Oral number: ORF28-05

Effect of CAM2029 on long-term biochemical and symptom control in patients with acromegaly and IGF-I ≤2×ULN according to prior injectable somatostatin receptor ligand dose: results from ACROINNOVA 2

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Conflicts of interest

Principal investigator at trial site; received trial support from Camurus AB

Institutional grants:

Recordati

Crinetics

Advisor to:

Camurus AB

Chiesi Farmaceutici S.p.A.

Crinetics Pharmaceuticals

Recordati

Background

- Biochemical control is an essential objective of acromegaly treatment to alleviate symptoms and comorbidities and reduce mortality[1,2]
- Many patients with acromegaly do not achieve biochemical control with injectable SRLs such as octreotide LAR and lanreotide ATG (called SoC in this study)[2,3]

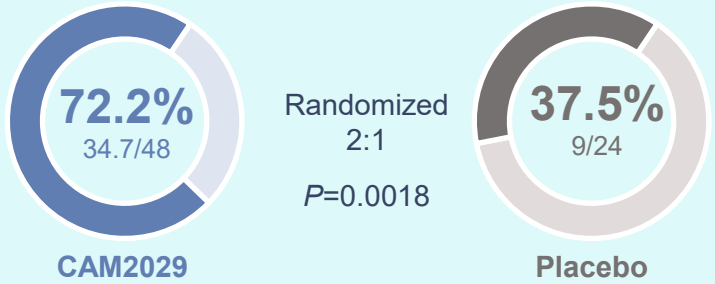
CAM2029 is a novel, long-acting octreotide SC depot developed using the FluidCrystal® technology[4,5]

- Self-administered monthly via a **ready-to-use autoinjector** with a small-gauge needle[5–7]

ACROINNOVA 1

(Patients with IGF-I ≤ULN on SoC at screening)[5]

Proportion of patients with IGF-I ≤ULN at study end



CAM2029 is **approved** for adults with acromegaly in Europe and the UK[6,7]

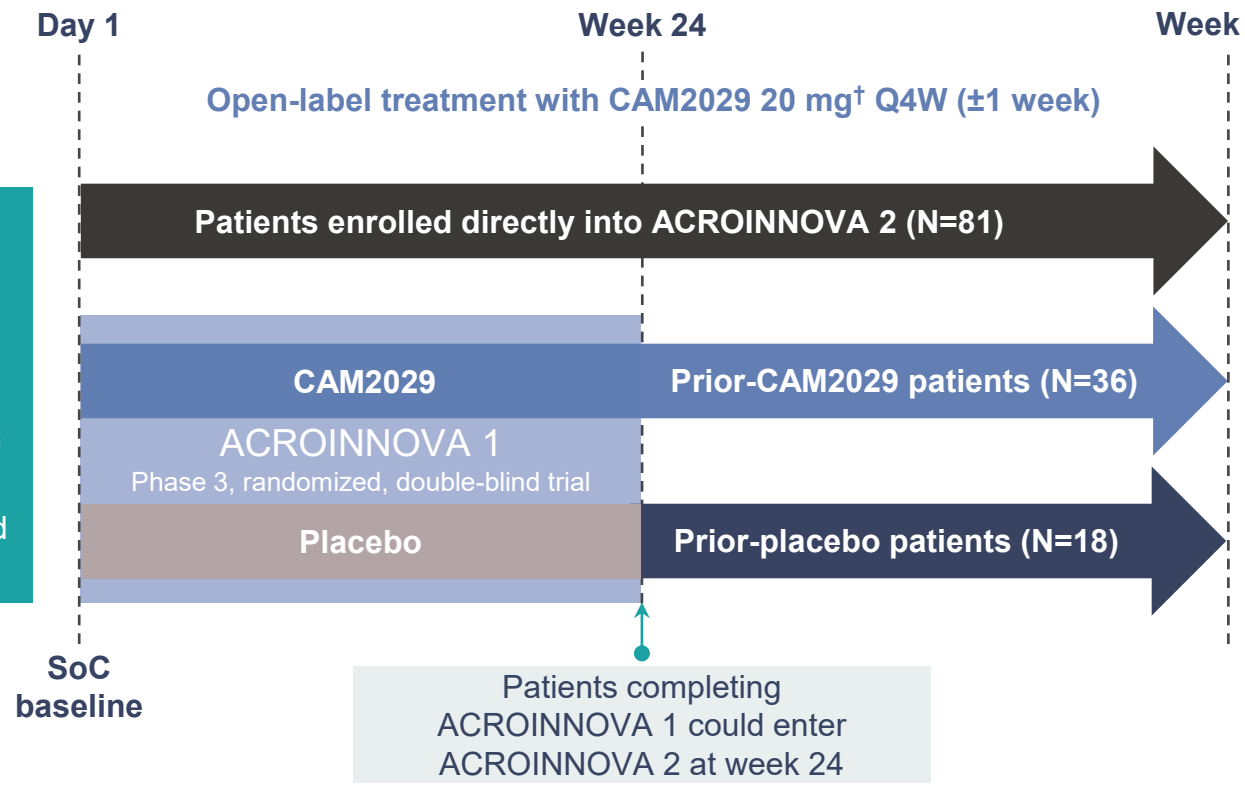
ATG, Autogel; IGF-I, insulin-like growth factor I; LAR, long-acting repeatable; SC, subcutaneous; SoC, standard of care; SRL, somatostatin receptor ligand; ULN, upper limit of normal per age and sex.

