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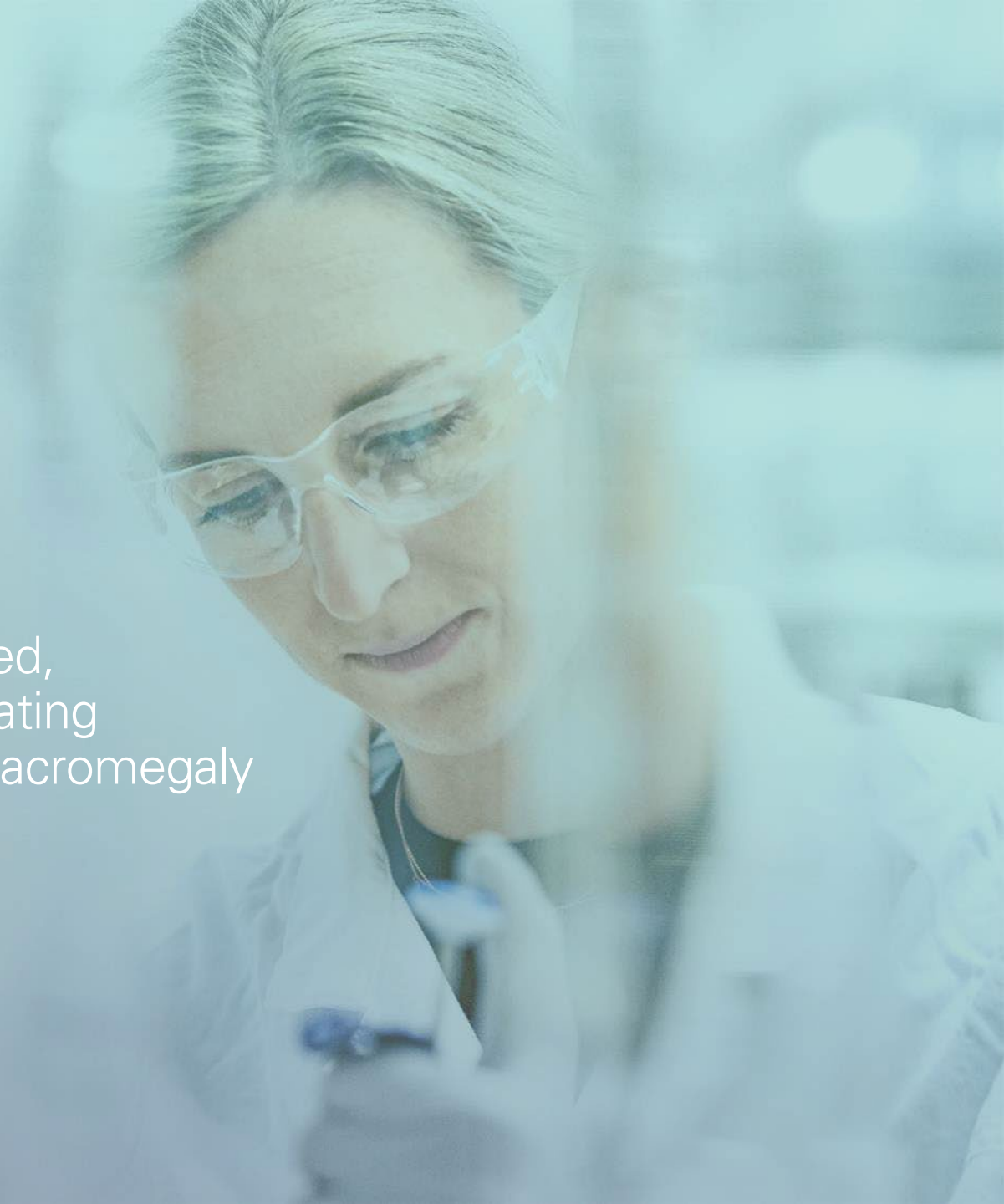
ACROINNOVA 1
Phase 3 results

Topline results from a 24-week, randomized, double-blind, placebo-controlled trial evaluating octreotide SC depot in adult patients with acromegaly

20 June 2023



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Octreotide SC depot (CAM2029) is an investigational medical product.

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.

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Camurus undertakes no obligation to update forward-looking statements

Agenda

- Acromegaly and octreotide SC depot
- The ACROINNOVA program
- Phase 3 topline results of ACROINNOVA 1
- Next steps towards regulatory submissions
- Questions

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Octreotide SC depot (CAM2029) showed high level of disease control and positive PRO outcomes

- ✓ Primary endpoint of superiority met with 72.2% IGF-1 response in the CAM2029 group versus 37.5% in the placebo group
- ✓ Key secondary endpoint of superiority met with 70.0% IGF-1 and GH response in the CAM2029 group versus 37.5% in the placebo group
- ✓ All sensitivity and supportive analyses confirmed the conclusion of the main analyses
- ✓ IGF-1, GH and symptoms were well controlled over time with CAM2029
- ✓ Improved quality of life indicated for CAM2029 versus standard of care (SoC) at baseline
- ✓ Improved patient satisfaction and treatment satisfaction convenience score for CAM2029 versus SoC at baseline
- ✓ Well tolerated safety profile

PRO – patient reported outcomes

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CAM2029 – octreotide subcutaneous depot in Phase 3 development

Investigational treatment of three, serious, rare diseases with high unmet medical needs

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

Designed for enhanced efficacy and improved convenience

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Acromegaly – a rare growth hormone disorder with significant morbidity

- Rare pituitary disorder caused by a benign tumor and excess of growth hormone
- Slowly developing chronic disease with progressive physical changes or disability, often unrecognized, leading to late diagnosis
- Uncontrolled acromegaly leads to increased risk of severe symptoms and mortality[3]
- Acromegaly patients have reduced quality of life (QoL)[4]
- Unmet medicals needs include enhanced disease and symptom control and improved QoL for patients[5]
  - Recurring symptoms and compromised QoL are reported also in patients that are biochemically controlled[5]

PREVALENCE:
50-70 cases
per million[1]

Around 40 years
at diagnosis[2]

Men and women
equally affected[2]

Source: 1. National Organization for Rare DIsorders (NORD), Acromegaly: https://rarediseases.org/rare-diseases/acromegaly/#affected, accessed June 2023; 2. Chanson P and Salenave S. Orphanet J Rare Dis. 2008;3:17; 3. Kasuki L et al. Arch Endocrinol Metab. 2019;63(6):630-637; 4. Webb SM and Badia X. Neuroendocrinology. 2016;103(1):10611; 5. Geer EB, et al. BMC Endocr Disord. 2020;20(1):117.

