Long-term CAM2029 octreotide depot maintains biochemical and symptom control in acromegaly across a 4-week dosing interval and during intervals >28 days: data from the ACROINNOVA 2 trial

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Poster no. MON-038

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BACKGROUND

- Waning biochemical and symptom control have been reported in patients with acromegaly toward the end of dosing intervals with previously approved injectable somatostatin receptor ligands (SRLs; octreotide long-acting repeatable [LAR] and lanreotide Autogel [ATG])[1–4]
- CAM2029 is a prolonged-release octreotide subcutaneous depot developed using FluidCrystal® technology that can be self-administered via a pre-filled autoinjector[5–7] (see **Supplementary Figure 1**, available via the QR code)
- In ACROINNOVA 1 (NCT04076462), CAM2029 demonstrated stable biochemical (insulin-like growth factor I [IGF-I] ≤upper limit of normal per age and sex [ULN]) and symptom control across 4-week dosing intervals in patients controlled at baseline on previously approved injectable SRLs[8]
- We report descriptive data for biochemical and symptom stability over the final dosing interval for patients with acromegaly receiving long-term CAM2029 in ACROINNOVA 2 (NCT04125836)

CONCLUSIONS

Long-term CAM2029 maintains stable biochemical and symptom control over a 4-week post-dose interval

These results reinforce the findings from ACROINNOVA 1, in which disease control was stable across the dosing interval at 24 weeks of CAM2029 treatment

CAM2029 is an option for patients who are not controlled for the duration of the dosing interval on other injectable SRLs

METHODS

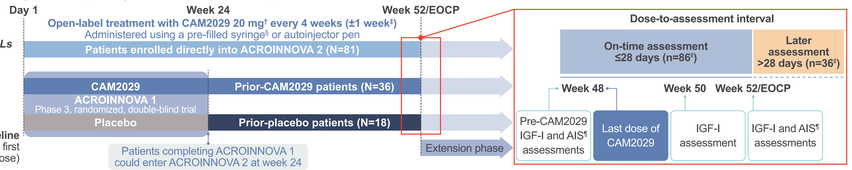
ACROINNOVA 2 core phase study design and split by on-time and later post-final dose assessment

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

ACROINNOVA 2 direct enrollment: 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

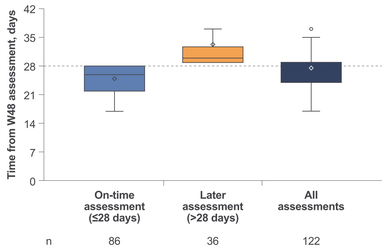
SoC baseline
(prior to receiving first CAM2029 or placebo dose)



*Octreotide LAR 10, 20, 30 or 40 mg or lanreotide ATG 60, 90 or 120 mg; †If required, dose reduction to CAM2029 10 mg 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 pre-filled 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 authorization;[5] ¶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; SoC, standard of care.

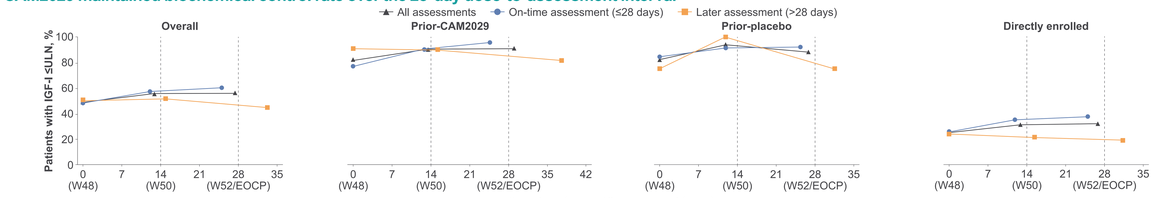
RESULTS

- A total of 135 patients were enrolled into ACROINNOVA 2
  - 122 patients received the final week 48 dose and had IGF-I assessment at week 52/EOCP and were included in the analysis reported here
  - Patient demographics and medical history are detailed in **Supplementary Table 1**
- Overall, 86 (70.5%) patients had on-time week 52/EOCP assessments (the on-time assessment group; prior-CAM2029 n=22, prior-placebo n=13, directly enrolled n=51) and 36 (29.5%) patients had later week 52/EOCP assessments (the later assessment group; prior-CAM2029 n=11, prior-placebo n=4, directly enrolled n=21)
- The mean (range) duration from week 48 dose to week 52/EOCP assessment (the final dosing interval) was:
  - 25.0 days (17–28) for the on-time assessment group
  - 33.2 days (29–115) 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). W, week.

