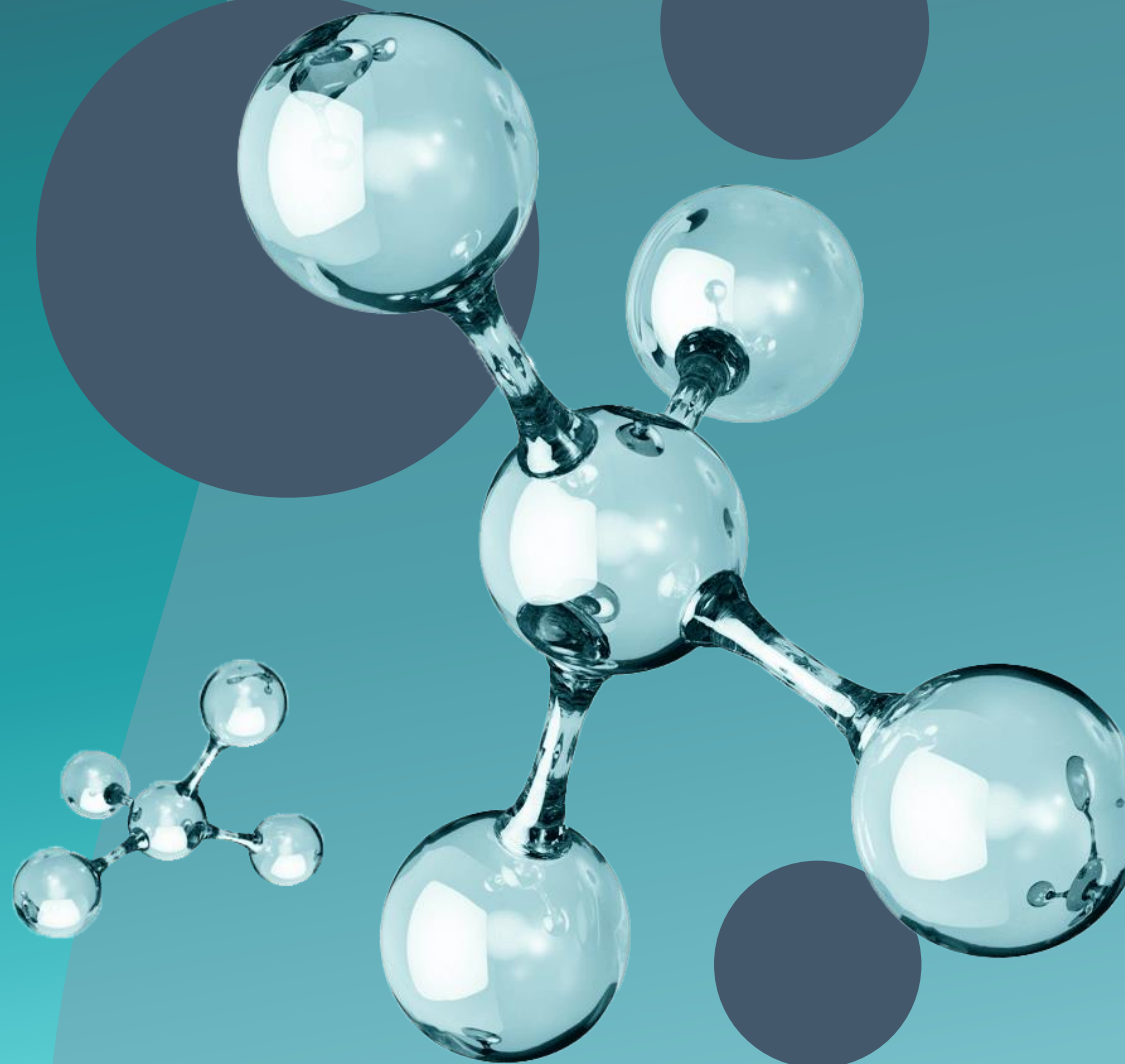




HERO/OLE Update



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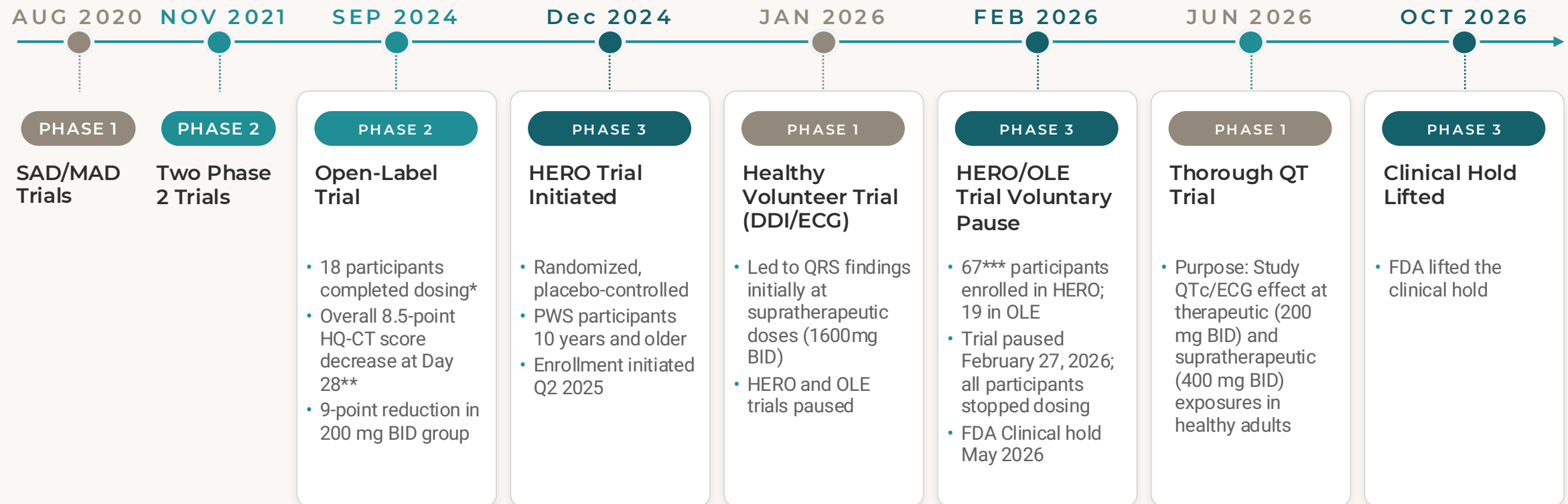
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ARD-101 Prader-Willi Syndrome (PWS) Program

Clinical proof-of-concept in hyperphagia, Phase 3 learnings, and a dedicated thorough QT study



*19 participants were enrolled in the Phase 2 trial and are included in the Safety Analysis Sets; 18 participants completed dosing.

**Average of overall per protocol HQ-CT score change is -8.5 from baseline to Day 28 (N=11).

***67 unique subjects randomized, 1 subject re-enrolled after randomization error (n=68), 3 subjects with baseline HQ-CT scores <13 were not included in ITT



Executive Summary

Clinical signals demonstrate rapid ARD-101 benefit, with a well-tolerated safety profile despite early trial termination.

1

HERO stopped early, enrollment truncated

- Did not reach the planned “n”, results should be considered exploratory
- Convergence of signals, directionality

2

Early response

- Rapid HQ-CT score reduction by Week 2
- Dose Escalation period

3

Placebo

- Placebo response as observed in other Prader-Willi Syndrome trials

4

OLE

- Former placebo participants have additional ~6-pt drop once on ARD-101 in open-label

5

Withdrawal data

- Symptoms rebound off-drug in the treated arm — potential drug-effect hallmark

6

Safety / SAE

- One Grade 4 cardiac event at 800 mg BID, DDI with pitolisant
- **No additional cardiac SAEs or clinically significant cardiac AEs observed for HERO**

7

Regulatory

- Clinical Hold Removal



Cardiac Safety: ECG and DDI Findings

ECG findings in healthy volunteers 2026

Before clinical hold

3 of 31 volunteers receiving ARD-101 at 1600 mg BID and 800 mg BID had QRS increases >25% of baseline (non-serious, reversible, no medical intervention required)



After clinical hold

Additional ECG studies with ARD-101 at 200 mg (n=45) and 400 mg (n=42) BID in healthy volunteers found no QRS prolongation.