1. Melmed S *et al. Nat Rev Endocrinol* 2025;21:718–37; 2. Fleseriu M *et al. Lancet Diabetes Endocrinol* 2022;10:804–26; 3. Gadelha MR *et al. Endocr Rev* 2025;46:838–55;
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. Camurus AB. Oczyesa® (CAM2029). EU summary of product characteristics, 2025;
7. Camurus AB. Oczyesa® (CAM2029). UK summary of product characteristics, 2025.

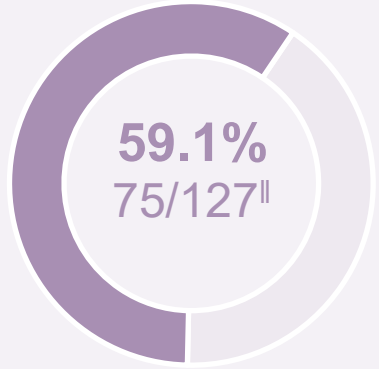
ACROINNOVA 2, a 52-week, Phase 3, open-label trial of CAM2029 in patients with acromegaly

Key eligibility criteria:

- Diagnosis of acromegaly
- Stable treatment with SoC for ≥3 months*
- **Biochemical control at screening:**
  - **ACROINNOVA 2**: IGF-I ≤2×ULN
  - **ACROINNOVA 1**: IGF-I ≤ULN and GH <2.5 µg/L[2]



Proportion of patients overall with IGF-I ≤ULN at ACROINNOVA 2 study end§[3]



ACROINNOVA 2 (NCT04125836).[1]
*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;
‡Upon completing the core phase in ACROINNOVA 2, patients could continue to receive CAM2029 for up to 104 weeks in total. §At SoC baseline in ACROINNOVA 2, 45.9% of patients overall had IGF-I ≤ULN;
‖All patients with available data at the timepoint; overall, 135 patients were enrolled into ACROINNOVA 2.
ATG, Autogel; GH, growth hormone; IGF-I, insulin-like growth factor I; LAR, long-acting repeatable; Q4W, every 4 weeks; SoC, standard of care; SRL, somatostatin receptor ligand;
ULN, upper limit of normal per age and sex.
1. Clinicaltrials.gov. NCT04125836; 2. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39; 3. Spencer-Segal JL *et al*. ESPE/ESE 2025; May 10–13, 2025; Copenhagen, Denmark; poster RC4.4a.

