

A woman with long, wavy brown hair is shown in profile, looking out over a body of water. She is wearing a dark, textured top. The background is a soft-focus view of a lake or sea with a distant shoreline. The entire image has a light blue-green tint.

camurus®

# Company presentation

August 2023

# 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: ~200

# Significant recent progress



## Strong financial performance

- ✓ High double-digit year-on-year revenue growth
- ✓ Profitable since 2022
- ✓ Robust cash position  
SEK 654 million end Q2 2023  
– no debt



## Commercialization execution

- ✓ Leader in long-acting opioid dependence treatment in Europe and Australia
- ✓ Strong sales growth supported by an expanding evidence base
- ✓ Further potential through geographic and label expansion



## Pipeline advancement

- ✓ Brixadi™ approved for treatment of opioid use disorder in the US
- ✓ Positive topline results from two Phase 3 trials of CAM2029 in acromegaly
- ✓ Four Phase 3 studies in rare disease indications



# Opioid dependence – escalating global health crisis

## Largest society burden of all drugs<sup>1</sup>

- 61 million opioid users worldwide<sup>1</sup>
- Opioid crisis worsened during COVID-19 pandemic

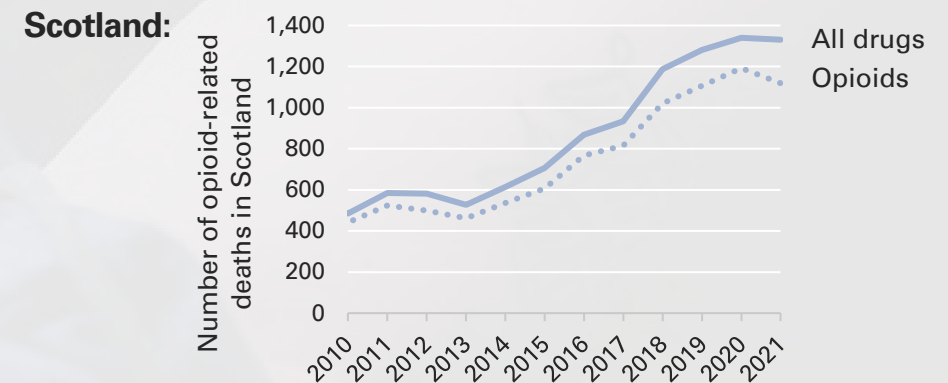
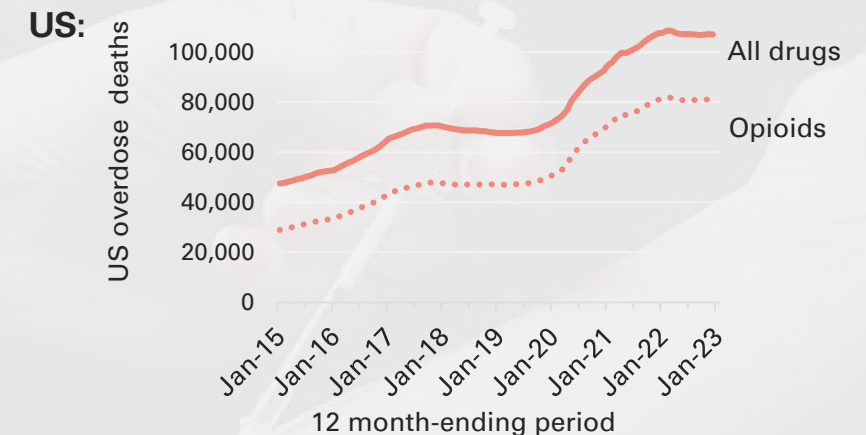
## High need for better access to care and new treatment alternatives

- Long-acting injections a new paradigm in opioid dependence treatment

## Significant limitation with current daily medications

- Diversion, misuse, risk of overdose, poor retention, burdens and stigma of daily medications

## Escalating opioid overdose deaths



<sup>1</sup>United Nations: World drug report 2022<sup>2</sup>SAMSHA;<sup>3</sup>EMCDDA;<sup>4</sup>[www.cdc.gov/hchs/nvss/vsrr/drug-overdose-data.htm](https://www.cdc.gov/hchs/nvss/vsrr/drug-overdose-data.htm)

<sup>5</sup><https://www.nrscotland.gov.uk/statistics-and-data/statistics/statistics-by-theme/vital-events/deaths/drug-related-deaths-in-scotland/2020>

# Buvidal / Brixadi – 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>*

**“It is absolutely amazing.  
Almost everything  
is as before.”**

Martin, Buvidal patient, Sweden

## Demonstrated significant 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>

<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

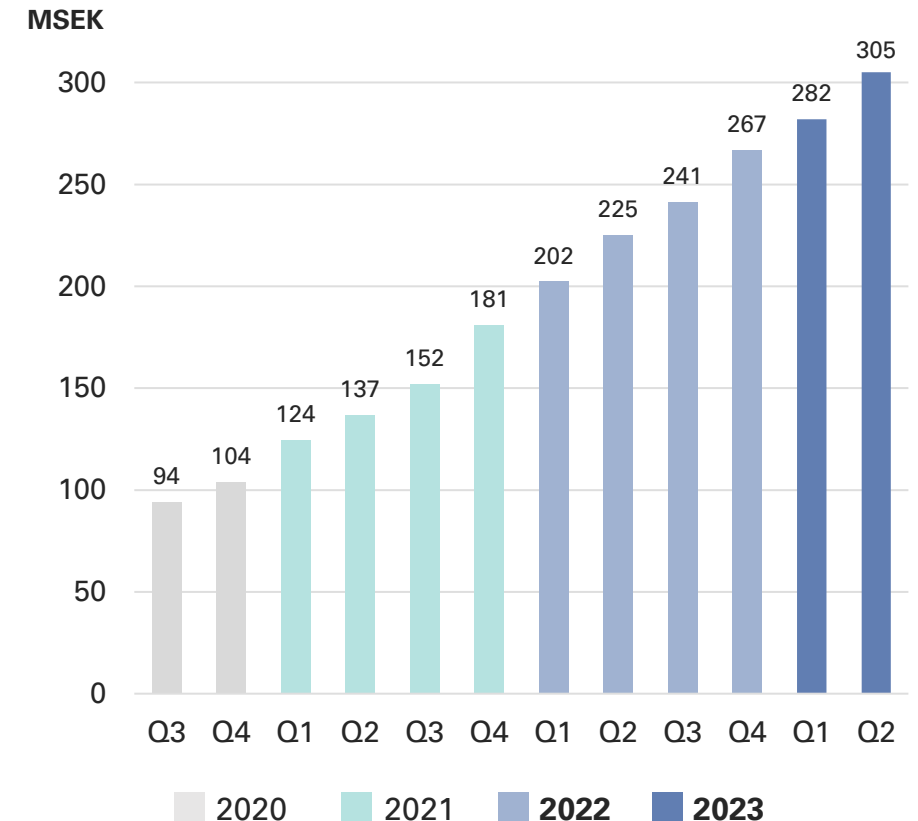
## Sales growth across all markets

- Continued high market penetration with Buvidal
- Est. 42,000 patients in treatment with Buvidal end Q2

## Regulatory and market expansion processes

- New price and reimbursement approval in Austria
- Four regulatory applications for Buvidal and four PMA submissions under review
- Strong development in criminal justice systems
  - National guidelines in Sweden and Belgium recommending Buvidal as first line treatment in criminal justice system

## Quarterly product sales



Weekly / Monthly

# Brixadi approved in the US!

23 May 2023:

*“Today’s approval expands dosing options and provides people with opioid use disorder a greater opportunity to sustain long-term recovery”*

*FDA Commissioner Robert M. Califf, M.D.*



# Brixadi and Buvidal – well differentiated

## 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>

	<small>ONCE-MONTHLY</small> <b>Sublocade™</b>	<b>Vivitrol®</b>	<b>Brixadi</b> 
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	EU, UK, AUS

