# CAM2029 octreotide subcutaneous depot maintains control of IGF-I and symptoms of acromegaly across a 4-week dosing interval and for intervals greater than 28 days: data from the ACROINNOVA 1 trial

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

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

Poster no. P191

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**Presenting author:** Diego Ferone

## BACKGROUND

- Acromegaly is characterised by the overproduction of growth hormone (GH) and insulin-like growth factor I (IGF-I), leading to substantial morbidity and reduced quality of life (QoL)[1]
- Biochemical control (IGF-I ≤upper limit of normal [ULN] per age)[2,3] can be provided by standard-of-care (SoC) medical treatment (first-generation injectable somatostatin receptor ligands [SRLs]; octreotide long-acting repeatable [LAR] or lanreotide Autogel [ATG])[4]
- For patients with acromegaly, symptom control is a priority.[5] However, some patients report worsening or re-emergence of symptoms towards the end of the SoC monthly dosing interval[6,7]
- CAM2029 is a novel octreotide subcutaneous depot (based on the FluidCrystal® technology) with a long-acting formula for convenient monthly self-administration via a ready-to-use pre-filled pen (autoinjector) with a small-gauge needle[8,9] (see **Supplementary Figure 1**, available via the QR code)
- ACROINNOVA 1 was a 24-week, Phase 3, randomised, double-blind, placebo-controlled trial (NCT04076462) of once-monthly CAM2029 (±1 week) in patients with IGF-I ≤ULN per age and sex while receiving SoC treatment at screening[9]
  - CAM2029 achieved superior IGF-I control versus placebo (72.2 vs 37.5% of patients, respectively; *P*=0.0018)
  - Patients receiving CAM2029 had well-controlled symptoms and improved QoL compared with baseline SoC
  - The safety profile was consistent with those of first-generation SRLs

## CONCLUSIONS

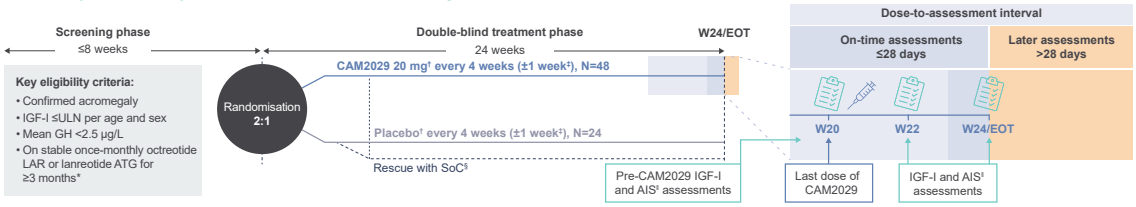
**In patients biochemically controlled at screening on SoC and receiving CAM2029 for 24 weeks, IGF-I control was maintained and symptoms were consistently well managed throughout a 4-week post-dose interval**

**More than half of patients had later assessments (intervals >28 days); these patients also maintained biochemical and symptom control**

**These findings provide useful information on the efficacy profile of CAM2029 lasting beyond a 28-day dosing window, reinforcing the potential of CAM2029 to control the burden of disease and address unmet needs among patients with acromegaly**

## METHODS

### The stability of IGF-I and symptom control was evaluated following the final CAM2029 dose in ACROINNOVA 1



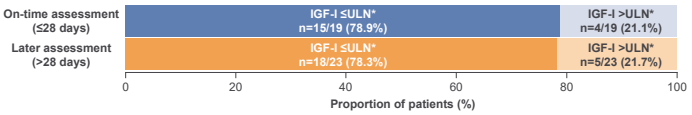

- We report descriptive data from W20, W22 and W24/EOT from patients completing their W20 CAM2029 dose and their W24/EOT assessments, with either assessments performed at ≤28 days post-dose (on-time assessments) or assessments performed at >28 days post-dose (later assessments):
  - Proportion of patients with IGF-I ≤ULN (W24/EOT only)
  - IGF-I/ULN values (subgroup means and individual patients)
  - AIS overall scores (subgroup means and individual patients)
  - Proportion of patients with individual symptoms of acromegaly (subgroups)