Across all studies

- No increases in QTc were observed at any dose in the healthy volunteer studies.
- No QRS findings were observed in available ECGs from the PWS studies.

Drug-Drug Interaction (DDI)

- At 800 mg BID, ARD-101 is a strong inhibitor of CYP2D6, which may affect the metabolism of certain concomitant medications.
- The SAE of polymorphic ventricular tachycardia in Phase 3 was observed in a participant who was concurrently dosing on pitolisant (a CYP2D6 substrate).

HERO and OLE Trial Design

ARD-101 in PWS with Hyperphagia | Phase 3 HERO and OLE Trial Designs

PHASE 3 HERO | 12-WEEK RANDOMIZED DOUBLE-BLIND TRIAL

Key Eligibility

- PWS with hyperphagia
- ≥ 10 years old
- Stable and consistent caregiver

RANDOMIZED 1:1

ARD-101 · n=45

Placebo · n=45

Endpoints

PRIMARY

Hyperphagia-related behavior measured by HQ-CT scores, in participants with an initial HQ-CT score of 13 or greater

SECONDARY

Caregiver-reported (CaGI-S, CaGI-C) and clinician-reported (CGI-S, CGI-C) outcomes



OLE | 1-YEAR OPEN-LABEL EXTENSION

Participants completing HERO Phase 3



ARD-101 open-label · Day 1 to Day 365



Safety follow-up to Day 393

Evaluating long-term safety of ARD-101 and change in HQ-CT score

DOSING (BOTH STUDIES) 200 mg BID Days 1-7 → 400 mg BID Days 8-14 → 800 mg BID thereafter (12 weeks in HERO; 1 year in HERO-OLE)



HERO and OLE Baseline Demographics

Parameter	Statistic	HERO ITT (HQ-CT ≥ 13)			OLE mITT ¹		
		Pooled (N=64)	Placebo (N=32)	ARD-101 (N=32)	Pooled (N=19)	Placebo (N=11)	ARD-101 (N=8)
Age, years	Mean (SD) (range)	19.9 (7.2) (10–43)	19.4 (6.8) (11–43)	20.3 (7.6) (10–43)	21.5 (7.4) (13–41)	21.4 (8.4) (13–41)	21.8 (6.5) (13–31)
Sex, n (%)	Female	33 (52%)	18 (56%)	15 (47%)	9 (47%)	7 (64%)	2 (25%)
	Male	31 (48%)	14 (44%)	17 (53%)	10 (53%)	4 (36%)	6 (75%)
BMI, kg/m ²	Mean (SD)	31.0 (8.5)	32.2 (8.9)	29.9 (8.1)	28.4 (6.4)	29.9 (6.8)	26.5 (5.7)
	BMI <30, n (%)	37 (58%)	16 (50%)	21 (66%)	13 (68%)	6 (55%)	7 (88%)
	BMI ≥ 30 , n (%)	27 (42%)	16 (50%)	11 (34%)	6 (32%)	5 (45%)	1 (12%)
HQ-CT Score Baseline	Mean (SD)	22.7 (6.4)	22.8 (6.7)	22.5 (6.2)	16.3 (8.90)	14.4 (7.89)	19.0 (10.03)
CGI-S Score Baseline	Mean (SD)	4.8 (0.7)	4.9 (0.6)	4.8 (0.8)	4.6 (0.96)	4.6 (0.92)	4.5 (1.07)
CaGI-S Score Baseline	Mean (SD)	5.6 (0.9)	5.5 (1.0)	5.7 (0.8)	4.5 (1.26)	4.2 (0.98)	4.9 (1.55)

¹Baseline at the start of OLE.

mITT: modified intent-to-treat population; all patients who completed the HERO trial, rolled over into the OLE trial, and received at least one dose of ARD-101.



OLE mITT Population at Baseline

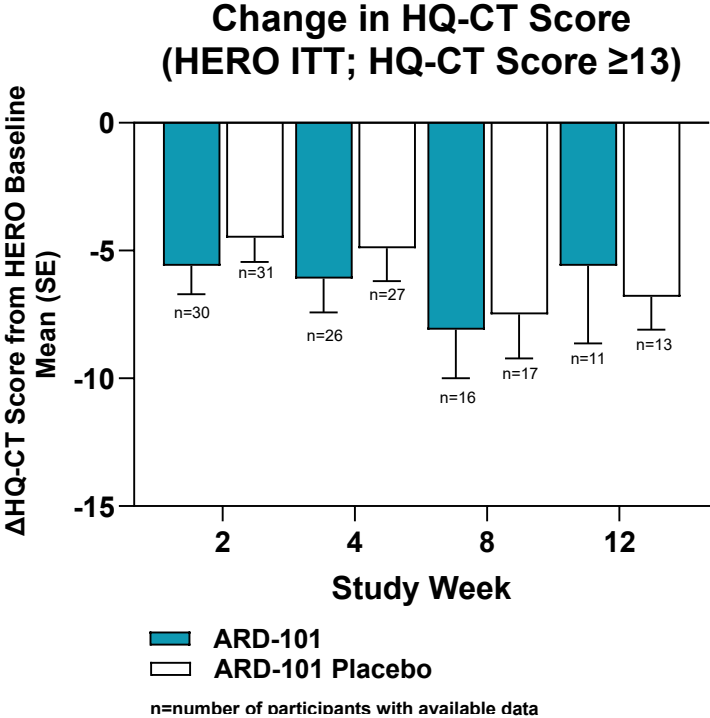
Efficacy Parameter	Treatment	HERO Baseline Mean (SD)	OLE Baseline Mean (SD)
HQ-CT Score	ARD-101 (n=8)	25.0 (7.3)	19.0 (10.0)
	Placebo (n=11)	20.4 (8.3)	14.4 (7.9)
CGI-S Score	ARD-101 (n=8)	5.1 (1.0)	4.5 (1.1)
	Placebo (n=11)	5.0 (0.6)	4.6 (0.9)
CaGI-S Score	ARD-101 (n=8)	6.0 (0.8)	4.9 (1.6)
	Placebo (n=11)	5.2 (1.0)	4.2 (1.0)



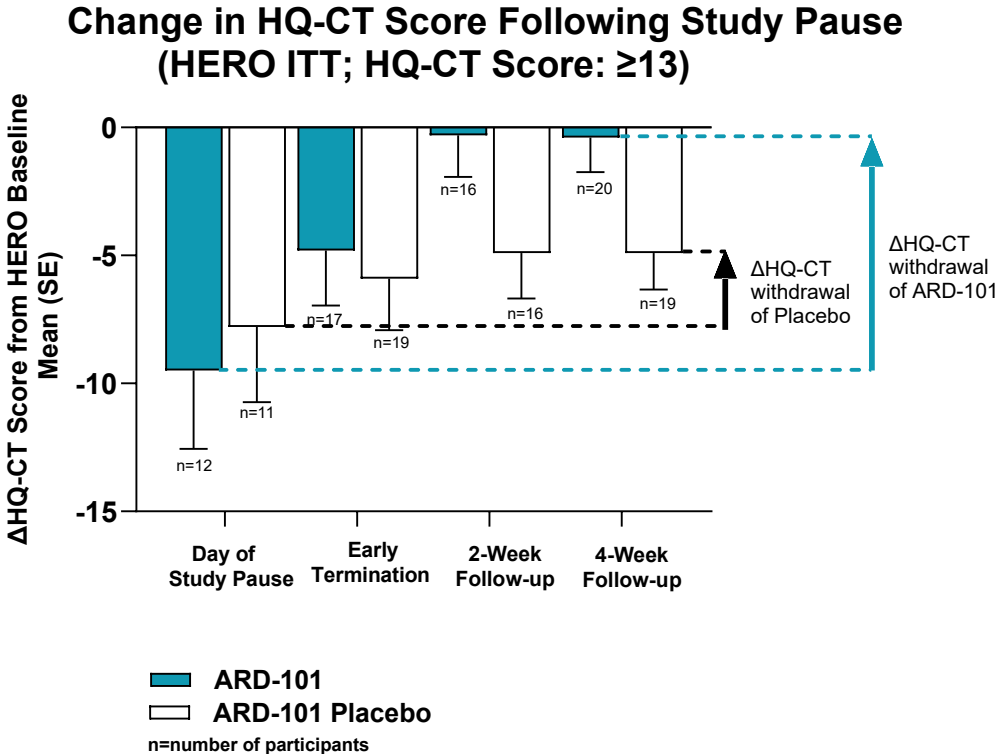
Change in HQ-CT Score During HERO and After Study Pause

Numerically greater HQ-CT score improvement with ARD-101 through Week 8; limited Week 12 data due to early study termination. The effect observed with ARD-101 was lost after treatment stopped, while the placebo response largely persisted.