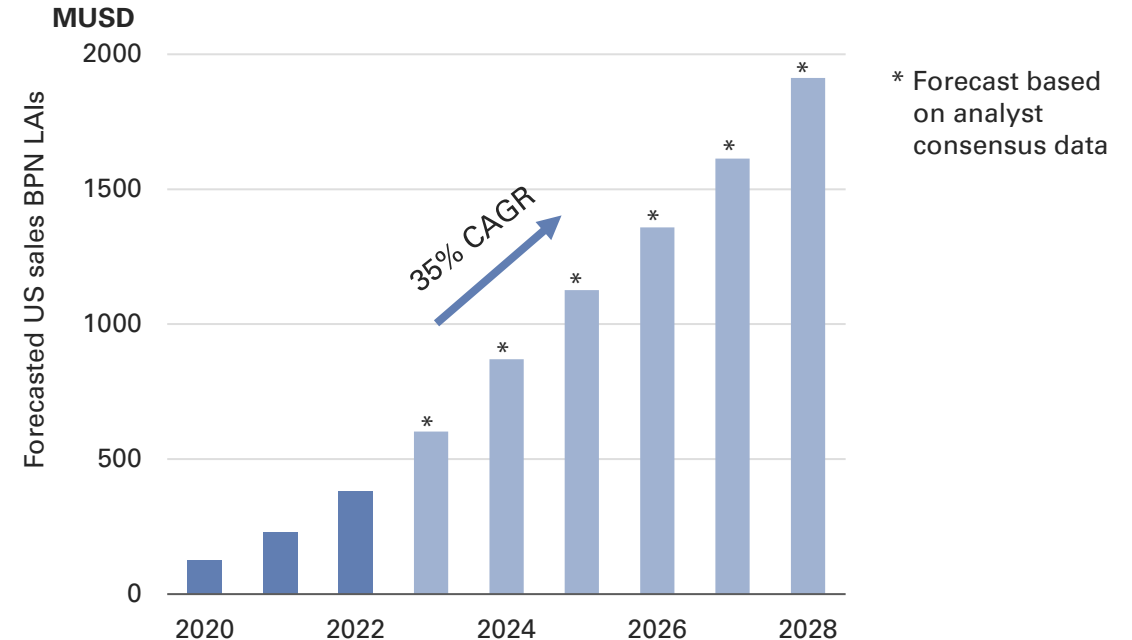
LAI – long acting injectable

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

# Imminent launch of Brixadi in the US

- US launch of Brixadi in September 2023
- Camurus' licensee Braeburn responsible for commercialization in North America
- Commercial organization and sales force in place
- Positive market dynamics – new funding and legislation, and improved access
- Brixadi market peak potential estimated > \$1 billion peak sales<sup>1</sup>

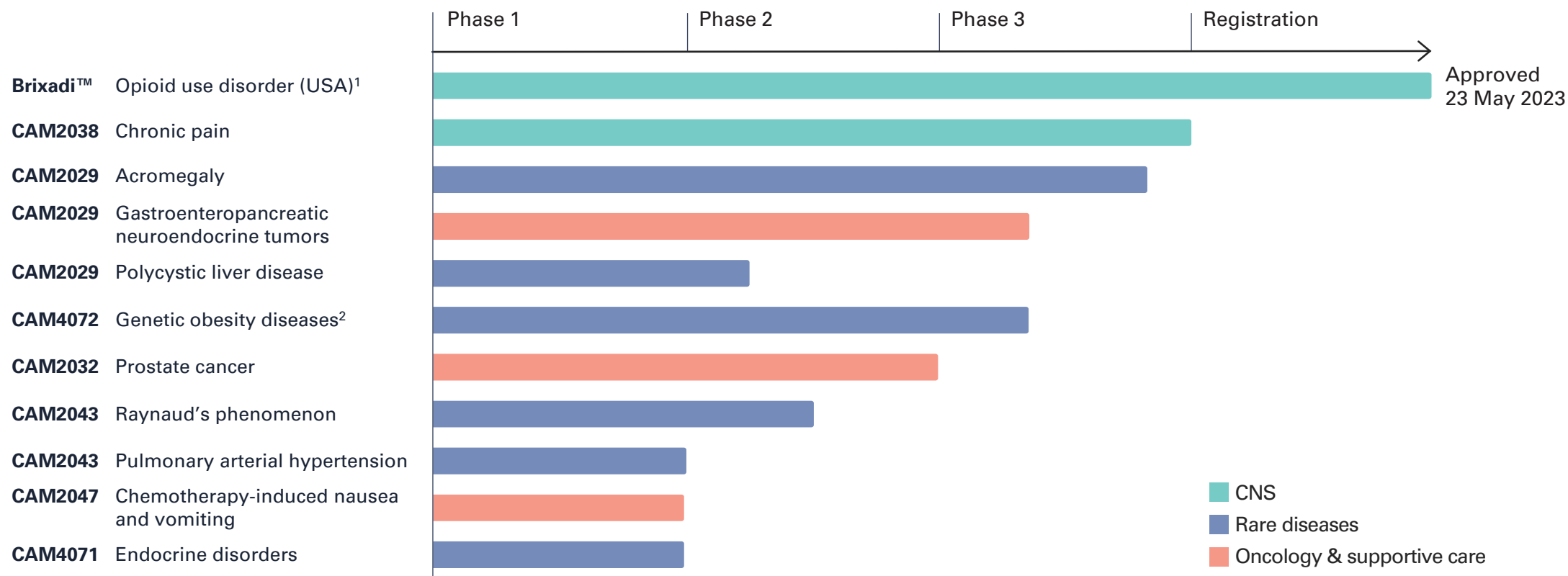
## Positive outlook on BPN LAI market growth<sup>2</sup>



LAI – long-acting injectable; BPN – buprenorphine

<sup>1</sup>Company estimate; <sup>2</sup>GlobalData 2023, sales data and analyst consensus including expected Sublocade® and Brixadi™ sales

# Broad and diversified mid- to late-stage pipeline



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



# Octreotide SC depot

CAM2029 under development in 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

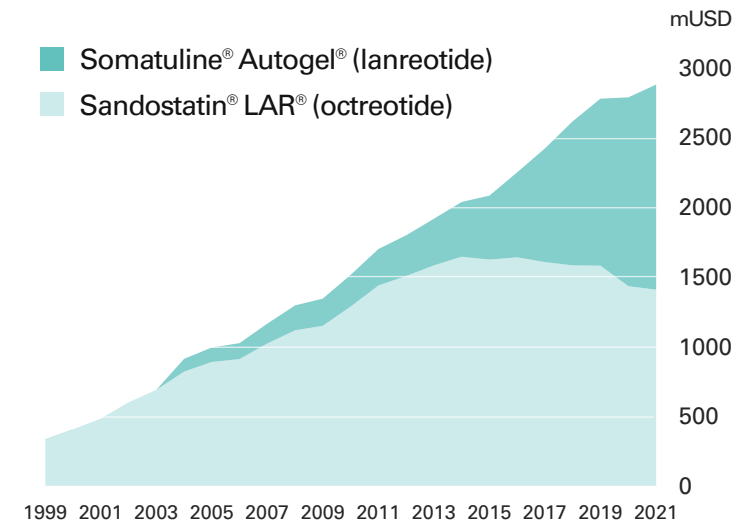
## CAM2029 best-in-class treatment potential

