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CAM2029 maintains IGF-I and acromegaly symptom control across the 4-week dosing interval and intervals >28 days: data from ACROINNOVA 1

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BACKGROUND

- Acromegaly is characterised by the overproduction of growth hormone (GH) and insulin-like growth factor I (IGF-I), leading to substantial morbidity and reduced quality of life (QoL)[1]
- Biochemical control (IGF-I ≤upper limit of normal [ULN] per age)[2,3] can be provided by standard-of-care (SoC) medical treatment (first-generation injectable somatostatin receptor ligands [SRLs]; octreotide long-acting repeatable [LAR] or lanreotide Autogel [ATG])[4]
- For patients with acromegaly, symptom control is a priority.[5] However, some patients report worsening or re-emergence of symptoms towards the end of the SoC monthly dosing interval[6,7]
- 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 pre-filled pen (autoinjector) with a small-gauge needle[8,9] (see **Supplementary Figure 1**, available via the QR code)
- ACROINNOVA 1 was a 24-week, Phase 3, randomised, double-blind, placebo-controlled trial (NCT04076462) of once-monthly CAM2029 (±1 week) in patients with IGF-I ≤ULN per age and sex while receiving SoC treatment at screening[9]
 - CAM2029 achieved superior IGF-I control versus placebo (72.2 vs 37.5% of patients, respectively; *P*=0.0018)
 - Patients receiving CAM2029 had well-controlled symptoms and improved QoL compared with baseline SoC
 - The safety profile was consistent with those of first-generation SRLs

CONCLUSIONS

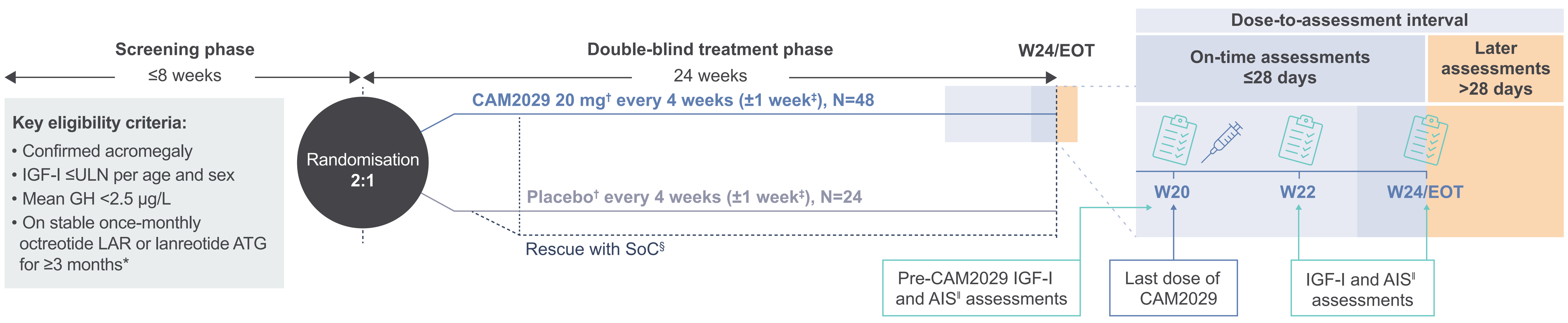
In patients biochemically controlled at screening on SoC and receiving CAM2029 for 24 weeks, IGF-I control was maintained and symptoms were consistently well managed throughout a 4-week post-dose interval

More than half of patients had later assessments (intervals >28 days); these patients also maintained biochemical and symptom control

These findings provide useful information on the efficacy profile of CAM2029 lasting beyond a 28-day dosing window, reinforcing the potential of CAM2029 to control the burden of disease and address unmet needs among patients with acromegaly

METHODS

The stability of IGF-I and symptom control was evaluated following the final CAM2029 dose in ACROINNOVA 1


