OC6.6

Long-term and sustained biochemical control of acromegaly and improved quality of life with CAM2029 octreotide subcutaneous depot: final analysis of the core phase of ACROINNOVA 2

Presenter: Diego Ferone

Robert D. Murray,[1] Harpal S. Randeva,[2,3] Tara Kearney,[4] Maria Fleseriu,[5] Beverly M. K. Biller,[6] Mônica R. Gadelha,[7] Jacob Råstam,[8] Maria Harrie,[8] Agneta Svedberg,[8] Alberto M. Pedroncelli,[8] Fredrik Tiberg,[8] Diego Ferone[9]

[1]Department of Endocrinology, St James's University Hospital, Leeds Teaching Hospitals NHS Trust, Leeds, UK; [2]Warwick Medical School, University of Warwick, Coventry, UK; [3]WISDEM, University Hospitals Coventry and Warwickshire NHS Trust, Coventry, UK; [4]Department of Endocrinology, Manchester Centre for Clinical Neurosciences, Salford Royal Foundation Trust, Manchester, UK; [5]Pituitary Center, Departments of Medicine and Neurological Surgery, Oregon Health and Science University, Portland, OR, USA; [6]Neuroendocrine and Pituitary Tumor Clinical Center, Massachusetts General Hospital, Boston, MA, USA; [7]Neuroendocrinology Research Center/Endocrinology Division, Medical School and Hospital Universitario Clementino Fraga Filho, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil; [8]Camurus AB, Lund, Sweden; [9]Endocrinology Unit, Department of Internal Medicine, IRCCS Ospedale Policlinico San Martino, Genova, Italy

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SfE BES 2026 - Conflict Of Interest

Name: Diego Ferone

☑ I have the following potential conflicts of interest to report:

- **☑ Research Contracts**
- **☑ Consulting**
- **☐ Employment in the Industry**
- **☐ Stockholder of a healthcare company**
- **☐ Owner of a healthcare company**
- **☐ Other(s)**

☐ I declare that I have no potential conflict of interest.

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Introduction

- Overproduction of GH and IGF-I in acromegaly leads to increased mortality, substantial morbidity and significantly reduced QoL[1,2]
- Injectable first-generation SRLs (octreotide LAR or lanreotide ATG; SoC) can provide effective biochemical control but are typically administered by an HCP and can result in a substantial treatment burden[3–7]
- There is an unmet need for therapies that can provide biochemical control, reduce symptoms and have a lower treatment burden[6,8]

CAM2029 is a novel octreotide subcutaneous depot based on the FluidCrystal® technology[9,10]

- CAM2029 has a long-acting formula for **convenient monthly self-administration** via a **ready-to-use autoinjector pen** with small-gauge needle[10,11]
- CAM2029 has received **marketing authorisation in Europe and the UK** following the results of the 24-week, Phase 3, randomised, double-blind controlled **ACROINNOVA 1** trial[10–12]
  - CAM2029 achieved **superior biochemical control versus placebo** (**72.2% vs 37.5% of patients, respectively, with IGF-I ≤ULN; *P*=0.0018**), **controlled symptoms** and **improved QoL** in patients with IGF-I ≤ULN* on SoC† at screening[9]

ACROINNOVA 1 (NCT04076462).
*IGF-I ≤ULN and mean GH <2.5 µg/L at screening; †Treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg) for ≥3 months.
ATG, Autogel; GH, growth hormone; HCP, healthcare professional; IGF-I, insulin-like growth factor I; LAR, long-acting repeatable; QoL, quality of life; SoC, standard of care; SRL, somatostatin receptor ligand; ULN, upper limit of normal per age and sex.
1. Kasuki L *et al. Arch Endocrinol Metab* 2019;63:630–7; 2. Giustina A *et al. J Clin Endocrinol Metab* 2020;105:e937–46; 3. Melmed S *et al. Nat Rev Endocrinol* 2018;14:552–61; 4. Geer EB *et al. BMC Endocr Disord* 2020;20:117;
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12. Camurus AB. Oczyesa® (CAM2029). UK summary of product characteristics, 2025.

