Effect of CAM2029 on long-term biochemical and symptom control in patients with acromegaly according to prior injectable somatostatin receptor ligand

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BACKGROUND

- Achieving biochemical control (insulin-like growth factor I [IGF-I] ≤upper limit of normal) is an essential objective of treatment for acromegaly to reduce symptom burden and improve mortality[1–4]
- However, many patients do not achieve biochemical control or symptom remission when treated with injectable first-generation somatostatin receptor ligands (SRLs; octreotide long-acting repeatable [LAR], lanreotide Autogel [ATG]; standard-of-care [SoC] in this study)[2,3,5,6]
- CAM2029 is a novel octreotide subcutaneous depot (based on FluidCrystal® technology) with a long-acting formula for convenient monthly self-administration via a ready-to-use autoinjector pen with a small-gauge needle (**Supplementary Figure 1**, available via the QR code)[7,8]
- CAM2029 was recently approved for maintenance treatment in adults with acromegaly in the UK and Europe[9,10]
- In the Phase 3 ACROINNOVA 2 study (NCT04125836), CAM2029 demonstrated improved long-term biochemical and symptom control in directly enrolled patients (patients with IGF-I ≤2×upper limit of normal per age and sex [ULN]) on baseline SoC[11,12]
- Here, we further evaluate the effect of CAM2029 on biochemical control and acromegaly symptoms in this subset of patients, stratified by last SRL therapy received prior to enrolment; descriptive data are reported

CONCLUSIONS

In patients with IGF-I ≤2×ULN on baseline injectable SRLs, 52 weeks of CAM2029 treatment at a standard dose of 20 mg every 4 weeks:

- **Was well tolerated**
- **Improved biochemical control rate from 14.8% at SoC baseline to 36.5% at week 50/52**
- **Progressively reduced the symptom burden**

Improvements in biochemical and symptom control with long-term CAM2029 were similar, regardless of previous SRL treatment

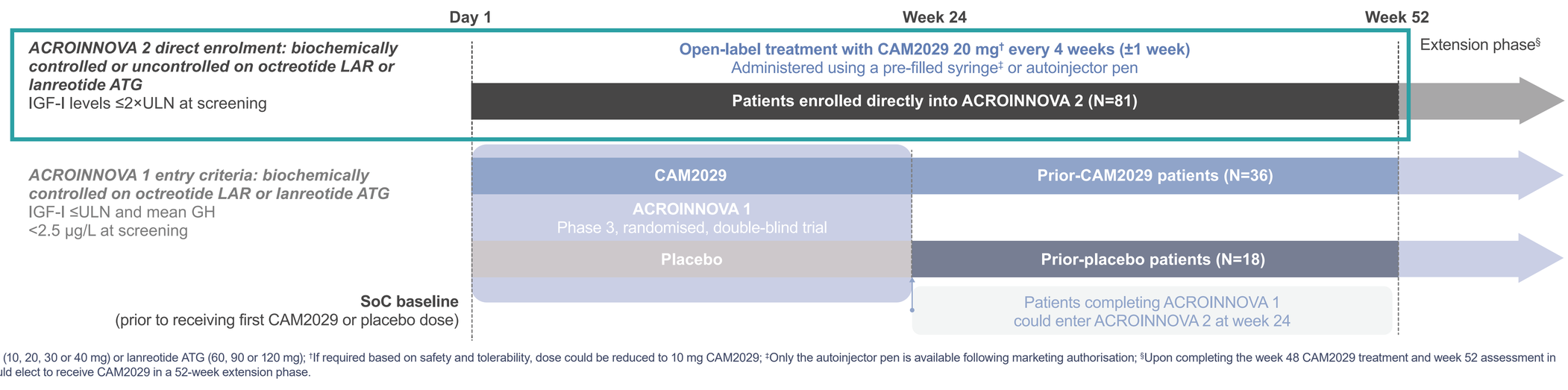
These results support CAM2029 as a long-term treatment option for acromegaly, including in some patients without biochemical control on octreotide LAR or lanreotide ATG

METHODS

Patients directly enrolled into ACROINNOVA 2 had IGF-I levels ≤2×ULN at baseline and were evaluated for up to 52 weeks in the core phase

Key eligibility criteria:

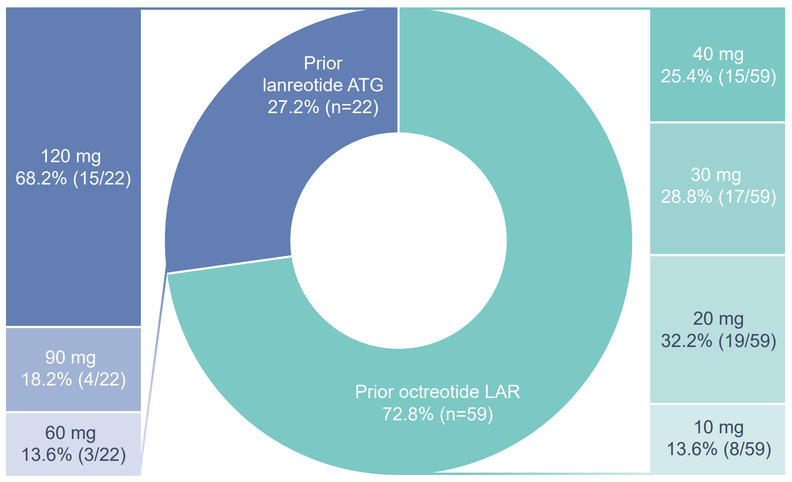
- Diagnosis of acromegaly
- Stable treatment with octreotide LAR or lanreotide ATG (SoC) for ≥3 months*



*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, dose could be reduced to 10 mg CAM2029; ‡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.

RESULTS

A total of 81 patients were directly enrolled into ACROINNOVA 2, and most were receiving octreotide LAR at baseline



Last medication for acromegaly taken prior to day 1 in ACROINNOVA 2. Patient disposition is outlined in **Supplementary Figure 2**.

	SRL at baseline		
	Any SRL (N=81)	Octreotide LAR (N=59)	Lanreotide ATG (N=22)
Mean age, years (SD)	51.8 (11.4)	51.3 (10.9)	53.3 (12.8)
Sex, n (%)			
Female	48 (59.3)	37 (62.7)	11 (50.0)
Male	33 (40.7)	22 (37.3)	11 (50.0)
Mean time since diagnosis, years (SD)	10.7 (7.4)	11.0 (7.3)	10.2 (7.9)
Prior pituitary surgery, n (%)	70 (86.4)	53 (89.8)	17 (77.3)
Past medications,* n (%)			
Octreotide	64 (79.0)	59 (100)	5 (22.7)
Lanreotide	25 (30.9)	3 (5.1)	22 (100)
Cabergoline	4 (4.9)	2 (3.4)	2 (9.1)
Bromocriptine	2 (2.5)	1 (1.7)	1 (4.5)
Pegvisomant	1 (1.2)	1 (1.7)	0
Pasireotide	1 (1.2)	0	1 (4.5)
IGF-I ≤ULN,† n/N (%)	12/81 (14.8)	9/59 (15.3)	3/22 (13.6)

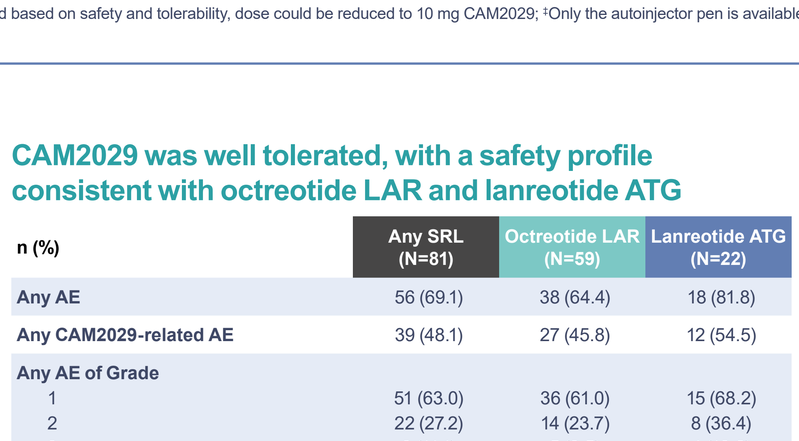
Safety analysis set.
*At any time prior to enrolment; †At SoC baseline, prior to receiving first CAM2029 dose; IGF-I values are means from assessments at week −2 and day 1 measurements. SD, standard deviation.

CAM2029 was well tolerated, with a safety profile consistent with octreotide LAR and lanreotide ATG

n (%)	Any SRL (N=81)	Octreotide LAR (N=59)	Lanreotide ATG (N=22)
Any AE	56 (69.1)	38 (64.4)	18 (81.8)
Any CAM2029-related AE	39 (48.1)	27 (45.8)	12 (54.5)
Any AE of Grade			
1	51 (63.0)	36 (61.0)	15 (68.2)
2	22 (27.2)	14 (23.7)	8 (36.4)
3	9 (11.1)	5 (8.5)	4 (18.2)
Any SAE	6 (7.4)	4 (6.8)	2 (9.1)
Any CAM2029-related SAE	0	0	0
Any AE leading to discontinuation of CAM2029*	2 (2.5)	2 (3.4)	0
Any AE leading to dose reduction	0	0	0
Any injection-site AE*	32 (39.5)	22 (37.3)	10 (45.5)