Screening phase
≤8 weeks
Key eligibility criteria:
• Confirmed acromegaly
• IGF-I ≤ULN per age and sex
• Mean GH <2.5 µg/L
• On stable once-monthly octreotide LAR or lanreotide ATG for ≥3 months*
Randomisation
2:1
Double-blind treatment phase
24 weeks
W24/EOT
CAM2029 20 mg† every 4 weeks (±1 week‡), N=48
Placebo† every 4 weeks (±1 week‡), N=24
Rescue with SoC§
Dose-to-assessment interval
On-time assessments
≤28 days
Later assessments
>28 days
W20
W22
W24/EOT
Pre-CAM2029 IGF-I and AIS‖ assessments
Last dose of CAM2029
IGF-I and AIS‖ assessments

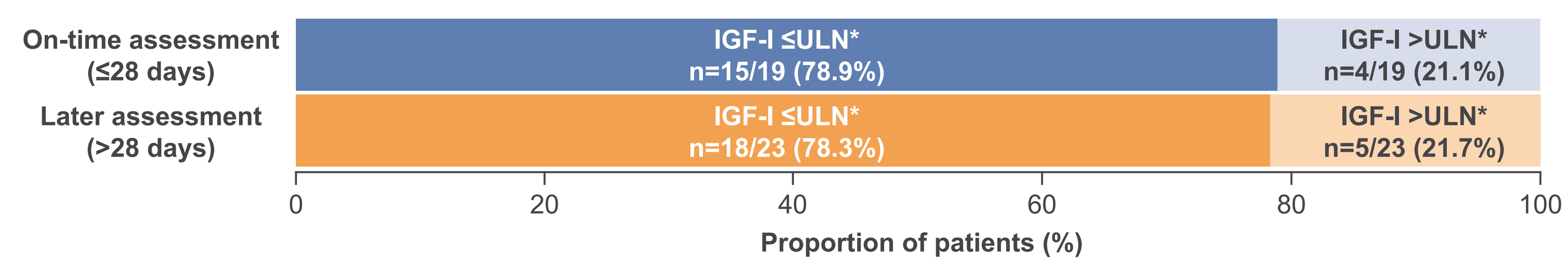
- We report descriptive data from W20, W22 and W24/EOT from patients completing their W20 CAM2029 dose and their W24/EOT assessments, with either assessments performed at ≤28 days post-dose (on-time assessments) or assessments performed at >28 days post-dose (later assessments):
 - Proportion of patients with IGF-I ≤ULN (W24/EOT only)
 - IGF-I/ULN values (subgroup means and individual patients)
 - AIS overall scores (subgroup means and individual patients)
 - Proportion of patients with individual symptoms of acromegaly (subgroups)

Adapted from Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39. *Octreotide LAR 10, 20, 30 or 40 mg or lanreotide ATG 60, 90 or 120 mg; †If required, dose reduction to 10 mg CAM2029 or 0.5 mL placebo for safety and tolerability; ‡For patient convenience, administration of CAM2029/placebo was permitted within a window of ±1 week around each scheduled 4-weekly dose. Dose timings were not adjusted in relation to any potential lack of efficacy or safety issue; §Patients who were rescued by switch to SoC continued to participate in the trial and attended all planned visits (n=1, placebo group); ‖Details of the AIS (evaluation of key acromegaly symptoms by clinician and patient together) are provided in **Supplementary Figure 2**, available via the QR code. AIS, Acromegaly Index of Severity; EOT, end of trial; W, week.