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Acromegaly symptoms and morbidity

Common symptoms
- Fatigue
- Headache
- Paresthesia
- Soft tissue swelling
- Excessive sweating
- Joint pain

Alterations of facial features and tongue enlargement

Cardiovascular
- Hypertension
- Left ventricular hypertrophy
- Cardiomyopathy
- Congestive heart failure
- Dysrhythmias
- Coronary atherosclerosis

Benign pituitary tumor causes excess GH secretion leading to increased IGF-1 levels

Pulmonary
- Sleep apnea
- Narcolepsy
- Obstruction of upper airways

Bone overgrowth and organ enlargement

Endocrine and metabolic
- Diabetes mellitus
- Impaired glucose tolerance
- Thyroid disorder
- Hyperprolactinemia
- Hypopituitarism

Reproductive
- Decreased libido
- Erectile dysfunction

GH, growth hormone; IGF-1, insulin-like growth factor-1
Source: Melmed S. J Clin Invest. 2009;119(11):3189-202; Kyriakakis N, et al. Endocrinol Diabetes Metab. 2020;3(3):e00158; Gadelha MR et al. Endocr Rev. 2019;40(1):268-332.

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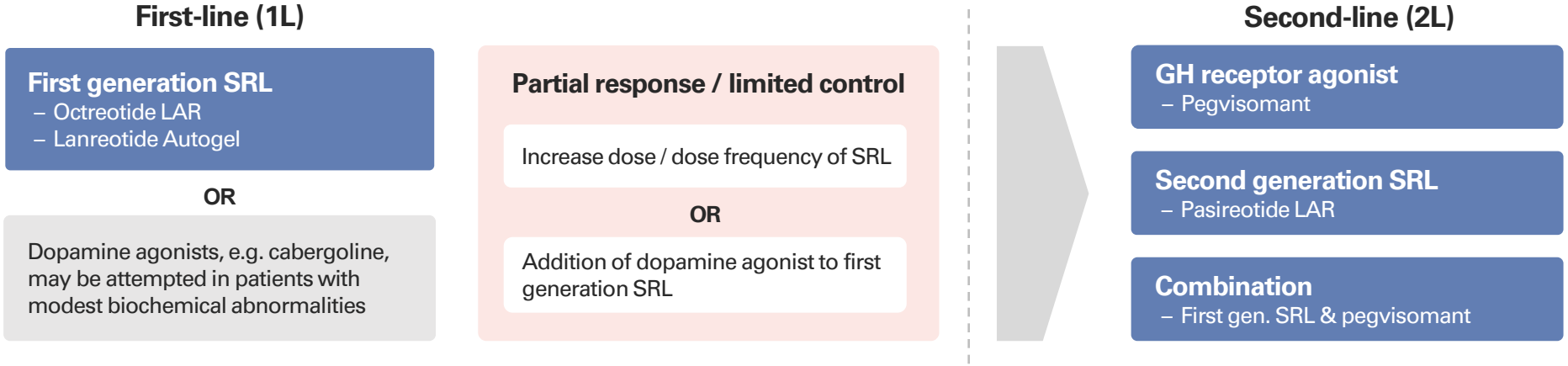
SRLs are first-line medical treatment

Transsphenoidal surgery of micro- and macro-adenomas

First-line medical treatment is first-generation, long-acting somatostatin receptor ligands (SRLs)

– Octreotide LAR and lanreotide Autogel (rarely dopamine agonist)
– Second-line therapy often includes pegvisomant and pasireotide



SRL, somatostatin receptor ligand; LAR, long-acting release
Source: Melmed S, et al., Nat Rev Endocrinol. 2018 Sep;14(9):552-561.

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First generation SRLs are standard of care for acromegaly – with improvement potential

Complex handling and inconvenient dosing

- Complex reconstitution – prone to handling errors and needle clogging (octreotide)
- Intramuscular or deep subcutaneous injections with large needles (octreotide and lanreotide)
- Lack of convenient dosing options and/or requirement for administration by healthcare professional
- Absence of viable self-administration option may impact on patient convenience and autonomy[1,2]

Efficacy limitations with modest response rates

- Octreotide LAR has low octreotide bioavailability (<20%) and low exposure
- Lanreotide Autogel has lower receptor binding affinity
- Only about half of acromegaly patients on current treatment are controlled (IGF-1 and GH)[3]
  - 57% and 67% for octreotide LAR
  - 47% and 48% for lanreotide autogel
- Persistent and breakthrough symptoms

Sources: 1. Somatuline® Depot Prescribing information, Ipsen Biopharmaceuticals; 2. Sandostatin LAR® Depot Prescribing information, Novartis Pharmaceuticals; 3. Colao AM, et al. Pituitary 2016; 19: 235–247.

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CAM2029 – targeting key unmet medical needs in acromegaly

Convenient dosing allowing for easy patient self-administration

– Ready to use, with no need for mixing, reconstitution, or temperature conditioning, and is stored at room temperature
– Subcutaneous administration with pre-filled syringe (automatic safety device) or pre-filled pen (thin "non-visible" needle)

High octreotide exposure with potential for improved efficacy

– Rapid onset and long-acting octreotide release
– Approximately 500% higher bioavailability vs octreotide LAR[1,2]
– Effective biochemical and symptom control indicated in Phase 2 proof-of-concept trial in acromegaly[2]

Octreotide subcutaneous depot (CAM2029)

ACROINNOVA 1 & 2

ACROINNOVA 2

Source: 1.Tiberg F, et al. Br J Clin Pharmacol. 2015 ;80:460-72; 2. Pavel M, et al. Cancer Chemother Pharmacol. 2019; 83:375–85

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ACROINNOVA 1 Topline results