ACROINNOVA 2 trial design

A 52-week, Phase 3, open-label trial of CAM2029 in patients with acromegaly previously receiving SoC[1]

Key eligibility criteria:

- Diagnosis of acromegaly
- Stable treatment with SoC for ≥3 months*

ACROINNOVA 2 direct enrolment:
IGF-I levels ≤2×ULN at screening

ACROINNOVA 1 entry criteria:[2]
IGF-I levels ≤ULN and
mean GH <2.5 µg/L at screening

Autoinjector pen

Day 1 — **Week 24** — **Week 52**

Open-label treatment with CAM2029 20 mg† every 4 weeks (±1 week)
Administered using a pre-filled syringe‡ or autoinjector pen

Extension phase§

Patients enrolled directly into ACROINNOVA 2 (N=81)

CAM2029

ACROINNOVA 1
Phase 3, randomised, double-blind trial

Placebo

Prior-CAM2029 patients (N=36)

Prior-placebo patients (N=18)

SoC baseline
(prior to receiving first CAM2029/placebo dose)

Patients completing ACROINNOVA 1 could enter ACROINNOVA 2 at week 24

ACROINNOVA 2 (NCT04125836).
*Treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg); †If required based on safety and tolerability, the dose could be reduced to 10 mg CAM2029; ‡Only the autoinjector pen is available following marketing authorisation; §Upon completing the core phase in ACROINNOVA 2, patients could continue to receive CAM2029 in a 52-week extension phase.
ATG, Autogel; GH, growth hormone; IGF-I, insulin-like growth factor I; LAR, long-acting repeatable; SoC, standard of care; ULN, upper limit of normal per age and sex.
1. Clinicaltrials.gov. NCT04125836; 2. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

ACROINNOVA 2 trial design

A 52-week, Phase 3, open-label trial of CAM2029 in patients with acromegaly previously receiving SoC[1]

We report safety, biochemical and symptom control, and PROs during the 52-week core phase for the full data set

Autoinjector pen

SoC baseline
(prior to receiving first CAM2029/placebo dose)

Patients completing ACROINNOVA 1 could enter ACROINNOVA 2 at week 24

ACROINNOVA 2 (NCT04125836).
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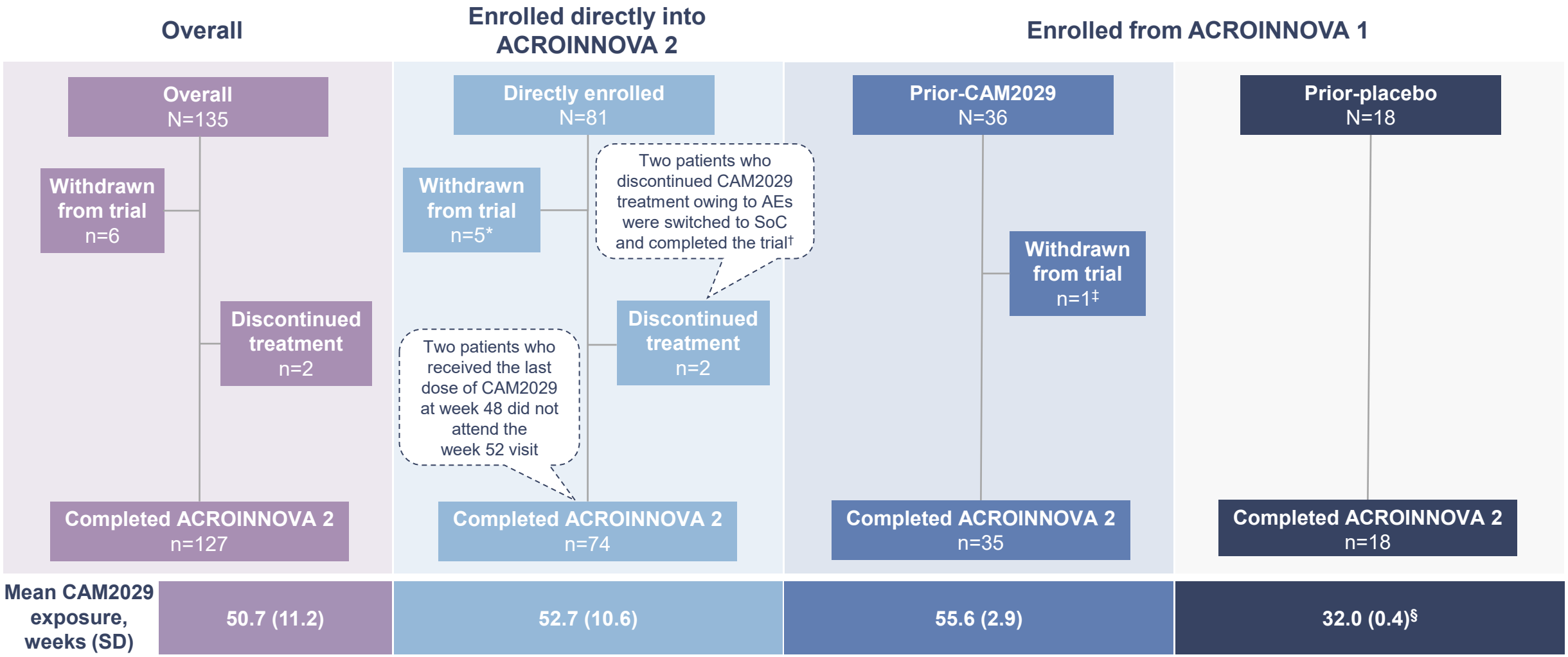
1. Clinicaltrials.gov .NCT04125836; 2. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