On ARD-101 or Placebo



Withdrawal of ARD-101 or Placebo



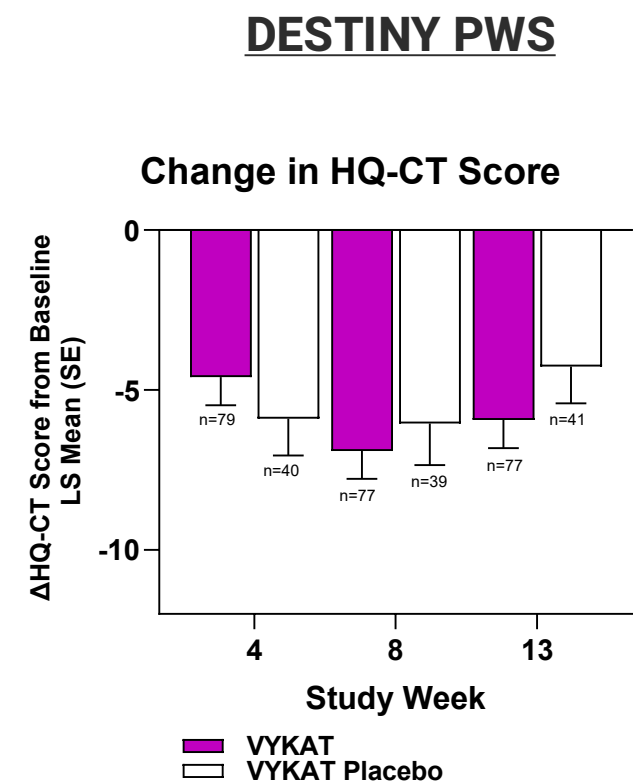
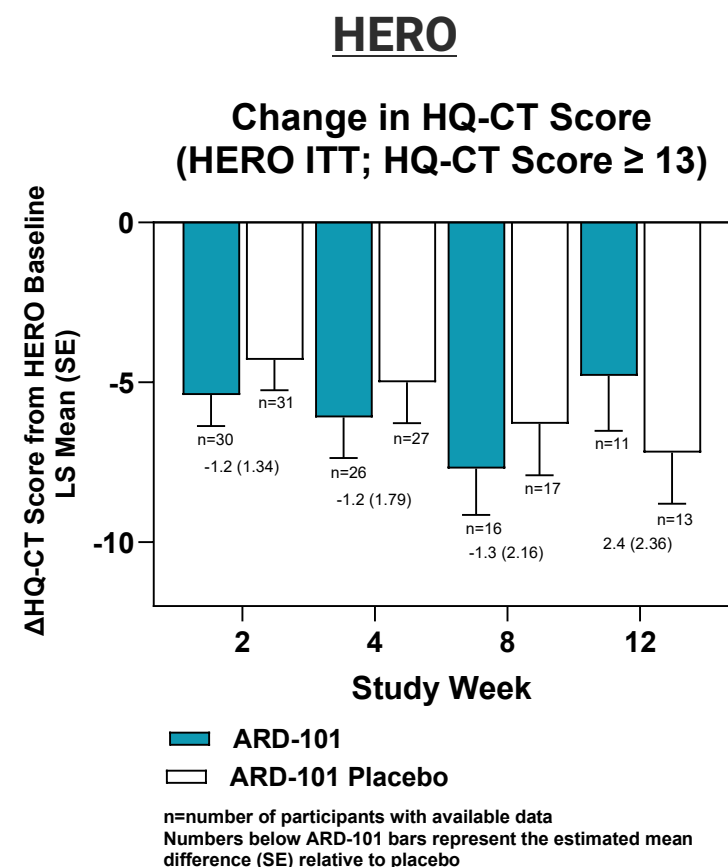
Data includes all participants (ITT) enrolled into the HERO study. No statistical adjustments were made for covariates, including baseline HQ-CT score.

Day of Study Pause: occurred on day treatment was paused. Early Termination: occurred after treatment had ended.



HERO Change in HQ-CT Score

Similar reductions in HQ-CT scores for ARD-101 relative to VYKAT XR's Randomized Control Study (DESTINY PWS)



Summary basis of approval NDA216665; LS mean value were estimated visually from Figure 3 at Week 4 and Week 8. n's below bars are from Figure 3 in Summary of approval NDA 216665 and Miller et al., 2023.

Data includes all participants (ITT) enrolled into the HERO study. Data present the primary analysis using the MMRM statistical model, which included covariates (e.g., baseline HQ-CT score).

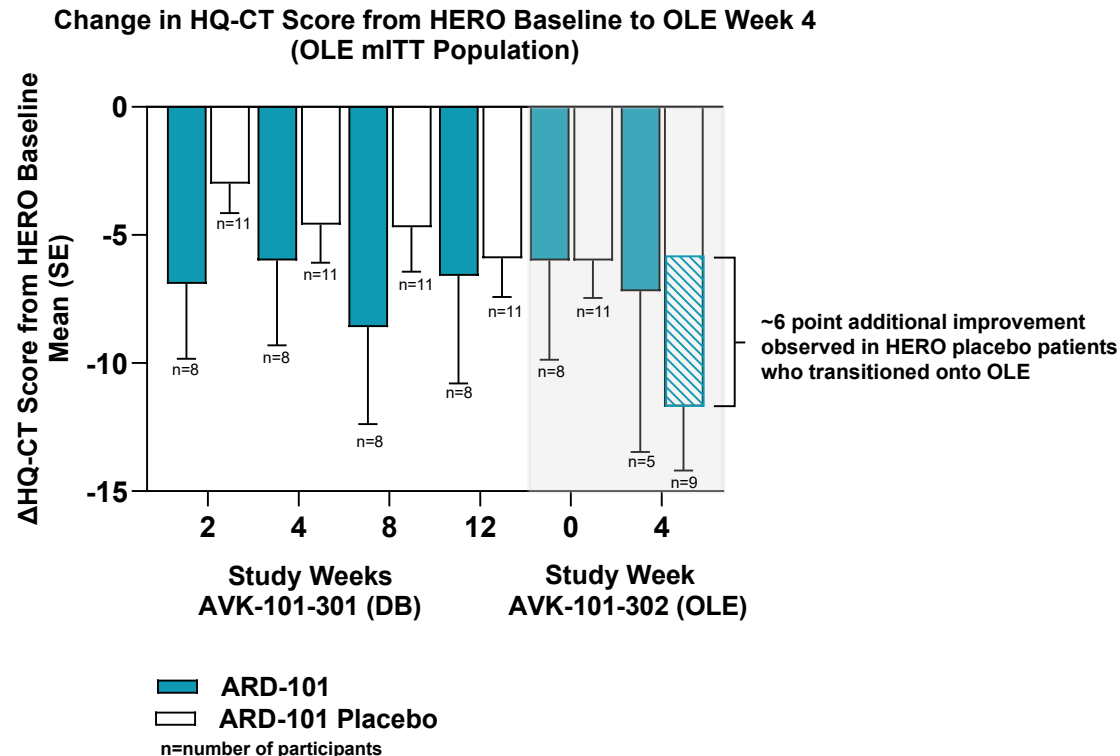
FOR ILLUSTRATIVE PURPOSES ONLY: These observations are derived from separate clinical settings; comparisons across ARD-101 and VYKAT trials are not based on head-to-head studies; Differences exist between trial designs and participant characteristics, and strong caution should be exercised when comparing data across unrelated trials.



