

Effect of CAM2029 on long-term biochemical and symptom control in patients with acromegaly and insulin-like growth factor I ≤2× upper limit of normal grouped by prior injectable somatostatin receptor ligand dose

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Presenter: Federico Gatto

BACKGROUND

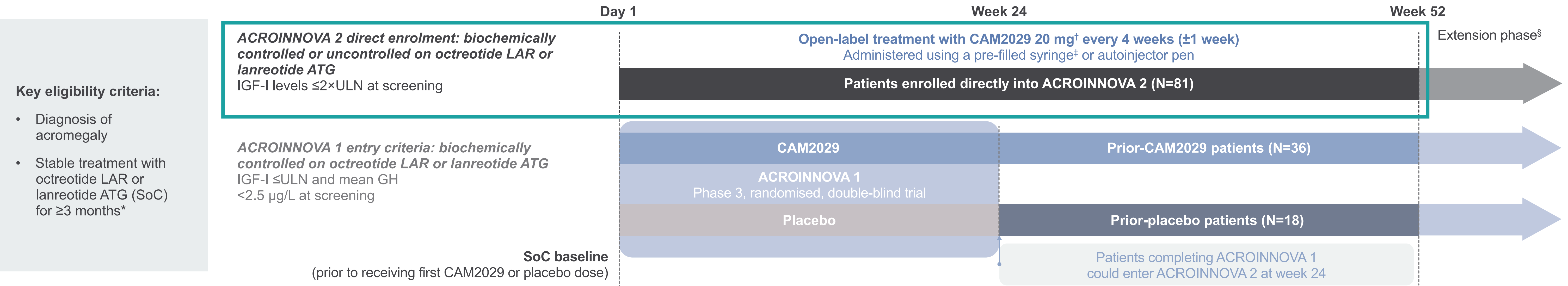
- Achieving biochemical control (insulin-like growth factor I [IGF-I] ≤upper limit of normal) is an essential objective of treatment for acromegaly to reduce symptom burden and improve mortality^{1–4}
- However, biochemical control or symptom remission is not always achieved in patients treated with 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 prior SRL dose at enrolment; descriptive data are reported

CONCLUSIONS

- In patients with acromegaly with IGF-I ≤2×ULN at baseline, 52 weeks of CAM2029 treatment at a dose of 20 mg every 4 weeks:
 - Was well tolerated
 - Improved biochemical control rate from 14.8% at SoC baseline (any SRL dose) to 36.5% at week 50/52
 - Progressively reduced the symptom burden
- Results suggested that improvements in biochemical and symptom control with long-term CAM2029 were independent of prior SRL dose
- These results support CAM2029 as an effective treatment option for acromegaly, including in patients with IGF-I ≤2×ULN on mid–high doses of octreotide LAR or lanreotide ATG