AEs refer to TEAEs.*AEs included injection site bruising, dermatitis, erythema, extravasation, haematoma, haemorrhage, hypertrophy, induration, mass, nodule, oedema, pain, pruritus and swelling. AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

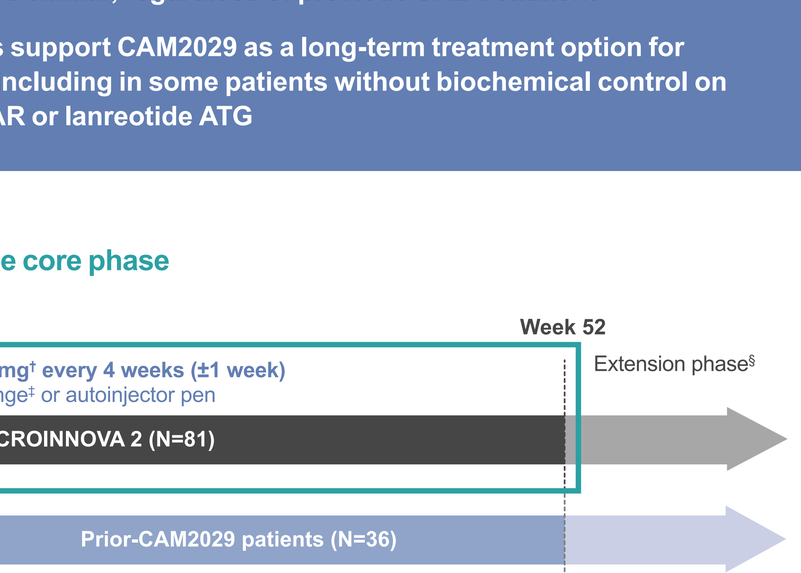
Switching to CAM2029 treatment improved biochemical control rates from SoC baseline to week 24 and week 52, regardless of prior SRL type



Intention-to-treat population. Figure includes all patients with available data at the time point.
*Prior to receiving the first CAM2029 dose; IGF-I values are means from assessments at week −2 and day 1;
†IGF-I values are means from assessments at weeks 50 and 52.

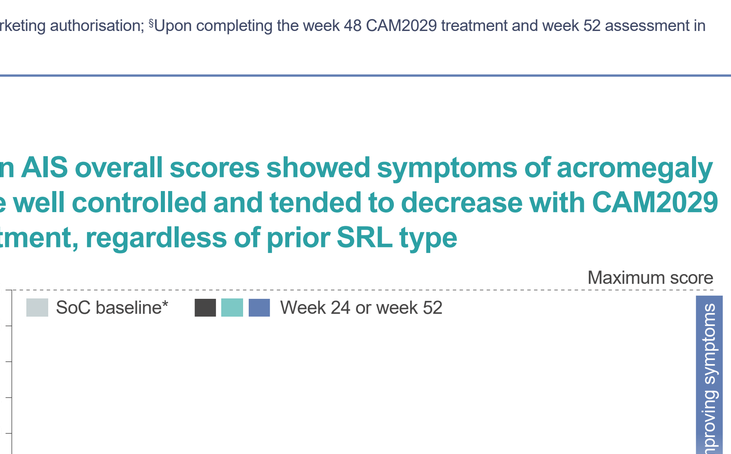
- In patients previously treated with octreotide LAR, largest observed improvement in biochemical control rate was seen in the first 24 weeks, whereas this was reached in the second half of the treatment period for patients who previously received lanreotide ATG

Mean AIS overall scores showed symptoms of acromegaly were well controlled and tended to decrease with CAM2029 treatment, regardless of prior SRL type



*The closest preceding measurement before the first dose of CAM2029. AIS 0–18; sum of scores (0–3; none–severe) for six symptoms (headache, sweating, fatigue, joint pain, paraesthesia and soft tissue swelling).[7] Details for AIS are provided in **Supplementary Figure 3**. AIS, Acromegaly Index of Severity; CI, confidence interval.

Acromegaly symptom control improved in most patients from baseline to week 52, regardless of prior SRL therapy



Any SRL n	81	81	81	81	79	79	76	76	76	76	75	75	74	73
Octreotide LAR n	59	59	59	59	57	57	55	55	55	55	55	54	53	53
Lanreotide ATG n	22	22	22	22	22	22	21	21	21	21	20	21	21	20

*The closest preceding measurement before the first dose of CAM2029. AIS 0–18; sum of scores (0–3; none–severe) for six symptoms (headache, sweating, fatigue, joint pain, paraesthesia and soft tissue swelling).[7] Details for AIS are provided in **Supplementary Figure 3**. AIS, Acromegaly Index of Severity; CI, confidence interval.

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