ACROINNOVA 2 core phase patient disposition



*Discontinued treatment and withdrawn from trial because of withdrawal of consent (n=5); †AE: injection site hemorrhage, Grade 1 (n=1), depression, Grade 1 (n=1); ‡Discontinued treatment and withdrawn from trial because patient declined to attend study site (n=1); §Patients received CAM2029 after 24 weeks of placebo.
AE, adverse event; SD, standard deviation; SoC, standard of care.

CAM2029 was well tolerated with no unexpected side effects

n (%)	Overall (N=135)	Directly enrolled (N=81)	Prior-CAM2029 (N=36)	Prior-placebo (N=18)
Any AE	**102 (75.6)**	**56 (69.1)**	**34 (94.4)**	**12 (66.7)**
Any CAM2029-related AE	74 (54.8)	39 (48.1)	23 (63.9)	12 (66.7)
Any Grade 3 AE	17 (12.6)	9 (11.1)	7 (19.4)	1 (5.6)
Any SAE	15 (11.1)	6 (7.4)	8 (22.2)	1 (5.6)
Any CAM2029-related SAE	1 (0.7)*	0	0	1 (5.6)*
AEs occurring in ≥10% of patients overall, by preferred term				
Injection site erythema	37 (27.4)	23 (28.4)	10 (27.8)	4 (22.2)
COVID-19	20 (14.8)	9 (11.1)	9 (25.0)	2 (11.1)
Injection site swelling	20 (14.8)	14 (17.3)	6 (16.7)	0
Headache	19 (14.1)	12 (14.8)	7 (19.4)	0
Arthralgia	17 (12.6)	7 (8.6)	10 (27.8)	0

