Long-term safety and efficacy of CAM2029 in patients with acromegaly: results from the ACROINNOVA 2 open-label extension

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BACKGROUND

- Long-term biochemical control of acromegaly is essential to manage symptoms and reduce mortality risk[1–3]
- CAM2029 is a novel octreotide subcutaneous depot (based on FluidCrystal® technology) with a long-acting formula for convenient monthly self-administration via a pre-filled autoinjector (see **Supplementary Figure 1**, available via the QR code)[4,5]
- Following the results of the Phase 3 ACROINNOVA 1 (NCT04076462) and 2 (NCT04125836) studies, CAM2029 was recently approved in Europe and the UK for the treatment of acromegaly[5–8]
- ACROINNOVA 2 demonstrated the long-term safety and efficacy of CAM2029, including among patients who were biochemically controlled (insulin-like growth factor I [IGF-I] ≤upper limit of normal, per age and sex [ULN]) and uncontrolled (IGF-I ≤2×ULN) on standard-of-care (SoC) injectable somatostatin receptor ligands (SRLs)[6]
  - CAM2029 provided long-term biochemical control, reduced symptom burden, and improved quality of life (QoL) and treatment satisfaction versus baseline[6,9]
- As acromegaly is a chronic condition for which many patients require lifelong treatment, longer-term safety and efficacy data are needed; we report data from the 1-year extension of ACROINNOVA 2

CONCLUSIONS

Long-term CAM2029 was well tolerated in patients with acromegaly for up to 104 weeks, with a safety profile similar to that of SoC[1]

Biochemical and symptom control, treatment satisfaction, and QoL were maintained in patients with acromegaly receiving long-term CAM2029

When loss of biochemical control followed a switch to SoC injectable SRLs, biochemical control was regained on restarting CAM2029

These results support CAM2029 as an effective and well tolerated long-term treatment option for patients with acromegaly

METHODS

Patients completing the 52-week core phase of ACROINNOVA 2 were eligible to enter the 52-week trial extension

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)

Open-label treatment with CAM2029 20 mg‡ every 4 weeks (±1 week)
Administered using pre-filled syringe[10] or pre-filled pen (autoinjector)

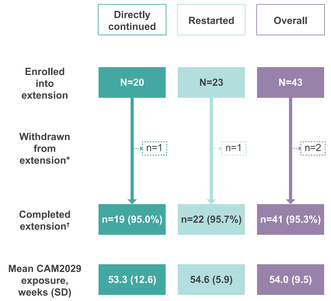
*Treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg); †If required based on safety and tolerability, the dose could be reduced to 10 mg CAM2029; ‡Core phase only; §Only the autoinjector pen is available following marketing authorization;[7] ¶Upon completing the week 48 CAM2029 treatment and week 52 assessment in the core phase of ACROINNOVA 2, patients could elect to receive CAM2029 in a 52-week extension phase. Patients either directly continued CAM2029 treatment from the core phase or restarted CAM2029 in the extension. Patients could restart CAM2029 if they had switched to SoC following completion of the core phase (regardless of time since completion) or if >4 weeks had elapsed since core phase completion. ATG, Autogel; GH, growth hormone; LAR, long-acting repeatable.

Primary endpoint
• Characterization of adverse events
Selected secondary endpoints
Biochemical control
• IGF-I levels over time
Symptoms of acromegaly
• Severity scores of clinical signs and symptoms* of acromegaly over time
PROs: patient satisfaction
• TSQM* scores over time
PROs: QoL
• AcroQoL* scores over time

*Details of the scores used are provided in **Supplementary Figure 2**. AcroQoL, Acromegaly Quality of Life Questionnaire; PRO, patient-reported outcome; TSQM, Treatment Satisfaction Questionnaire for Medication.

RESULTS

Overall, 41 (95.3%) patients completed the extension phase of ACROINNOVA 2



*Reasons for withdrawal: consent withdrawn (n=1, directly continued group); death (n=1, restarted group; suspected cardiac arrest assessed as not related to CAM2029); †Completed the ACROINNOVA 2 extension and received CAM2029 for ≥52 weeks. SD, standard deviation.

- Patient demographics and medical histories were collected at screening (see **Supplementary Table 1**, available via QR code)
  - Among the restarted group, 91.3% (21/23) received SoC SRLs (octreotide LAR or lanreotide ATG) between completion of the ACROINNOVA 2 core phase and the start of the extension
  - Median (range) time without CAM2029 treatment was 246.0 (104–664) days

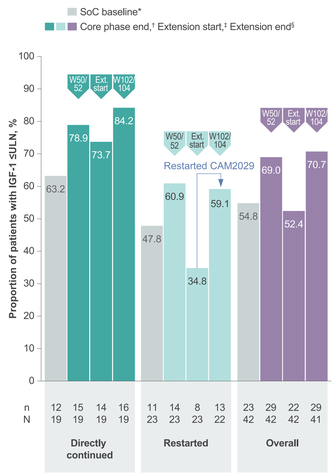
Long-term CAM2029 was well tolerated and no new safety findings were identified

n (%)	Directly continued (N=20)	Restarted (N=23)	Overall (N=43)
Any AE	14 (70.0)	16 (69.6)	30 (69.8)
Any CAM2029-related AE*	6 (30.0)	11 (47.8)	17 (39.5)
Any AE of Grade			
1	13 (65.0)	13 (56.5)	26 (60.5)
2	6 (30.0)	11 (47.8)	17 (39.5)
3	2 (10.0)	1 (4.3)	3 (7.0)
Any SAE	1 (5.0)	3 (13.0)	4 (9.3)
Any CAM2029-related SAE	0	1 (4.3)	1 (2.3)
Any AE leading to discontinuation of CAM2029†	0	1 (4.3)	1 (2.3)
Any AE leading to dose reduction	0	0	0
Any fatal SAE‡	0	1 (4.3)	1 (2.3)
Any injection site AE	4 (20.0)	8 (34.8)	12 (27.9)