24-week, Phase 3, randomized, double-blind, placebo-controlled trial of octreotide SC depot

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Patient demographics by treatment arm

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

		CAM2029	PLACEBO	OVERALL
Parameter (unit)	**Statistics or category**	**(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^2)	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)

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Phase 3 trial enrolled adult patients with acromegaly on stable treatment with SoC

Patients with documented acromegaly history (Intention-to-treat Analysis Set)

		CAM2029	PLACEBO	OVERALL
Parameter	**Category**	**(N=48) n (%)**	**(N=24) n (%)**	**(N=72) n (%)**
Time since Diagnosis (years)	Mean (SD)	10.8 (6.8)	13.0 (10.7)	11.5 (8.3)
Time since Diagnosis	<10 years, n (%)	23 (47.9)	11 (45.8)	34 (47.2)
	10-20 years, n (%)	19 (39.6)	9 (37.5)	28 (38.9)
	>=20 years, n (%)	5 (10.4)	4 (16.7)	9 (12.5)
Pituitary Surgery	Yes, n (%)	42 (87.5)	21 (87.5)	63 (87.5)
	No, n (%)	6 (12.5)	3 (12.5)	9 (12.5)
Treatment at baseline	Octreotide LAR, n (%)	25 (52.1)	14 (58.3)	39 (54.2)
	Lanreotide Autogel, n (%)	23 (47.9)	10 (41.7)	33 (45.8)

Phase 3 RCT evaluated efficacy and safety of octreotide SC depot in patients with 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 ≤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 ≤ULN at Week 22 and Week 24, including patients who had their dose decreased

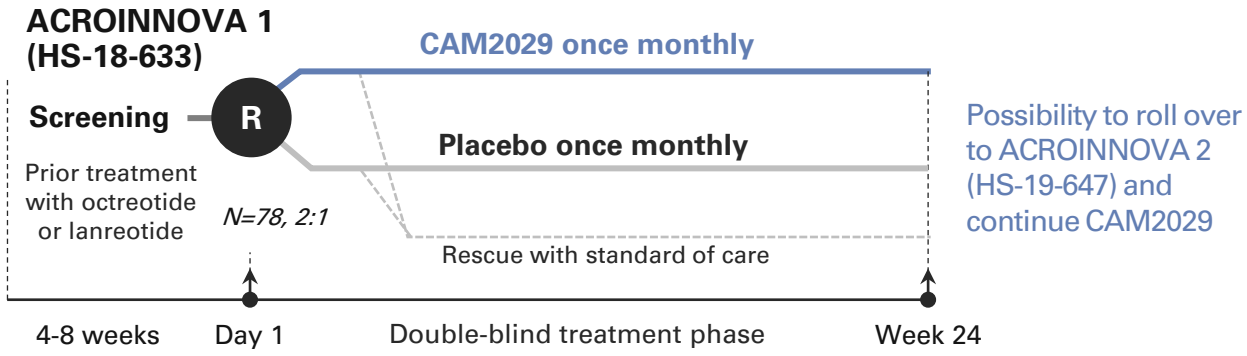
– Proportion of patients with mean IGF-1 levels ≤ULN at Week 22 and Week 24 and mean growth hormone (GH) cycle levels <2.5 µg/L at Week 24

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 ≤ULN and mean GH cycle levels <2.5 µg/L at screening



Possibility to roll over to ACROINNOVA 2 (HS-19-647) and continue CAM2029

Stratification by previous treatment

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Phase 3 RCT evaluated efficacy and safety of octreotide SC depot in patients with acromegaly

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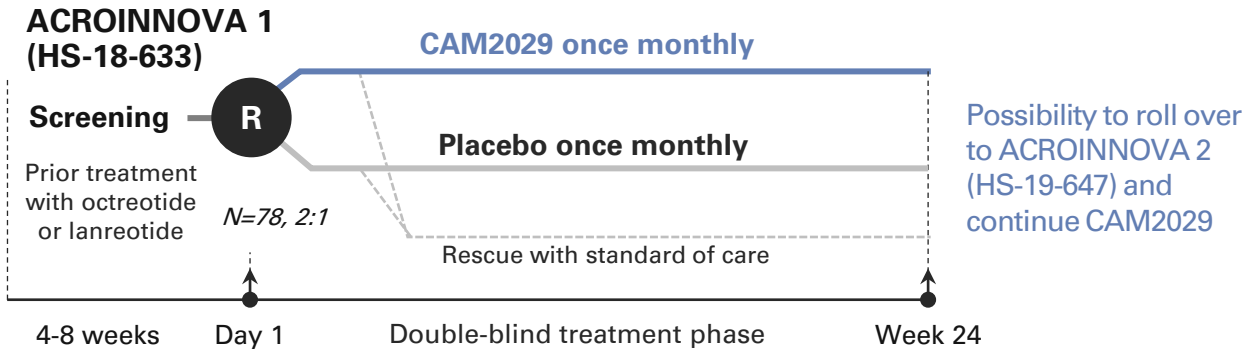
– Plasma concentrations of octreotide
– Safety

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 ≤ULN and mean GH cycle levels <2.5 µg/L at screening



Possibility to roll over to ACROINNOVA 2 (HS-19-647) and continue CAM2029

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)