METHODS

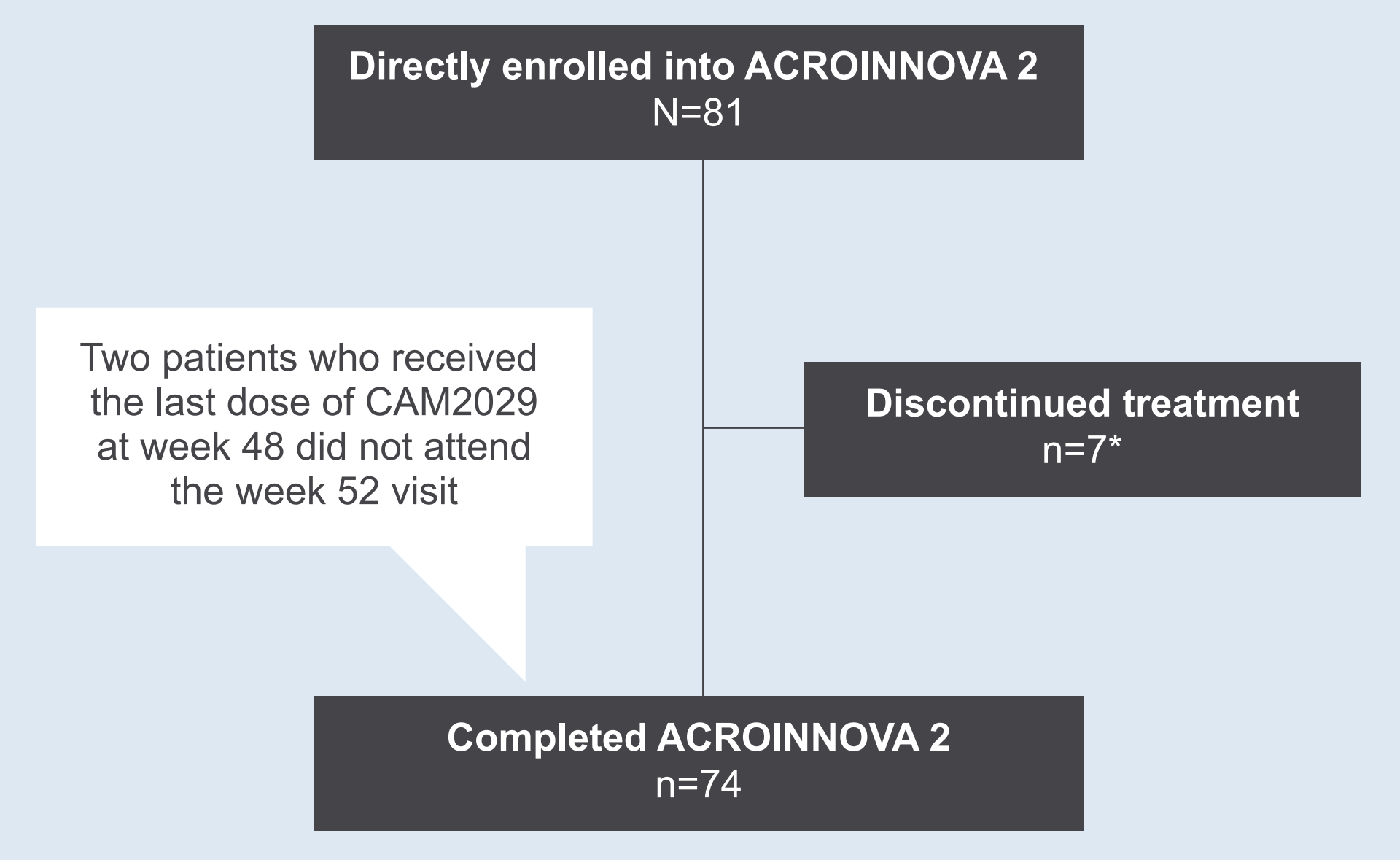
Patients directly enrolled into ACROINNOVA 2 had IGF-I levels ≤2×ULN at baseline and were evaluated for up to 52 weeks in the core phase



*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.