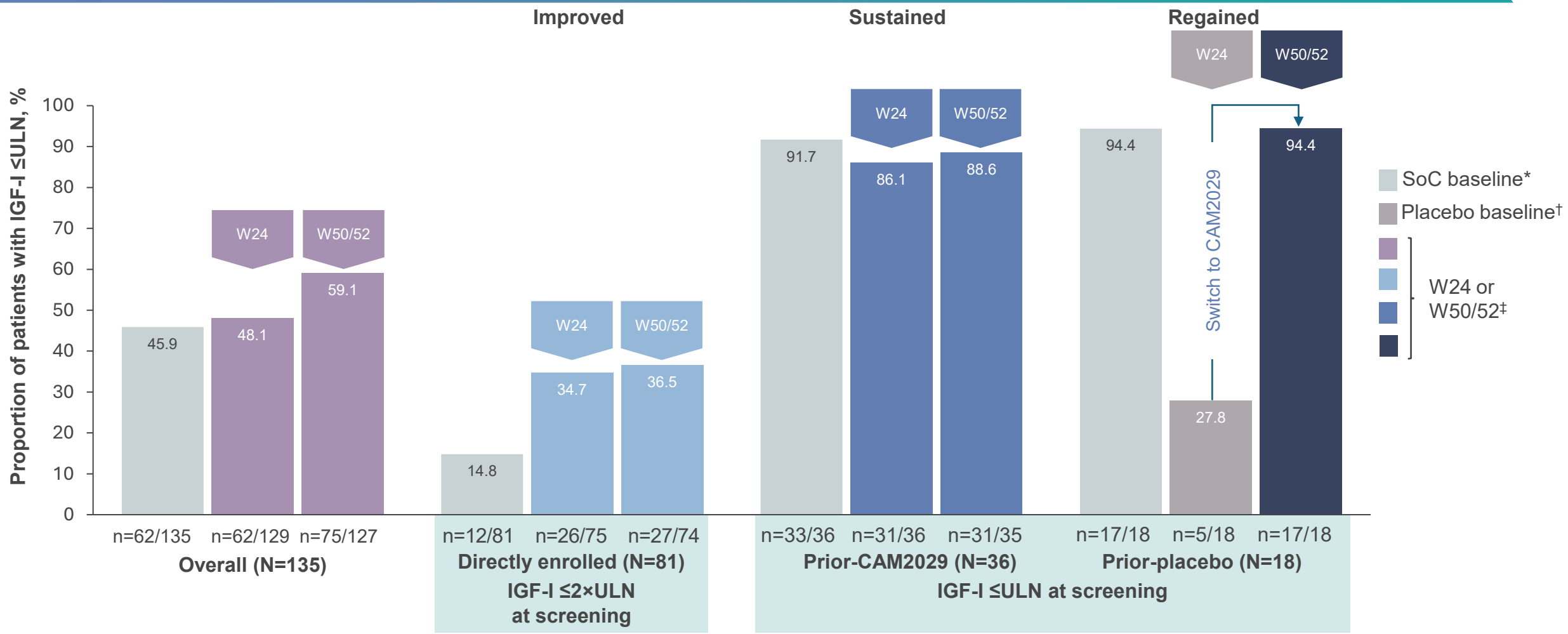
All injection site-related AEs were mild or moderate, and most were transient

AEs refer to treatment-emergent AEs. Only events reported from the first administration of CAM2029 and onwards are included. *Moderate (Grade 2) cholelithiasis (resolved).
AE, adverse event; n, number of patients experiencing the event; N, number of patients in the analysis set; COVID-19, Coronavirus Disease 2019; SAE, serious adverse event.

CAM2029 provided effective biochemical control of acromegaly for up to 52 weeks of treatment

Figure is based on all patients with available data at the timepoint. *Before receiving the first CAM2029/placebo dose; IGF-I values are means from assessments at week –2 and day 1; †Prior-placebo group includes one patient who switched to SoC from placebo during ACROINNOVA 1; IGF-I value is the mean from assessments at weeks 22 and 24; ‡IGF-I values are means from assessments at weeks 50 and 52.
IGF-I, insulin-like growth factor I; SoC, standard of care; ULN, upper limit of normal per age and sex; W, week.

CAM2029 provided effective biochemical control of acromegaly for up to 52 weeks of treatment