Adapted from Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39. *Octreotide LAR 10, 20, 30 or 40 mg or lanreotide ATG 60, 90 or 120 mg; †If required, dose reduction to 10 mg CAM2029 or 0.5 mL placebo for safety and tolerability; ‡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; §Patients who were rescued by switch to SoC continued to participate in the trial and attended all planned visits (n=1, placebo group); ‖Details of the AIS (evaluation of key acromegaly symptoms by clinician and patient together) are provided in **Supplementary Figure 2**, available via the QR code. AIS, Acromegaly Index of Severity; EOT, end of trial; W, week.

## RESULTS

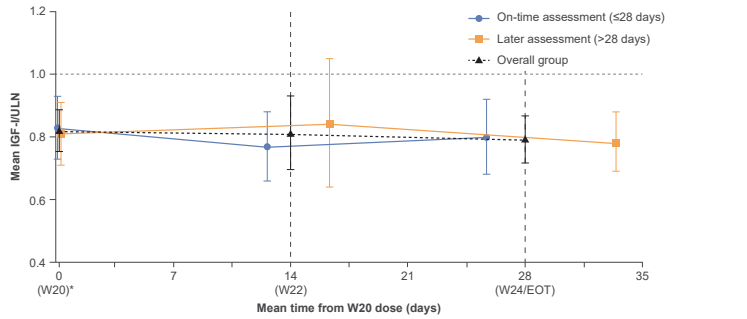
- 48 patients were randomised to CAM2029 in ACROINNOVA 1 (see **Supplementary Table 1** for more details, available via the QR code)[9]
- 42 (87.5%) patients completed CAM2029 treatment and formed the population for the analyses reported here[9]
  - Two patients withdrew from the trial and four discontinued treatment because of adverse events
- W24/EOT assessments were performed ≤28 days post-dose (on time) for 19 (45.2%) patients and were later (>28 days post-dose) for 23 (54.8%) patients (including six patients with assessments delayed >35 days post-dose). Some later assessments were due to COVID-19
- The mean (range) duration of the final dosing interval was:
  - 25.7 (21–28) days for the on-time assessment group
  - 33.4 (29–42) days for the later assessment group

### Most patients achieved biochemical control at W24/EOT, including those with assessments performed >28 days post-W20 dose



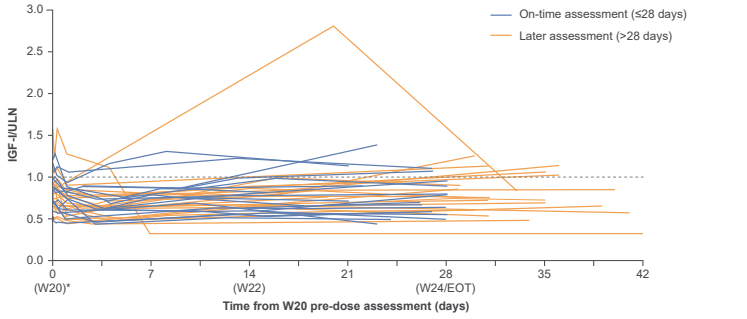

Data are for patients who completed their W20 dose and post-final dose assessments (N=42). *ULN per age and sex.

### Mean IGF-I values remained stable throughout the dose-to-assessment interval, including in patients with assessments performed >28 days post-W20 dose



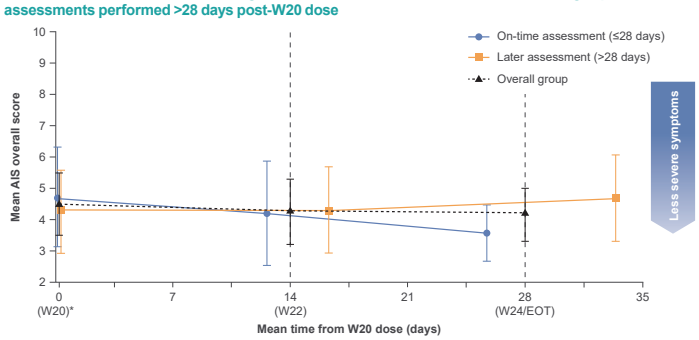

*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). Error bars represent ±95% CI. The grey horizontal rule represents ULN per age and sex. CI, confidence interval.