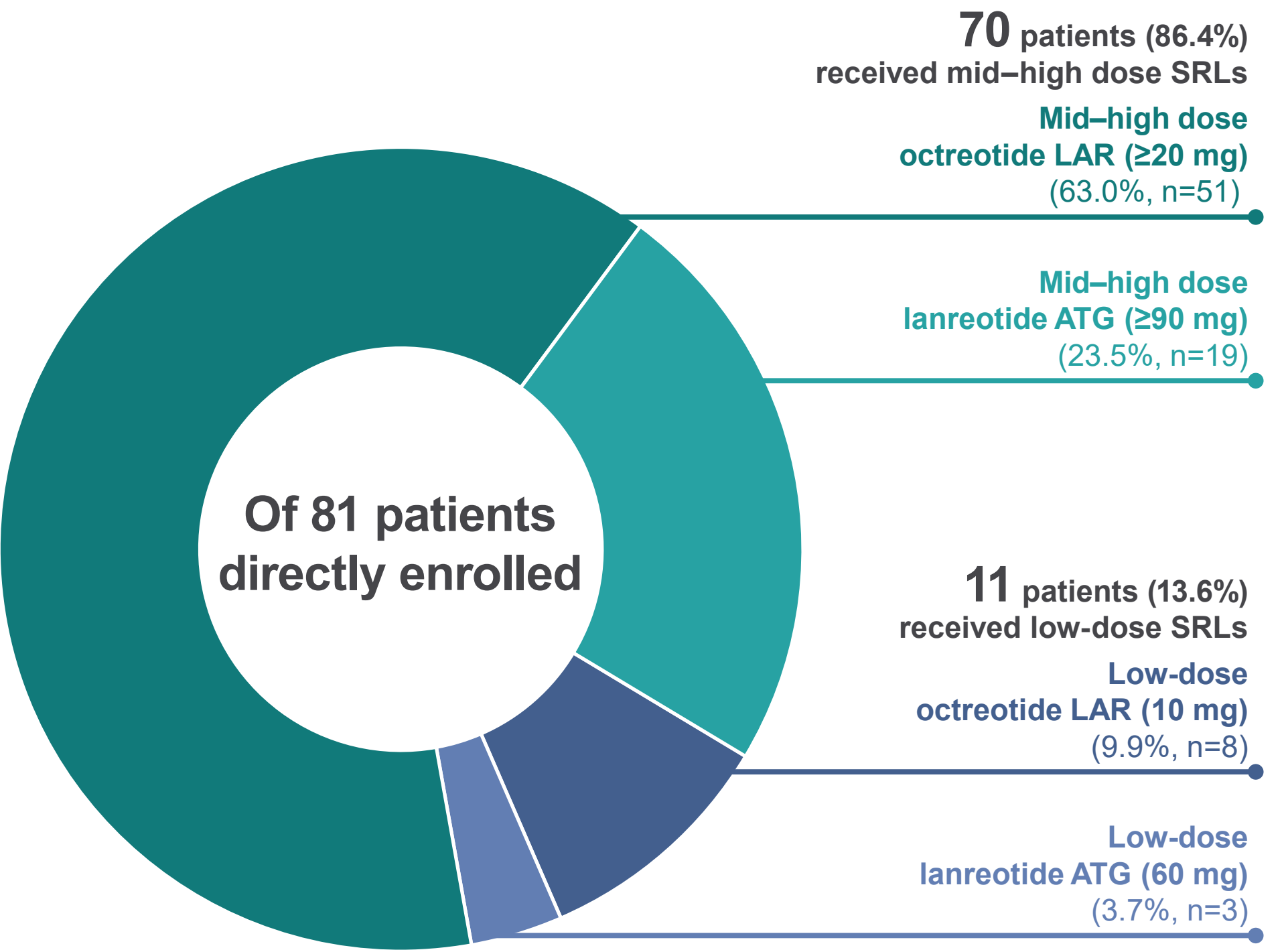
RESULTS

A total of 81 patients were directly enrolled into ACROINNOVA 2, and most were receiving mid–high doses of octreotide LAR or lanreotide ATG at baseline



*Discontinued treatment and withdrawn from trial because of withdrawal of consent (n=5); discontinued treatment owing to adverse events (AEs), switched to SoC and completed the trial (n=2); injection site haemorrhage, Grade 1 [n=1]; depression, Grade 1 [n=1].

- Mean (standard deviation [SD]) exposure to CAM2029 was 52.7 weeks (10.6)
- 91.4% of directly enrolled patients completed ACROINNOVA 2