RESULTS

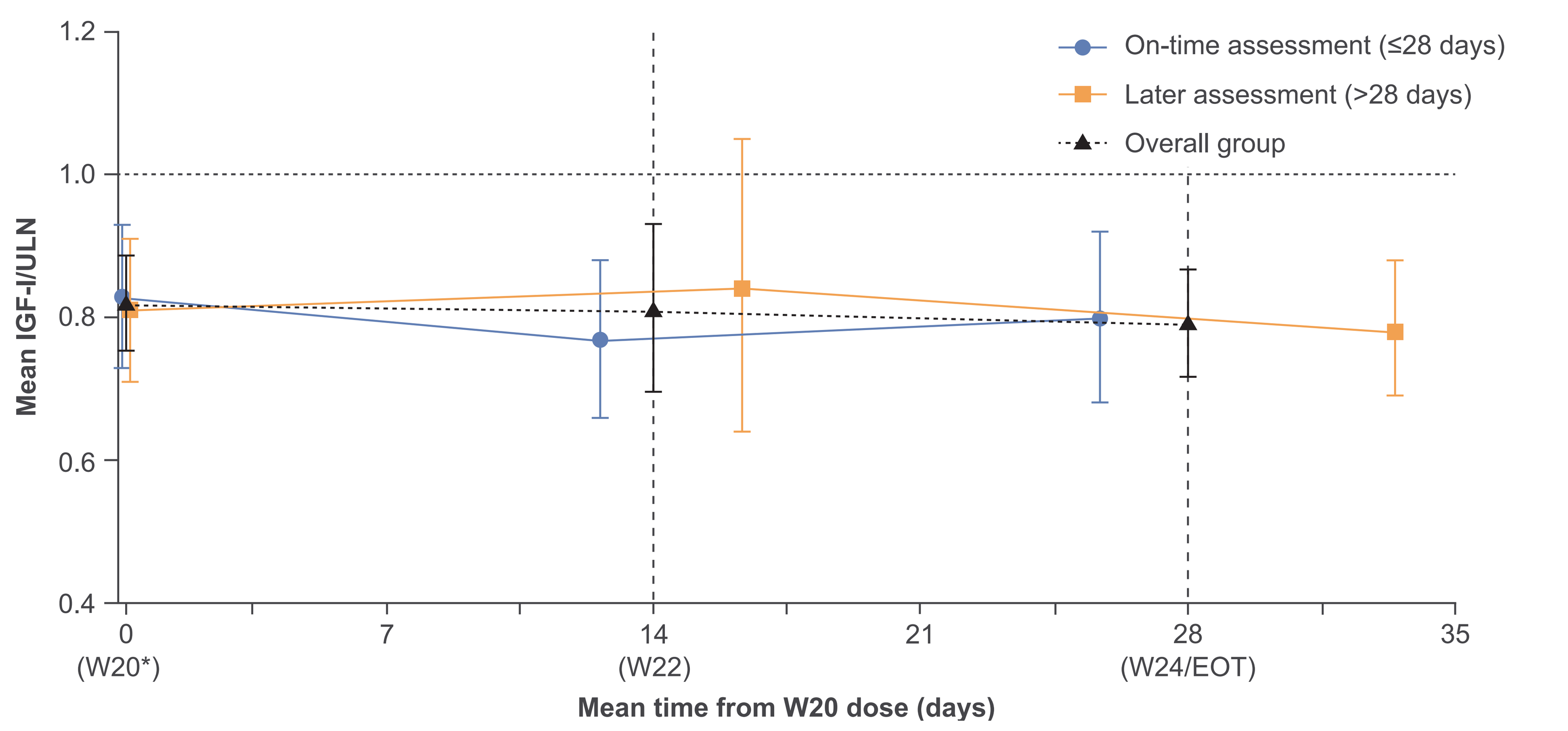
- 48 patients were randomised to CAM2029 in ACROINNOVA 1 (see **Supplementary Table 1** for more details, available via the QR code)[9]
- 42 (87.5%) patients completed CAM2029 treatment and formed the population for the analyses reported here[9]
 - Two patients withdrew from the trial and four discontinued treatment because of adverse events
- W24/EOT assessments were performed ≤28 days post-dose (on time) for 19 (45.2%) patients and were later (>28 days post-dose) for 23 (54.8%) patients (including six patients with assessments delayed >35 days post-dose). Some later assessments were due to COVID-19
- The mean (range) duration of the final dosing interval was:
 - 25.7 (21–28) days for the on-time assessment group
 - 33.4 (29–42) days for the later assessment group

Most patients achieved biochemical control at W24/EOT, including those with assessments performed >28 days post-dose