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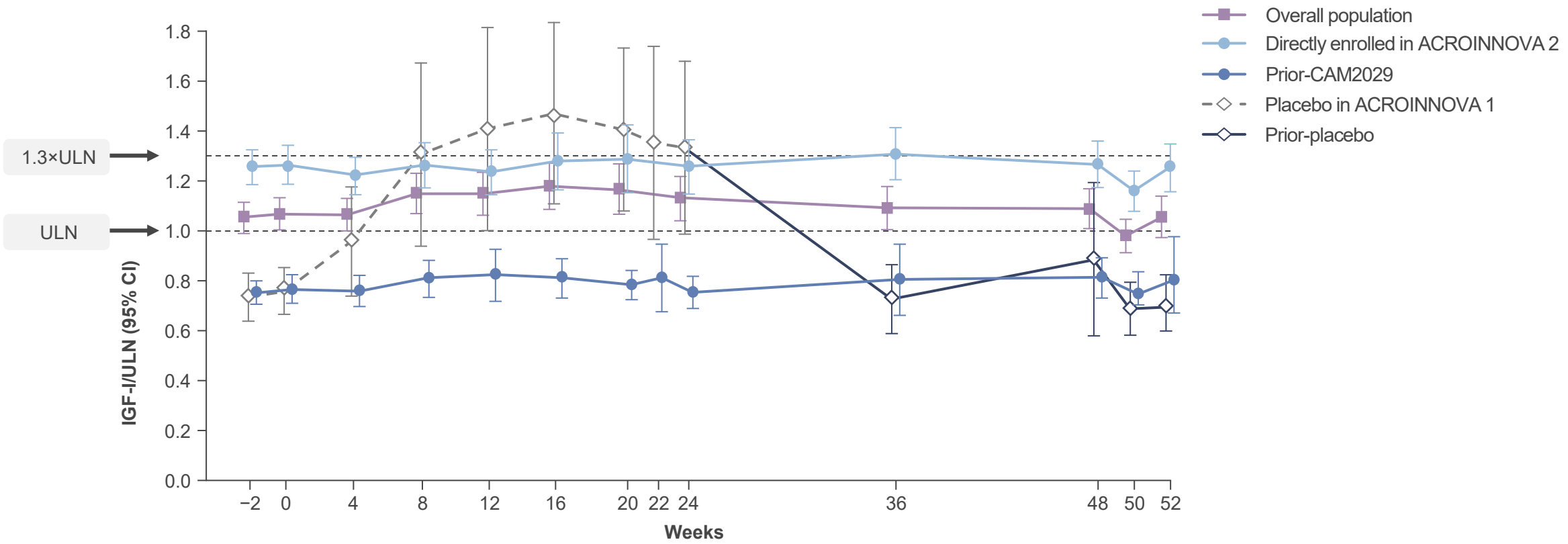
IGF-I, insulin-like growth factor I; SoC, standard of care; ULN, upper