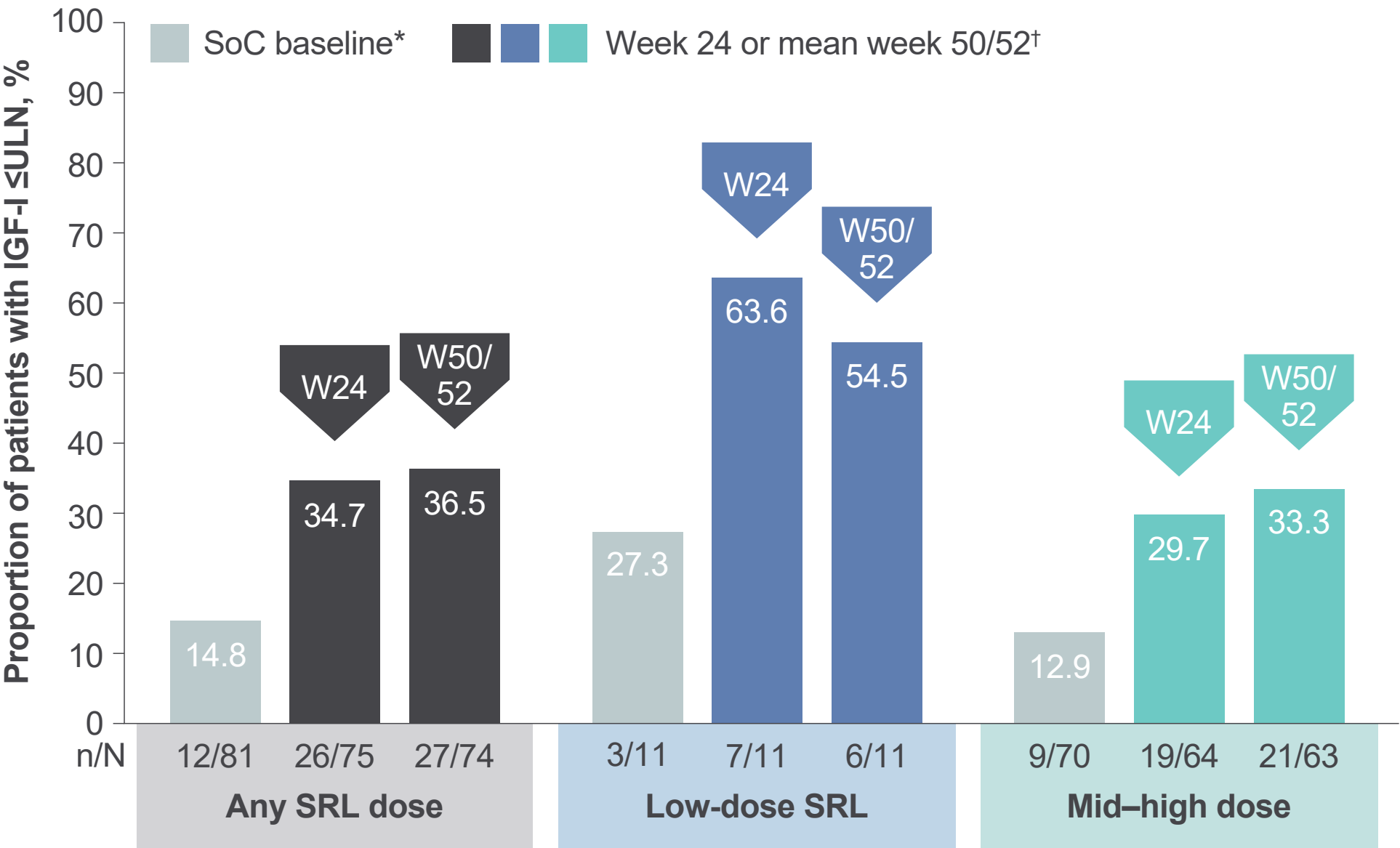
Last medication for acromegaly taken prior to enrolment in ACROINNOVA 2.

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

n (%)	Low-dose SRL (N=11)	Mid–high dose SRL (N=70)
Any AE	8 (72.7)	48 (68.6)
Any CAM2029-related AE	6 (54.5)	33 (47.1)
Any AE of Grade		
1	8 (72.7)	43 (61.4)
2	3 (27.3)	19 (27.1)
3	2 (18.2)	7 (10.0)
Any CAM2029-related SAE	0 (0)	0 (0)
Any AE leading to discontinuation of CAM2029	1 (9.1)	1 (1.4)
Any AE leading to dose reduction	0 (0)	0 (0)
Any injection site AE*	6 (54.5)	26 (37.1)