HQ-CT Score During HERO, OLE, and After Study Pause

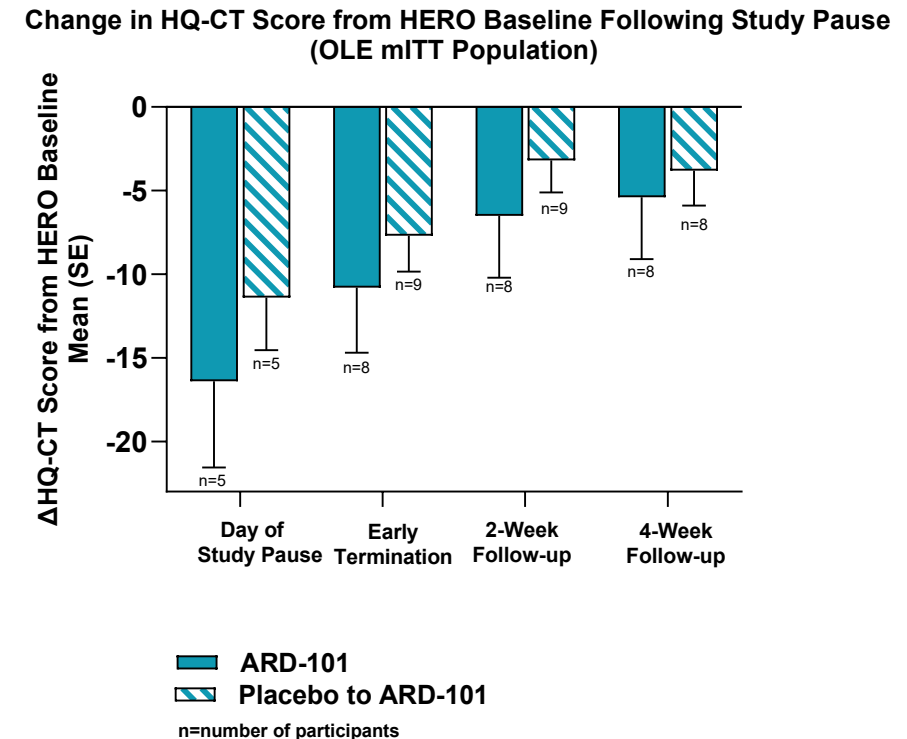
HQ-CT scores improved after switching from placebo to ARD-101 and worsened in both groups after dosing stopped.

On ARD-101 or Placebo



Data includes all participants who completed the HERO study and were enrolled in the open-label extension (OLE)

Withdrawal of ARD-101



Day of Study Pause: occurred on the day treatment was paused. Early Termination: occurred after treatment had ended.

HERO baseline mean HQ-CT score:

ARD-101=25.0

Placebo=20.4



Efficacy Observations

A trend for improvement in hyperphagia was observed with ARD-101

- A modest reduction in HQ-CT scores over placebo was observed with ARD-101 in HERO.
- Upon discontinuation of ARD-101, the HQ-CT score of the ARD-101-treatment group returned to near baseline while the placebo treated group had less rebound to baseline.
- Additional reductions in HQ-CT score were observed in placebo participants who switched to ARD-101 in the OLE.
- A similar pattern was observed for caregiver and clinician outcome measures including Caregiver Global Impression and Clinician Global Impression Severity scores.



Additional Assessments Reviewed: HERO

All prespecified assessments were collected and reviewed. No clear differences in responses to lipids, HbA1c, body weight/BMI; however, interpretation is limited as these would be long term effects and the HERO trial and OLE trial were stopped early.

Assessment	When collected	What the data showed
Lipids (total cholesterol, LDL, HDL, triglycerides)	Screening and Week 12 only; n=10 ARD-101, 11–13 placebo	Between-arm differences small on every parameter (largest LDL, -0.25 mmol/L [p=0.3])
HbA1c	Screening and Week 12 only	Between-arm difference 0.01%; baseline 5.55–5.67% (near-normal), so little room to move (HbA1c > 8.5% was an exclusion criterion)
Body weight, BMI	Baseline , Week 4, and Week 12	Minimal changes
DEXA	Baseline, Week 12/Early Termination	Minimal changes
CaGI-C, CGI-C (change scales)	All visits	Minimal changes
Vital signs	All clinic visits	No difference relative to placebo
ECG	Screening/EOT+	No difference relative to placebo
Plasma pharmacokinetics	Days 1, 28 and 84	Minimal systemic exposure consistent with ARD-101 primarily residing in the gut which is the site of action

OLE: No clear safety or metabolic signals



Most Common Adverse Events for All Participants in HERO

Adverse Event PT	Overall # of participants reporting event (%) (N=67)	# of ARD-101 participants reporting event (%) (N=33)	# of Placebo participants reporting (%) (N=34)
Diarrhoea	6 (9.0)	3 (9.1)	3 (8.8)
Nasal congestion	6 (9.0)	3 (9.1)	3 (8.8)
Nausea	4 (6.0)	2 (6.1)	2 (5.9)
Headache	3 (4.5)	2 (6.1)	1 (2.9)
Abdominal pain	3 (4.5)	0	3 (8.8)
Taste disorder/ Dysgeusia*	3 (4.5)	2 (6.1)	1 (2.9)
Dizziness	2 (3.0)	2 (6.1)	0
Contusion	2 (3.0)	1 (3.0)	1 (2.9)
Accidental overdose	2 (3.0)	2 (6.1)	0
Anxiety	2 (3.0)	0	2 (5.9)
Dermatillomania	2 (3.0)	0	2 (5.9)
Nasopharyngitis	2 (3.0)	1 (3.0)	1 (2.9)

*Dysgeusia was the preferred term for the AE that occurred in the Placebo participant



Safety Summary — HERO & OLE

KEY MESSAGE Generally well tolerated. In the open-label extension, participants previously on ARD-101 had zero related adverse events.

HERO N = 67 · 33 ARD-101 / 34 placebo

- **88 TEAEs**; ~51% of all participants; majority mild–moderate.
- Related: **28 events in 12 pts (18%)** — fewer on ARD-101 (**5 pts, 15%**) than placebo (**7 pts, 21%**).
- 3 SAEs*; **1 related, also on pitolisant**: Grade 4 polymorphic VT at 800 mg BID (SUSAR)
- No other cardiac events
- All psychiatric adverse events** were in placebo group (**17.6% vs 0%**).

OLE N = 19 · all on ARD-101

- **19 TEAEs in 9 pts (47%)**; all mild–moderate; **no SAEs**.
- Related: **8 events in 3 pts (16%)** — 100% in former-placebo (newly treated) participants.
- **0 related AEs** in participants previously on ARD-101.
- **7 of 8** related events were mild.

