CAM2029 octreotide subcutaneous depot maintains biochemical and symptom control across a 4-week dosing interval and for intervals >28 days: data from the ACROINNOVA 2 trial

Mônica R. Gadelha,[1] Diego Ferone,[2] Maria Fleseriu,[3] Pietro Maffei,[4] Robert D. Murray,[5] Jochen Seufert,[6] Julie M. Silverstein,[7] Joanna L. Spencer-Segal,[8] Jacob Råstam,[9] Alberto M. Pedroncelli,[9] Fredrik Tiberg,[9] Beverly M. K. Biller[10]

[1]Neuroendocrinology Research Center/Endocrinology Division, Medical School and Hospital Universitario Clementino Fraga Filho, Universidade Federal do Rio de Janeiro, Rio de Janeiro, Brazil; [2]Endocrinology Unit, Department of Internal Medicine, IRCCS Ospedale Policlinico San Martino, Genova, Italy; [3]Pituitary Center, Departments of Medicine and Neurological Surgery, Oregon Health and Science University, Portland, OR, USA; [4]Department of Medicine, Padua University Hospital, Padua, Italy; [5]Department of Endocrinology, St James's University Hospital, Leeds Teaching Hospitals NHS Trust, Leeds, UK; [6]Division of Endocrinology and Diabetology, Department of Medicine II, Medical Centre – University of Freiburg, Freiburg, Germany; [7]Division of Endocrinology, Metabolism and Lipid Research, Department of Neurosurgery, Washington University School of Medicine, St. Louis, MO, USA; [8]Department of Internal Medicine and Michigan Neuroscience Institute, University of Michigan, Ann Arbor, MI, USA; [9]Camurus AB, Lund, Sweden; [10]Neuroendocrine and Pituitary Tumor Clinical Center, Massachusetts General Hospital, Boston, MA, USA

Poster no. P274

Scan QR code
for poster and supplement

Presenting author: Mônica R. Gadelha

BACKGROUND

- Biochemical control of acromegaly (insulin-like growth factor I [IGF-I] ≤upper limit of normal per age [ULN]) can be achieved by previously approved injectable somatostatin receptor ligands (SRLs; octreotide long-acting repeatable [LAR] and lanreotide Autogel [ATG])[1–3]
- Patients with acromegaly may experience waning biochemical and symptom control towards the end of monthly dosing intervals with previously approved injectable SRLs[4–7]
- CAM2029 is a prolonged-release octreotide subcutaneous depot (developed using FluidCrystal® technology) that can be self-administered via a pre-filled autoinjector[8–10] (**Supplementary Figure 1**, available via the QR code)
- CAM2029 was recently approved in Europe and the UK for the treatment of acromegaly following the results of the Phase 3 ACROINNOVA 1 (NCT04076462) and ACROINNOVA 2 (NCT04125836) trials[8,10–12]
- CAM2029 demonstrated stable IGF-I and symptom control across 4-week and >28-day dosing intervals in ACROINNOVA 1[13]
- We report descriptive data for IGF-I and symptom control over the final dosing interval for patients receiving long-term CAM2029 in ACROINNOVA 2

CONCLUSIONS

Long-term CAM2029 maintains stable IGF-I levels and symptom control across the 4-week post-dose interval in patients biochemically controlled or uncontrolled on standard of care (SoC) at screening

In patients with later assessments, biochemical control did not appear to markedly deteriorate in any treatment subgroup

Together with findings from ACROINNOVA 1, these results support the potential of long-term CAM2029 to reduce waning of disease control at the end of dosing intervals that can be observed with other injectable SRLs