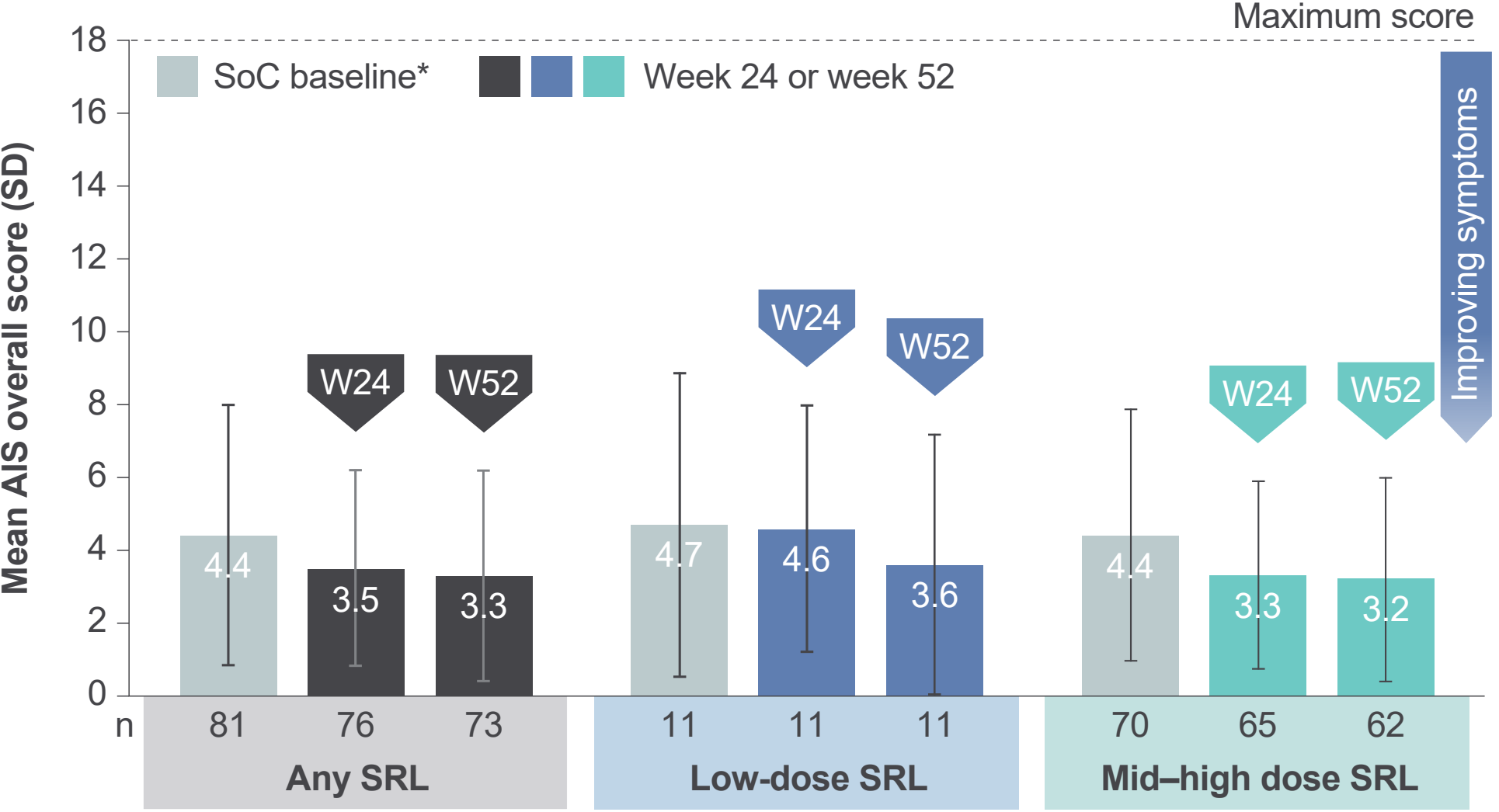
AEs refer to TEAEs. *AEs included injection site bruising, dermatitis, erythema, extravasation, haematoma, haemorrhage, hypertrophy, induration, mass, nodule, oedema, pain, pruritus, and swelling. AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

Switching to CAM2029 improved biochemical control rates from SoC baseline to W24 and W52, regardless of prior SRL dose



