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

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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

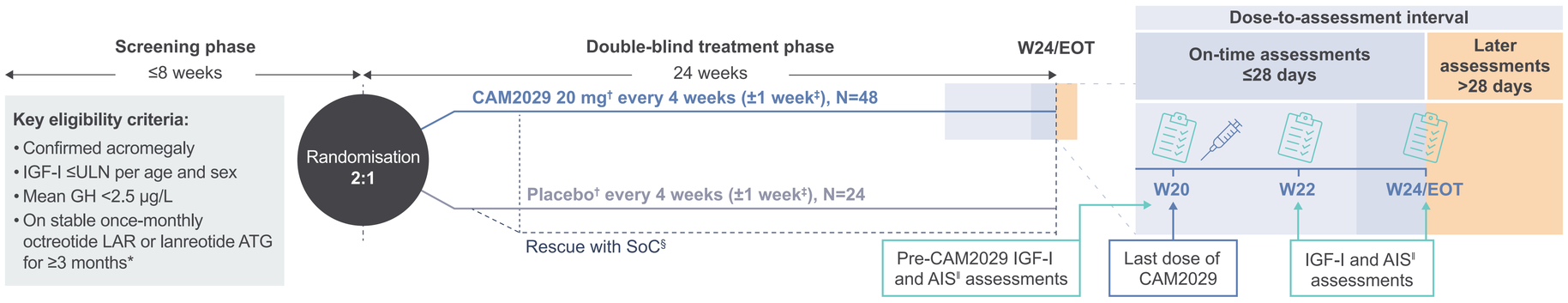
In patients biochemically controlled at screening on SoC and receiving CAM2029 for 24 weeks, IGF-I control was maintained and symptoms were consistently well managed throughout a 4-week post-dose interval

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



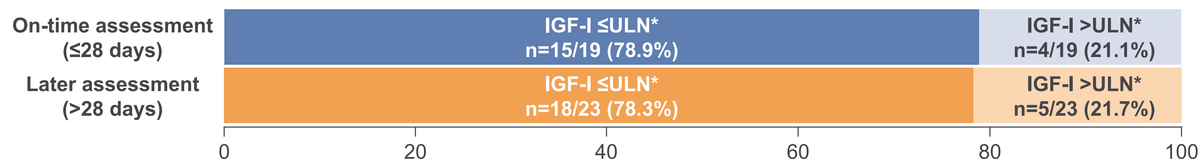
- We report descriptive data from W20, W22 and W24/EOT from patients completing their W20 CAM2029 dose and their W24/EOT assessments, with either assessments performed at ≤28 days post-dose (on-time assessments) or assessments performed at >28 days post-dose (later assessments):
  - Proportion of patients 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

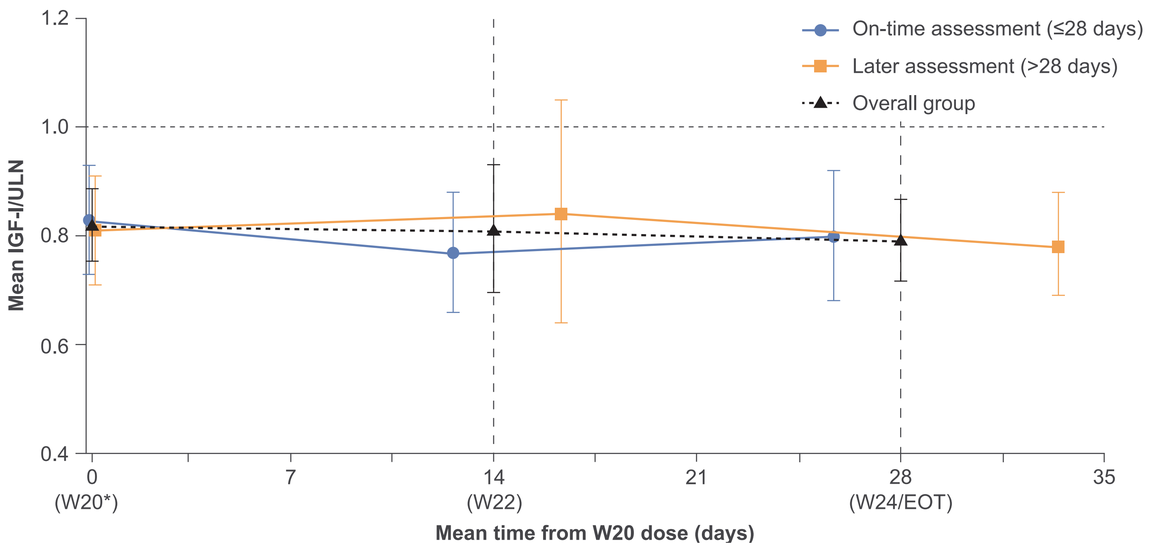
- 48 patients were randomised to CAM2029 in ACROINNOVA 1 (see **Supplementary Table 1** for more details, available via the QR code)[9]
- 42 (87.5%) patients completed CAM2029 treatment and formed the population for the analyses reported here[9]
  - Two patients withdrew from the trial and four discontinued 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-dose



