Long-term safety, biochemical control and symptom management with CAM2029 in the 52-week ACROINNOVA 2 open-label extension

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BACKGROUND

- Excess growth hormone (GH) and insulin-like growth factor I (IGF-I) in acromegaly leads to substantial morbidity and significantly reduced quality of life[1]
- Long-term biochemical control of acromegaly is essential to manage symptoms and reduce risk of mortality[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 (**Supplementary Figure 1**, available via the QR code)[4,5]
- CAM2029 was recently approved in Europe and the UK for the treatment of acromegaly following the results of the Phase 3 ACROINNOVA 1 (NCT04076462) and 2 (NCT04125836) studies[5–8]
- ACROINNOVA 2 demonstrated the long-term safety and efficacy of CAM2029, including in patients who were biochemically controlled (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]
- Some patients with acromegaly require lifelong treatment; therefore, long-term safety and efficacy data are needed
- Here we report results from the 1-year extension of ACROINNOVA 2, further examining the long-term safety and efficacy of CAM2029

CONCLUSIONS

- **Long-term CAM2029 was well tolerated in patients with acromegaly, with a safety profile similar to that of SoC[3]**
- **Biochemical control rate and symptom scores remained stable with long-term CAM2029 treatment**
- **CAM2029 restored biochemical control in patients who had switched to SoC and then resumed 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

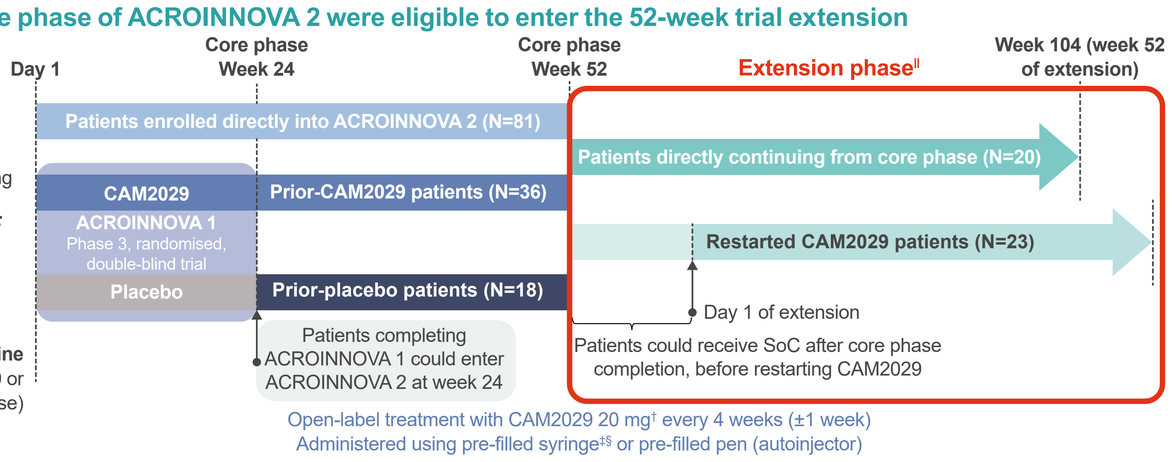
Key eligibility criteria:

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

ACROINNOVA 2 direct enrolment: 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)



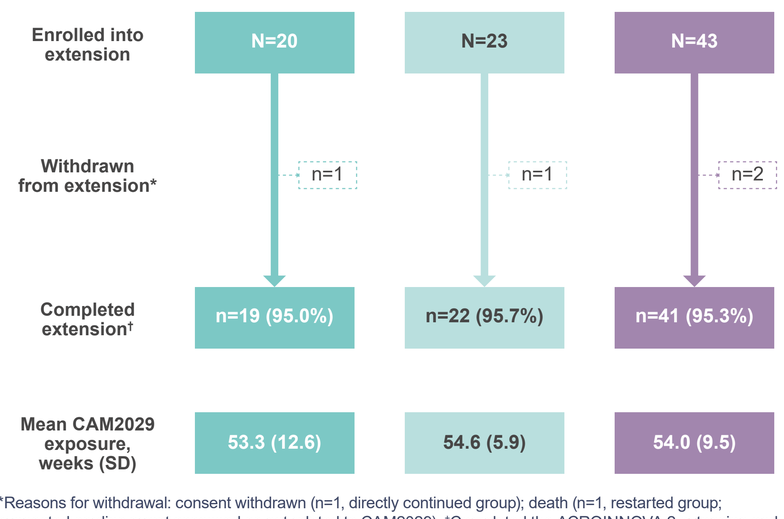
*Treatment with a stable dose of octreotide LAR (10, 20, 30 or 40 mg) or lanreotide ATG (60, 90 or 120 mg); †If required based on safety and tolerability, the dose could be reduced to 10 mg CAM2029; ‡Core phase only; §Only the autoinjector pen is available following marketing authorisation; ‖Upon completing 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; LAR, long-acting repeatable.