limit of normal per age and sex; W, week.

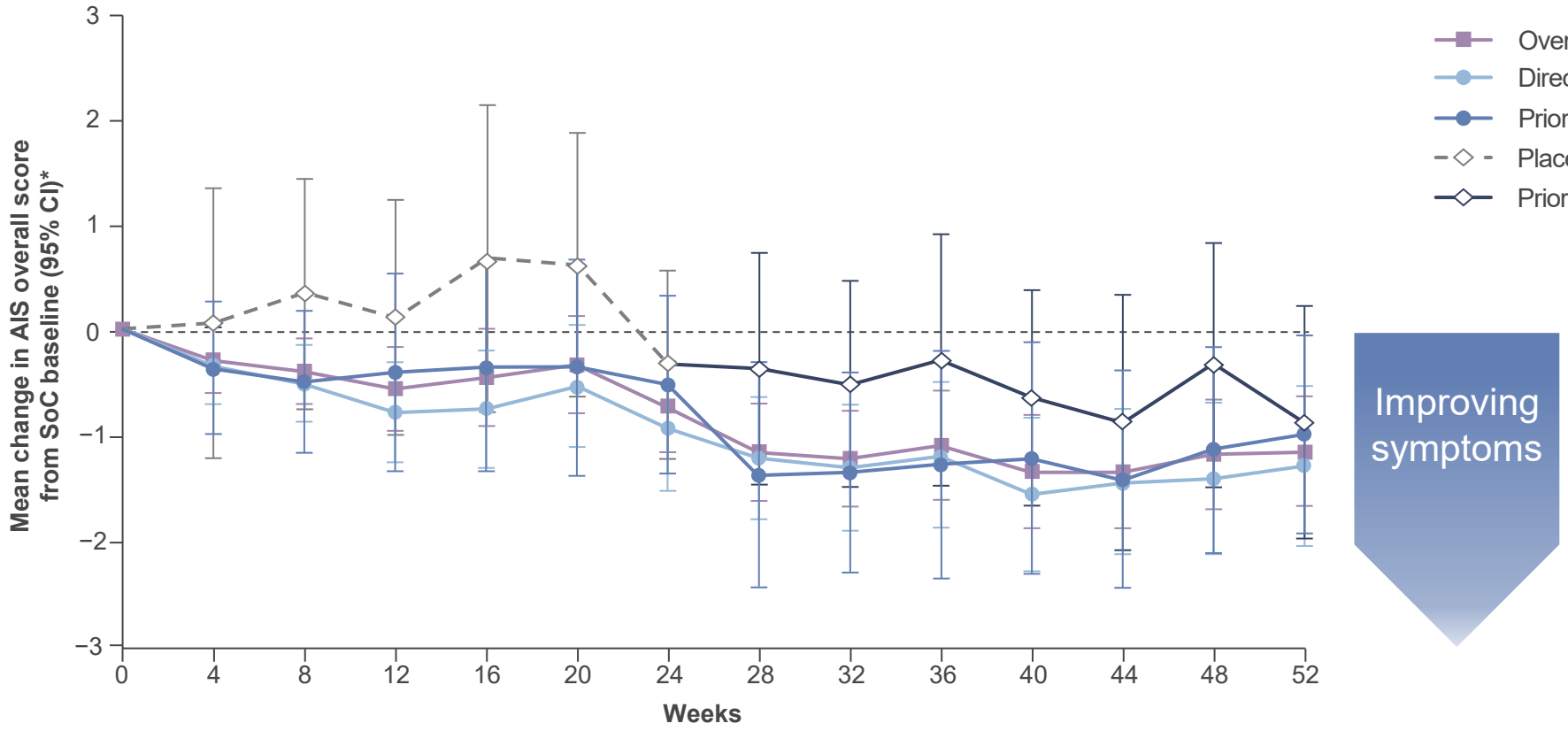
Mean IGF-I levels were stable in the overall population during CAM2029 treatment



