## **Camurus**<sub>®</sub>

# First quarter 2023 results

Audiocast presentation 10 May 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.

## Agenda

- Business highlights
- Financial performance
- Commercial development
- R&D pipeline update
- Key take-aways
- Q&A

#### **Company participants**

Fredrik Tiberg, PhD President & CEO, CSO

Jon Garay Alonso Chief Financial Officer

Richard Jameson Chief Commercial Officer



## **Business highlights**

## Excellent progress in the first quarter



#### **Grow Buvidal**

- ✓ Strengthened leadership in LAI treatments for opioid dependence
- ✓ Buvidal net sales SEK 282 m, +40% vs Q1 2022
- ✓ Market expansion through new MAA and PMA approvals
- ✓ Brixadi<sup>™</sup> US PDUFA date for opioid use disorder 23 May



#### Advance the R&D pipeline

- ✓ Four Phase 3 trials progressing across three indications
- ✓ Pivotal ACROINNOVA Phase 3 trial of CAM2029 under completion
- ✓ 50 percent randomized in SORENTO Phase 3 trial of CAM2029 in GEP-NET
- Completed patient recruitment in Rhythm's Phase 3 trial of weekly setmelanotide

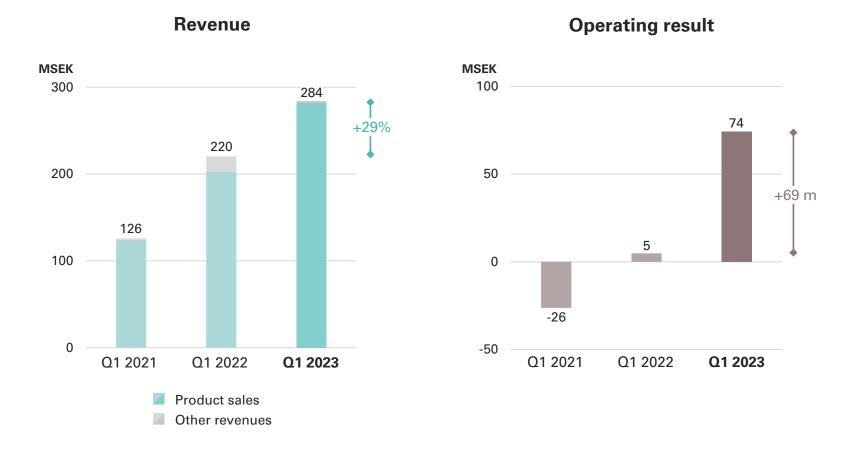


#### Build and diversify our business

- ✓ Fourth consecutive profitable quarter, net profit SEK 59 m, +60 m vs Q1 2022
- ✓ Strengthened cash position
- ✓ Alberto M. Pedroncelli, MD, PhD appointed as CMO and EMT member
- ✓ Started build-up of a US commercial infrastructure for CAM2029

## Financial performance

### Revenue growth and result improvement



#### Cash position SEK 586 million +47% vs Q1 2022



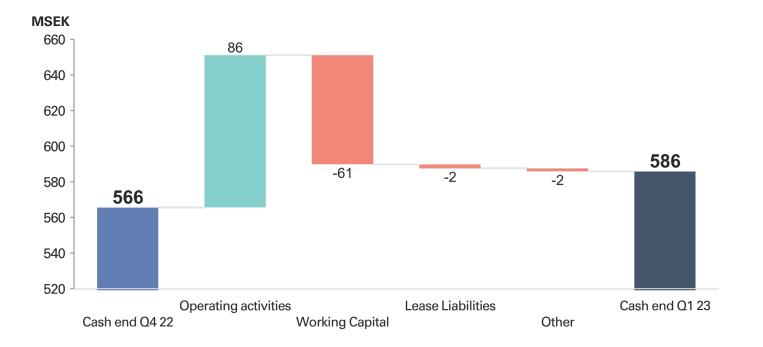
## Reported Q1 profit and loss

MSEK	Jan – Mar 2023	Change vs. 2022	CER Change vs. 2022
Total revenues	284	+29%	+24%
Gross margin	255	+175bps	+139bps
Marketing and distribution costs	-76	+32%	+27%
Administrative expenses	-9	+37%	+32%
Research and development costs	-99	-15%	-18%
Other operating expenses	3	_	_
Operating result	74	1,452%	642%



## Strong cash generation – no debt

Continued generation of positive cash flow





#### **Capital allocation priorities**

- Reinvest in our business:
  - Buvidal market penetration & geographical expansion
  - CAM2029 development to market
- Synergistic inorganic growth opportunities enhancing company value