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



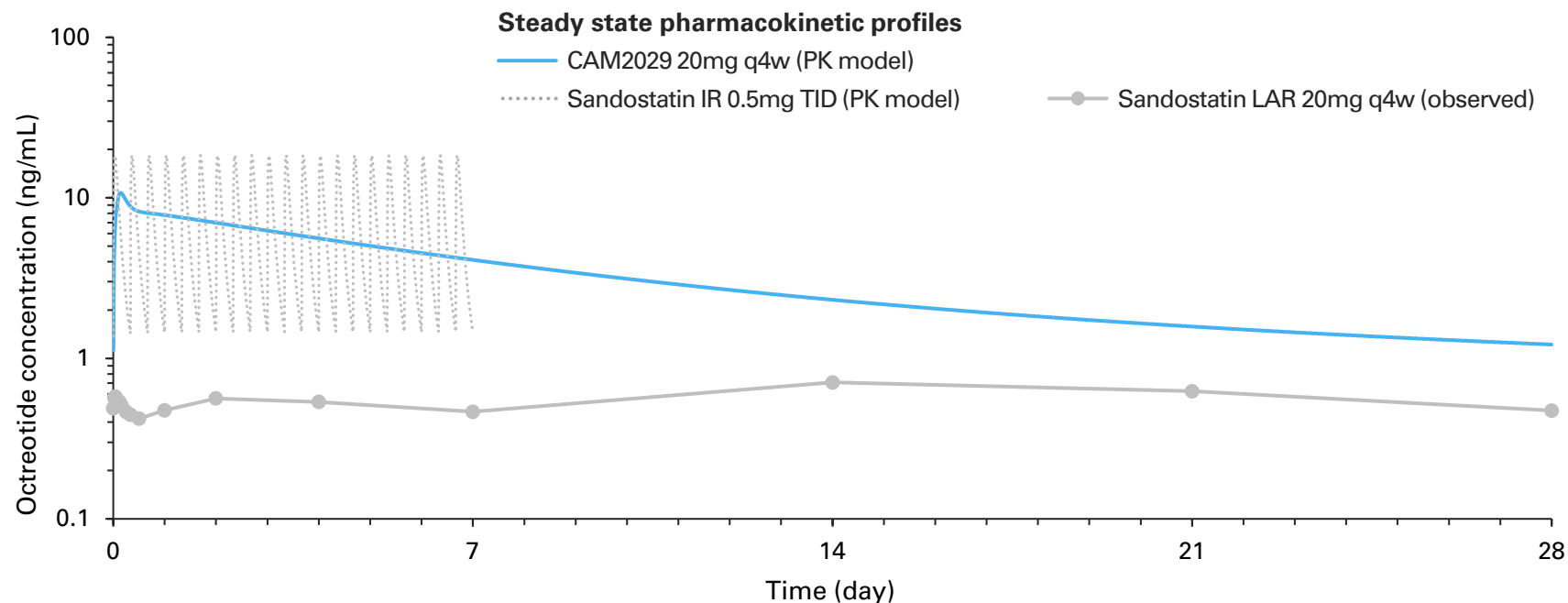
- 5-fold increase of octreotide plasma exposure (dose adjusted)
- Potential for improved disease control and treatment outcomes

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

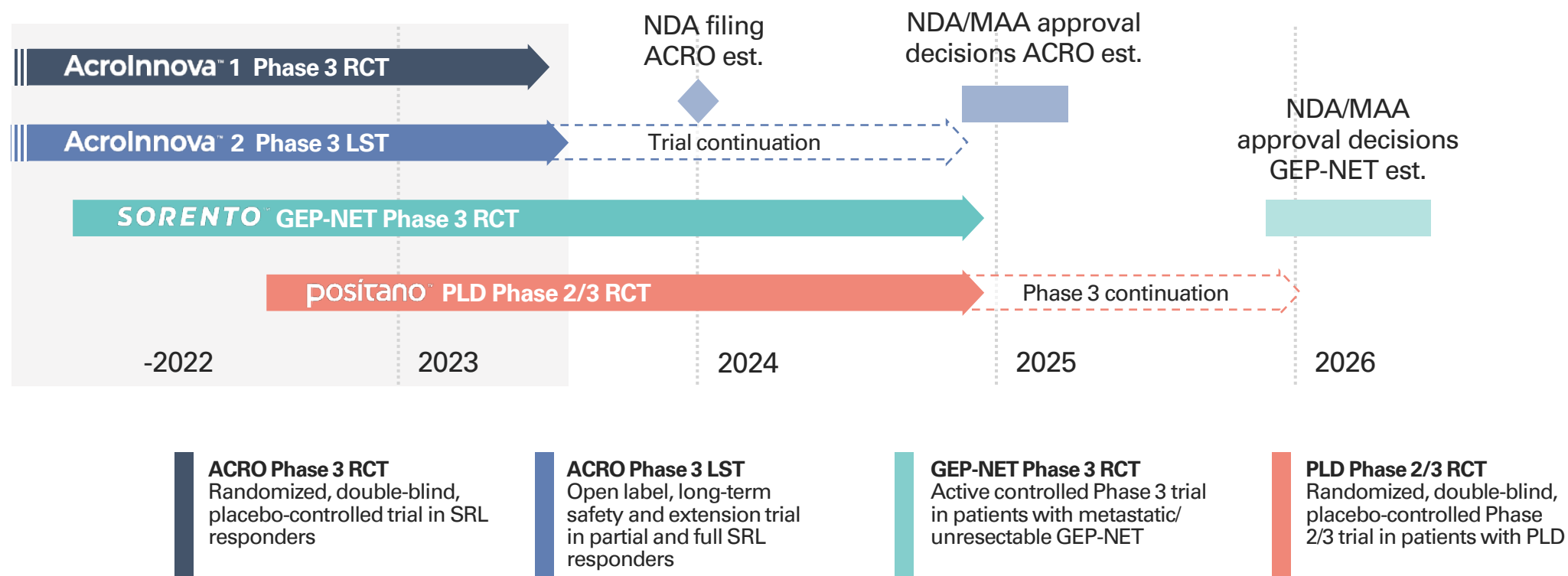


# CAM2029 provides high SSA exposure

- ~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



*Timelines are indicative. RCT – randomized control trial; LST – long-term safety trial; ACRO – acromegaly, GEP-NET – gastroenteropancreatic neuroendocrine tumors; PLD – polycystic liver disease*

# Positive topline Phase 3 results from ACROINNOVA 1<sup>1</sup>

- ✓ Met both primary and key secondary endpoints of superiority versus placebo
- ✓ Confirmed by all sensitivity and supportive analyses
- ✓ IGF-1, GH and symptoms were well controlled over time with CAM2029
- ✓ Improved patient and treatment satisfaction (PSS, TSQM) versus standard of care at baseline
- ✓ Improved quality of life (Acro QoL) versus standard of care at baseline
- ✓ Well tolerated safety profile

1. ACROINNOVA 1 topline Phase 3 results: <https://www.camurus.com/files/Presentations/Camurus-ACROINNOVA-1-Phase-3-results.pdf>

IGF-1 – Insulin-like growth factor 1; PSS – Patient Satisfaction Score; TSQM – Treatment Satisfaction Questionnaire for Medication; AcroQoL – Acromegaly Quality of Life Questionnaire; SoC – standard of care



# Positive interim results from ACROINNOVA 2 Phase 3 long-term safety study<sup>1</sup>

- ✓ Reinforced favorable safety profile over 52-weeks
- ✓ Improved IGF-1 response in the full, partially controlled and treatment naïve populations
- ✓ Stable response in controlled patients
- ✓ Improved symptoms versus standard of care at baseline
- ✓ Improved treatment satisfaction (PSS, TSQM) versus standard of care at baseline
- ✓ Improved quality of life (AcroQoL, EQ-5D-5L VAS) vs standard of care at baseline

1. ACROINNOVA 2 interim results: <https://www.camurus.com/files/Presentations/Camurus-Q2-2023-presentation.pdf>  
IGF-1 – Insulin-like growth factor 1; PSS – Patient Satisfaction Score; TSQM – Treatment Satisfaction Questionnaire for Medication; AcroQoL – Acromegaly Quality of Life Questionnaire; EQ-5D-5L VAS – a standardized measure of health-related quality of life

# CAM2029 development status update

## AcroInnova™

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

- ✓ Two Phase 3 trials ongoing, ACROINNOVA 1 and 2
- ✓ **Positive ACROINNOVA 1 results 20 June 2023**
- ✓ **Positive ACROINNOVA 2 results 17 July 2023**
- ❑ Pre-NDA meeting planned for Q3 2023
- ❑ Regulatory submission in the US and EU targeted for end 2023 and early 2024