TAKEAWAY ARD-101 was well tolerated across both studies. Adverse events were infrequent and mostly mild-to-moderate, with no meaningful difference in overall incidence between the active and placebo arms (52% ARD-101 vs. 50% placebo of participants in the HERO trial)

*2 Unrelated SAEs are impaired gastric emptying and mental impairment

**Psychiatric Adverse Events: anxiety, behavior disorder, dermatillomania, irritability



Fireside Chat

Perspectives on Prader-Willi Syndrome and Hyperphagia



Manasi Jaiman, MD, MPH

Chief Medical Officer
Aardvark Therapeutics



Lynne Bird, MD

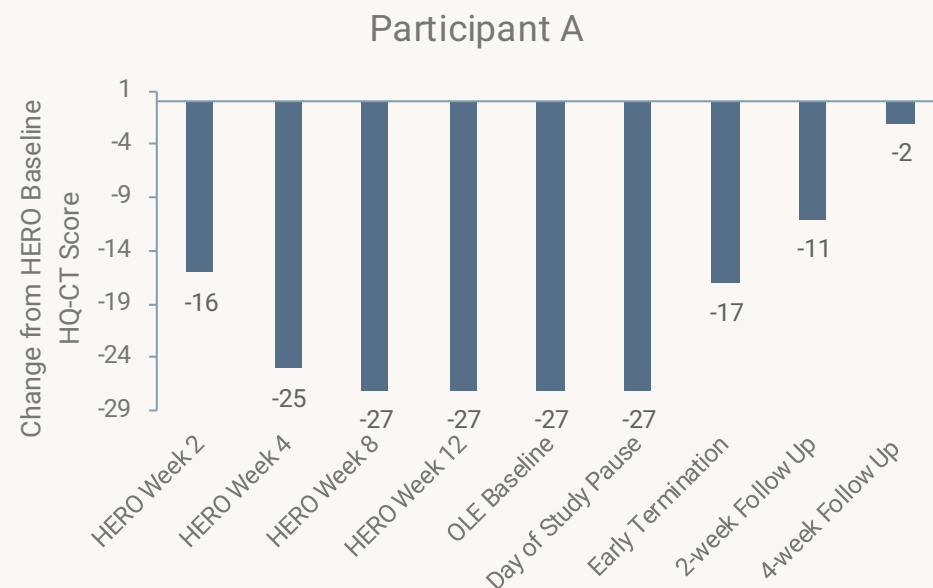
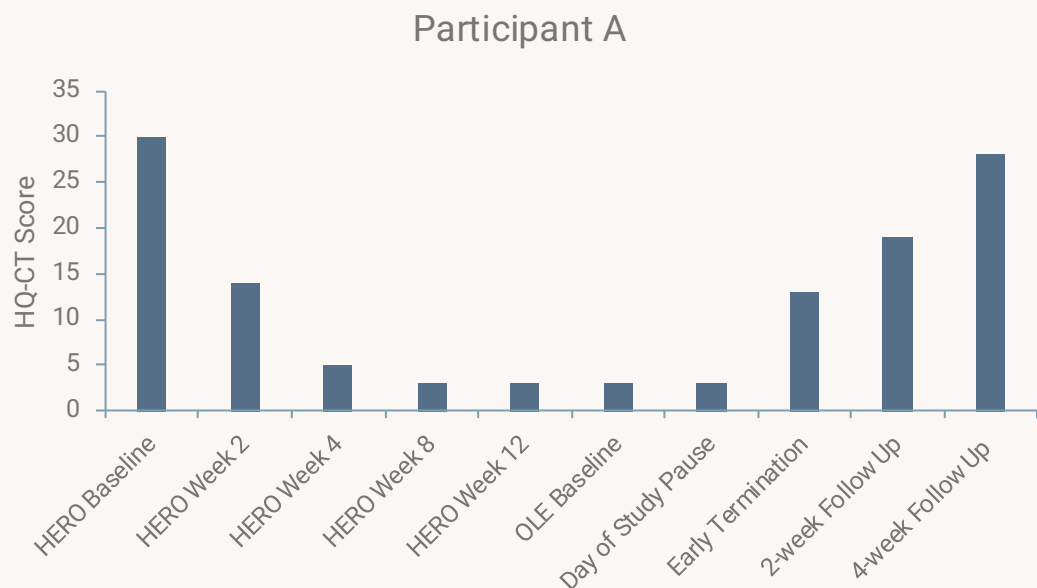
Medical Director, Prader-Willi Syndrome Clinic
Rady Children's Hospital | UC San Diego

Excited to be resuming
clinical development!



Participant A: Multiracial, Female, age 13 years

- Medical history: sleep apnea, growth hormone deficiency, hypothyroidism, allergy to penicillin, far sightedness, oculomotor dysfunction
- Randomized to ARD-101, completed HERO and rolled into the Open Label Extension
- Ended Treatment (OLE Study day 30 due to study pause), total ARD-101 Treatment Days: 114
- Baseline: HQ-CT=30, CGI-S= 5, CaGI-S= 6
- End of Treatment in OLE: HQ-CT= 3, CGI-S= 3, CaGI-S= 2

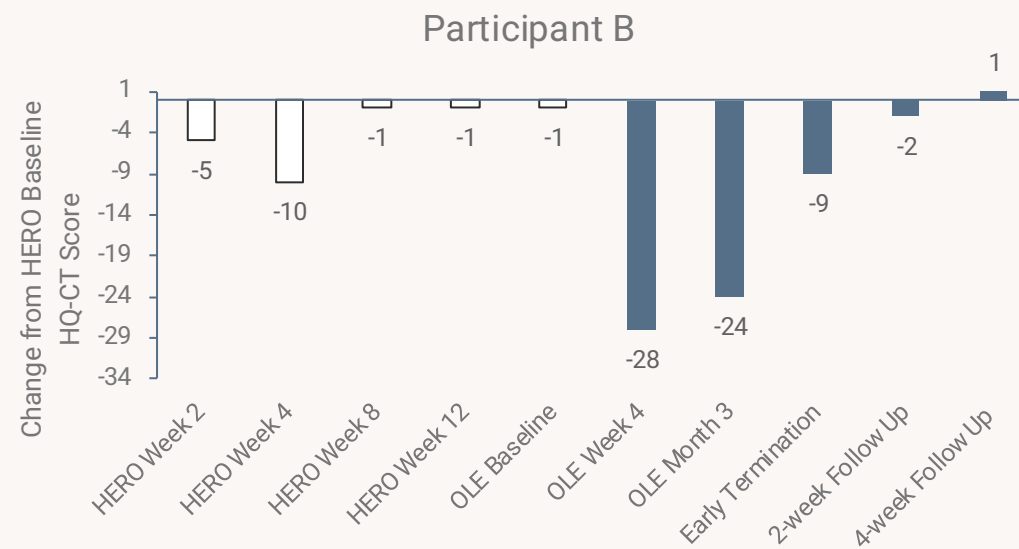
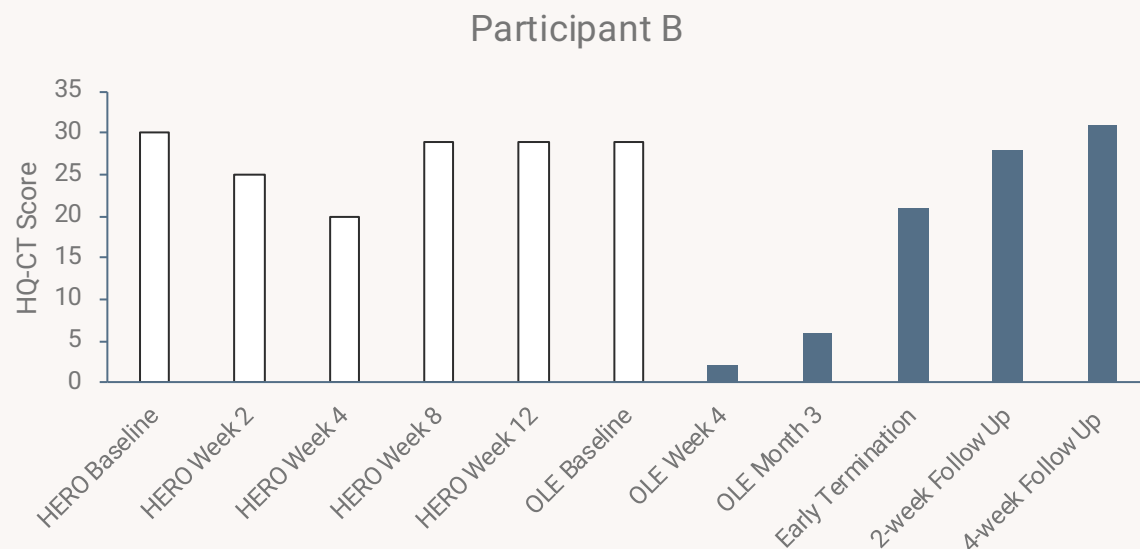


- At time of HERO Study Termination, HQ-CT score improved to 3, a 27 point improvement prior to enrolling into OLE. HQ-CT score improvement was sustained during OLE. All scores rebounded back to baseline by the 4 week follow up following early termination.