## Commercial development

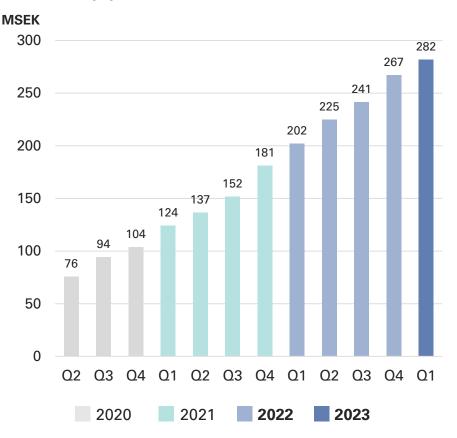
## Buvidal continuing to grow in Europe, Australia and MENA

#### Solid sales growth

- Net sales was SEK 282 million; +40% YoY, +6% QoQ
  - Continued growth in Australia and Nordics from a high base (market share >20% of treated patients)
  - UK exceeding 5% market share (~20% of the buprenorphine segment)
- Est. 39,000 patients in treatment with Buvidal end Q1

#### Regulatory and market expansion processes

- Marketing authorization in the United Arab Emirates
- Price and reimbursement approvals in Greece and UAE
- Four regulatory applications for Buvidal and four PMA submissions under review
- Increased use of Buvidal in criminal justice systems
- Variation application to expand Buvidal indication to chronic pain in opioid dependent patients withdrawn



#### Quarterly product sales

## US approval decision for Brixadi<sup>™</sup> is imminent

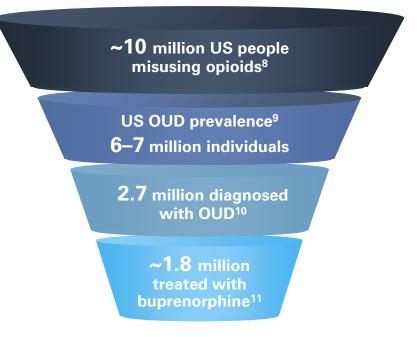
#### Brixadi<sup>1</sup> NDA under review by US FDA

- ✓ NDA resubmission with Priority Review
- NDA approval decision by PDUFA date 23 May 2023
- US commercialization by Braeburn under license agreement with Camurus

#### Significant market opportunity in the US

- High medical need with 80,000 annual deaths in opioid overdoses<sup>2</sup>
- New government initiatives to improve access to opioid use disorder (OUD) treatment<sup>3-5</sup>
- Growing OUD market driven by long-acting injectables<sup>6-7</sup>
- Brixadi is well differentiated and positioned





#### PDUFA – Prescription Drug User Fee Act

<sup>1</sup>Brixadi<sup>™</sup> is the US trade name for Buvidal<sup>®</sup>,<sup>2</sup>CDC Provisional Drug Overdose Death Counts; <sup>3</sup>H.R.2471 - Consolidated Appropriations Act, 2022; <sup>4</sup>The White House – Consolidated Appropriations Act, 2023; <sup>5</sup>Justice Department Issues Guidance on Protections for People with Opioid Use Disorder, 5 Apr 2022; <sup>6</sup>Fortune Business Insights 2023; <sup>7</sup>GlobalData 2023, sales data and analyst consensus including expected Sublocade<sup>®</sup> and Brixadi<sup>™</sup> sales; <sup>8</sup>2018 National Survey on Drug Use and Health; <sup>9</sup>Keyes KM, et al. Drug Alc. Dep. Reports 2022; <sup>10</sup>CDC 2023; <sup>11</sup>Symphony Health data

# Recent initiatives to address treatment hurdles in the US



#### President Biden's Unity Agenda<sup>1</sup>

 Combating opioid epidemic key item in State of the Union 2022 and 2023



#### Increased funding of treatment<sup>2</sup>

 Over \$6 billion to address opioid epidemic and substance misuse in 2022



#### Improved access to treatment<sup>3</sup>

- DATA 2000 waiver removed
- Removed limitation on the number of patients a healthcare professional can treat with medication
- Increased number of days HCPs can store buprenorphine in the clinic from 14 to 45 days



## Expand access to patients in criminal justice system<sup>4</sup>

 New guidance on OUD treatment within criminal justice system issued by Department of Justice