Stratification by previous treatment

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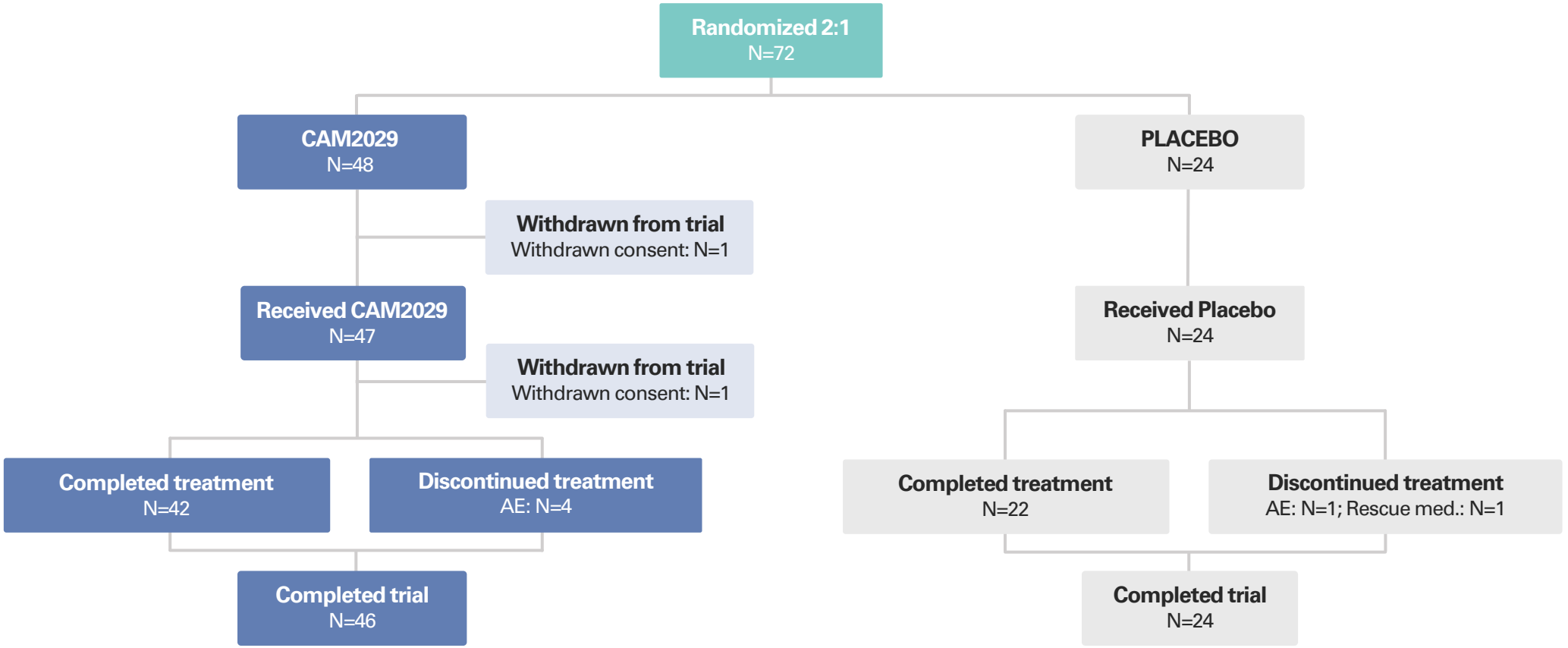
ACROINNOVA 1 trial patient disposition



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Topline efficacy results

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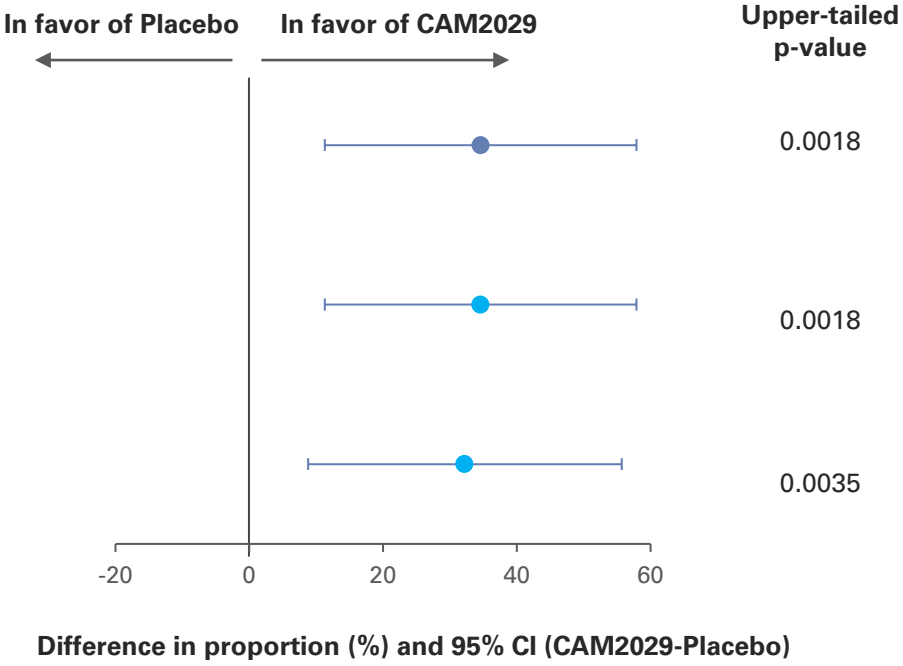
Octreotide SC depot achieved superiority for IGF-1 and GH response

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

	CAM2029 % responders	Placebo % responders	CAM2029-Placebo % (95% CI)	Upper-tailed p-value
Primary efficacy endpoint - Proportion of patients with mean IGF-1≤ULN at Week 22 and Week 24	72.2	37.5	34.6 (11.3, 57.9)	0.0018
Key secondary efficacy endpoint - Proportion of patients with mean IGF-1≤ULN at Week 22 and 24, incl. patients with IMP dose reduction	72.2	37.5	34.6 (11.3, 57.9)	0.0018
Key secondary efficacy endpoint - Proportion of patients with mean IGF-1≤ULN at Week 22 and Week 24 and mean GH cycle <2.5 ug/L at Week 24	70.0	37.5	32.3 (8.8, 55.7)	0.0035