Primary endpoint
• Characterisation of AEs
Selected secondary endpoints
Biochemical control
• IGF-I levels over time
Symptoms of acromegaly
• Severity scores of clinical signs and symptoms of acromegaly over time

AE, adverse event.

RESULTS

Most patients who continued from ACROINNOVA 2 to the extension completed CAM2029 treatment



*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 are provided in **Supplementary Table 1**
- Among the restarted group, the median (range) time between completion of the ACROINNOVA 2 core phase and the start of the extension (ie time without CAM2029 treatment) was 246 (104–664) days
  - During the time between last dose of ACROINNOVA 2 core phase and the start of extension, most patients (91.3%) received an injectable SRL (43.5% octreotide LAR, 47.8% lanreotide ATG); two patients did not receive an interim therapy

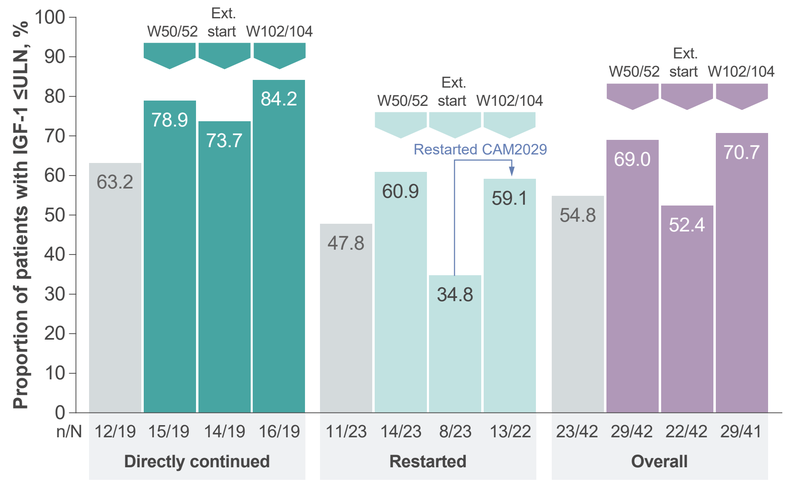
Long-term CAM2029 was well tolerated and no new safety signals were identified up to week 104

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 ≥1 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. *One patient in the directly continued 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. SAE, serious adverse event; TEAE, treatment-emergent adverse event.

- Most AEs were mild or moderate
  - 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%; **Supplementary Table 2**)
  - The most frequent CAM2029-related AEs were injection site AEs; overall, 12 (27.9%) of patients experienced at least one injection site AE

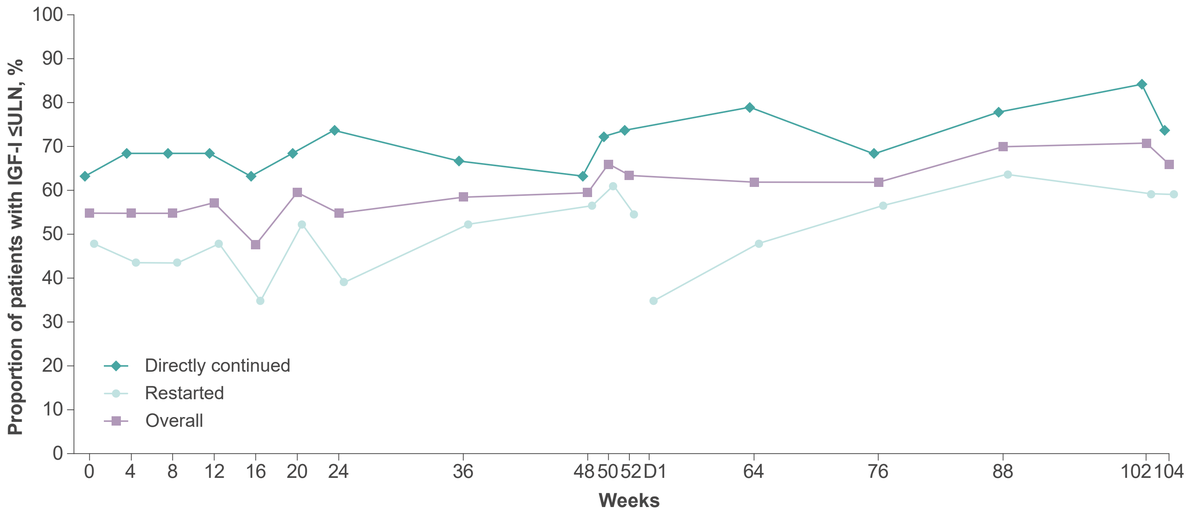
Biochemical control rates from end of core phase to end of extension were stable for the directly continued group and restored in the restarted group



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 weeks 102 and 104. W, week.