## US opioid use disorder market expected to grow to >\$3.5 billion in five years

Forecasted North America opioid use disorder (OUD) market size<sup>1</sup>

MUSD 4000 8ºlo CAGR 3000 2000 1000 0

MUSD 2000 Forecasted US sales buprenorphine LAIs 1500 350% CAER 1000 500

Expected growth primarily from

buprenorphine LAI products<sup>2</sup>

\* Forecast based on analyst consensus data

2024

2026

2028

2022



**Buprenorhine** LAI share 2022 ~18%

of overall OUD market value

with only

3-5%

of treated patients<sup>3</sup>



Forecasted OUD sales in North America 2020 2022 2024 2026 2020 2028 <sup>1</sup>Fortune Business Insights 2023; <sup>2</sup>GlobalData 2023, sales data and analyst consensus including expected Sublocade® and Brixadi™ sales; <sup>3</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

## Brixadi and Buvidal – well differentiated

#### Flexible dosing and posology

- Weekly and monthly dosing
- Multiple dose options (four weekly, three monthly)
- Choice of multiple injection sites (buttock, thigh, abdomen or upper arm)
- Thin needle and small dose volumes

#### Easy switch from daily medication

 Switch from daily sublingual buprenorphine using conversion table for dose equivalency

#### Enabling treatment initiation on Day 1

 Direct initiation of treatment following a single dose of transmucosal buprenorphine

#### Improved storage

- Room temperature (no cold chain required)

LAI features <sup>1</sup>	Sublocade"	Vivitrol	Brixadi
Weekly dosing	-	_	✓
Monthly dosing	$\checkmark$	1	$\checkmark$
Multiple doses	-	_	$\checkmark$
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	_	_	$\checkmark$
Day one initiation	_	_	~
Clin. data vs active control	_	_	~
Launched	US, CAN, AUS,SE, FI, IL	US	EU, UK, AUS

## R&D pipeline update



## Octreotide SC depot

## CAM2029 under assessment in three serious rare-disease indications

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

Designed for enhanced efficacy and patient convenience



## CAM2029 has block buster potential

#### Somatostatin analog treatments established with limitations

- First-line treatment of acromegaly and neuroendocrine tumors
- 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
- Enhanced SSA exposure (500% bioavailability increase)
- Potential for improved disease control and treatment outcomes

#### High peak sales potential USD >2 billion across indications

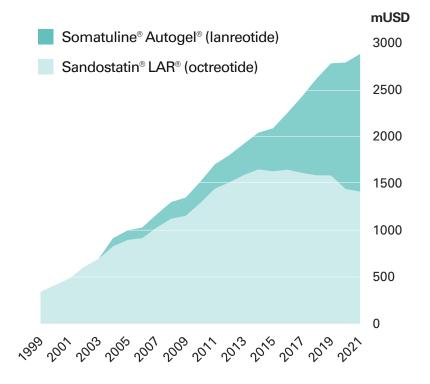
- Majority of value in the neuroendocrine tumor indication

#### Own commercialization in major markets

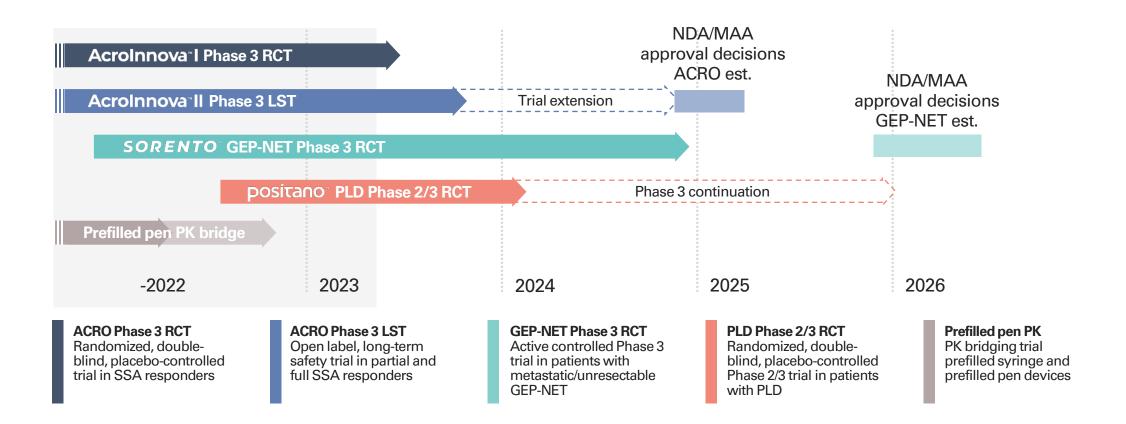
- Fit with Camurus' commercial strategy
- Concentrated target audience
- Differentiated product features
- Switch opportunity from established first-line treatments