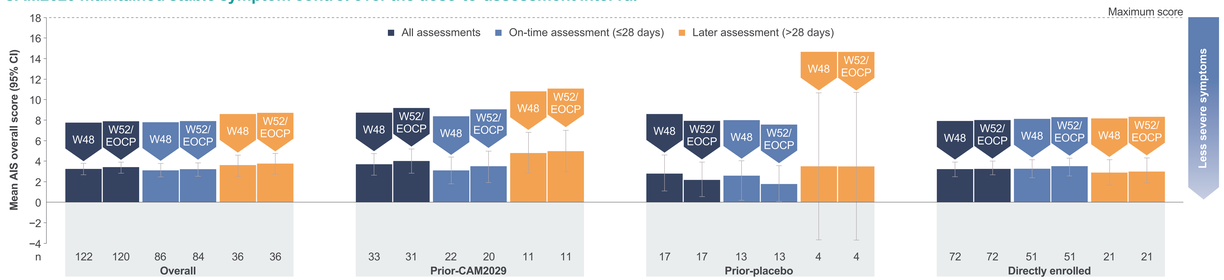
CAM2029 maintained biochemical control rate over the 28-day dose-to-assessment interval



n/N												
▲	59/122	64/115	68/122	27/33	28/31	30/33	14/17	15/16	15/17	18/72	21/68	23/72
●	41/86	47/82	52/86	17/22	19/21	21/22	11/13	11/12	12/13	13/51	17/49	19/51
■	18/36	17/33	16/36	10/11	9/10	9/11	3/4	4/4	3/4	5/21	4/19	4/21

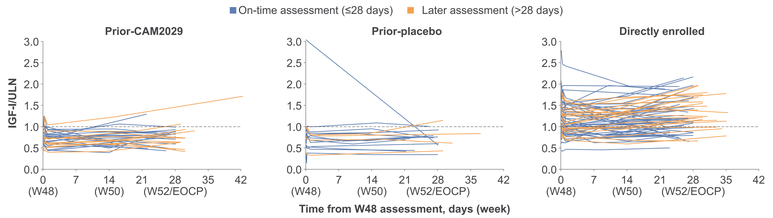
Data are for patients who completed their week 48 dose and week 52/EOCP assessment. Days describe the duration from week 48 dose to week 52/EOCP assessment.

CAM2029 maintained stable symptom control over the dose-to-assessment interval



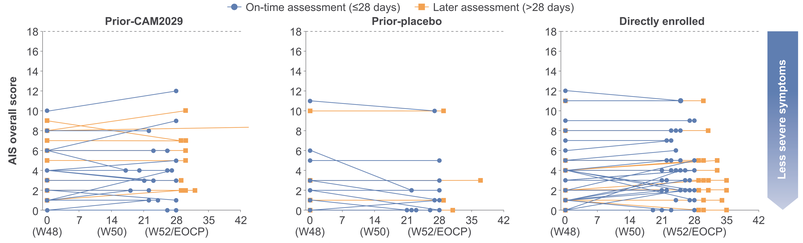
AIS scores range from 0 (lowest) to 18 (highest); sum of 6 scores (0–3; none–severe) for headache, sweating, fatigue, joint pain, paresthesia, and soft tissue swelling. A reduction in AIS overall score indicates improvement in symptoms. CI, confidence interval.

IGF-I values were generally 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 gray horizontal rule represents ULN per age and sex.

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



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ENDO TOPICAL CATEGORY
NEUROENDOCRINOLOGY AND PITUITARY

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Acknowledgments 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, Alberto M. Pedroncelli, is an employee and shareholder of Camurus AB, and is a shareholder of Novartis AG and Recordati.

Presented at the Endocrine Society's Annual Meeting (ENDO) 2026; Chicago, IL, USA; June 13–16, 2026.