On-time assessment (≤28 days)
IGF-I ≤ULN* n=15/19 (78.9%)
IGF-I >ULN* n=4/19 (21.1%)
Later assessment (>28 days)
IGF-I ≤ULN* n=18/23 (78.3%)
IGF-I >ULN* n=5/23 (21.7%)
0 20 40 60 80 100
Proportion of patients (%)

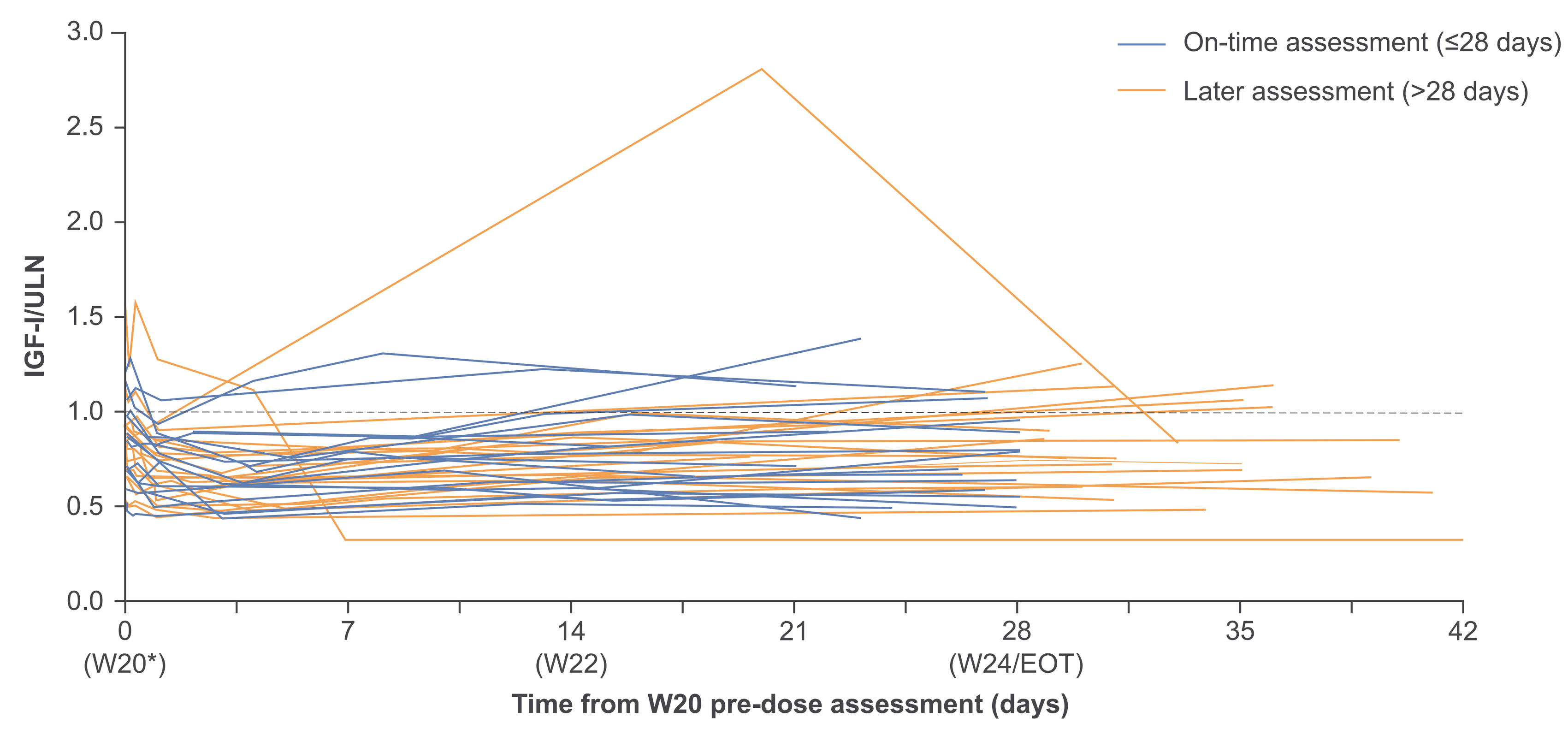
Data are for patients who completed their W20 dose and post-final dose assessments (N=42). *ULN per age and sex.