METHODS

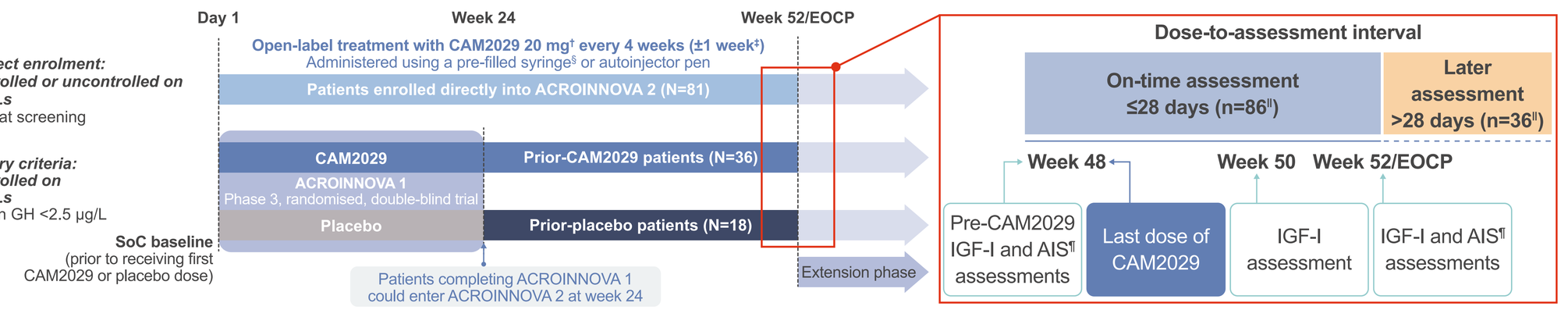
The stability of IGF-I and symptom control with long-term CAM2029 was evaluated over the final dosing interval of ACROINNOVA 2

Key eligibility criteria:

- Diagnosis of acromegaly
- Stable treatment with octreotide LAR or lanreotide ATG (SoC) for ≥3 months*

ACROINNOVA 2 direct enrolment: biochemically controlled or uncontrolled on first-generation SRLs
IGF-I levels ≤2×ULN at screening

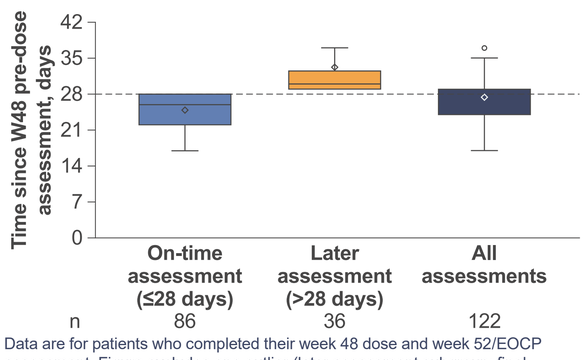
ACROINNOVA 1 entry criteria: biochemically controlled on first-generation SRLs
IGF-I ≤ULN and mean GH <2.5 µg/L at screening



*Octreotide LAR 10, 20, 30 or 40 mg or lanreotide ATG 60, 90 or 120 mg; †If required, dose reduction to 10 mg CAM2029 for safety and tolerability was permitted; ‡For patient convenience, administration of CAM2029/placebo was permitted within a window of ±1 week around each scheduled 4-weekly dose. Dose timings were not adjusted in relation to any potential lack of efficacy or safety issue; §A prefilled 1.0 mL syringe was used in ACROINNOVA 1; the autoinjector pen was introduced in ACROINNOVA 2; only the autoinjector pen is available following marketing authorisation; ‖Patients who completed week 48 treatment and week 52/EOCP IGF-I assessments; ¶Details of the AIS are provided in **Supplementary Figure 2**, available via the QR code. AIS, Acromegaly Index of Severity; EOCP, end of ACROINNOVA 2 core phase; GH, growth hormone; ULN, upper limit of normal per age and sex.