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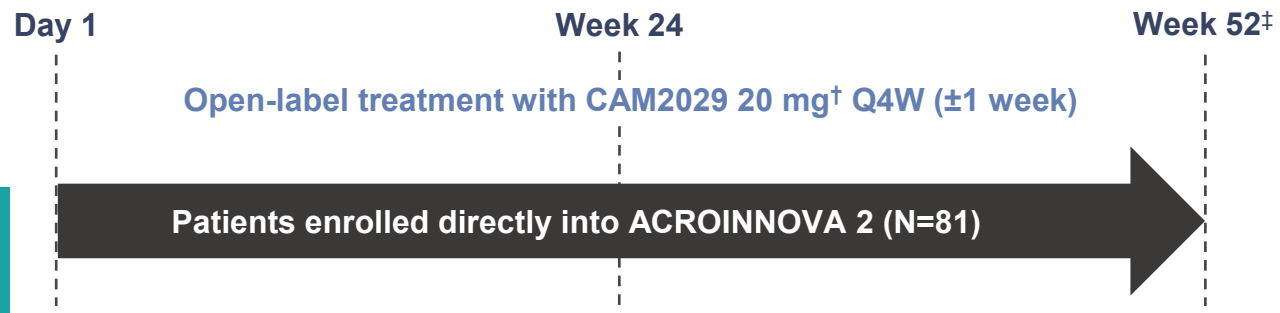

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We report descriptive biochemical and symptom control data during the 52-week core phase for directly enrolled patients, stratified by prior SRL dose at enrollment into the ACROINNOVA 2 study