### IGF-I values generally remained stable in individual patients, including in those with assessments performed >28 days post-W20 dose



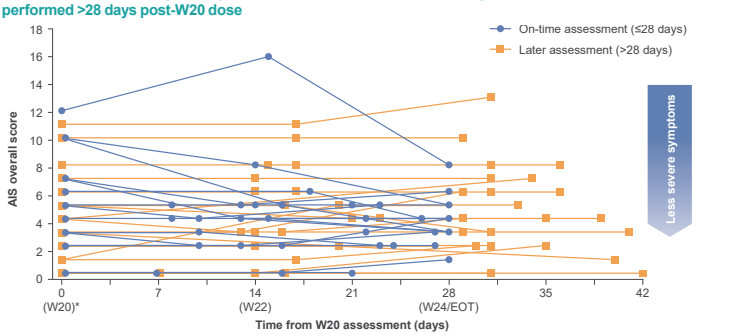

*W20 assessments were conducted prior to CAM2029 administration. Additional samples were taken at 2±1 hours, 5±1 hours, 8±1 hours, 24±4 hours and 96±24 hours post-CAM2029 administration are shown here. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). The grey horizontal rule represents ULN per age and sex. Results for the W22 assessment show a single outlier result with raised IGF-I; this patient had normal IGF-I levels at W20 and W24/EOT assessments, suggesting this result is an artefact.

### AIS overall scores were stable throughout the dose-to-assessment interval, including in patients with assessments performed >28 days post-W20 dose




*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). 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. Error bars represent ±95% CI. Individual patient AIS scores were generally stable, including among those with later assessments. Control of individual symptoms was maintained throughout the dose-to-assessment interval, including among patients with assessments performed >28 days post-dose. See **Supplementary Figure 3** for more details, available via the QR code.

### AIS overall scores were generally stable in individual patients, including in those with assessments performed >28 days post-W20 dose




*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). 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.** Gadelha MR *et al. Endocr Rev* 2019;40:268–332; **2.** Giustina A *et al. Pituitary* 2024;27:7–22; **3.** Giustina A *et al. Rev Endocr Metab Disord* 2020;21:667–78; **4.** Fleseriu M *et al. Lancet Diabetes Endocrinol* 2022;10:804–26; **5.** Gurel MH *et al. Patient Prefer Adherence* 2014;8:53–62; **6.** Strasburger CJ *et al. Eur J Endocrinol* 2016;174:355–62; **7.** Geer EB *et al. BMC Endocr Disord* 2020;20:117; **8.** Tiberg F *et al. Br J Clin Pharmacol* 2015;80:460–72; **9.** Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.



## Acknowledgements and disclosures

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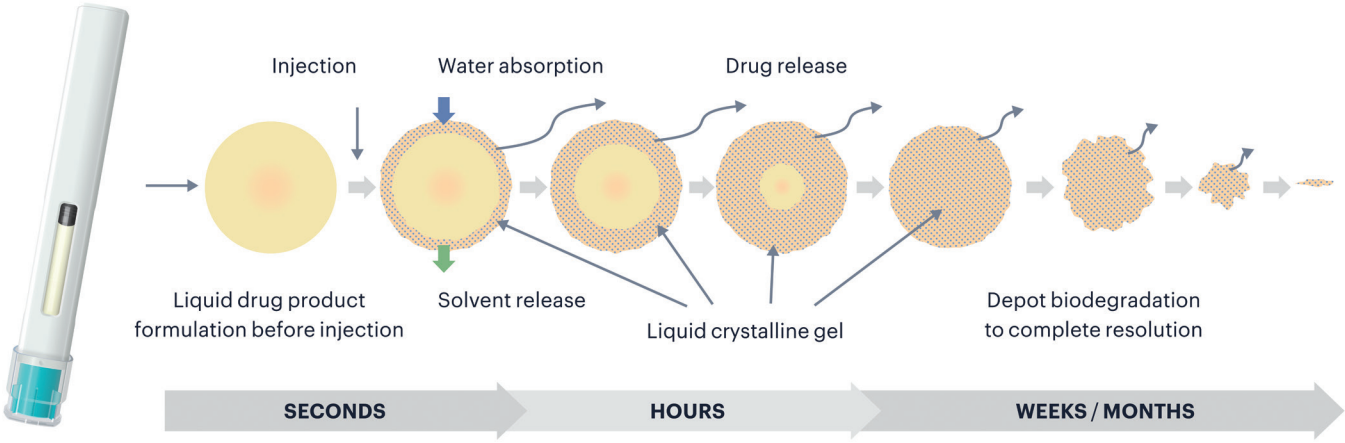
# Supplementary material