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

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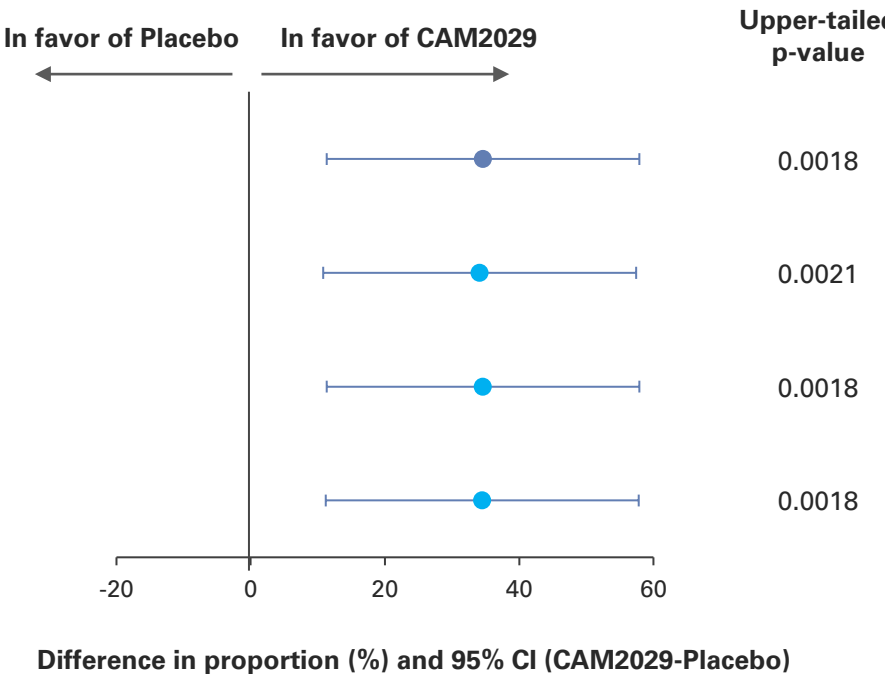
Sensitivity analyses confirmed the main analysis

Main and sensitivity analyses of the primary endpoint (ITT)

	CAM2029 % responders	Placebo % responders	CAM2029-Placebo % (95% CI)	Upper-tailed p-value
Primary efficacy endpoint	72.2	37.5	34.6 (11.3, 57.9)	0.0018
Sensitivity analysis II Pattern-Mixture Model (PMM) using control-based wash-out imputation	71.6	37.5	34.1 (10.8, 57.4)	0.0021
Sensitivity analysis III PMM assuming data missing at random Missing data due to reasons other than adverse events or lack of efficacy	72.2	37.5	34.6 (11.3, 57.9)	0.0018
Sensitivity analysis V PMM assuming data missing at random Data missing or delayed due to COVID-19	72.1	37.5	34.5 (11.2, 57.8)	0.0018

Sensitivity analysis I could not be performed due to few retrieved dropouts
Sensitivity analysis IV was a tipping point analysis for patients with missing values (n=1); p-values 0.0025 and 0.0014



ITT – intention-to-treat analysis set.

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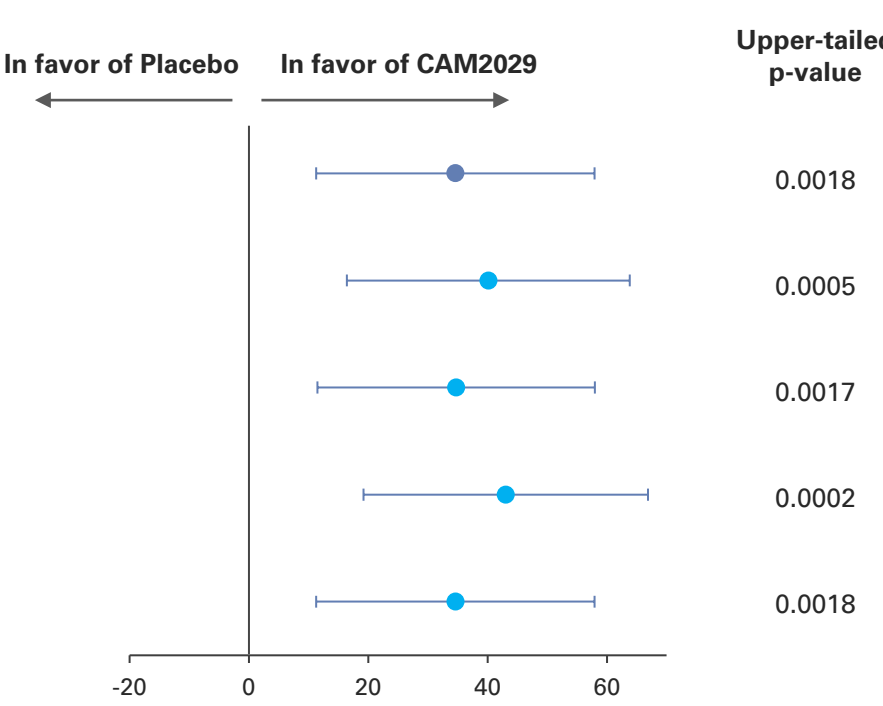
Supportive analyses confirmed the main analysis

Main and supportive analyses of the primary endpoint

	CAM2029 % responders	Placebo % responders	CAM2029-Placebo % (95% CI)	Upper-tailed p-value
Primary efficacy endpoint	72.2	37.5	34.6 (11.3, 57.9)	0.0018
Supportive analysis I Patients who received their Week 20 dose of IMP	81.0	40.9	40.1 (16.4, 63.8)	0.0005
Supportive analysis II Full Analysis Set	72.3	37.5	34.7 (11.5, 58.0)	0.0017
Supportive analysis IV Per Protocol Analysis Set	81.0	38.1	43.0 (19.2, 66.9)	0.0002
Supportive analysis V Primary analysis with ULN by age at assessment	72.2	37.5	34.6 (11.3, 57.9)	0.0018



Supportive analysis III could not be performed as no patient had missing data for the primary endpoint due to COVID-19