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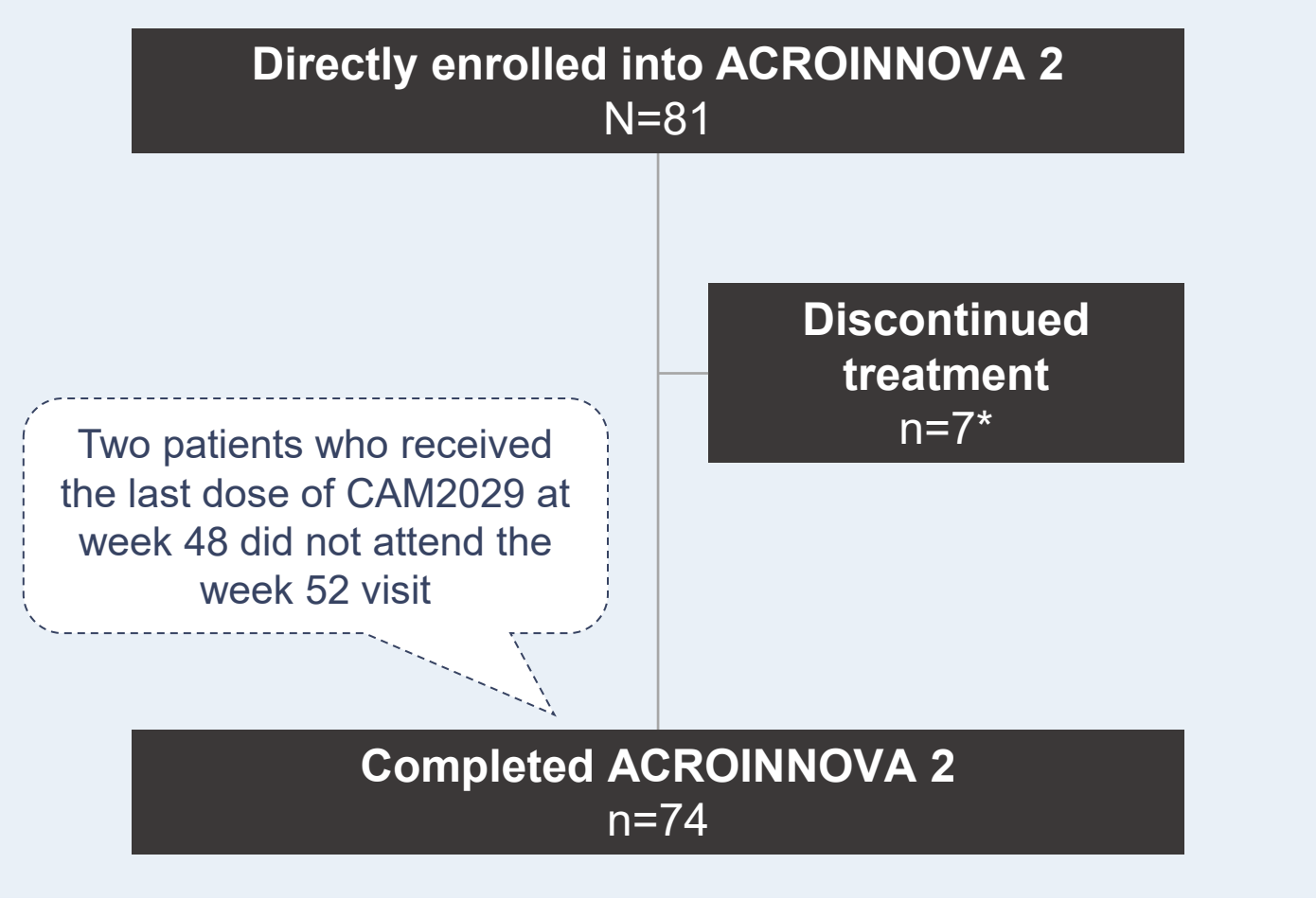
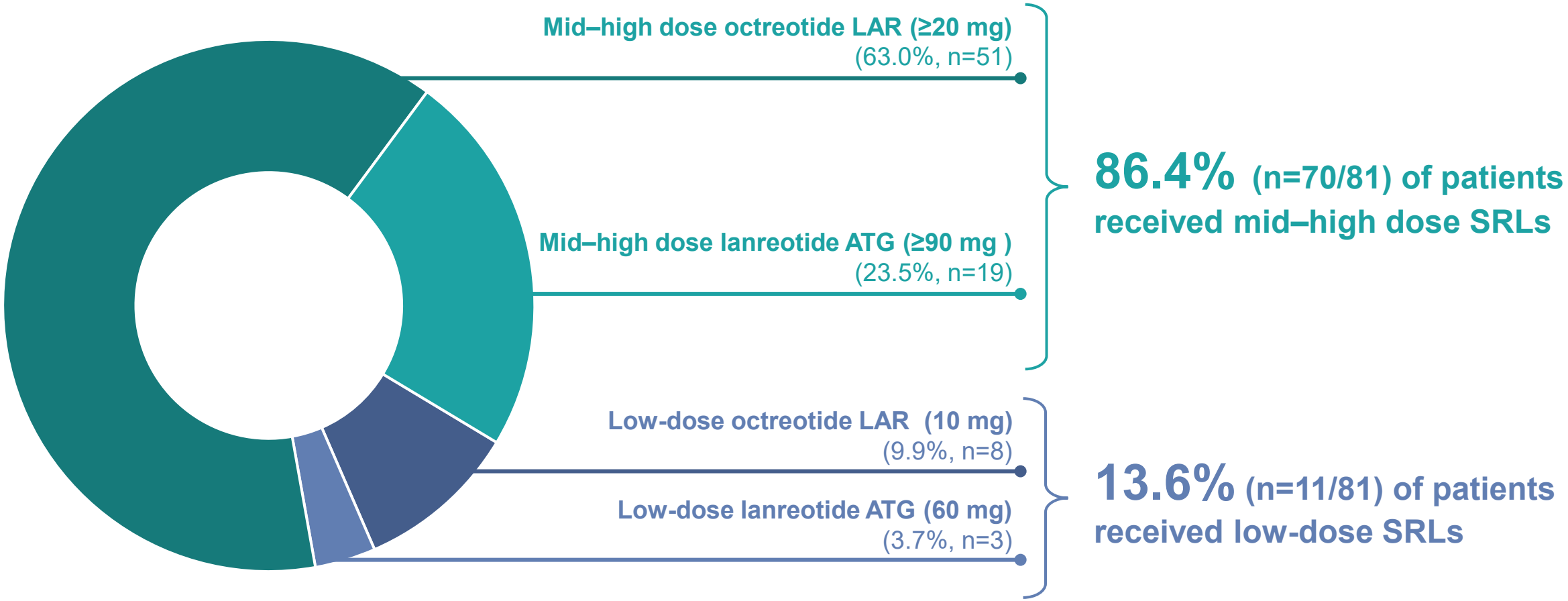
ACROINNOVA 2 directly enrolled group patient disposition