## SORENTO™

Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine Tumors

- ✓ SORENTO Phase 3 trial ongoing
- ✓ **200 of 302 patients enrolled**
- ❑ **Estimated enrollment completion H2 2023**
- ❑ Primary efficacy readout after 194 PFS events
- ❑ Estimated NDA/MAA submissions 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
- ✓ **30 of 69 patients enrolled**
- ❑ **Estimated enrollment completion H2 2023**
- ❑ Topline results 2024

# Preparing own commercialization of CAM2029

## Regulatory

- ✓ Request for Pre-NDA meeting submitted
- ❑ NDA submission targeted around year end 2023

## Commercial

- ✓ Pre-launch preparations initiated – medical team expanded
- ✓ Camurus Inc. operational since Q2 2023
- ❑ Launch ready mid-2024

## Manufacturing

- ✓ Process validation completed
- ❑ Stability studies for submissions ongoing
- ❑ Human factor validation studies ongoing

## Medical affairs – activities Q2 2023

- ACROINNOVA 1 study design presented at the ENDO meeting 15-19 June in Chicago
- SORENTA investigator meeting held in connection to the NANETS meeting 26-27 May in Toronto

## CAM2029 peak sales estimates > \$2 billion<sup>1</sup>

	EST. PEAK SALES EU/AUS	EST. PEAK SALES US
ACRO <sup>1</sup>	€30 – 65 million	\$150 – 280 million
NET <sup>1</sup>	€300 – 400 million	\$1,200 – 1,500 million
PLD <sup>1</sup>	€80 – 100 million	\$200 – 300 million

<sup>1</sup>Globe Life Science 2022, data on file. Patient numbers extrapolated from 4EU+UK estimates by assuming same prevalence across European countries and Australia

# Key takeaways

-  Strong revenue growth and profitability in H1 2023
-  Imminent launch of Brixadi in opioid use disorder in the US
-  Continued growth of Buvidal in Europe and Australia
-  Positive Phase 3 results for CAM2029 in acromegaly
-  Camurus Inc. operational in the US



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# Key milestones in 2023

## Advancing the pipeline

- ✓ Topline Phase 3 efficacy results in acromegaly
- ✓ First readout Phase 3 long-term safety study
- ❑ Pre-NDA meeting for CAM2029 in acromegaly
- ❑ Completed recruitment in SORENTA study in GEP-NET
- ❑ Completed recruitment in POSITANO study in PLD
- ❑ Topline Phase 3 PK results for weekly setmelanotide by Rhythm
- ❑ Start Phase 3 “de novo” study of weekly setmelanotide by Rhythm

## Commercial and corporate development

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



# Experienced and committed management team



**Fredrik Tiberg, PhD**  
*President & CEO, CSO*  
**In Company since:** 2002  
**Holdings:** 1,680,000 shares,  
15,000 subscription warrants  
& 102,000 employee options

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



**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 subscription  
warrants 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:** 29,193 shares, 8,000  
subscription warrants 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 Joabsson, 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 Johnsson**  
*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:** 2004 shares &  
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:** -

**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.

# Shareholders and analyst coverage

Shareholders as of 31 July 2023	Number of shares	% of capital	% of votes
Sandberg Development AB	21,875,692	39.5	39.5
Fjärde AP-fonden	3,116,100	5.6	5.6
Avanza Pension	2,299,387	4.2	4.2
Fredrik Tiberg, CEO	1,600,000	2.9	2.9
State Street Bank and Trust	1,369,151	2.5	2.5
JP Morgan Chase Bank	994,595	1.8	1.8
Handelsbankens fonder	856,136	1.5	1.5
Afa Försäkring	814,583	1.5	1.5
Svenskt Näringsliv	650,000	1.2	1.2
Lancelot Avalon Master	625,000	1.1	1.1
Öhman Fonder	593,555	1.1	1.1
The Bank of New York Mellon SA/NV	541,762	1.0	1.0
Backahill Utveckling	487,359	0.9	0.9
Camurus Lipid Research Foundation	486,350	0.9	0.9
Swedbank Robur Fonder	464,401	0.8	0.8
Other shareholders	19,148,823	34.3	34.3
<b>In total</b>	<b>55,458,493</b>	<b>100.0</b>	<b>100.0</b>

## Analysts

### Carnegie

Erik Hultgård

### DNB

Patrik Ling

### Handelsbanken

Suzanna Queckbörner

Mattias Häggblom

### Jefferies

James Vane-Tempest

### Nordea

Viktor Sundberg

### Pareto

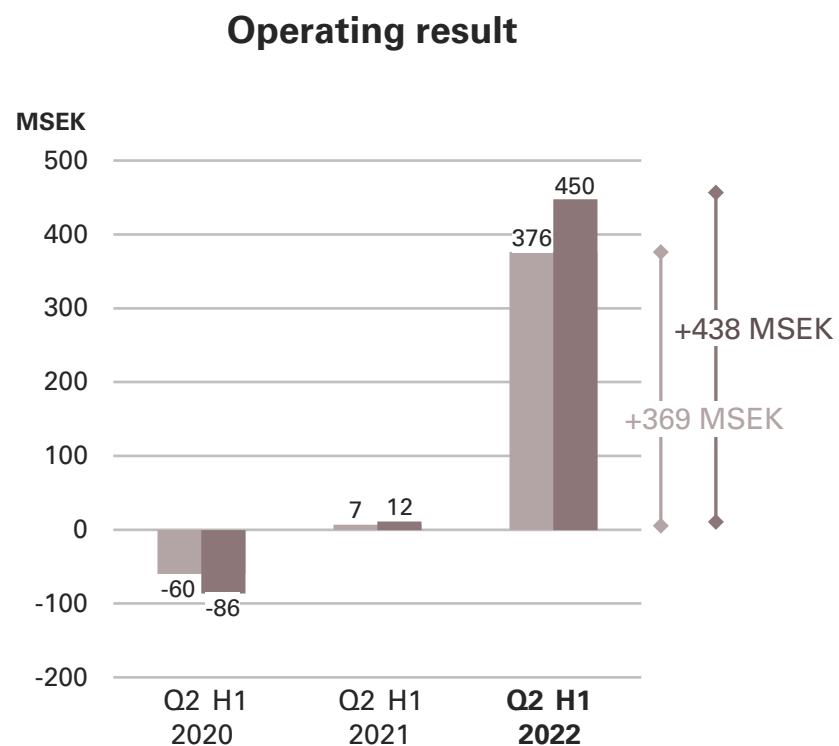
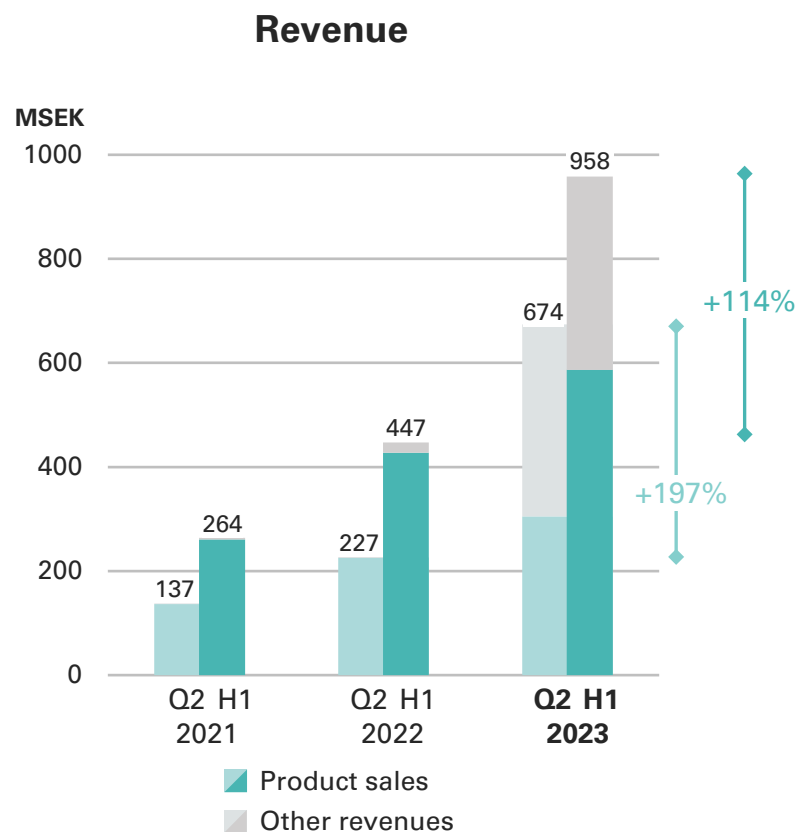
Peter Östling