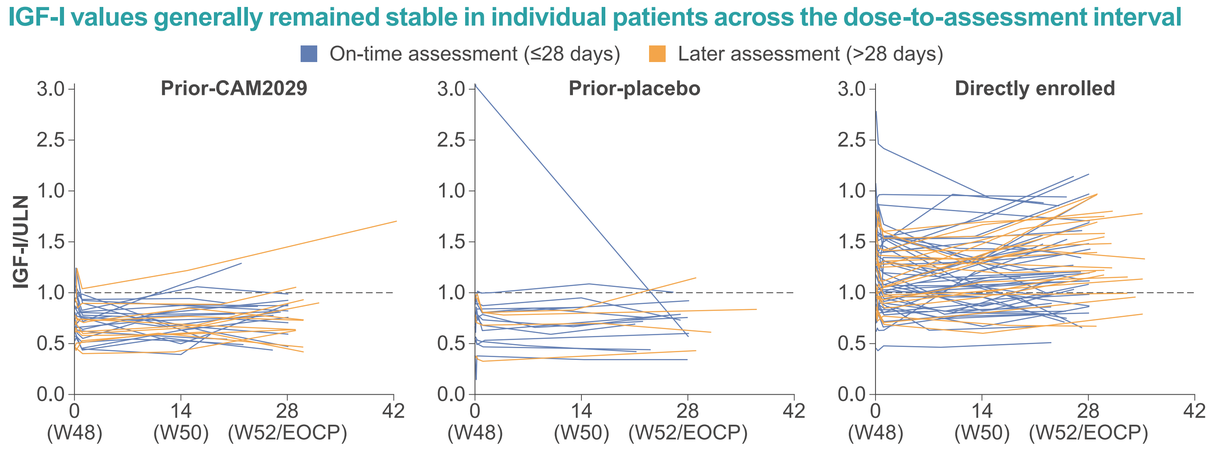
RESULTS

- A total of 135 patients were enrolled into ACROINNOVA 2, and 127 patients completed the trial
- Of patients completing ACROINNOVA 2, 122 received the week 48 CAM2029 dose and completed the IGF-I assessment at week 52/EOCP and are included in the current analysis
- Patient demographics and medical history are outlined in **Supplementary Table 1**
- Week 52/EOCP assessments were performed **on time** for 86 (70.5%) patients (the on-time assessment group) and were **later** for 36 (29.5%) patients (the later assessment group)
- The mean (range) duration of the final dose-to-assessment interval was:
  - 25.0 (17–28) days for the on-time assessment group
  - 33.2 (29–115) days for the later assessment group



Data are for patients who completed their week 48 dose and week 52/EOCP assessment. Figure excludes one outlier (later assessment subgroup; final dose-to-assessment interval 115 days). Box and whisker plot show median (middle line), interquartile range (top and bottom of box plot), mean (diamond), range (box plot whiskers) and outlier (circle).

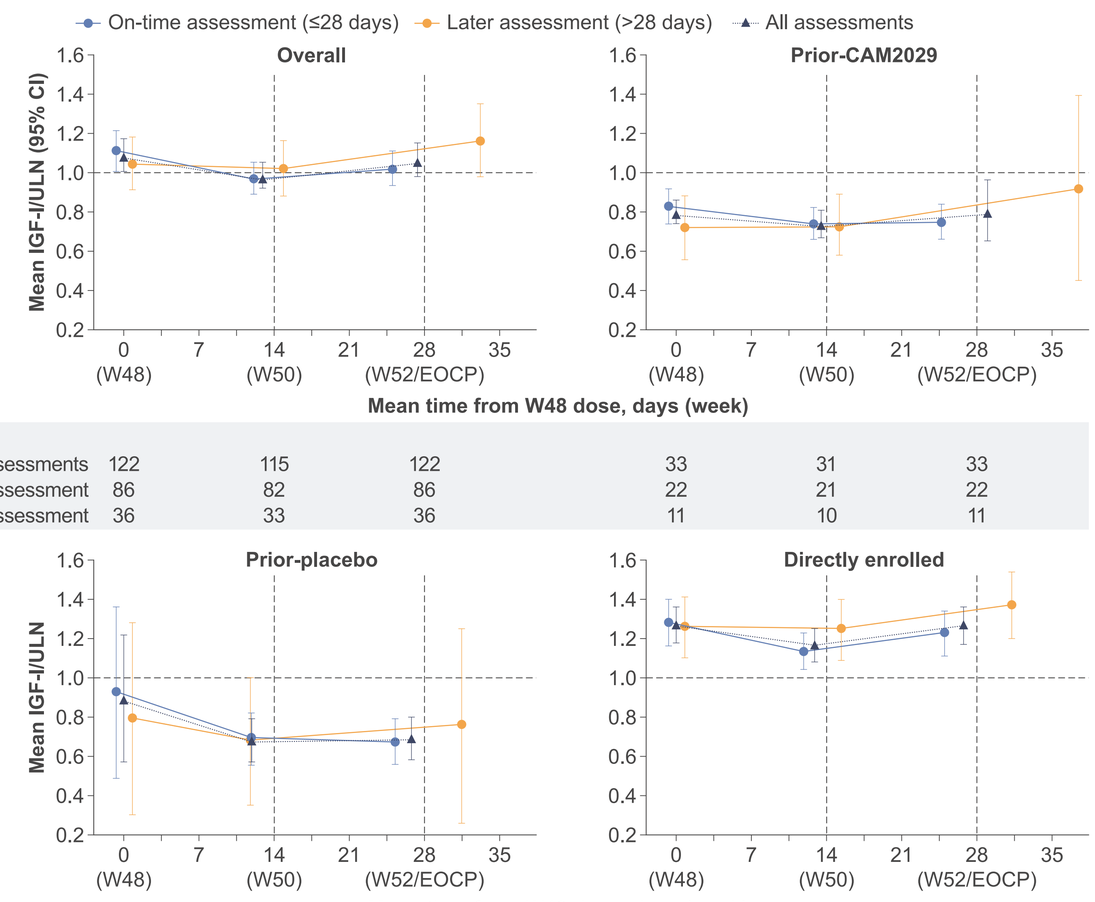
IGF-I values generally remained stable in individual patients across the dose-to-assessment interval