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

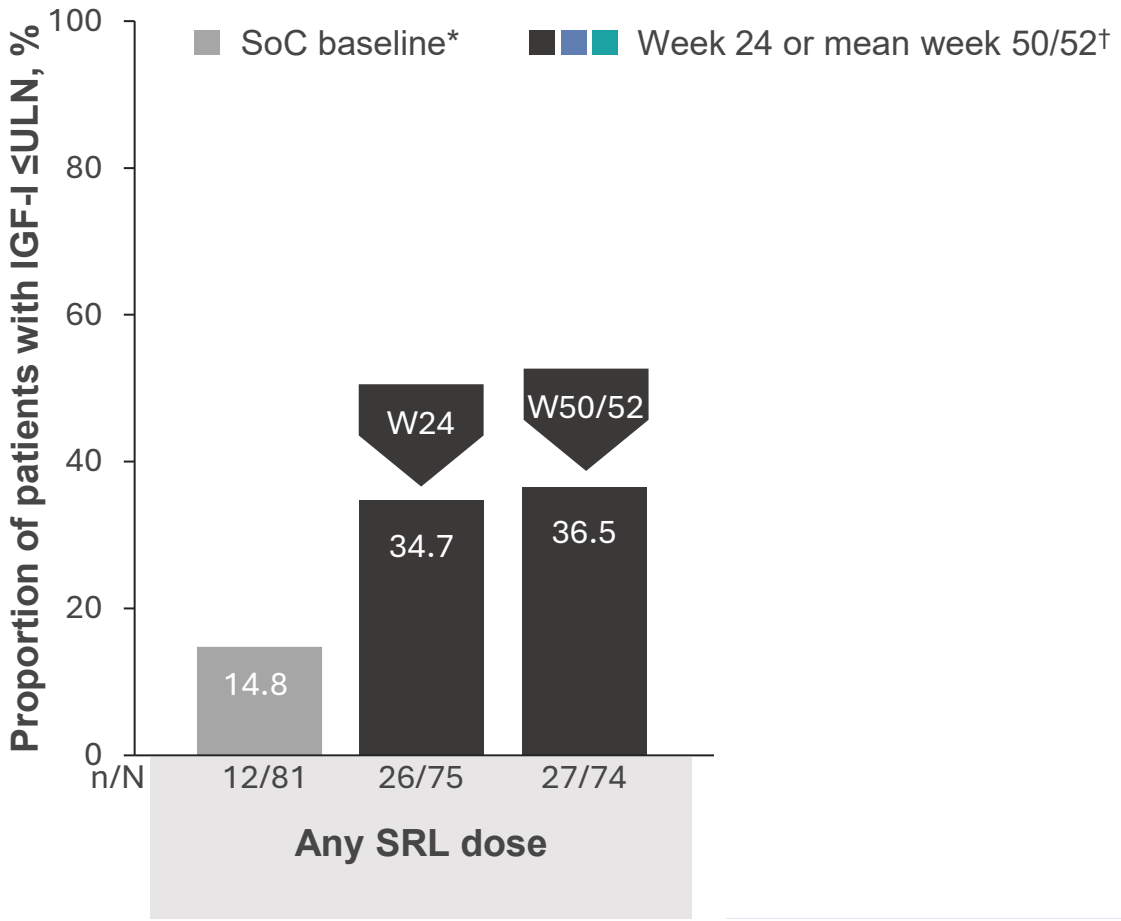
*Discontinued treatment and withdrawn from trial because of withdrawal of consent (n=5); discontinued treatment owing to AEs, switched to SoC and completed the trial (n=2; injection site hemorrhage, Grade 1 [n=1]; depression, Grade 1 [n=1]).
AE, adverse event; SD, standard deviation; SoC, standard of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

Most patients in the directly enrolled group of ACROINNOVA 2 received mid–high dose SRL therapy prior to enrollment



Last medication for acromegaly taken prior to enrollment in ACROINNOVA 2.
ATG, Autogel; LAR, long-acting repeatable; SRL, somatostatin receptor ligand.

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.
IGF-I, insulin-like growth factor I; SoC, standard of care; SRL, somatostatin receptor ligand; ULN, upper limit of normal per age and sex; W, week.