### Bryan Garnier

Alex Cogut



# Strong revenue growth and result Q2 2023



Cash position  
**SEK 654 million**  
**+53% vs Q2 2022**

Q2

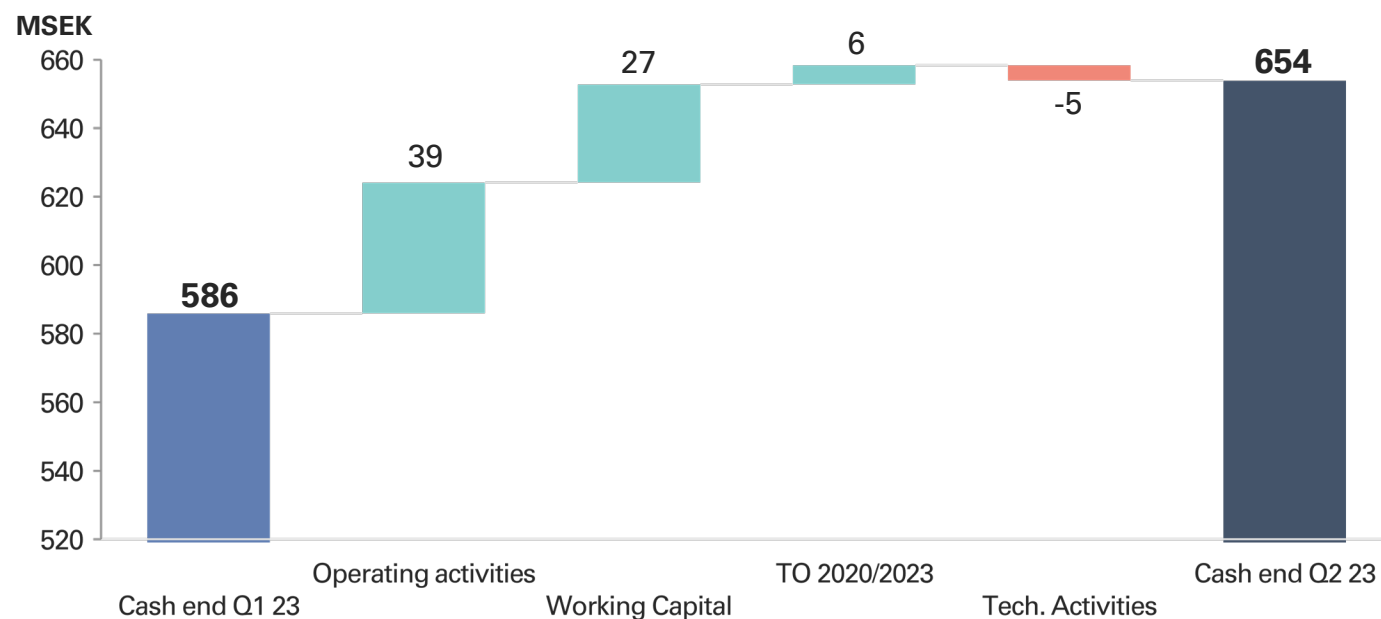
# Reported Q2 2023 profit and loss

MSEK	Apr – Jun 2023	Change vs. 2022	CER Change vs. 2022	YTD Jan – Jun 2023	Change YTD vs. 2022	CER Change YTD vs. 2022
Total revenues	674	+197%	+185%	958	+114%	+105%
<i>out of which Brixadi milestone</i>	<i>369</i>			<i>369</i>		
Gross margin	645	+676bps	+689bps	901	+544bps	+536bps
<i>% GM excluding Brixadi milestone</i>	<i>90,5%</i>	<i>+157bps</i>	<i>+147bps</i>	<i>90,2%</i>	<i>+167bps</i>	<i>+144bps</i>
Marketing and distribution costs	-94	+32%	+26%	-170	+32%	+26%
Administrative expenses	-12	+38%	+31%	-21	+38%	+32%
Research and development costs	-161	+39%	+32%	-260	+12%	+7%
Other operating expenses	-3	–	–	1	–	–
Operating result	376	+369	+354	450	+439	+407

YTD – year-to-date

# Strong cash generation – no debt

## Continued generation of positive cash flow



### FY 2023 guidance maintained

Total revenue and profit before taxes expected in the mid to high end of the interval:

#### Revenue

SEK 1,530 – 1,650 million  
+ 60 – 73% vs. 2022

#### Profit before taxes

SEK 425 – 525 million  
+ 482 – 620% vs. 2022

*One off Brixadi milestone \$35M has been removed from both Operating activities (+\$35M) and Working Capital (-\$35M) to avoid data distortion in our Quarter cash performance as it is neutral.*

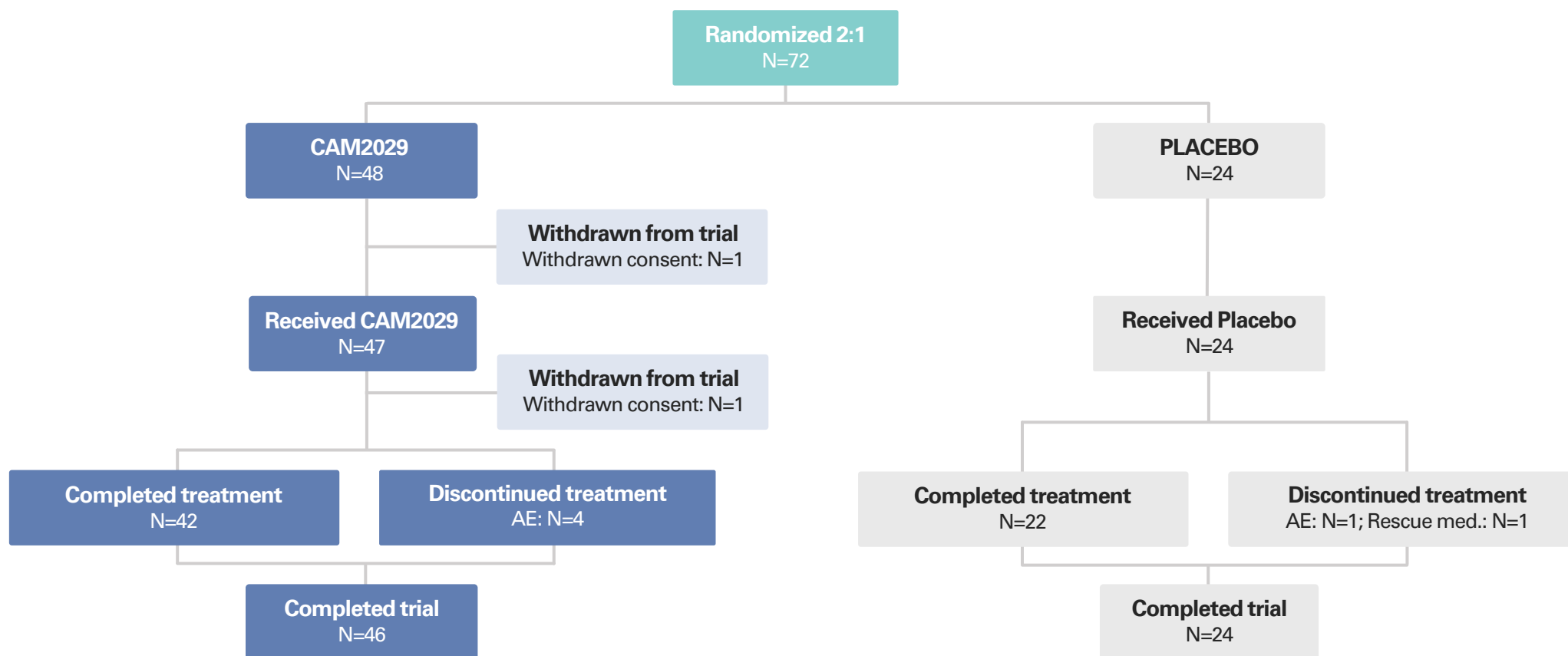
# ACROINNOVA 1

## Patient demographics by treatment arm

Balanced demographics with patients of different ages: Intention to Treat (ITT) analysis set