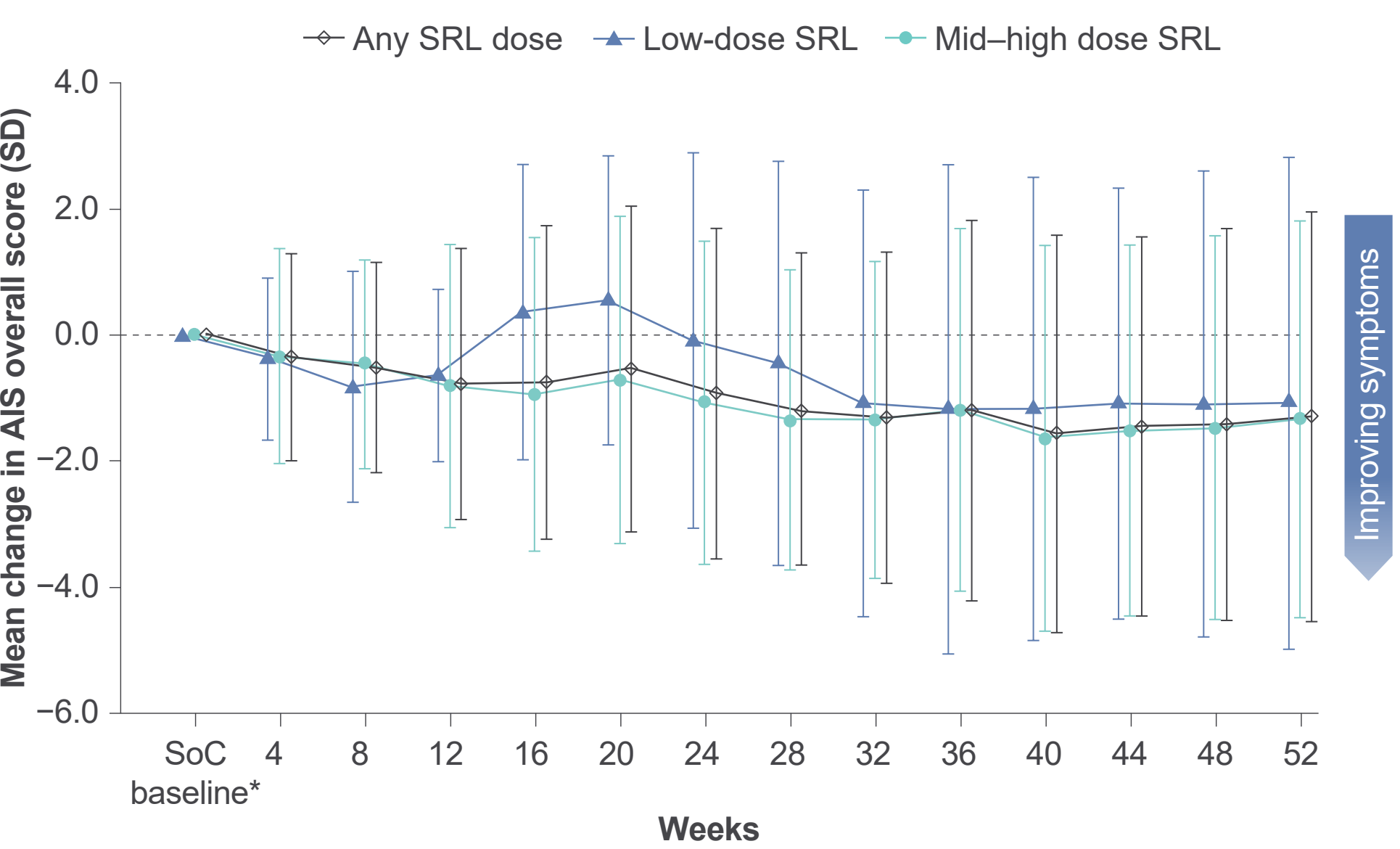
Intention-to-treat population. *Prior to receiving the first CAM2029 dose; IGF-I values are means from assessments at week –2 and day 1; †IGF-I values are means from assessments at weeks 50 and 52. W, week.

Mean AIS overall scores moderately improved from SoC baseline to weeks 24 and 52, regardless of prior SRL dose



*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 2**. AIS, Acromegaly Index of Severity.

Results suggest that CAM2029 progressively improved symptoms from baseline to end of the core phase



SRL dose	n	Any	Low	Mid-high
Any	81	11	70	70
Low	11	11	11	11
Mid-high	70	70	68	65

*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 2**. AIS, Acromegaly Index of Severity; SD, standard deviation; SoC, standard of care; SRL, somatostatin receptor ligand.

References

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