Participant B: White, Male, age 20 years

- Medical history: Global Hypotonia, Myopia, Behavioral Outburst, Dry Eye, Nerve Pain, Hypercholesterolemia, Anxiety, Depression, Congenital Hypodontia, Growth Hormone Deficiency, Hypogonadism, Scoliosis, Excessive Daytime Sleepiness, Headaches, Effusion of Left Knee, Knee Surgery
- Randomized to Placebo, completed HERO Study and rolled into the Open Label Extension
- Ended Treatment (OLE Study day 110 due to study pause) total ARD-101 Treatment Days: 110
- Baseline: HQ-CT=30, CGI-S= 6, CaGI-S= 5
- End of Treatment in OLE: HQ-CT= 6, CGI-S= 3, CaGI-S= 2



- During the Placebo HERO period, there was minimal change in HQ-CT scores. Once the participant entered the OLE period and was treated with ARD-101, there was an improvement of HQ-CT scores by 27 points. All scores rebounded back to baseline by the time of the 4-Week Follow Up following early termination.

Abbreviations

AE Adverse event

ADaM Analysis Data Model

BID Twice daily

BMI Body mass index

CaGI-C Caregiver Global Impression of Change

CaGI-S Caregiver Global Impression of Severity

CGI-C Clinical Global Impression of Change

CGI-S Clinical Global Impression of Severity

DB Double-blind

DCCR Diazoxide choline extended-release

DDI Drug-drug interaction

ECG Electrocardiogram

FDA U.S. Food and Drug Administration

HERO Phase 3 study AVK-101-301

HQ-CT Hyperphagia Questionnaire for Clinical Trials

ITT Intent-to-treat

LS Mean Least squares mean

mITT Modified intent-to-treat

MMRM Mixed model for repeated measures

MOA Mechanism of action

OLE Open-label extension study AVK-101-302

PD Pharmacodynamics

PT Preferred term

PWS Prader-Willi syndrome

QTc Corrected QT interval

SAD/MAD Single/Multiple Ascending Dose

SAE Serious adverse event

SD Standard deviation

SE Standard error

SOC System organ class

SUSAR Suspected unexpected serious adverse reaction

TEAE Treatment-emergent adverse event

TLF Tables, listings and figures

VT Ventricular tachycardia

VYKAT XR DCCR; approved PWS hyperphagia therapy

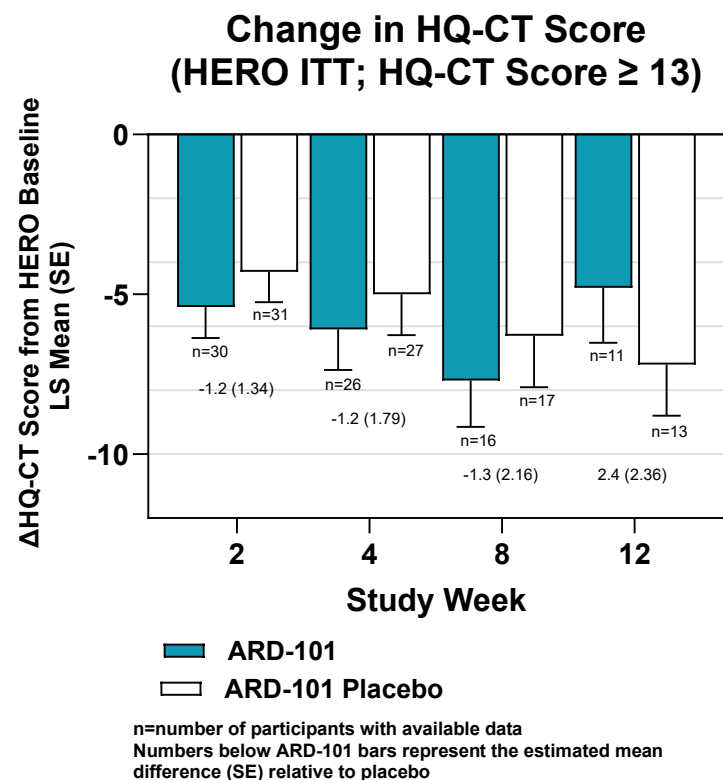


Questionnaires – HQ-CT, CaGI-S, CGI-S

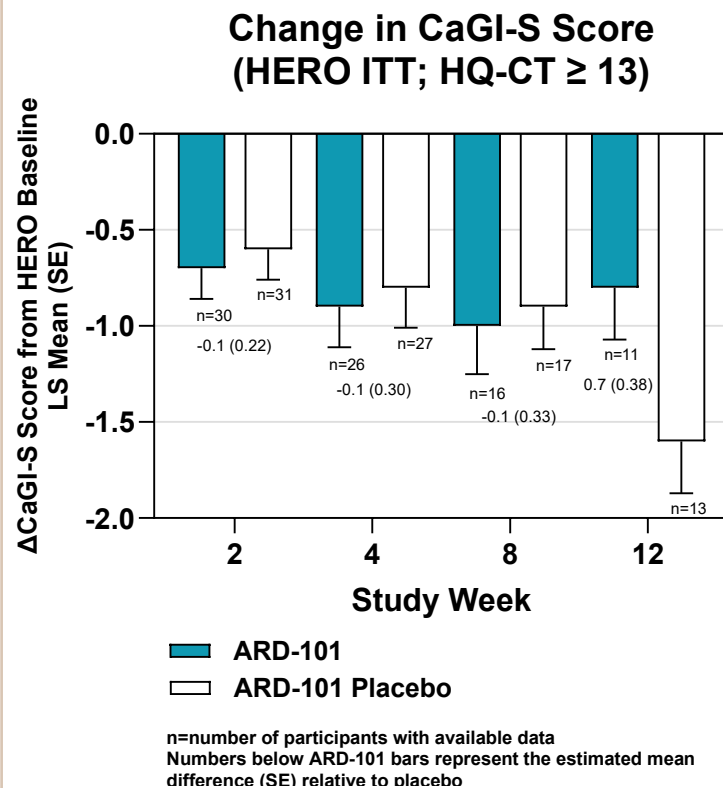
- **Hyperphagia Questionnaire for Clinical Trials (HQ-CT)**
 - A 9-question clinical outcome assessment where each food-related problem behavior question has a scoring range from 0 (never, not at all, infrequent, etc.) to 4 (extremely, frequently, etc.). The maximum score on this questionnaire is 36. The higher scores describe a more severe hyperphagia state.
- **Caregiver Global Impression-Severity (CaGI-S)**
 - Assesses the severity of hyperphagia from a caregiver's perspective at the clinic visit with a look back period of seven days. There is one question asking the caregiver to describe the severity of the patient's hyperphagia (excessive hunger). Scores range from 1 (Not Present) to 7 (Extremely Severe).
- **Clinical Global Impression-Severity (CGI-S)**
 - Assesses the severity of hyperphagia from a clinician's perspective at the clinic visit with a look back period of seven days. There is one question asking the clinician to rate the patient's current level of hyperphagia considering the clinician's experience with the PWS population. Scores range from 1 (Normal, not at all ill) to 7 (Among the most extremely ill patients).