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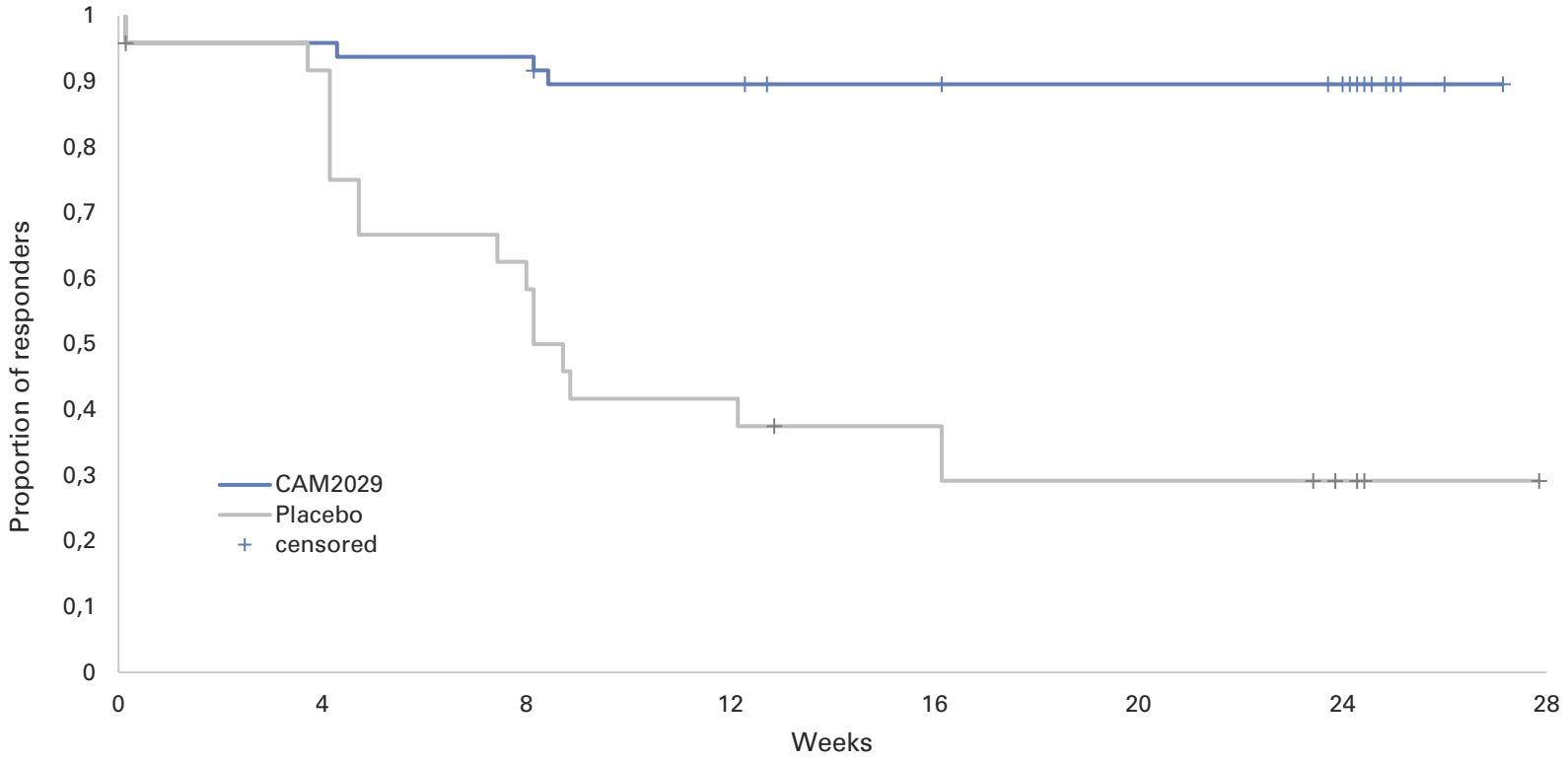
High statistical difference in time to loss of biochemical response: IGF-1>ULN

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



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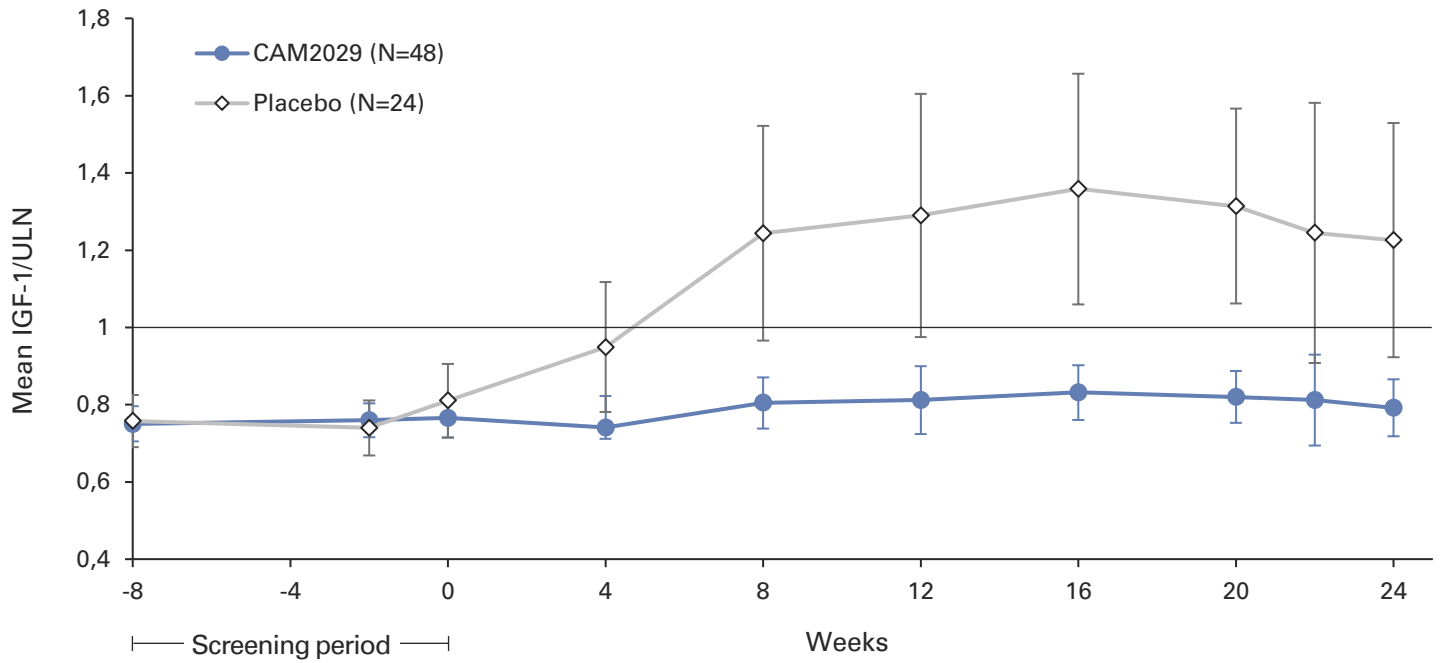
IGF-1 over time confirms efficacy of CAM2029