#### USD 3 billion SSA market

Annual sales of first generation SSAs<sup>1</sup>



## CAM2029 Phase 3 programs advancing



## ACROINNOVA 1: Phase 3 efficacy trial in acromegaly

#### Pivotal randomized, placebo-controlled Phase 3 trial

- Rigorous, 24-week, randomized, double-blind, placebocontrolled trial of CAM2029 in patients with acromegaly
- Filling regulatory requirement for efficacy

#### **Patient population**

 Acromegaly patients on stable doses of long-acting octreotide or lanreotide with IGF-1 levels ≤1xULN and mean GH cycle levels <2.5 µg/L at screening</li>

#### **Primary endpoint**

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

#### Secondary endpoints:

- Biochemical response (IGF-1, GH)
- Clinical signs and symptoms
- Tumor size
- PROs (e.g., treatment satisfaction, quality of life)
- Plasma concentrations of octreotide
- Safety



IGF-1 - insulin-like growth factor 1; ULN - upper limit of normal; GH - growth hormone; PRO - patient reported outcome

## CAM2029 clinical trials status update

## **AcroInnova**<sup>™</sup>

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

- ✓ Two Phase 3 trials ongoing, ACROINNOVA 1 and 2
- ✓ Patient recruitment goals reached in both trials
- ✓ Last dose administrated in ACROINNOVA 1
- Topline ACROINNOVA 1
   efficacy results June 2023
- Interim ACROINNOVA 2 results in Q3 2023
- Target NDA and MAA submissions late 2023 / early 2024

## SORENTO

Subcutaneous Octreotide Randomized Efficacy in Neuroendocrine TumOrs

- ✓ SORENTO Phase 3 trial ongoing
- ✓ >50% of 302 patients enrolled
- Estimated enrollment completion H2 2023
- Completion SORENTO efficacy part after 194 PFS events
- Estimated NDA/MAA submissions 2025

## <u>posíτano</u>™

Polycystic liver Safety and efficacy TriAl with subcutaneous Octreotide

- ✓ Orphan drug designation (US)
- ✓ New PROs developed and aligned with FDA
- ✓ Phase 2b trial started June 2022
- Estimated enrollment
   completion H2 2023
- □ Topline results 2024

## Ongoing preparations for launches of CAM2029

#### Manufacturing

- ✓ Commercial manufacturing process established
- ✓ Process validation completed
- □ Stability studies for submissions ongoing

#### Commercial – EU and Australia

- ✓ Scalable commercial infrastructure
- Pre-launch preparations initiated medical team expanded
- Stepwise commercial team build-up along with approvals in each indication

#### Commercial – US

- Establishment of own US commercial infrastructure initiated
- Ready mid-2024

#### Medical affairs – activities Q1 2023

- Investigator meeting in the SORENTO study held at the European NeuroEndocrine Tumor Society (ENETS) meeting 22-24 March 2023 in Vienna, Austria
- Three meeting abstracts accepted for presentation at ISPOR in Boston in May and ENDO in Chicago in June

#### Scientific conferences



### Key takeaways

- Strong start to the year with robust top and bottom-line growth
- Buvidal market penetration and expansion continues
  - Significant progress in the late-stage R&D pipeline
- FDA approval decision for Brixadi expected in the next two weeks
- Phase 3 results for CAM2029 late June

## Key expected 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 SORENTO 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





## Key figures first quarter 2023

MSEK	Jan – Mar 2023	Jan – Mar 2022	Change	Jan – Dec 2022
Total revenues	284	220	29%	956
whereof product sales	202	202	+40%	935
Operating expenses	184	189	-4%	789
Operating result	74	5	69	72
Result for the period	59	-1	60	56
Result per share, after dilution, SEK	1.02	-0.01	1.03	0.97
Cash position	586	400	47%	566