Parameter (unit)	Statistics or category	CAM2029	PLACEBO	OVERALL
		(N=48)	(N=24)	(N=72) n (%)
Age (years)	Mean (SD)	57 (11.2)	52 (15.1)	55 (12.8)
	Min-Max	29-79	20-82	20-82
	18-64, n (%)	34 (70.8)	19 (79.2)	53 (73.6)
	>= 65, n (%)	14 (29.2)	5 (20.8)	19 (26.4)
Sex (number)	Female n (%)	28 (58.3)	12 (50.0)	40 (55.6)
	Male n (%)	20 (41.7)	12 (50.0)	32 (44.4)
Weight (kg)	Mean (SD)	85 (17.6)	87 (17.3)	86 (17.4)
Height (cm)	Mean (SD)	168 (11.0)	172 (8.2)	169 (10.2)
BMI (kg/m <sup>2</sup> )	Mean (SD)	30 (5.6)	30 (5.8)	30 (5.6)
Region, n (%)	EU	15 (31.3)	9 (37.5)	24 (33.3)
	Europe, non-EU	29 (60.4)	11 (45.8)	40 (55.6)
	United States	4 (8.3)	4 (16.7)	8 (11.1)

# ACROINNOVA 1 trial patient disposition





## ACROINNOVA 2

## Patient demographics by patient group

		Placebo Rollover	CAM2029 Rollover	CAM2029 New	Full population
Parameter (unit)	Statistics or category	(N=18) n (%)	(N=36) n (%)	(N=81) n (%)	(N=135) n (%)
Age (years)	Mean (SD)	50.3 (15.4)	56.6 (10.5)	51.8 (11.4)	52.9 (11.9)
	Min-Max	20-82	35-79	25-81	20-82
	18-64, n (%)	15 (83.3)	27 (75.0)	72 (88.9)	114 (84.4)
	>= 65, n (%)	3 (16.7)	9 (25.0)	9 (11.1)	21 (15.6)
Sex (number)	Female n (%)	10 (55.6)	18 (50.0)	48 (59.3)	76 (56.3)
	Male n (%)	8 (44.4)	18 (50.0)	33 (40.7)	59 (43.7)
Weight (kg)	Mean (SD)	88.2 (19.8)	85.4 (17.5)	87.6 (17.7)	87.1 (17.8)
Height (cm)	Mean (SD)	171.5 (8.9)	168.4 (11.8)	171.0 (11.0)	170.4 (11.0)
BMI (kg/m <sup>2</sup> )	Mean (SD)	30.0 (6.5)	30.1 (5.6)	29.9 (4.7)	29.9 (5.2)
Region, n (%)	EU	7 (38.9)	12 (33.3)	32 (39.5)	41 (30.4)
	Europe, non-EU	7 (38.9)	21 (58.3)	53 (65.4)	81 (60.0)
	United States	4 (22.2)	3 (8.3)	6 (7.4)	13 (9.6)

# ACROINNOVA 1

## Phase 3 RCT efficacy and safety trial

### Primary objective

- To assess the superiority of CAM2029 compared to placebo in biochemical response for insulin-like growth factor-1 (IGF-1)

### Primary endpoint

- Proportion of patients with mean IGF-1 levels  $\leq$  upper limit of normal (ULN) at Week 22 and Week 24 (average of the 2 measurements)

### Key secondary endpoints

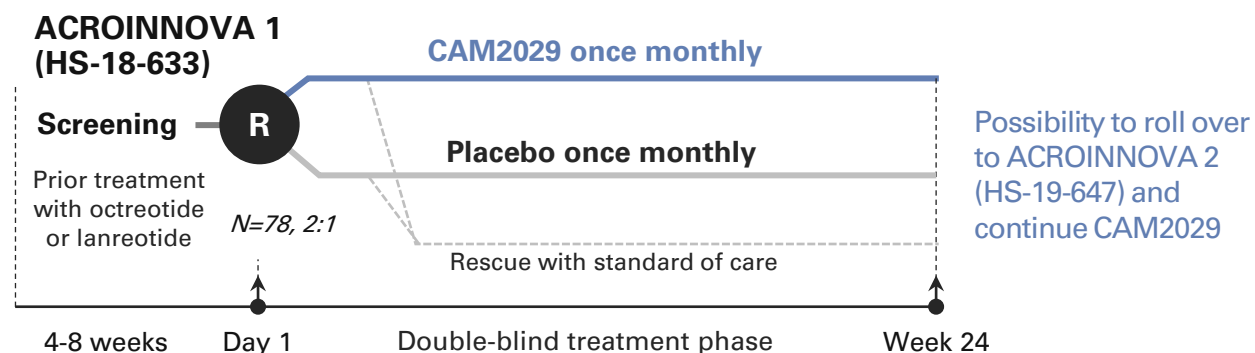
- Proportion of patients with mean IGF-1 levels  $\leq$  ULN at Week 22 and Week 24, including patients who had their dose decreased
- Proportion of patients with mean IGF-1 levels  $\leq$  ULN at Week 22 and Week 24 and mean growth hormone (GH) cycle levels  $< 2.5 \mu\text{g/L}$  at Week 24

### Other secondary endpoints

- Biochemical response (IGF-1 and GH)
- Patient satisfaction and quality of life
- Clinical signs and symptoms of acromegaly
- Self- or partner administration
- Plasma concentrations of octreotide
- Safety

### Patient population

- Patients (n=72) with confirmed acromegaly on treatment with a stable dose of octreotide LAR or lanreotide autogel for at least 3 months with IGF-1 levels  $\leq$  ULN and mean GH cycle levels  $< 2.5 \mu\text{g/L}$  at screening



Stratification by previous treatment

### 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

### Study design

- 52-week, open-label, long-term safety, switch and extension trial of CAM2029 in patients with acromegaly
- Filling regulatory requirements for safety exposure

### Primary endpoint

- Safety and tolerability of CAM2029

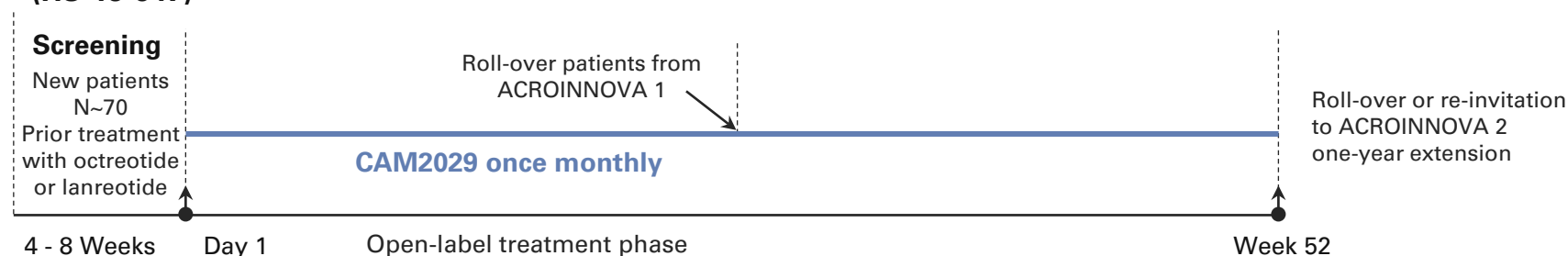
### Key secondary endpoints

- Biochemical response (IGF-1, GH)
- Clinical signs and symptoms
- Tumor size
- PROs (treatment satisfaction, quality of life, self/partner-administration)
- Plasma concentrations of octreotide