- Biochemical control rate remained stable from end of core phase to end of extension for patients who directly continued from ACROINNOVA 2
- In the restarted group, the biochemical control rate decreased from 60.9% (14/23) to 34.8% (8/23) during the period between the end of the ACROINNOVA 2 core phase and the start of the extension, in which these patients were not receiving CAM2029
  - By the end of the extension phase, the biochemical control rate was restored and had increased to 59.1% (13/22)

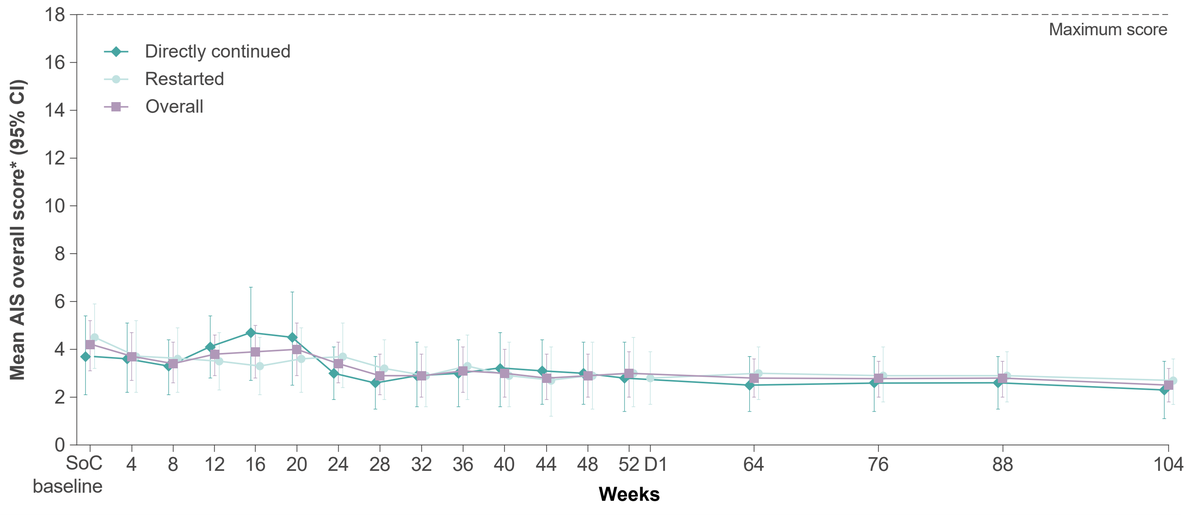
Long-term CAM2029 provided effective biochemical control over 104 weeks from start of ACROINNOVA 2 core phase to end of extension



Directly continued	n	19	19	19	19	19	19	19	18	19	18	19	NA	19	19	18	19	19
Restarted	n	23	23	23	23	23	23	23	23	23	23	22	23	23	23	22	22	22
Overall	n	42	42	42	42	42	42	42	41	42	41	41	23	42	42	40	41	41

Extension efficacy analysis set (all patients who received ≥1 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 time point.

AIS overall scores were low, with a tendency to decrease throughout the treatment period



Directly continued	n	19	19	19	19	19	19	19	19	19	18	18	19	19	18	NA	19	19	19	19
Restarted	n	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	22	22
Overall	n	42	42	42	42	42	42	42	42	42	41	41	42	42	41	23	42	42	41	41

Extension efficacy analysis set. Data shown include the 24-week placebo period before the prior-placebo group in ACROINNOVA 1 was switched to CAM2029. *Details for AIS are provided in **Supplementary Figure 2**. AIS 0–18; sum of scores (0–3; none–severe) for six symptoms (headache, sweating, fatigue, joint pain, paraesthesia and soft tissue swelling).[5] AIS, Acromegaly Index of Severity; CI, confidence interval.

References

1. Giustina A *et al. J Clin Endocrinol Metab* 2020;105:e937–46; **2**. Giustina A *et al. Pituitary* 2024;27:7–22; **3**. Fleseriu M *et al. Lancet Diabetes Endocrinol* 2022;10:102–11; **4**. Tiberg F *et al. Br J Clin Pharmacol* 2015;80:460–72; **5**. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39; **6**. Spencer-Segal JL *et al.* ESPE/ESE 2025; Poster RC4.4a; **7**. Camurus AB. Oczyesa® (CAM2029). EU Summary of Product Characteristics, 2025; **8**. Camurus AB. Oczyesa® (CAM2029). UK Summary of Product Characteristics, 2025.

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