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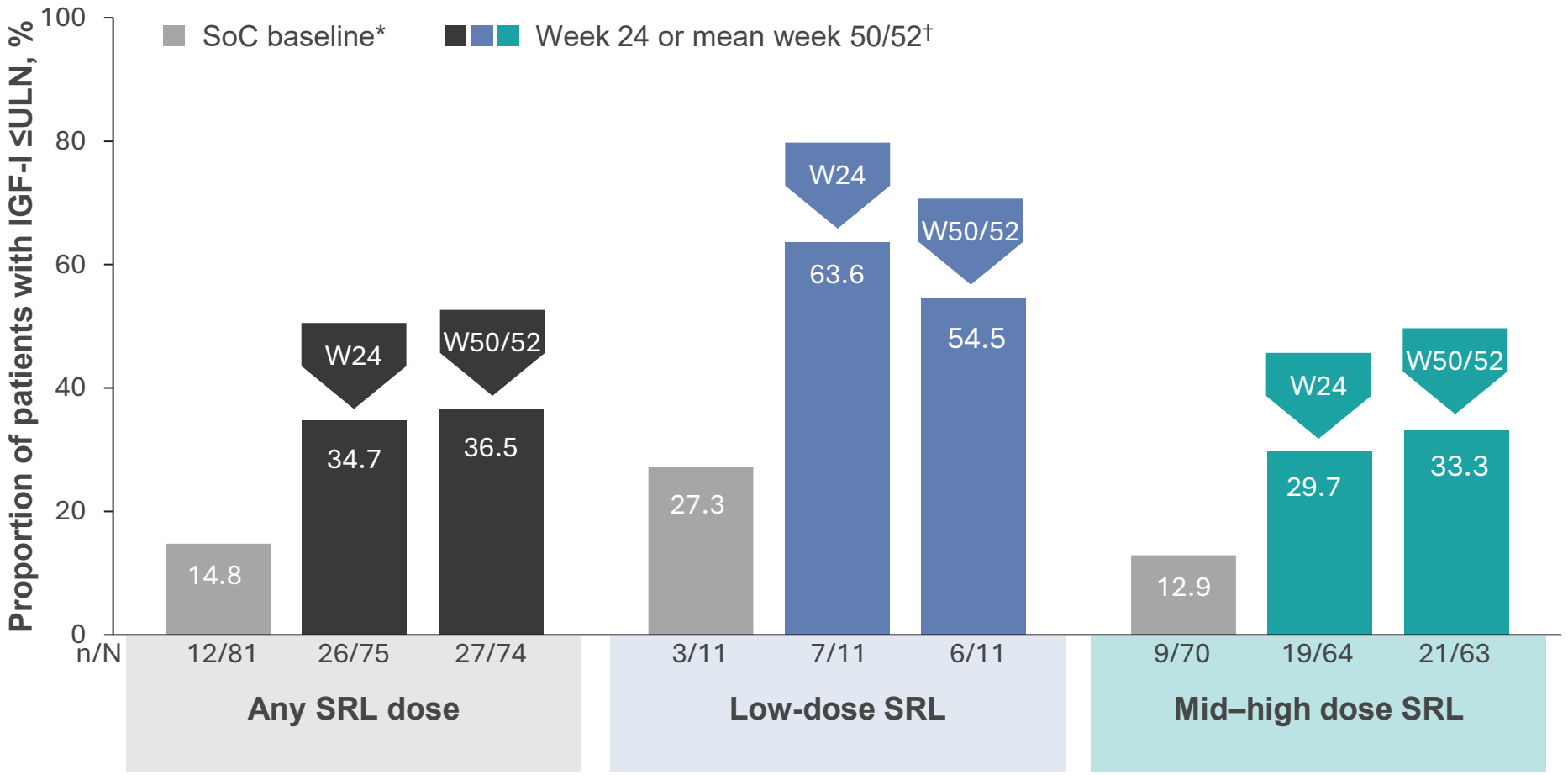