Mean IGF-I values remained stable throughout the dose-to-assessment interval, including in patients with assessments performed >28 days post-dose


On-time assessment (≤28 days)
Later assessment (>28 days)
Overall group
Mean IGF-I/ULN
1.2
1.0
0.8
0.6
0.4
0 (W20*)
7
14 (W22)
21
28 (W24/EOT)
35
Mean time from W20 dose (days)

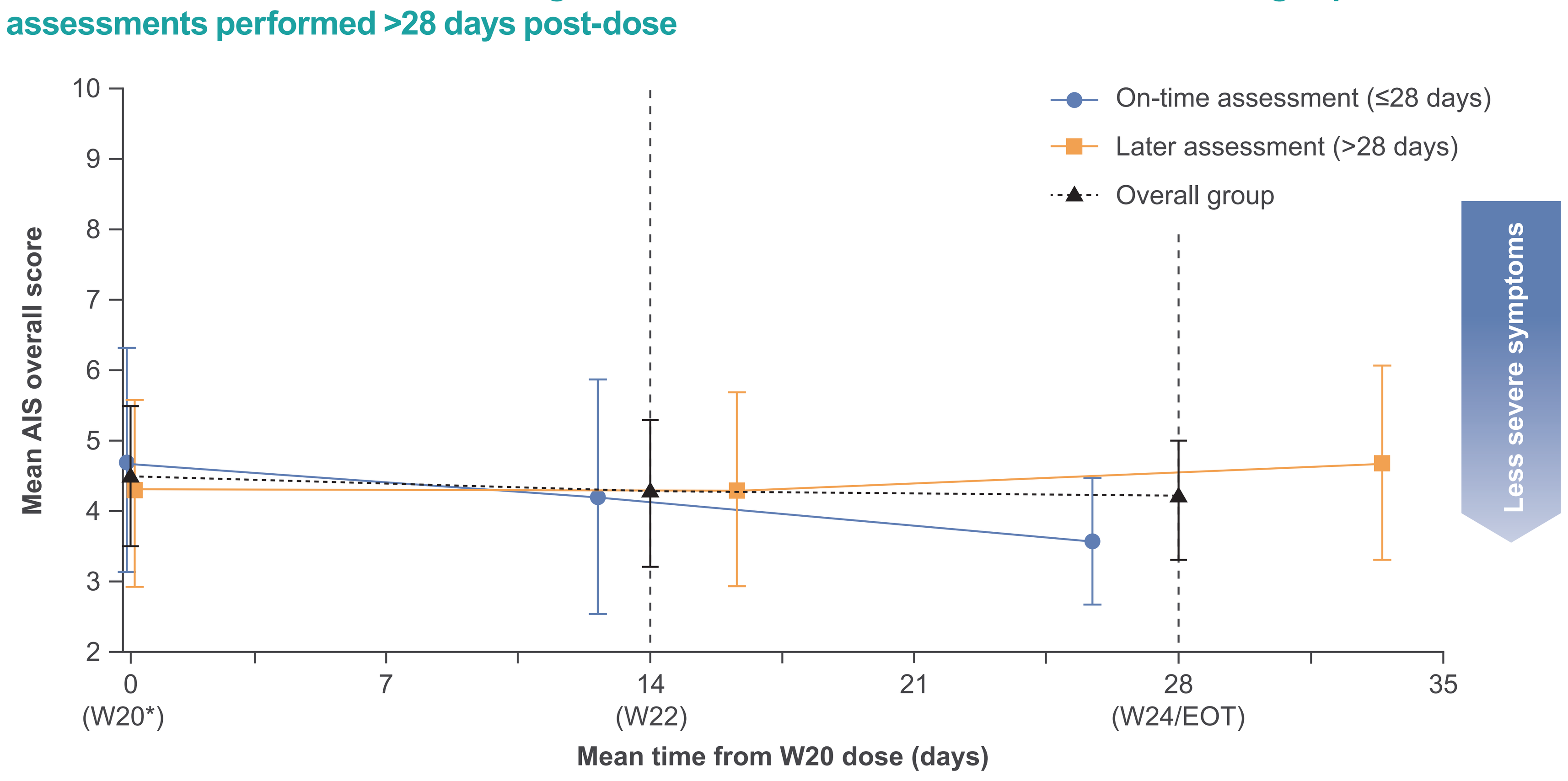
*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). Error bars represent ±95% CI. The grey horizontal rule represents ULN per age and sex. CI, confidence interval.

