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

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BACKGROUND

- Overproduction of growth hormone (GH) and insulin-like growth factor I (IGF-I) in acromegaly lead to substantial morbidity and significantly reduced quality of life (QoL)[1]
- Biochemical control is essential to alleviate the symptoms and comorbidities of acromegaly[1]
- The ability to self-administer medication and the associated ease of administration are important for patients with acromegaly[2]
- Injectable first-generation somatostatin receptor ligands (SRLs; octreotide long-acting repeatable [LAR] or lanreotide Autogel [ATG]) can provide effective biochemical control but are typically administered by a healthcare professional and can result in a substantial treatment burden[3–7]
- There is an unmet need for therapies that can provide biochemical control, reduce symptoms, have a lower treatment burden and do not require administration by healthcare professionals[6,8]
- 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 autoinjector pen with small-gauge needle[9,10] (see **Supplementary Figure 1**, available via the QR code)
- In ACROINNOVA 1 (NCT04076462), a 24-week, Phase 3, randomised, double-blind trial, CAM2029 achieved superior biochemical control versus placebo (72.2% vs 37.5% of patients, respectively, with IGF-I ≤ upper limit of normal, per age and sex [ULN]; *P*=0.0018), controlled symptoms and improved QoL in patients with IGF-I ≤ULN on standard-of-care (SoC) treatment (octreotide LAR/lanreotide ATG) at screening[9]
- ACROINNOVA 2 (NCT04125836) is a Phase 3, open-label trial in which the long-term safety and efficacy of CAM2029 are being assessed in patients with acromegaly previously receiving first-generation SRLs
  - We report biochemical and symptom control and patient-reported outcomes (PROs) during the 52-week core phase for the full data set

CONCLUSIONS

Long-term CAM2029 was well tolerated, with a safety profile similar to SoC[14]

CAM2029 provided long-term biochemical control among patients who were biochemically controlled and uncontrolled on first-generation SRLs. Biochemical control was:

- **Improved in the overall population and those directly enrolled into ACROINNOVA 2 (IGF-I ≤2×ULN at screening)**
- **Sustained among patients who had previously achieved control with CAM2029**
- **Regained among patients who received placebo during the ACROINNOVA 1 trial (IGF-I ≤ULN at screening)**

Symptom burden progressively reduced over 52 weeks of CAM2029 treatment

Long-term CAM2029 treatment continuously improved QoL and treatment satisfaction versus SoC baseline

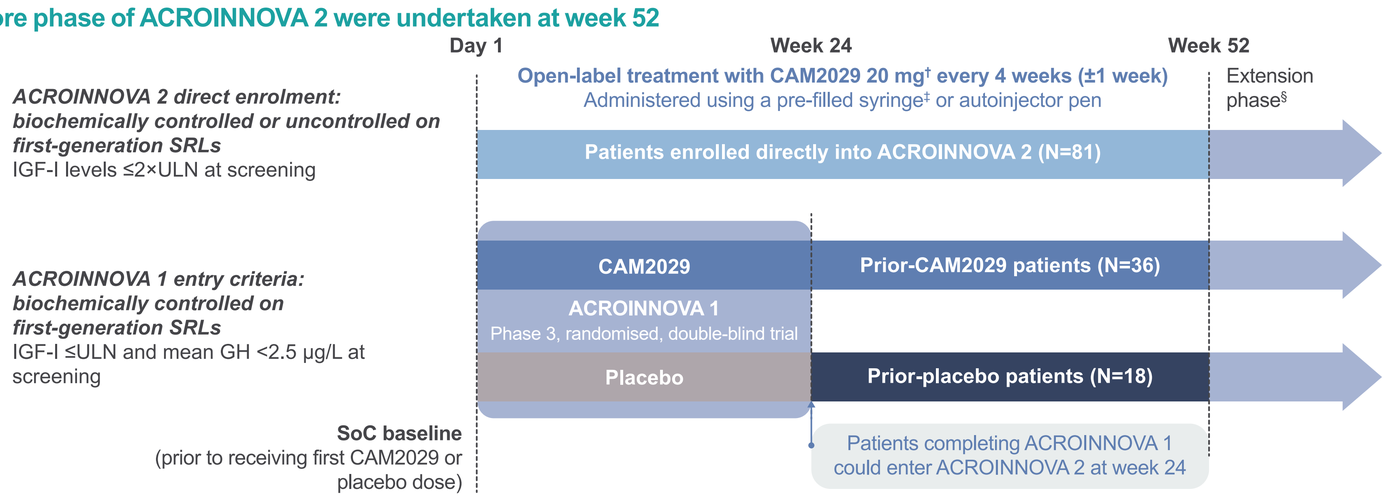
These long-term findings support CAM2029 as an effective and well-tolerated new treatment for acromegaly with the combined benefits of convenience and improved QoL