### Patient population

- Incomplete IGF-1 responders
- Complete IGF-1 responders
- Patients with prior pituitary radiotherapy (3 years cut-off)
- Roll-over CAM2029 and placebo patients from ACROINNOVA 1

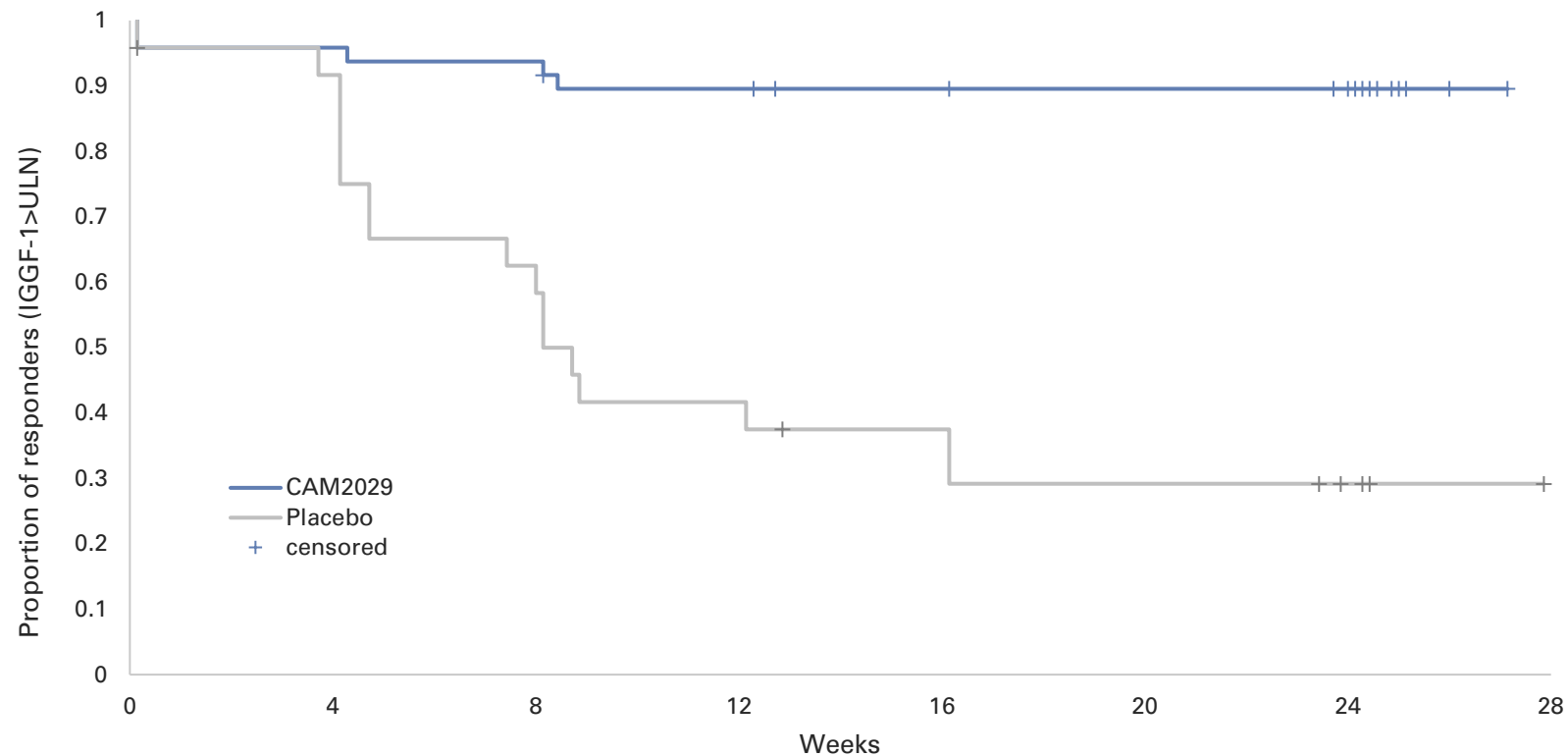
### ACROINNOVA 2 (HS-19-647)



# ACROINNOVA 1

## High statistical difference in time to loss of response

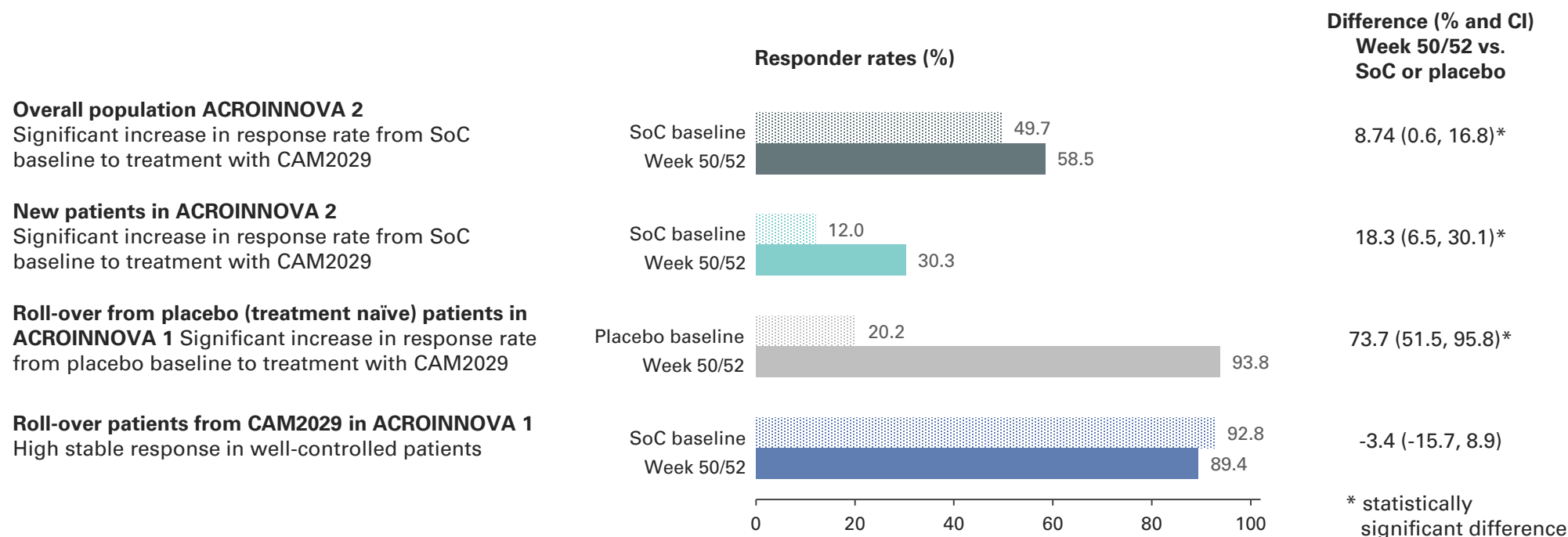
Cox regression analysis (ITT): Hazard ratio=0.1;  $p<0.0001$



ITT – intention-to-treat analysis set.