IGF-I values generally remained stable in individual patients, including in those with assessments performed >28 days post-dose


On-time assessment (≤28 days)
Later assessment (>28 days)
IGF-I/ULN
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0 (W20*)
7
14 (W22)
21
28 (W24/EOT)
35
42
Time from W20 pre-dose assessment (days)

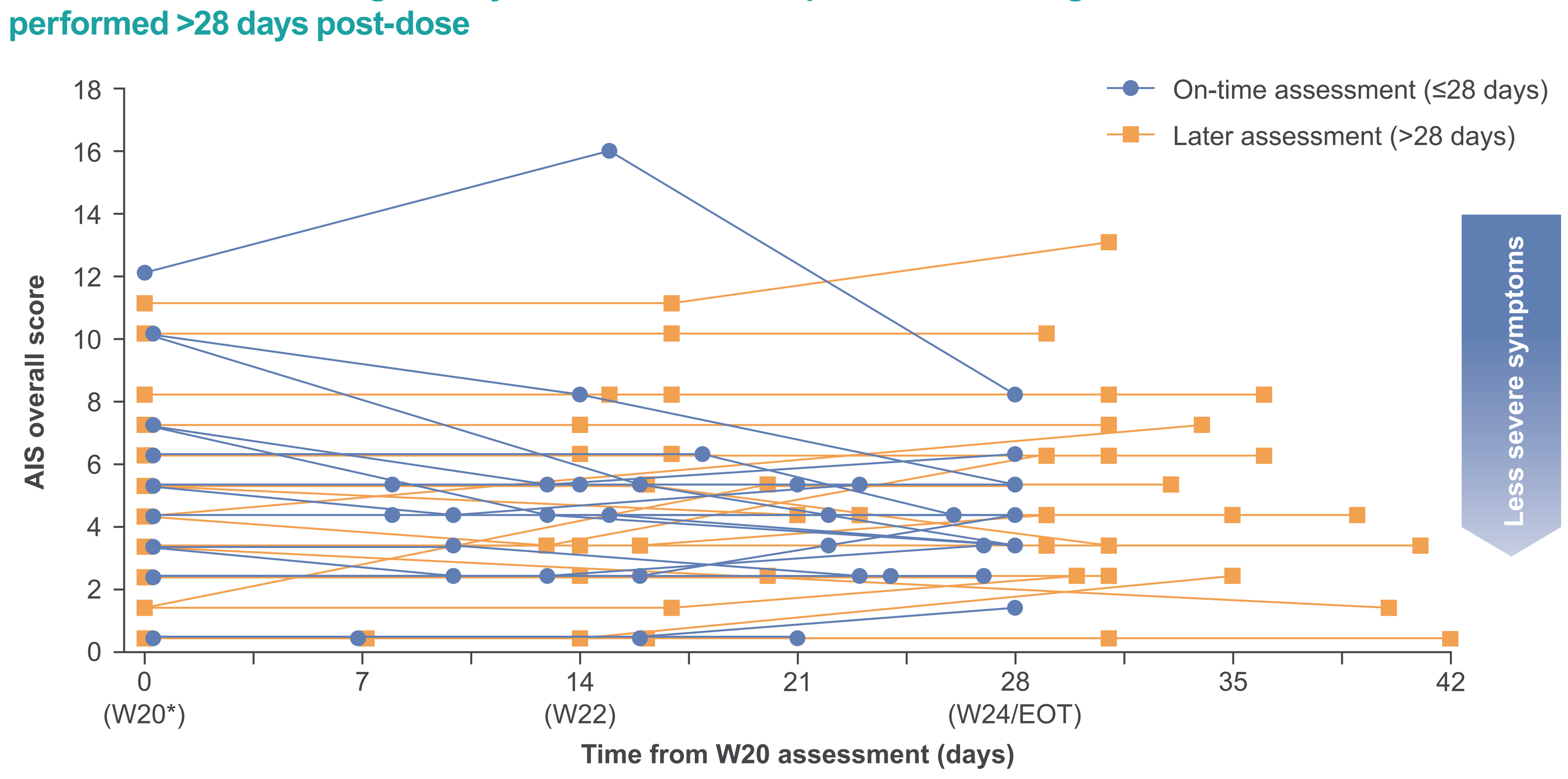
*W20 assessments were conducted prior to CAM2029 administration. Additional samples taken at 2±1 hours, 5±1 hours, 8±1 hours, 24±4 hours and 96±24 hours post-CAM2029 administration are shown here. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). The grey horizontal rule represents ULN per age and sex. Results for the W22 assessment show a single outlier result with raised IGF-I; this patient had normal IGF-I levels at W20 and W24/EOT assessments, suggesting this result is an artefact.