Extension safety analysis set (all patients in the directly continued group and all patients in the restarted group who received at least one dose of CAM2029 during the extension). AEs refer to TEAEs. AEs and SAEs reported during the extension phase are included. In the extension phase, treatment discontinuation resulted in withdrawal from the trial. *The most frequent CAM2029-related AEs were injection site AEs; †One patient in the directly enrolled group experienced an injection site AE with onset during the core phase of the trial; following this AE, the patient withdrew in the extension phase before receiving the first CAM2029 dose; ‡Suspected cardiac arrest assessed as not related to CAM2029. AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

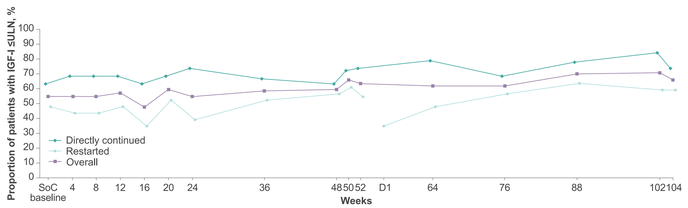
- Most AEs were mild (Grade 1) or moderate (Grade 2)
- The most frequently occurring AEs in the overall population (≥10% of patients) were headache (18.6%), arthralgia (16.3%), injection site mass (11.6%), and injection site swelling (11.6%; see **Supplementary Table 2**)
  - Injection site mass and injection site swelling were mild-moderate in severity and may reflect the presence of the depot under the skin

Biochemical control rate was maintained in the directly continued group and regained in the restarted group



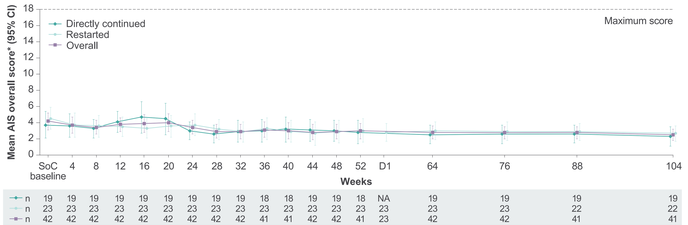
Extension efficacy analysis set. Data shown include the 24-week placebo period before the prior-placebo group in ACROINNOVA 1 was switched to CAM2029. *Mean of week −2 and day 1 measurements; †Mean of week 50 and 52 of core phase; ‡Extension start is the closest preceding measurement before the first dose of CAM2029 in the extension phase (directly continued group, week 52/end of core phase; restarted group, day 1 of the extension phase); §Mean of week 102 and week 104. W, week.

Long-term CAM2029 provided effective biochemical control over 104 weeks



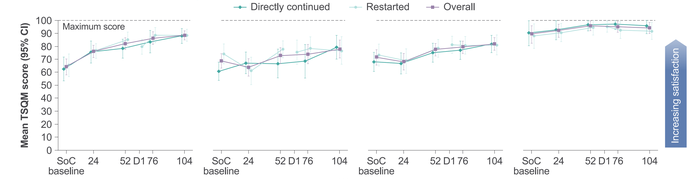
Extension efficacy analysis set (all patients who received at least one dose of CAM2029 and completed at least one efficacy assessment during the extension). Data shown include the 24-week placebo period before the prior-placebo group in ACROINNOVA 1 was switched to CAM2029. D, day; n, number of patients with evaluable data at the specified timepoint.

Long-term CAM2029 sustained symptom control throughout the extension



Extension efficacy analysis set. Data shown include the 24-week placebo period before the prior-placebo group in ACROINNOVA 1 was switched to CAM2029. *AIS 0–18; sum of scores (0–3; none–severe) for six symptoms (headache, sweating, fatigue, joint pain, paresthesia, and soft tissue swelling).[4] Error bars represent 95% CI. AIS, Acromegaly Index of Severity; CI, confidence interval.

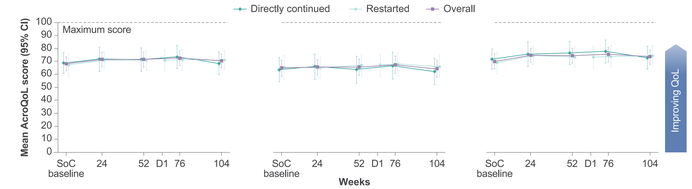
TSQM scores were mostly stable during the extension with long-term CAM2029 treatment



Data are for the extension efficacy analysis set and include the 24-week placebo period before the prior-placebo group switched to CAM2029. TSQM score range: 0–100.[10]

- Mean TSQM convenience domain scores increased from start to end of the extension by 9.9 (95% CI 3.2, 16.7) in the directly continued group and by 7.8 (95% CI 2.9, 12.8) in the restarted group
- In the overall population, 53.7% (22/41) of patients had a TSQM global satisfaction score ≥80 at the extension end

QoL remained stable during long-term CAM2029 treatment in the trial extension



Data are for the extension efficacy analysis set and include the 24-week placebo period before the prior-placebo group switched to CAM2029. Score range: 0–100.[11]

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