Directly enrolled	n	81	81	80	80	80	79	78	NA	75	74	74	69	74
Prior-CAM2029	n	36	35	35	35	36	36	36	35	36	35	35	33	33
Prior-placebo	n	18	18	18	18	18	18	18	17	18	17	18	17	17
Overall	n	135	134	133	133	134	133	132	NA	129	126	127	119	124

Data are from the intention-to-treat population. Data shown include the 24-week placebo period before the prior-placebo group was switched to CAM2029 (pale grey diamonds); these patients are also included in the overall population.
CI, confidence interval; IGF-I, insulin-like growth factor; ULN, upper limit of normal, per age and sex.

Symptoms continuously improved from baseline to week 52 in the overall population



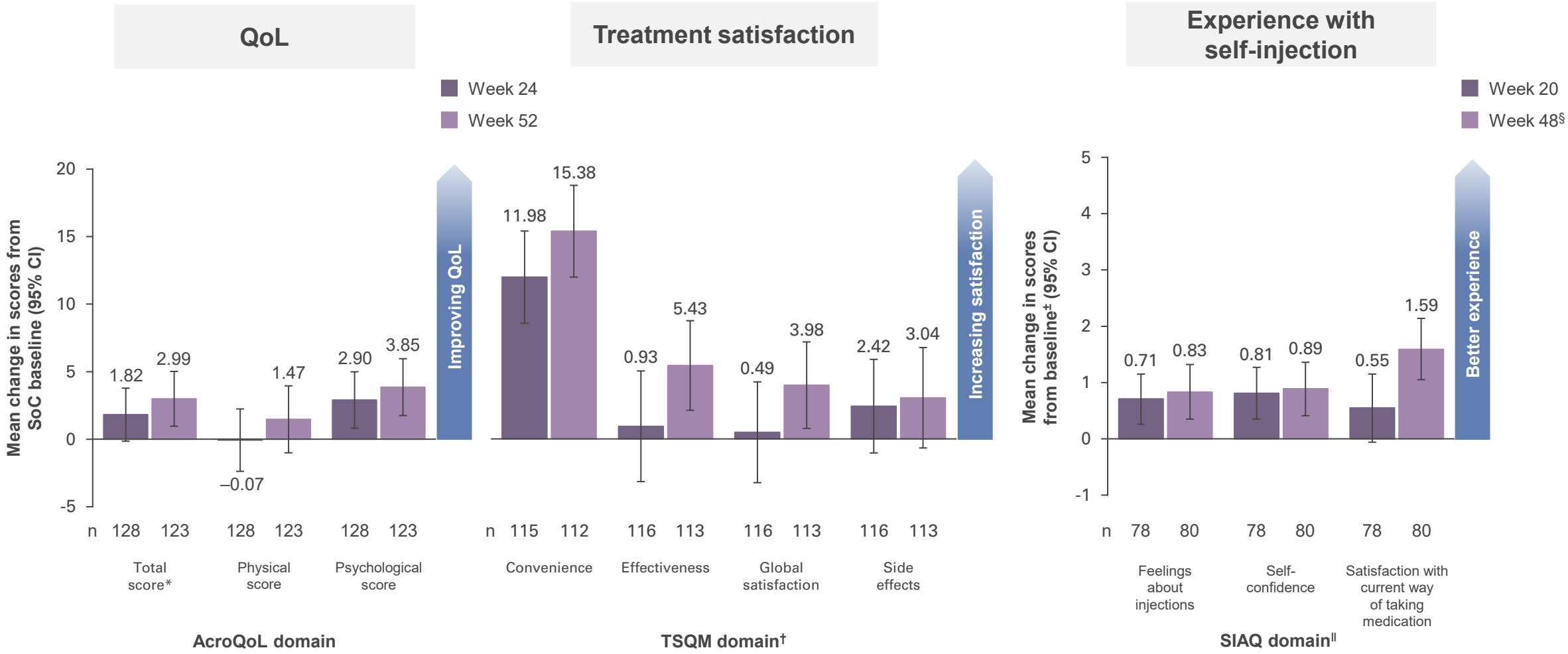
Directly enrolled	n	81	81	81	81	79	79	76	76	76	76	75	75	74	73
Prior-CAM2029	n	36	35	36	36	36	36	36	36	36	35	35	35	35	33
Prior-placebo	n	18	18	18	18	18	18	18	16	17	17	17	18	18	18
Overall	n	135	134	135	135	133	133	130	128	129	128	127	128	127	124

Data include the 24-week placebo period before the prior-placebo group switched to CAM2029 (pale grey diamonds); the group is also included in the overall population. *AIS 0–18; sum of scores (0–3; none–severe) for six symptoms (headache, sweating, fatigue, joint pain, paraesthesia and soft tissue swelling).[1]

AIS, Acromegaly Index of Severity; CI, confidence interval; SoC, standard of care.

1. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

In the overall population, PRO scores numerically improved from baseline and were maintained long-term



Data include the 24-week placebo period before the prior-placebo group switched to CAM2029; the group is also included in the overall population. *AcroQoL score range: 0–100.[1] †TSQM score range: 0–100.[2] ‡Baseline is defined as the last pre-treatment values before the first self-administration. §Patients assessed at week 48 or closest visit. ‖Score range: 0–10.[3] AcroQoL, Acromegaly Quality of Life Questionnaire; CI, confidence interval; PRO, patient-reported outcome; QoL, quality of life; SC, subcutaneous; SoC, standard of care; SIAQ, Self-Injection Assessment Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

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Conclusions

- CAM2029 was **well tolerated**, and **no unexpected safety signals** were observed with long-term treatment
- CAM2029 provided long-term biochemical control for up to 52 weeks. Biochemical control was:
  - **Improved** in the overall population and in patients directly enrolled (IGF-I ≤2×ULN at screening)
  - **Sustained** in prior-CAM2029 patients (IGF-I ≤ULN at screening,* CAM2029 in ACROINNOVA 1)
  - **Regained** in prior-placebo patients (IGF-I ≤ULN at screening,* placebo in ACROINNOVA 1)
- **Symptom burden progressively reduced** over 52 weeks of CAM2029 treatment
- Long-term CAM2029 treatment **continuously improved QoL and treatment satisfaction** versus SoC baseline

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These long-term findings support CAM2029 as an effective and well-tolerated new treatment for acromegaly, with the combined benefits of convenience and improved QoL

*IGF-I ≤ULN and mean GH <2.5 µg/L at screening, on treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg) for ≥3 months.
ATG, Autogel; GH, growth hormone; IGF-I, insulin-like growth factor I; LAR, long-acting repeatable; QoL, quality of life; SoC, standard-of-care; ULN, upper limit of normal per age and sex.

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