Week 48 assessments were conducted prior to CAM2029 administration. Additional samples, taken for pharmacokinetic analysis, were obtained at 2±1 hours, 5±1 hours, 8±1 hours and 24±4 hours post-CAM2029 administration and are shown here. Data are for patients who completed their week 48 dose and assessment at week 52/EOCP. The dashed grey horizontal rule represents ULN per age and sex.

- In the prior-CAM2029 and prior-placebo groups (IGF-I ≤ULN at baseline), IGF-I values remained stable below the ULN for most individuals, regardless of assessment timing
- IGF-I values appeared mostly stable among individuals in the directly enrolled group (IGF-I ≤2×ULN at baseline), irrespective of biochemical control during the dose-to-assessment interval

Mean IGF-I values were generally stable across the dose-to-assessment interval



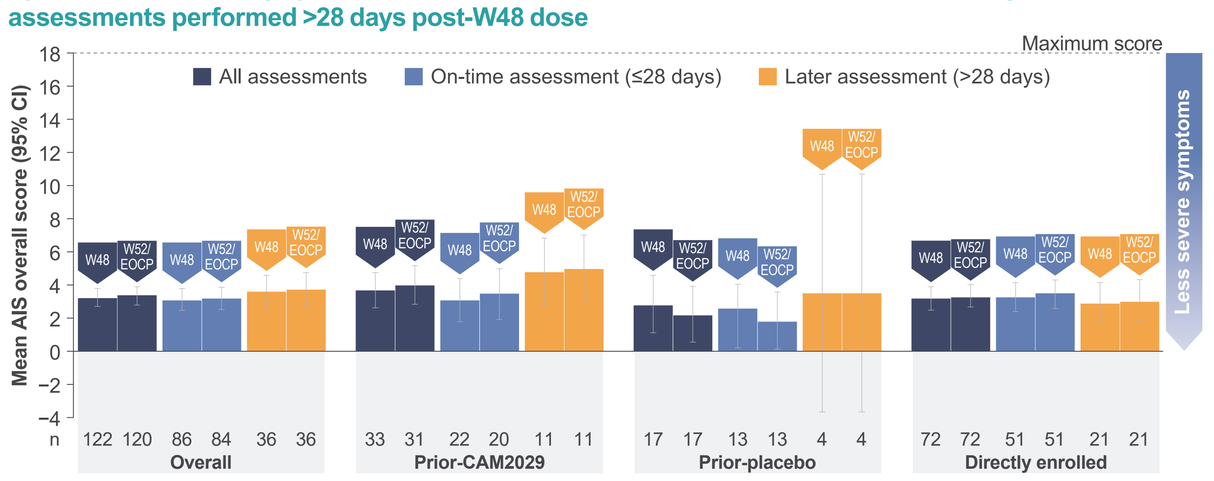
Patients, n						
All assessments	122	115	122	33	31	33
On-time assessment	86	82	86	22	21	22
Later assessment	36	33	36	11	10	11

Patients, n						
All assessments	17	16	17	72	68	72
On-time assessment	13	12	13	51	49	51
Later assessment	4	4	4	21	19	21

Week 48 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their week 48 dose and week 52/EOCP assessment. The dashed grey horizontal rule represents ULN per age and sex. CI, confidence interval; W, week.