METHODS

Analyses for the core phase of ACROINNOVA 2 were undertaken at week 52

Key eligibility criteria:

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



Primary endpoint
• Characterisation of AEs
Selected secondary endpoints
Biochemical control
• Proportion of patients with mean IGF-I≤ULN (average of week 50 and 52 measurements)
Symptoms of acromegaly*
• Change in AIS* score from baseline to week 52
PROs: QoL
• **AcroQoL:** disease-specific scale to assess QoL in patients with acromegaly*
PROs: patient satisfaction
• **TSQM:** patients' satisfaction with medication*
• **SIAQ:** patients' overall experience with subcutaneous self-injection*

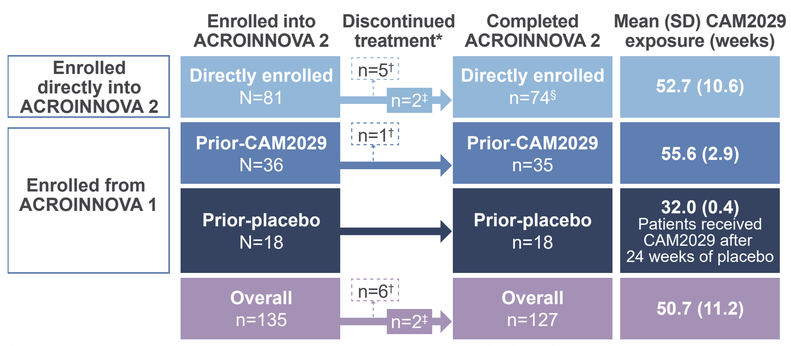
*Treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg); †If required based on safety and tolerability, the dose could be reduced to 10 mg CAM2029; ‡Only the autoinjector pen will be available following marketing authorisation; §Upon completing the core phase in ACROINNOVA 2, patients could continue to receive CAM2029 in a 52-week extension phase.

*Details for AIS and each PRO are provided in Supplementary Figure 2.
AE, adverse event; AcroQoL, Acromegaly Quality of Life Questionnaire; AIS, Acromegaly Index of Severity, SIAQ, Self-Injection Assessment Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

RESULTS

Patient demographics and medical history

- Of the 135 patients enrolled, mean (standard deviation [SD]) age was 52.9 (11.9) years, 56.3% of patients were female, and 88.1% had undergone prior pituitary surgery (**Supplementary Table 1**)
- Overall, 127 patients (94.1%) completed the core phase in ACROINNOVA 2



Data shown are for patients completing the 52-week core phase of ACROINNOVA 2. *Reasons for discontinuation: consent withdrawn (n=5, directly enrolled group); AEs (directly enrolled group, n=2: injection site haemorrhage [Grade 1] and depression [Grade 1]); patient declined to attend study site (prior-CAM2029 group, n=1); †Discontinued and withdrew from trial; ‡Patients discontinued treatment but were followed up to the end of the trial; §Two patients completed treatment with CAM2029 but did not attend the week 52 visit.