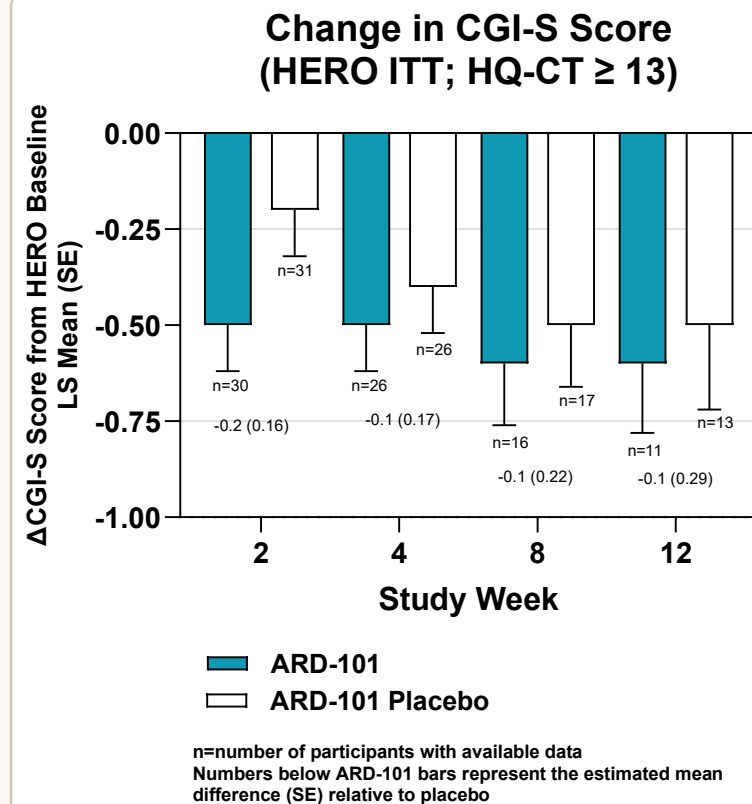
HERO HQ-CT, CaGI-S and CGI-S Scores (ITT Population; HQ-CT ≥ 13)



Baseline mean HQ-CT score:
 ARD-101 = 22.5
 Placebo = 22.8

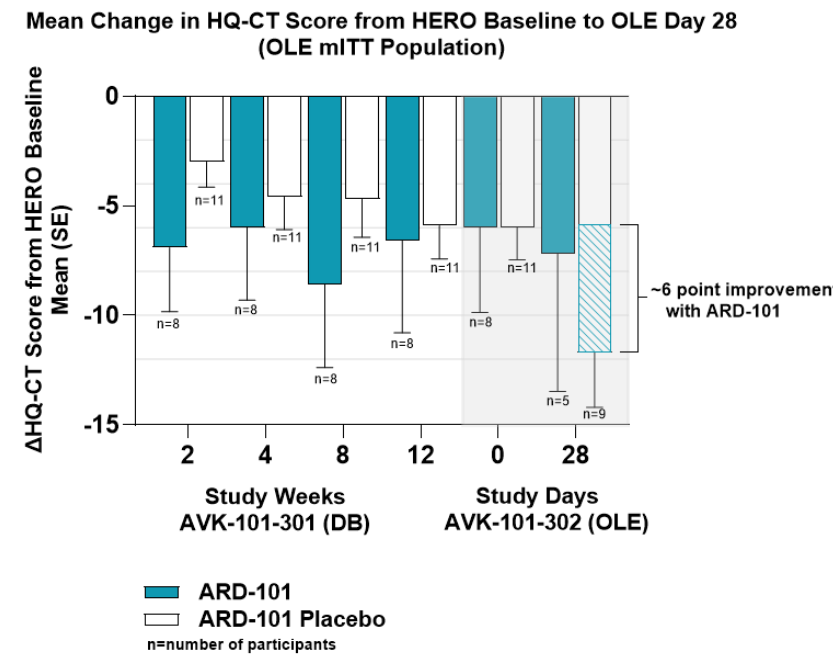


Baseline mean CaGI-S score:
 ARD-101=5.7
 Placebo=5.5

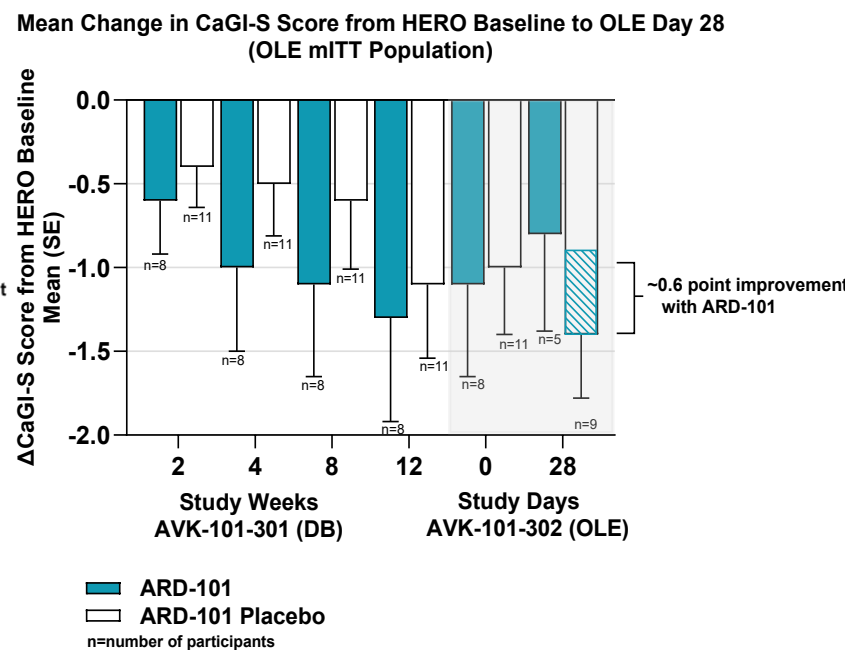


Baseline mean CGI-S score:
 ARD-101=4.8
 Placebo=4.9

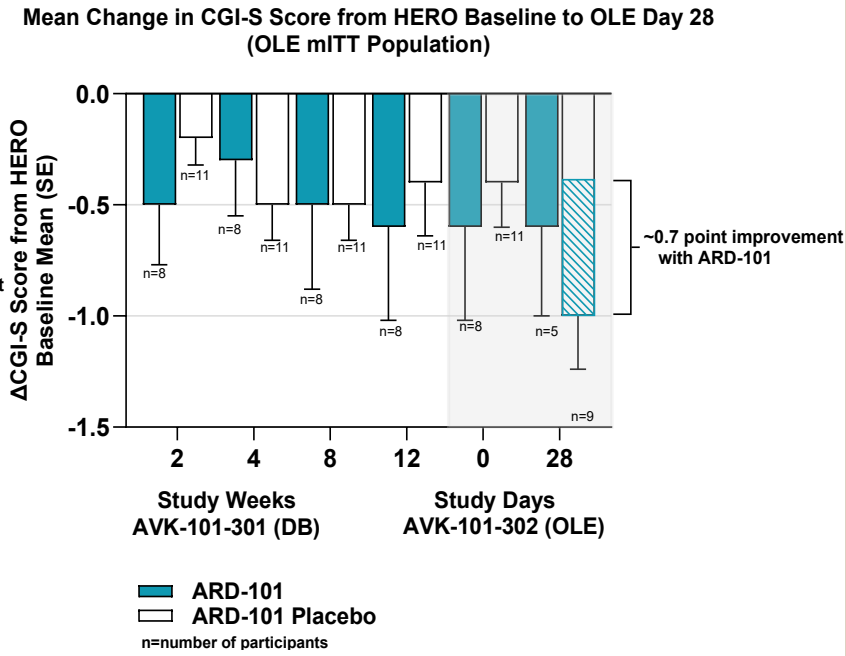
HERO to OLE Mean Change in HQ-CT Score from HERO Baseline (OLE mITT Population; N=19)