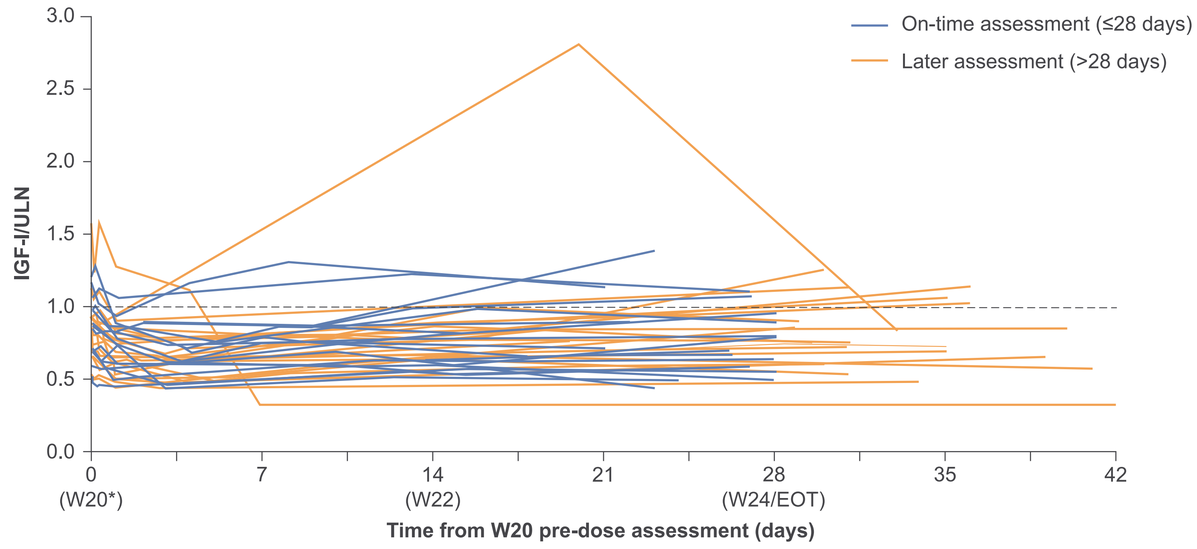
Data are for patients who completed their W20 dose and post-final dose assessments (N=42). *ULN per age and sex.