CAM2029 was well tolerated with no new safety signals

- Most AEs reported following CAM2029 treatment were mild, and no new safety signals were observed up to week 52 (**Supplementary Table 2**)
- All injection site AEs were mild (Grade 1) or moderate (Grade 2)

CAM2029 provided effective long-term biochemical control

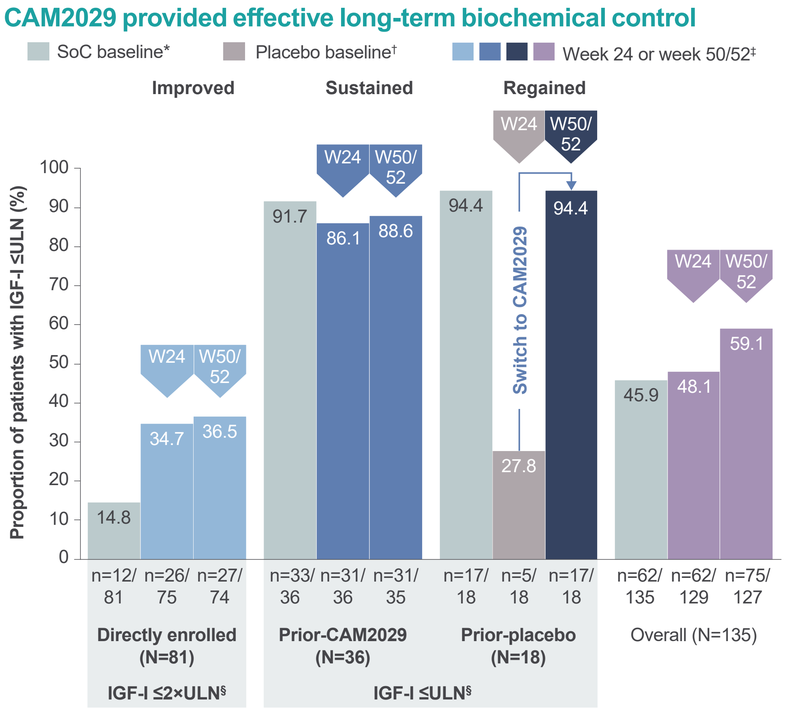


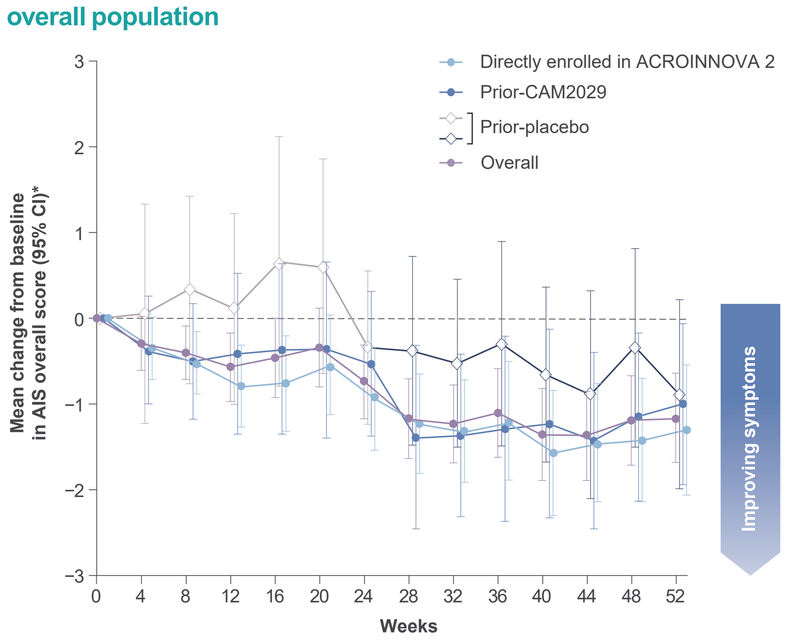
Figure is based on all patients with available data at the timepoint. *Before receiving the first CAM2029/placebo dose; IGF-I values are means from assessments at week −2 and day 1; †Prior-placebo group includes one patient who switched to SoC from placebo during ACROINNOVA 1; IGF-I value is the mean from assessments at weeks 22 and 24; ‡IGF-I values are means from assessments at weeks 50 and 52; §At screening. 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. Dashed horizontal rules represent ULN and 1.3×ULN. CI, confidence interval.