IGF-1 values for CAM2029 stable over time (mean, 95% CI)



	IGF-1/ULN Week 24 vs. Baseline
LS Mean CAM2029	0.04
LS Mean Placebo	0.51
Mean Difference (CAM2029 – Placebo)	-0.47
95% CI of Difference	-0.72, -0.21
p-value	0.0004

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Patient reported outcomes

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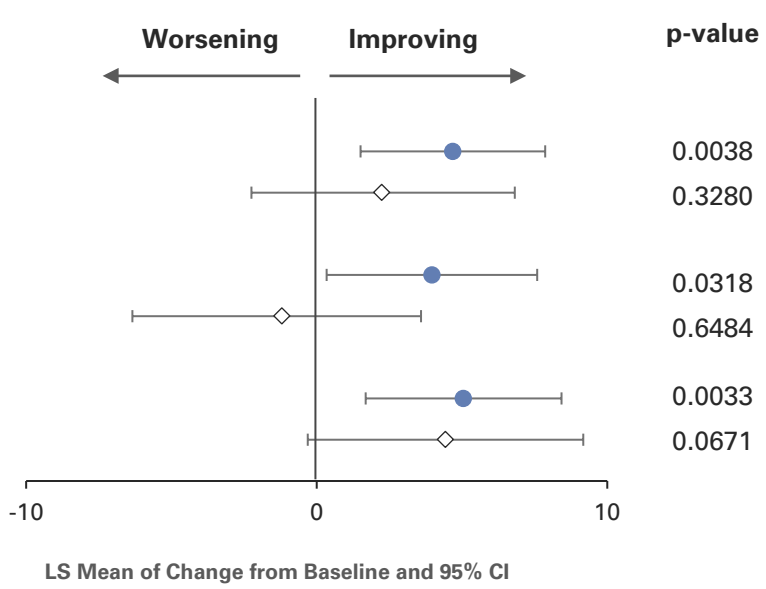
Significant improvement in patient's QoL indicated versus SoC at baseline

Significant treatment differences with CAM2029 versus baseline

AcroQoL	Treatment arm	LS Mean of Change from Baseline	p-value
Total Score	CAM2029	4.685 (1.510, 7.861)	0.0038
	Placebo	2.237 (-2.246, 6.721)	0.3280
Physical Domain Score	CAM2029	3.968 (0.346, 7.590)	0.0318
	Placebo	-1.198 (-6.348, 3.952)	0.6484
Psychological Domain Total Score	CAM2029	5.054 (1.684, 8.424)	0.0033
	Placebo	4.433 (-0.313, 9.178)	0.0671



QoL, quality of life; SoC , standard of care with octreotide LAR or lanreotide autogel; AcroQoL, Acromegaly Quality of Life

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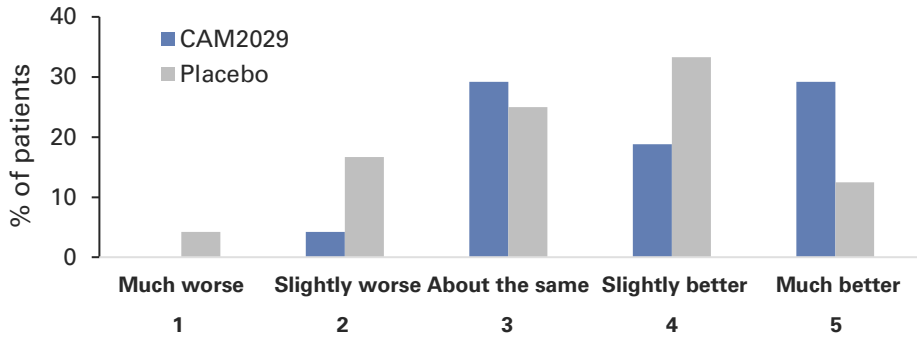
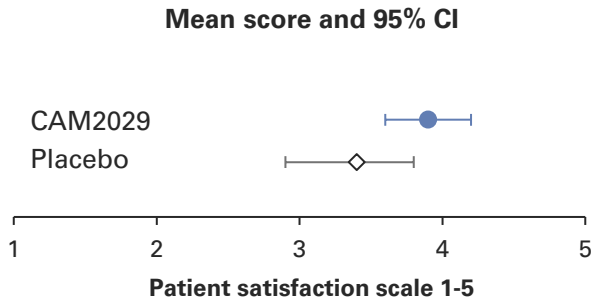
High patient reported treatment satisfaction with CAM2029 versus baseline

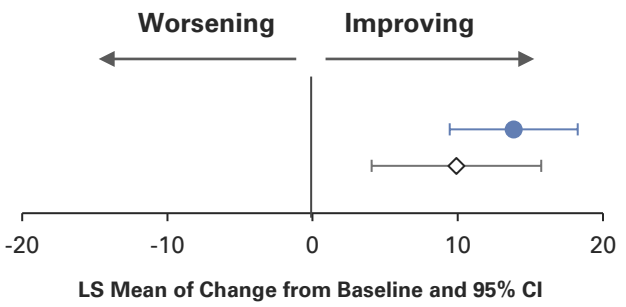
Answers to Patient Satisfaction Scale at Week 24 versus previous treatment by treatment arm





TSQM convenience score by treatment arm from baseline to Week 24

TSQM	Treatment arm	LS Mean of Change from Baseline	p-value
Convenience Score	CAM2029	13.85 (9.45, 18.25)	<0.0001
	Placebo	9.90 (4.06, 15.75)	0.0009



TSQM, Treatment Satisfaction Questionnaire for Medication

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Safety and adverse events overview

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Summary of adverse events by treatment arm

Adverse events (AEs) were mostly mild, and none of the serious or severe AEs were related to octreotide SC depot (Safety analysis set)