# Positive long-term biochemical response in ACROINNOVA 2

Responder rates (IGF-1 ≤ ULN) after treatment with CAM2029 compared to SoC baseline, or placebo



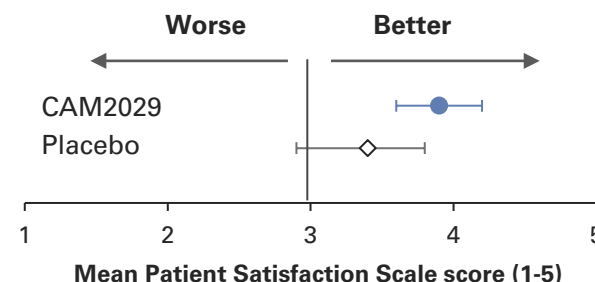
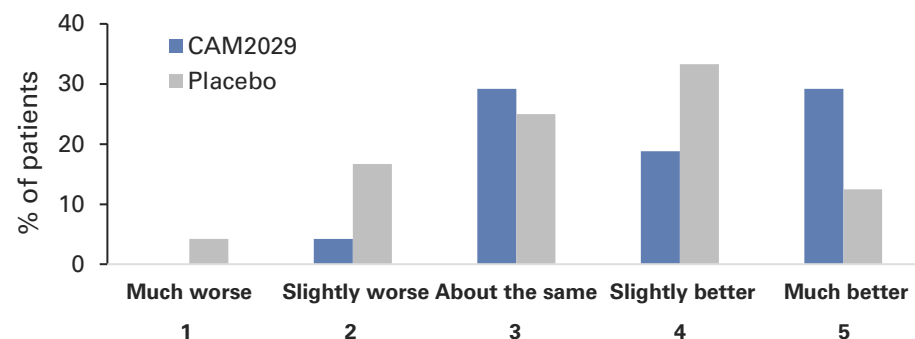
Patients completing treatment at the cut-off timepoint for the interim analysis (N=103)



# ACROINNOVA 1

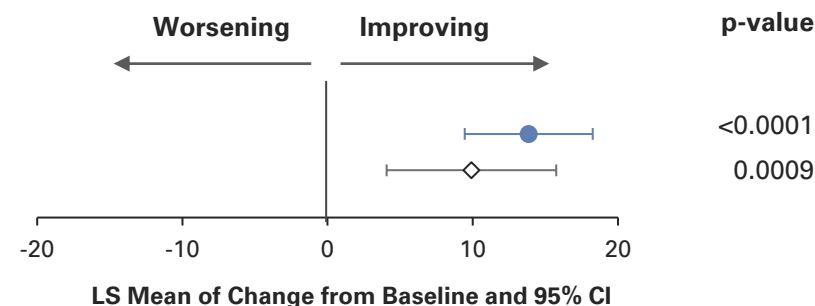
## High patient reported treatment satisfaction

### Patient Satisfaction Scale at Week 24 compared to previous SOC treatment in ACROINNOVA 1



### TSQM convenience score change from SoC baseline to Week 24 in ACROINNOVA 1

TSQM	Treatment arm	LS Mean of Change from Baseline
Convenience Score	CAM2029	13.85 (9.45, 18.25)
	Placebo	9.90 (4.06, 15.75)



# 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

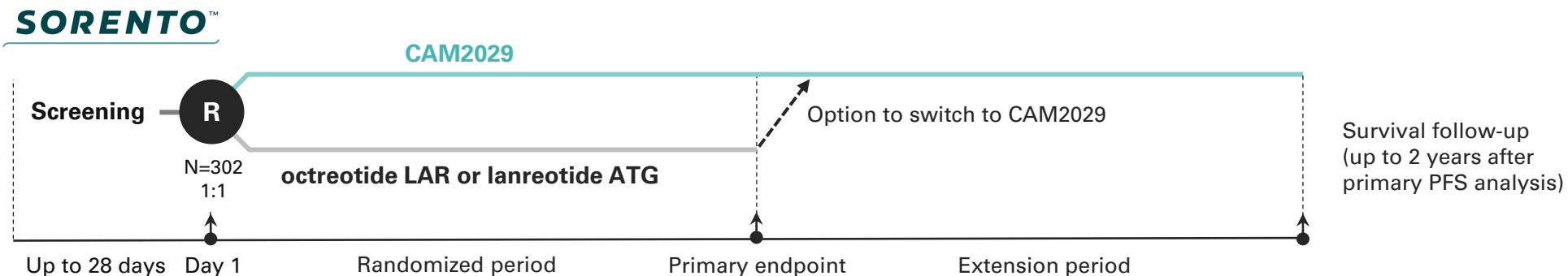
- Patients with confirmed, advanced (unresectable and/or metastatic), and well-differentiated GEP-NET (grade 1 to grade 3)

### 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



# ACROINNOVA 1

## Phase 3 RCT trial of CAM2029 in acromegaly

### Primary objective

- To assess the superiority of CAM2029 compared to placebo in biochemical response for insulin-like growth factor-1 (IGF-1)

### Primary endpoint

- Proportion of patients with mean IGF-1 levels  $\leq$  upper limit of normal (ULN) at Week 22 and Week 24 (average of the 2 measurements)

### Key secondary endpoints

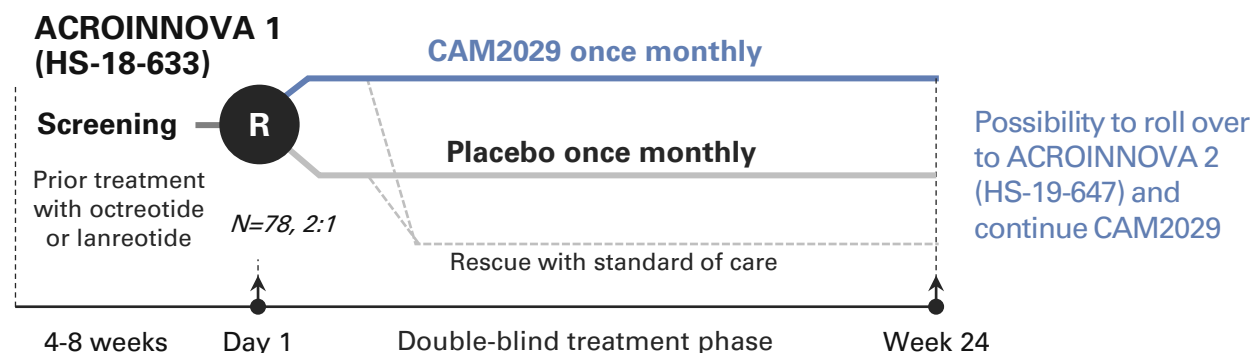
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### Statistical assumption primary endpoint:

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# ACROINNOVA 2:

## Phase 3 long-term safety trial in acromegaly

### Long-term safety Phase 3 trial

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- Filling regulatory requirements for safety exposure

### Patient population

- Incomplete IGF-1 responders
- Complete IGF-1 responders
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- Roll-over CAM2029 and placebo patients from ACROINNOVA 1

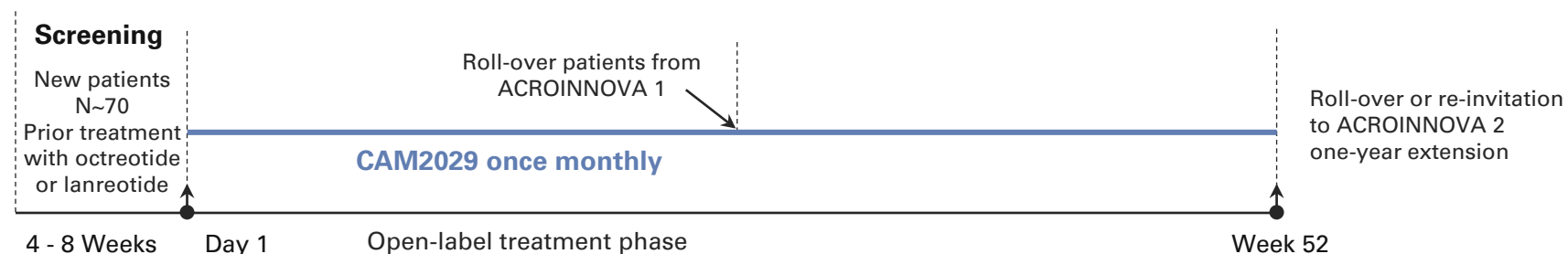
### Primary endpoint

- Safety and tolerability of CAM2029

### Secondary endpoints include

- Biochemical response (IGF-1, GH)
- Clinical signs and symptoms
- Tumor size
- PROs (treatment satisfaction, quality of life, self/partner-administration)
- Plasma concentrations of octreotide

### ACROINNOVA 2



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