AIS overall scores were stable throughout the dose-to-assessment interval, including in patients with assessments performed >28 days post-dose


On-time assessment (≤28 days)
Later assessment (>28 days)
Overall group
Less severe symptoms
Mean AIS overall score
10
9
8
7
6
5
4
3
2
0 (W20*)
7
14 (W22)
21
28 (W24/EOT)
35
Mean time from W20 dose (days)

*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). AIS scores range from 0 (lowest) to 18 (highest); sum of 6 scores (0–3; none–severe) for headache, sweating, fatigue, joint pain, paraesthesia, and soft tissue swelling. A reduction in AIS overall score indicates improvement in symptoms. Error bars represent ±95% CI. Individual patient AIS scores were generally stable, including among those with later assessments. Control of individual symptoms was maintained throughout the dose-to-assessment interval, including among patients with assessments performed >28 days post-dose. See **Supplementary Figure 3** for more details, available via the QR code.

AIS overall scores were generally stable in individual patients, including in those with assessments performed >28 days post-dose


On-time assessment (≤28 days)
Later assessment (>28 days)
Less severe symptoms
AIS overall score
18
16
14
12
10
8
6
4
2
0
0 (W20*)
7
14 (W22)
21
28 (W24/EOT)
35
42
Time from W20 assessment (days)

*W20 assessments were conducted prior to CAM2029 administration. Data are for patients who completed their W20 dose and post-final dose assessments (on-time assessments at W20, W22 and W24/EOT, n=19; later assessments at W20 and W24/EOT, n=23; later assessments at W22, n=22). AIS scores range from 0 (lowest) to 18 (highest); sum of 6 scores (0–3; none–severe) for headache, sweating, fatigue, joint pain, paraesthesia, and soft tissue swelling. A reduction in AIS overall score indicates improvement in symptoms.

References

1. Gadelha MR *et al. Endocr Rev* 2019;40:268–332; **2.** Giustina A *et al. Pituitary* 2024;27:7–22; **3.** Giustina A *et al. Rev Endocr Metab Disord* 2020;21:667–78; **4**. Fleseriu M *et al. Lancet Diabetes Endocrinol* 2022;10:804–26; **5.** Gurel MH *et al. Patient Prefer Adherence* 2014;8:53–62; **6.** Strasburger CJ *et al. Eur J Endocrinol* 2016;174:355–62; **7**. Geer EB *et al. BMC Endocr Disord* 2020;20:117; **8**. Tiberg F *et al. Br J Clin Pharmacol* 2015;80:460–72; **9.** Ferone D *et al. J Clin Endocrinol Metab* 2025;110:1729–39.

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