Category	CAM2029 (N=47) n (%)	PLACEBO (N=24) n (%)	OVERALL (N=71) n (%)
Any AE	37 (78.7)	19 (79.2)	56 (78.9)
Any Related AE	24 (51.1)	15 (62.5)	39 (54.9)
Any Grade 1 AE	34 (72.3)	18 (75.0)	52 (73.2)
Any Grade 2 AE	19 (40.4)	8 (33.3)	27 (38.0)
Any Grade 3 or Higher AE	5 (10.6)	2 (8.3)	7 (9.9)
Any SAE	4 (8.5)	2 (8.3)	6 (8.5)
Any Related SAE	0	1 (4.2)	1 (1.4)
Any AE Leading to Treatment Discontinuation	4 (8.5)	1 (4.2)	5 (7.0)
Any AE Leading to Withdrawal from Trial	0	0	0
Any AE Leading to Dose Reduction	0	0	0
Any Fatal SAE	0	0	0
Any COVID-19-Related AE	5 (10.6)	3 (12.5)	8 (11.3)

AE, adverse event; SAE, serious adverse event

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Adverse event summary by preferred term

Adverse events reported by at least 5% of patients in any treatment arm by preferred term (Safety Analysis Set)

	CAM2029	PLACEBO	OVERALL
Preferred term	**(N=47) n (%)**	**(N=24) n (%)**	**(N=71) n (%)**
Any AE	37 (78.7)	19 (79.2)	56 (78.9)
Injection site erythema	12 (25.5)	5 (20.8)	17 (23.9)
Arthralgia	8 (17.0)	2 (8.3)	10 (14.1)
Injection site swelling	7 (14.9)	2 (8.3)	9 (12.7)
Injection site mass	3 (6.4)	5 (20.8)	8 (11.3)
Injection site pruritus	7 (14.9)	1 (4.2)	8 (11.3)
Injection site induration	4 (8.5)	3 (12.5)	7 (9.9)
Injection site pain	4 (8.5)	3 (12.5)	7 (9.9)
COVID-19	4 (8.5)	3 (12.5)	7 (9.9)
Injection site nodule	4 (8.5)	1 (4.2)	5 (7.0)
Fatigue	3 (6.4)	1 (4.2)	4 (5.6)
Pruritus	4 (8.5)	0	4 (5.6)
Anaemia	1 (2.1)	3 (12.5)	4 (5.6)
Abdominal pain upper	3 (6.4)	0	3 (4.2)
Headache	3 (6.4)	0	3 (4.2)
Injection site rash	0	2 (8.3)	2 (2.8)
Leukopenia	0	2 (8.3)	2 (2.8)

AE, adverse event

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Summary and conclusions

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Positive topline Phase 3 results from ACROINNOVA 1

Primary and key secondary endpoints met with robust, statistical significance

– All sensitivity and supportive analyses confirmed efficacy
– Trial met multiple additional secondary endpoints on biochemical control of IGF-1 and GH with octreotide SC depot

Patients were well controlled

– IGF-1, GH and symptoms were stable over time

Improvements seen in patient reported outcomes

– Treatment satisfaction improved compared to SoC at baseline
– Acromegaly Quality of Life (AcroQoL) improved compared to SoC at baseline

Well tolerated safety profile

– Comparable to approved first generation SRLs
– No new or unexpected safety findings

Further and expanded data on CAM2029 efficacy, patient reported outcomes and safety profile expected from ACROINNOVA 2

GH, growth hormone; IGF-1, insulin-like growth factor-1

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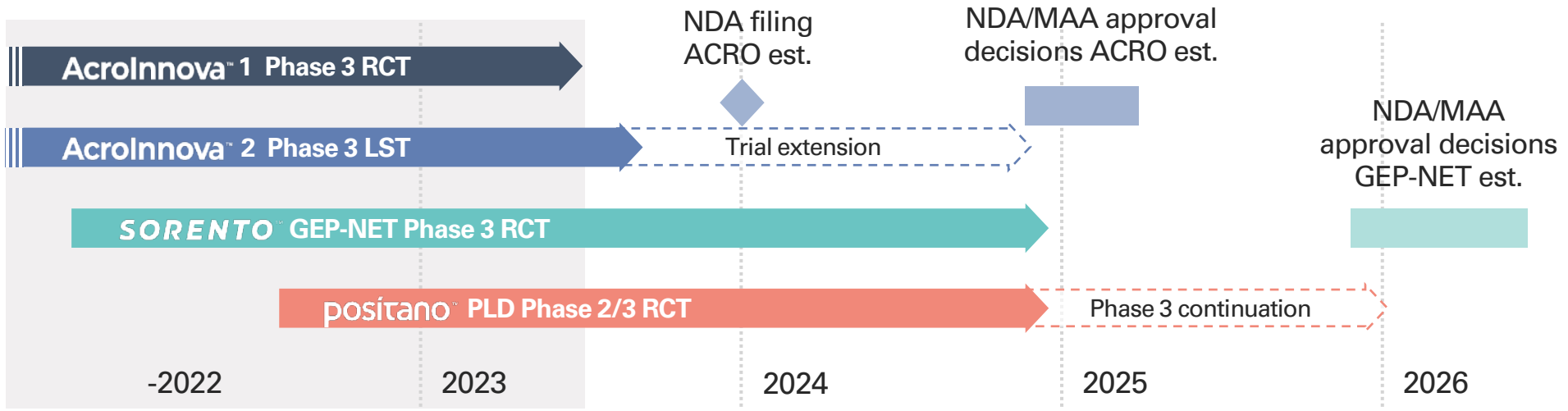
Upcoming key milestones: ACROINNOVA program

- [ ] Full results from ACROINNOVA 1 trial, Q3 2023
- [ ] Interim results ACROINNOVA 2, Q3 2023
- [ ] Pre-NDA meeting Q3/Q4 2023
- [ ] NDA submission around the turn of the year 2023/24
- [ ] Further regulatory submission in EU and RoW

camurus.

CAM2029 Phase 3 programs progressing



ACRO Phase 3 RCT
Randomized, double-blind, placebo-controlled trial in SRL responders

ACRO Phase 3 LST
Open label, long-term safety trial in partial and full SRL responders

GEP-NET Phase 3 RCT
Active controlled Phase 3 trial in patients with metastatic/ unresectable GEP-NET

PLD Phase 2/3 RCT
Randomized, double-blind, placebo-controlled Phase 2/3 trial in patients with PLD

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

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Questions