## Supplementary Figure 1: The FluidCrystal® drug delivery system[1–5]

CAM2029 pre-filled pen (autoinjector)



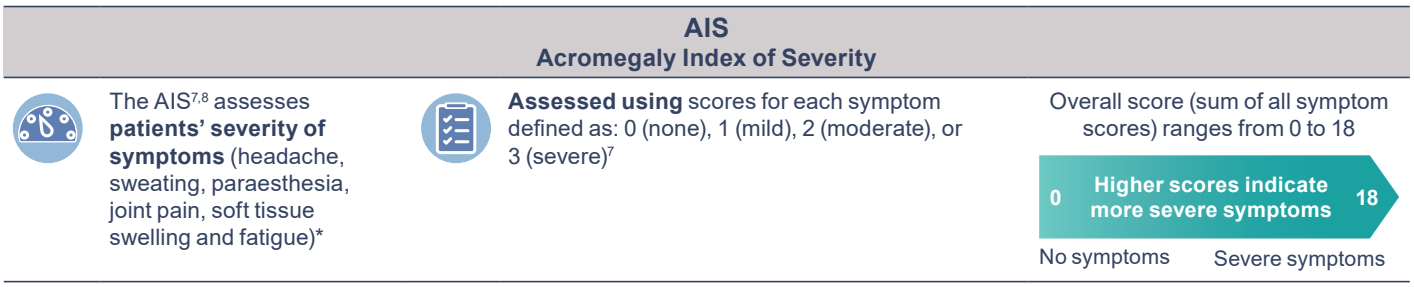

In ACROINNOVA 1, CAM2029 was administered via pre-filled syringes.[5] Only the pre-filled pen (autoinjector) is available following marketing authorisation.[6]

## Supplementary Table 1: Patient demographics and medical history

| | Overall[5] N=48 | On-time assessment (≤28 days) n=19 | Later assessment (>28 days) n=23 |
|---|---|---|---|
| **Mean age**, years (SD) | 57 (11.2) | 59 (9.4) | 54 (12.7) |
| **Sex,** n (%) | | | |
| Female | 28 (58.3) | 13 (68.4) | 11 (47.8) |
| Male | 20 (41.7) | 6 (31.6) | 12 (52.2) |
| **Mean time since diagnosis**, years (SD) | 10.8 (6.8) | 13 (8.5) | 9 (5.5) |
| **Prior pituitary surgery history,** n (%) | 42 (87.5) | 17 (89.5) | 20 (87.0) |
| **Baseline treatment,** n (%) | | | |
| Octreotide LAR | 25 (52.1) | 9 (47.4) | 13 (56.5) |
| Lanreotide ATG | 23 (47.9) | 10 (52.6) | 10 (43.5) |