## Experienced and committed management team

C.	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	<b>Education</b> : Bachelor in Business Administration by Universidad Comercial de Deusto. Executive MBA by IESE Business School. <b>Previous experience</b> : 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	<b>Education:</b> B.Sc: in Business and Economics, Uppsala University <b>Previous experience:</b> 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.	0	Richard Jameson Chief Commercial Officer In Company since: 2016 Holdings: 29, 193 shares, 8,000 subscription warrants and 57,750 employee options	<ul> <li>Education: B.Sc. in Applied Biological Sciences from University West of England</li> <li>Previous experience: General Manager, UK &amp; Nordics for Reckitt Benckiser (2010 – 2013) and Area Director Europe, Middle East and Africa for Indivior (2013 – 2016).</li> </ul>
(all )	Fredrik Joabsson, PhD Chief Business Dev. Officer In Company since: 2001 Holdings: 50, 170 shares & 38,500 employee options	<ul> <li>Education: M.Sc. in Chemistry, PhD in Physical Chemistry, Lund University</li> <li>Previous experience: More than 20 years of experience in pharmaceutical R&amp;D, business development and alliance management.</li> </ul>		Markus Johnsson Senior VP R&D In Company since: 2003-2017, 2019- Holdings: 21,000 shares & 23,500 employee options	<b>Education:</b> Ph.D. in physical chemistry and M.Sc. in chemistry from Uppsala University. <b>Previous experience:</b> More than 20 years of experience from pharmaceutical development and project management
60	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.	B	Annette Mattsson VP Regulatory Affairs In Company since: 2017 Holdings: 2004 shares & 38,500 employee options	<b>Education</b> : Bachelor of Pharmacy, Uppsala University and Business Economics, Lund University <b>Previous experience</b> : 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.
P	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 <b>Previous experience</b> : More than 25 years of experience in drug development, incl. as COO at Zealand Pharma, CEO of Cantarona, Senior VP Clinical Development at Germab.			

Cantargia, Senior VP Clinical Development at Genmab



## Shareholders and analyst coverage

Shareholders as of 30 April	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	2,277,315	4.1	4.1
Didner & Gerge Fonder	2,024,044	3.6	3.6
Fredrik Tiberg, CEO	1,680,000	3.0	3.0
State Street Bank and Trust	1,090,029	2.0	2.0
JP Morgan Chase Bank	921,073	1.7	1.7
Backahill Utveckling	826,491	1.5	1.5
Svenskt Näringsliv	800,000	1.4	1.4
Lancelot Avalon	600,000	1.1	1.1
Öhman Fonder	593,555	1.1	1.1
Afa Försäkring	569,060	1.0	1.0
Camurus Lipid Research Foundation	486,350	0.9	0.9
Handelsbankens fonder	457,293	0.8	0.8
COJ Service AB	425,000	0.8	0.8
Other shareholders	17,681,041	31.9	31.9
In total	55,423,043	100.0	100.0

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

## ACROINNOVA 2: Phase 3 long-term safety trial in acromegaly

#### Long-term safety Phase 3 trial

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

#### **Patient population**

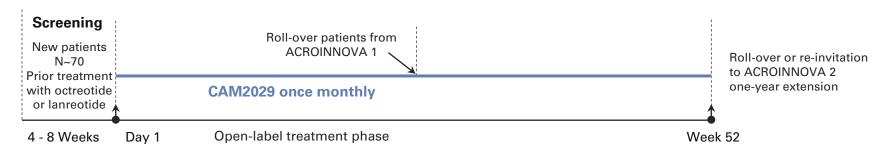
- Incomplete IGF-1 responders
- Complete IGF-1 responders
- Patients with prior pituitary radiotherapy (3 years cut-off)
- Roll-over CAM2029 and placebo patients from ACROINNOVA 1

#### **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/partneradministration
- Plasma concentrations of octreotide



#### AcroInnova<sup>\*</sup>

IGF-1 – insulin-like growth factor 1; ULN – upper limit of normal; GH – growth hormone; PRO - patient reported outcome

## 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

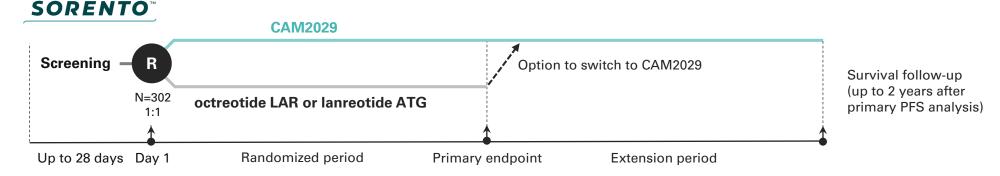
 Patients with confirmed, advanced (unresectable and/or metastatic), and well-differentiated GEP-NET (grade 1 to grade 3)

#### **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



#### GEP-NET – gastroenteropancreatic neuroendocrine tumors; PFS – progression free survival; PRO - patient reported outcome; LAR – long-acting release; ATG - autogel