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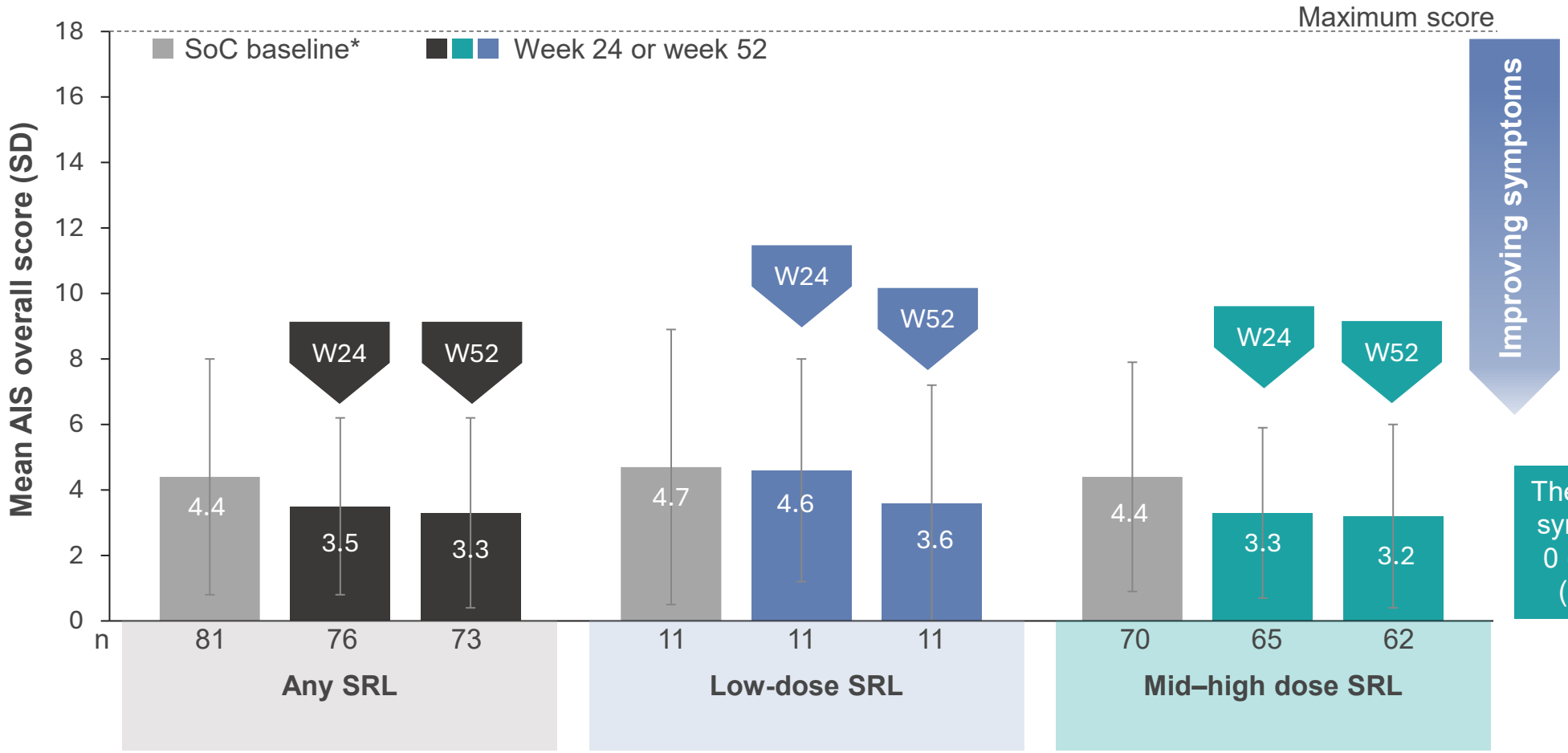
IGF-I, insulin-like growth factor I; SoC, standard of care; SRL, somatostatin receptor ligand; ULN, upper limit of normal per age and sex; W, week.