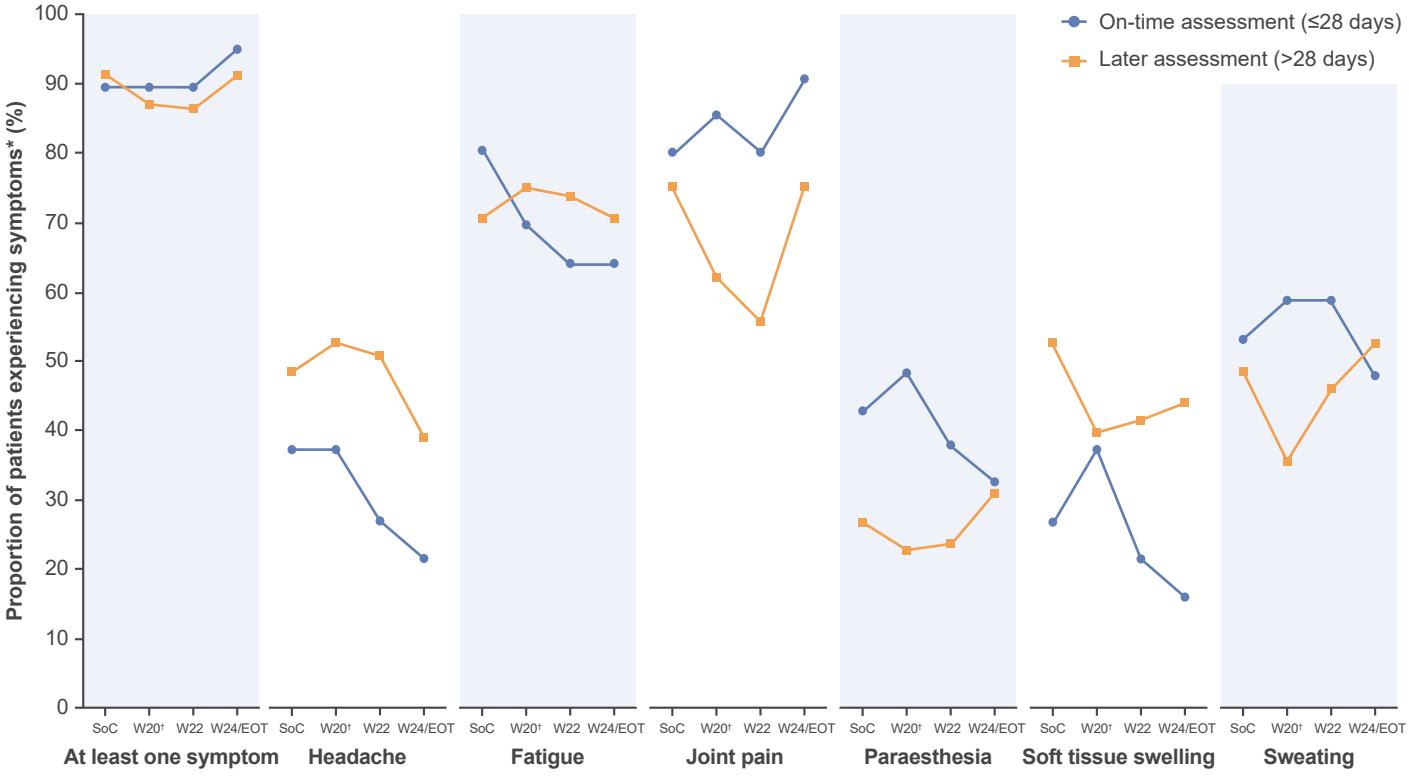
Adapted from Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39. ATG, Autogel; LAR, long-acting repeatable; SD, standard deviation.

## Supplementary Figure 2: Overview of AIS




ACROINNOVA 1 was not powered to assess changes in acromegaly symptom severity using the AIS. *In ACROINNOVA 1, paraesthesia was included in addition to the five symptoms assessed with the AIS in Fleseriu *et al* 2020.[5] AIS, Acromegaly Index of Severity.

## Supplementary Figure 3: Control of individual symptoms was maintained throughout the dose-to-assessment interval, including among patients with assessments performed >28 days post-dose




*Symptoms included in the AIS assessment; †W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). W20 assessments were conducted prior to CAM2029 administration.
EOT, end of trial; SoC, standard of care; W, week.

## References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