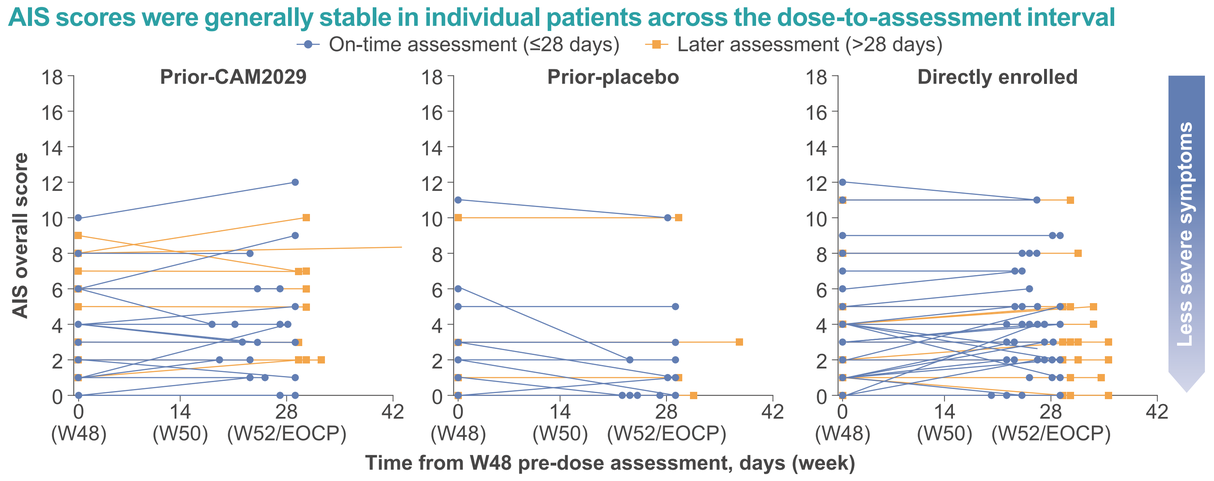
- In the prior-CAM2029 and prior-placebo groups, mean IGF-I levels remained ≤ULN at week 52/EOCP, regardless of assessment timing
- In the directly enrolled group (biochemically controlled or uncontrolled at screening), mean IGF-I was stable across the dose-to-assessment interval, regardless of timing
- Mean IGF-I levels showed greater variation when dose-to-assessment intervals were prolonged at later assessments compared with shorter intervals at on-time assessments

Symptoms of acromegaly were well controlled across the treatment interval, including in patients with assessments performed >28 days post-W48 dose



AIS scores range from 0 (lowest) to 18 (highest); sum of 6 scores (0–3; none–severe) for headache, sweating, fatigue, joint pain, paraesthesia, and soft tissue swelling. A reduction in AIS overall score indicates improvement in symptoms.

AIS scores were generally stable in individual patients across the dose-to-assessment interval



AIS scores range from 0 (lowest) to 18 (highest); sum of 6 scores (0–3; none–severe) for headache, sweating, fatigue, joint pain, paraesthesia, and soft tissue swelling. A reduction in AIS overall score indicates improvement in symptoms.

References

1. Giustina A *et al. Pituitary* 2024;27:7–22; **2.** Melmed S *et al. Nat Rev Endocrinol* 2025;21:718–37; **3.** Fleseriu M *et al. Lancet Diabetes Endocrinol* 2022;10:804–26; **4.** Maione L *et al. J Clin Endocrinol Metab* 2022;107:e3644–53; **5.** Strasburger CJ *et al. Eur J Endocrinol* 2016;174:355–62; **6.** Geer EB *et al. BMC Endocr Disord* 2020;20:117; **7.** Remba-Shapiro I *et al. Eur J Endocrinol* 2025;193:564–73; **8.** Camurus AB. Oczyesa® (CAM2029). EU Summary of Product Characteristics, 2025; **9.** Tiberg F *et al. Br J Clin Pharmacol* 2015;80:460–72; **10.** Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39; **11.** Spencer-Segal JL *et al.* ESPE/ESE 2025; Poster RC4.4a; **12.** Camurus AB. Oczyesa® (CAM2029). UK Summary of Product Characteristics, 2025; **13.** Gadelha MR *et al.* ENDO 2025; Poster SUN-097.

Acknowledgements and disclosures

The ACROINNOVA 2 trial was funded by Camurus AB. Thank you to the patients, investigators, nurses and trial coordinators who made this trial possible. Medical writing assistance was provided by Esther Illman, MSc, MBChB, at Amiculum® and was funded by Camurus AB.

The presenter, Mônica R. Gadelha, has received speaker fees from Recordati, Novo Nordisk A/S, Crinetics Pharmaceuticals and Camurus AB, has attended advisory boards for Camurus AB, Novo Nordisk A/S, Recordati and Crinetics Pharmaceuticals, and is principal investigator in trials for Alexion Pharmaceuticals, Crinetics Pharmaceuticals and DebioPharm.

Presented at the European Congress of Endocrinology (ECE) 2026; Prague, Czech Republic; 9–12 May 2026.