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



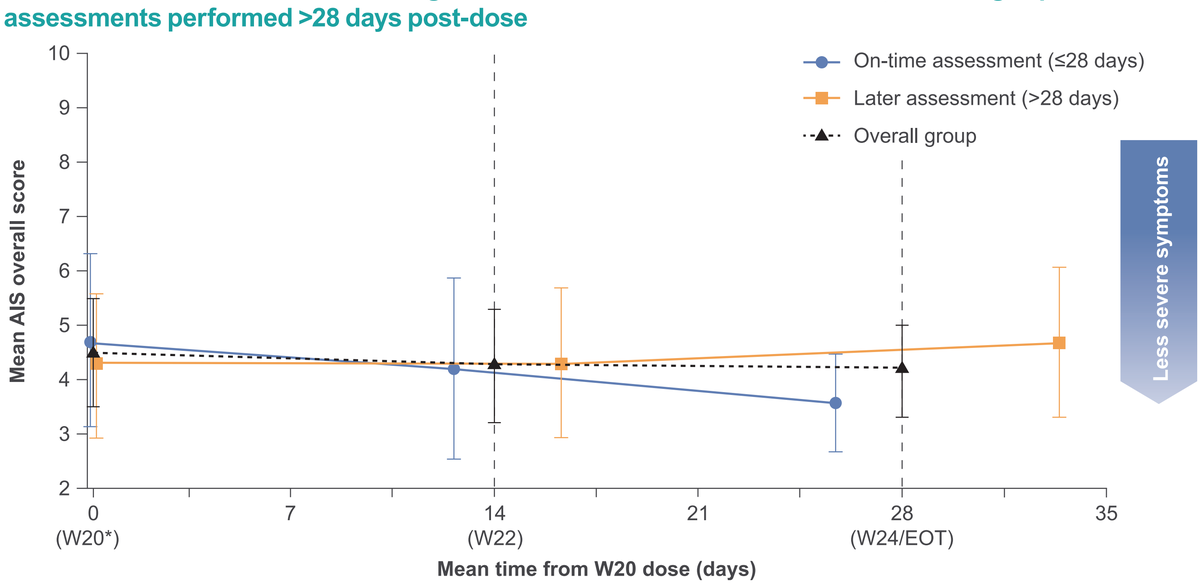
*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). W20 assessments were conducted prior to CAM2029 administration. 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-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-dose



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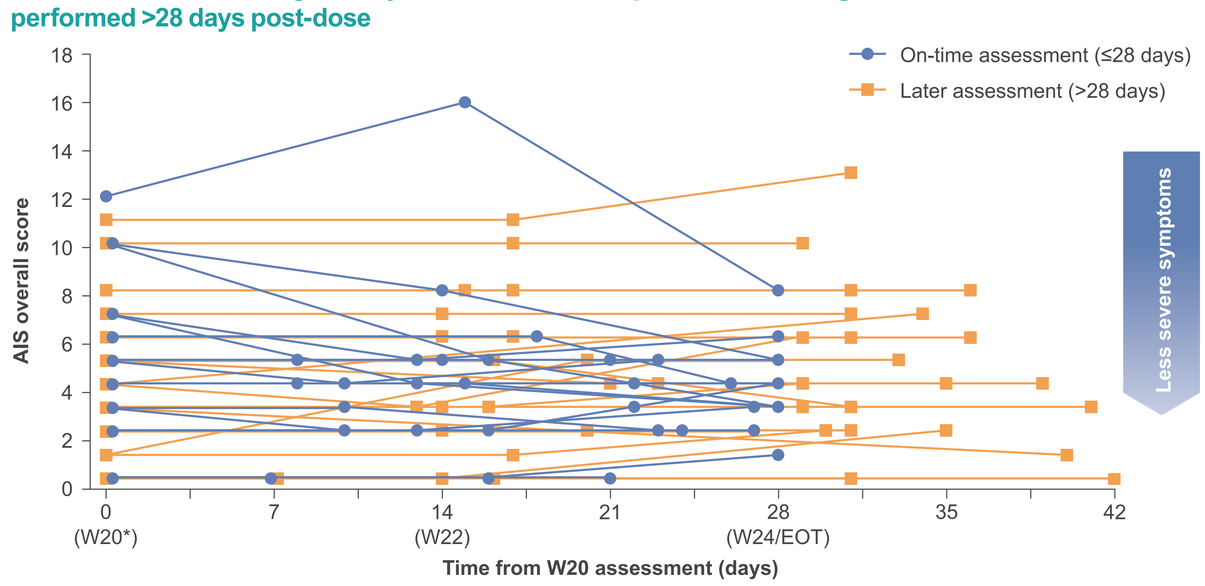
AIS overall scores were generally stable in individual patients, including in those with assessments performed >28 days post-dose



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