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

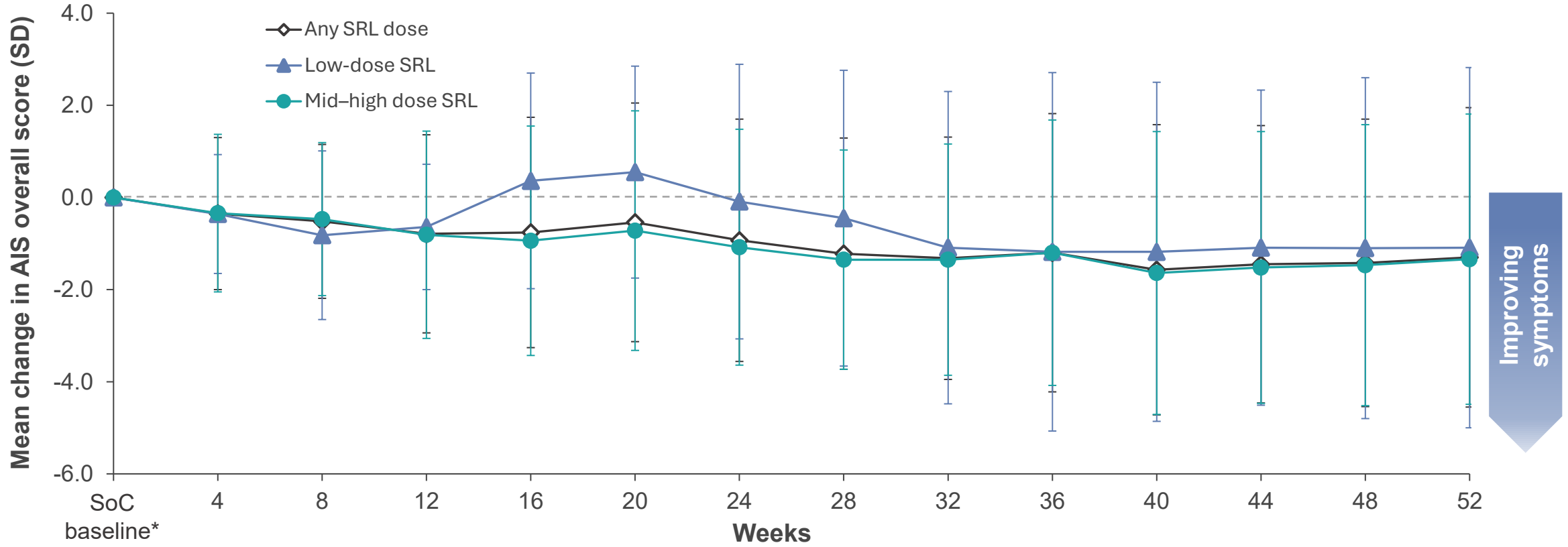


The **AIS** score assesses symptoms, scored from 0 (no symptoms) to 18 (severe symptoms)[1]

*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, paresthesia and soft tissue swelling).[1]
AIS, Acromegaly Index of Severity; SD, standard deviation; SoC, standard of care; SRL, somatostatin receptor ligand.

1. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

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



Any SRL dose	n	81	81	81	81	79	79	76	76	76	76	75	75	74	73
Mid–high dose	n	70	70	70	70	68	68	65	65	65	65	64	64	64	62
Low dose	n	11	11	11	11	11	11	11	11	11	11	11	11	10	11

*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, paresthesia and soft tissue swelling).[1]
AIS, Acromegaly Index of Severity; SD, standard deviation; SoC, standard of care; SRL, somatostatin receptor ligand.

1. Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

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, hematoma, hemorrhage, hypertrophy, induration, mass, nodule, edema, pain, pruritus, and swelling.
AE, adverse event; ATG, Autogel; LAR, long-acting repeatable; SAE, serious adverse event; SRL, somatostatin receptor ligand; TEAE, treatment-emergent adverse event.

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

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These results support CAM2029 as an effective treatment option for acromegaly, including patients with controlled or uncontrolled IGF-I on mid–high doses of octreotide LAR or lanreotide ATG

ATG, Autogel; IGF-I, insulin-like growth factor; LAR, long-acting repeatable; SRL, somatostatin receptor ligand; ULN, upper limit of normal per age and sex.

Acknowledgments

Thank you to the patients, investigators, nurses and trial coordinators who made this trial possible

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