phase 3 RCT efficacy and safety trial

### ACROINNOVA 1 trial design

- 24-week, randomized, double blind, placebo-controlled trial

### Key eligibility criteria:

- Patients with acromegaly on treatment with a stable dose of octreotide LAR or lanreotide ATG for at least 3 months with
- IGF-1 levels  $\leq 1 \times \text{ULN}$  at screening

### Primary endpoint:

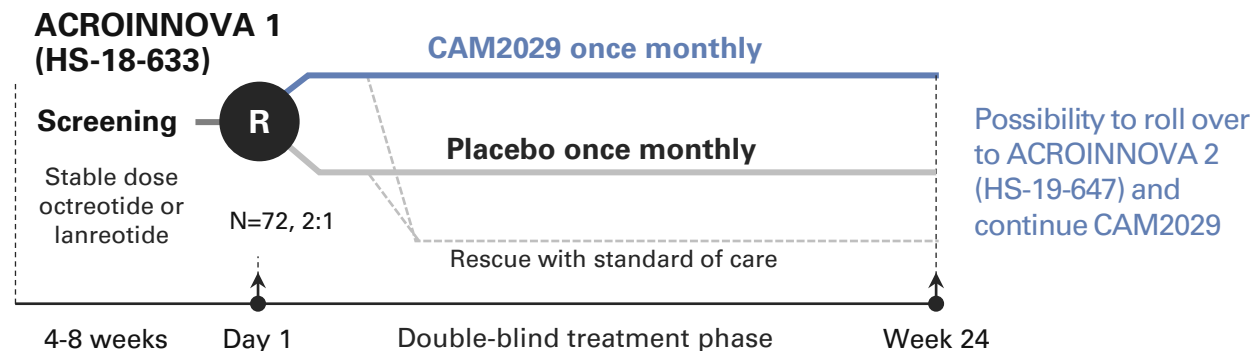
- Proportion of patients with mean IGF-1  $\leq 1 \times \text{ULN}$  (week 22 and 24)

### Key secondary endpoints:

- Proportion of patients with mean IGF-1 levels  $\leq 1 \times \text{ULN}$ , incl. patients with decreased dose
- Proportion of patients with mean IGF-1 levels  $\leq 1 \times \text{ULN}$  and GH cycle levels  $< 2.5 \mu\text{g/L}$

### Secondary endpoints, e.g.:

- Time to loss of IGF-1 response
- IGF-1 and GH over time and change from baseline
- Clinical signs and symptoms (AIS score)
- Patient satisfaction and treatment satisfaction (PSS and TSQM)
- Acromegaly quality of life (AcroQoL)
- Self-injection assessments (SiAQ)
- Plasma concentrations of octreotide
- Safety and tolerability



### Statistical assumption primary endpoint:

- 90% power to show treatment difference with 80% response for CAM2029 vs 40% response for placebo, based on Chi-squared test (with continuity correction)

# ACROINNOVA 2

## Phase 3 long-term safety and extension trial

### ACROINNOVA 2 trial design

- 52-week, open-label, long-term safety and extension trial

### Patient population

- New patients in trial; IGF-1 < 2xULN (n=81)
- Roll-over CAM2029 patients; IGF-1 ≤ 1xULN (n=36)
- Roll-over placebo patients; IGF-1 ≤ 1xULN (n=18)  
from ACROINNOVA 1

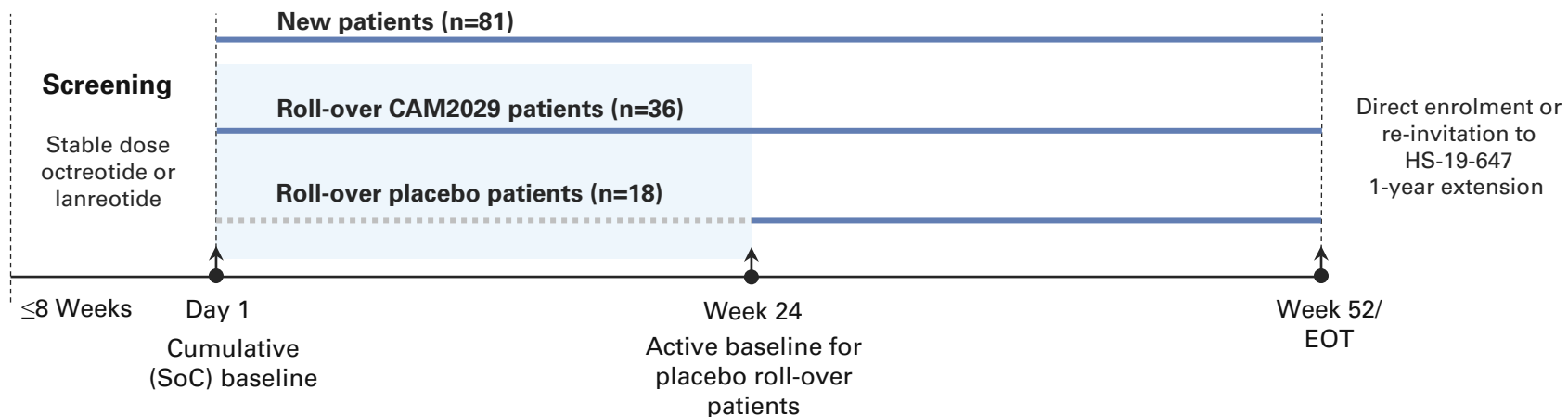
### Primary endpoint:

- Long-term safety and tolerability

### Secondary endpoints:

- Biochemical response (IGF-1, GH)
- Mean IGF-1 and GH over time
- Clinical signs and symptoms (AIS)
- Patient and treatment satisfaction (TSQM)
- Quality of life (AcroQoL, EQ-5D-5L)
- Self-Injection Assessment Questionnaire (SiAQ)
- Octreotide concentrations

### ACROINNOVA 2 (HS-19-647)



# SORENTO: Largest Phase 3 trial of SSA in NET

## Randomized, active-controlled Phase 3 trial

- Randomized, multi-center, open-label, active-controlled Phase 3 trial of CAM2029 vs. long-acting octreotide or lanreotide in patients with GEP-NET
- Single trial fulfilling regulatory requirements for safety and efficacy

## Patient population

- Patients with confirmed, advanced (unresectable and/or metastatic), and well-differentiated GEP-NET (grade 1 to grade 3)

## Primary endpoint

- Superiority in progression free survival, PFS, vs. standard of care (first-line medical treatment)
- Assessed after 194 progression events

## Secondary endpoints include

- Overall survival
- PROs (e.g., treatment satisfaction, quality of life)
- Plasma concentrations of octreotide
- Safety