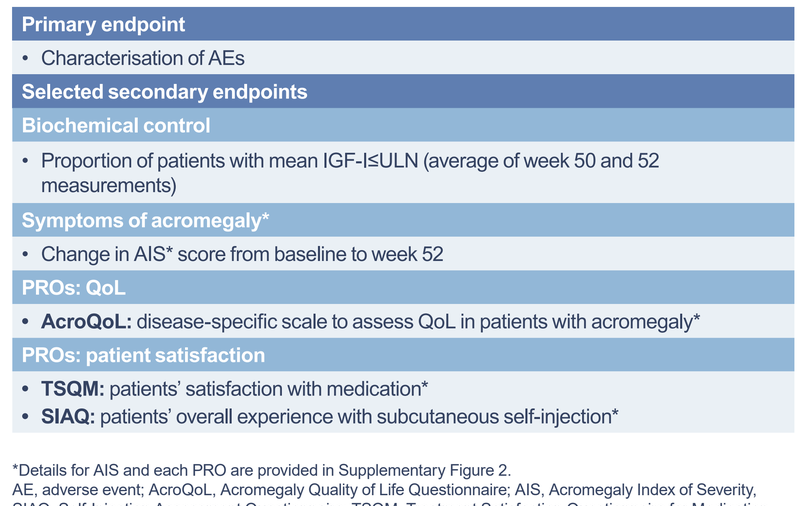
Symptoms continuously improved from baseline to week 52 in the overall population



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).

AcroQoL* and TSQM† scores mostly improved from baseline to week 24 and continued to improve to week 52

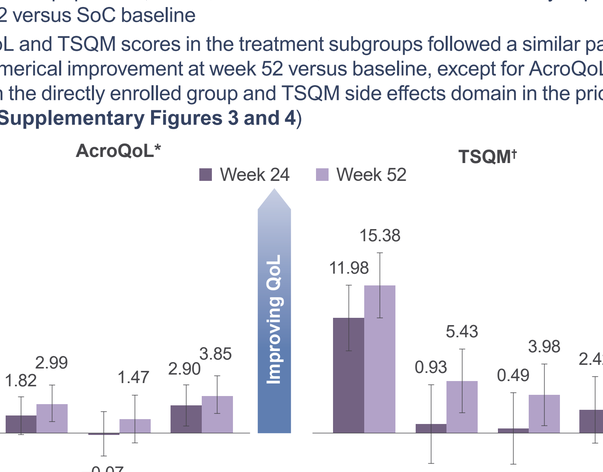
- In the overall population, AcroQoL and TSQM scores were numerically improved at week 52 versus SoC baseline
- AcroQoL and TSQM scores in the treatment subgroups followed a similar pattern, with numerical improvement at week 52 versus baseline, except for AcroQoL physical score in the directly enrolled group and TSQM side effects domain in the prior-placebo group (**Supplementary Figures 3 and 4**)



Data are for the overall population and include the 24-week placebo period before the prior-placebo group switched to CAM2029. *AcroQoL score range: 0–100;[11] †TSQM score range: 0–100.[12]

SIAQ* scores and treatment satisfaction improved from baseline and were maintained long term

- In the overall population, most (91.1%) patients (or partners) opted to self-administer CAM2029
  - Similar trends were observed in the directly enrolled, prior-CAM2029 and prior-placebo subgroups (**Supplementary Figure 5**)



Patients assessed at week 48 or closest visit. Data are for the overall population and include the 24-week placebo period before the prior-placebo group switched to CAM2029. Baseline is defined as the last pre-treatment values before the first self-administration. *Score range: 0–10.[13]

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