HERO baseline HQ-CT mean score:
ARD-101=25.0
Placebo=20.4



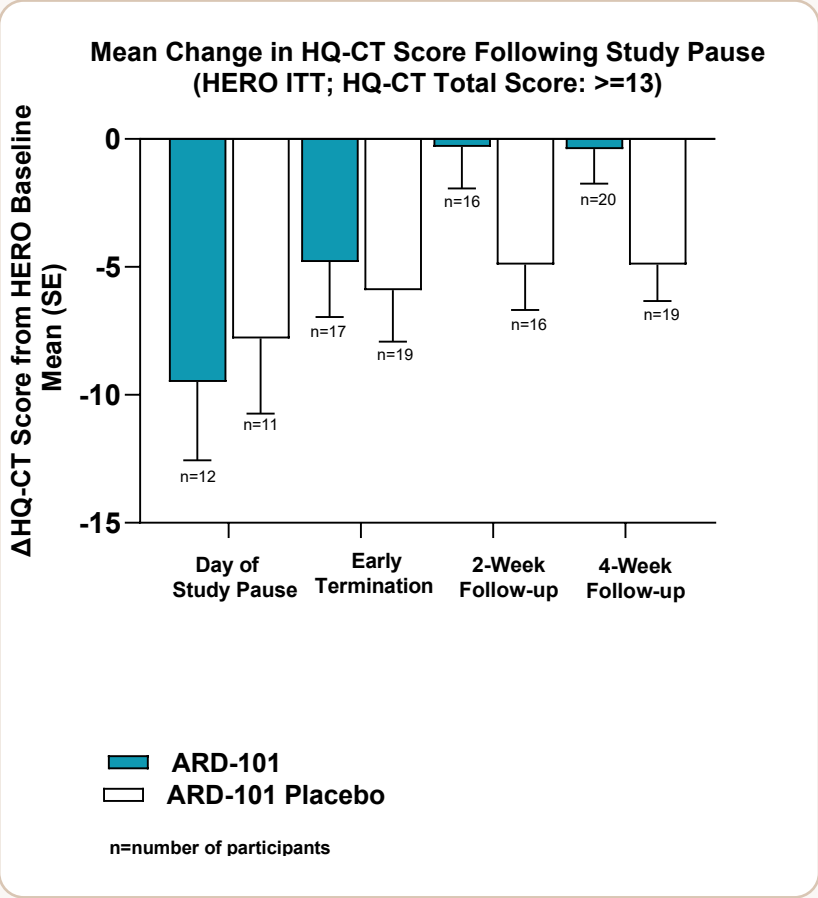
HERO baseline CaGI-S mean score:
ARD-101=6.0
Placebo=5.2



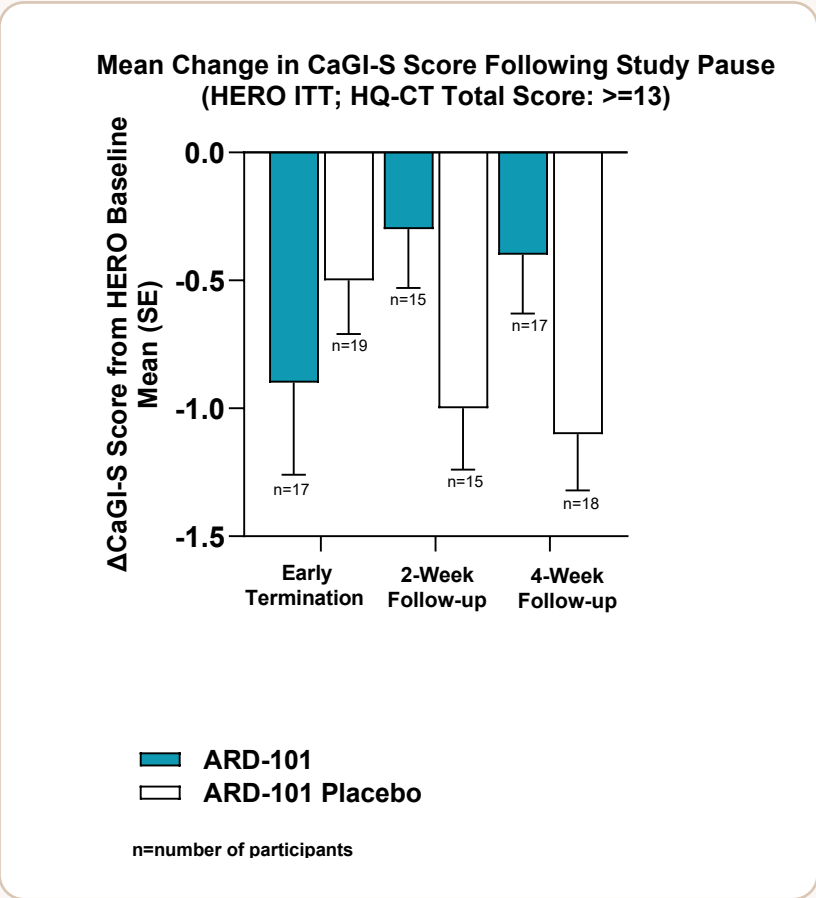
HERO baseline CGI-S mean score:
ARD-101=5.1
Placebo=5.0



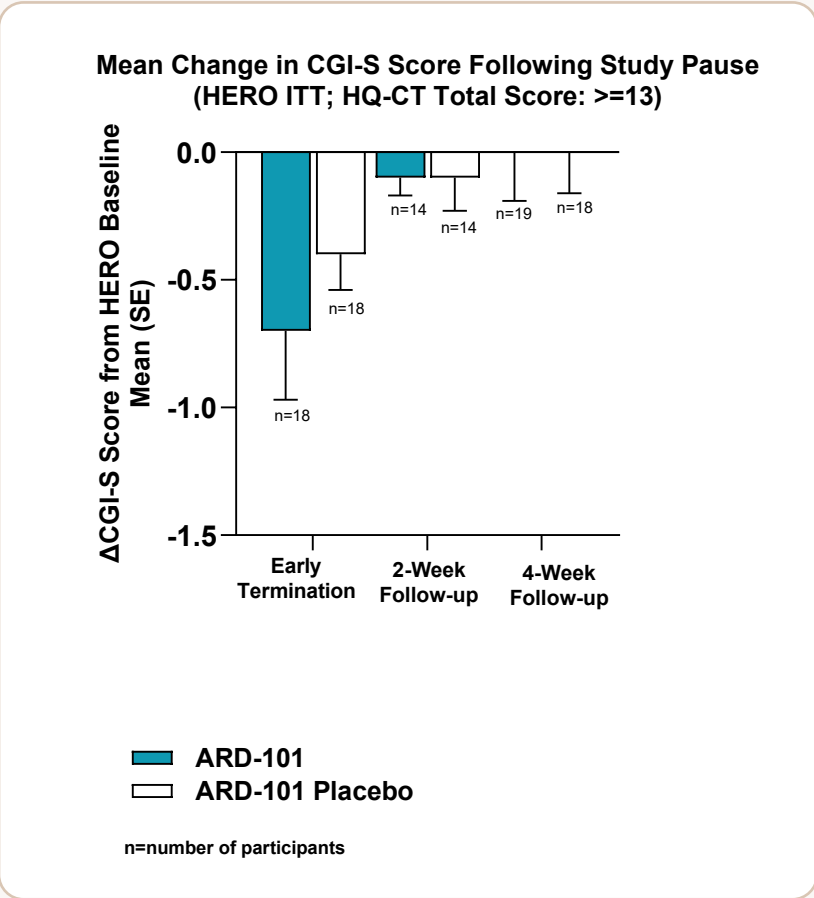
HERO Mean Change in HQ-CT, CaGI-S, CGI-S Scores Following Study Pause (HERO ITT; HQ-CT ≥ 13)



Baseline mean HQ-CT Score:
ARD-101 = 22.5
Placebo = 22.8



Baseline mean CaGI-S score:
ARD-101=5.7
Placebo=5.5

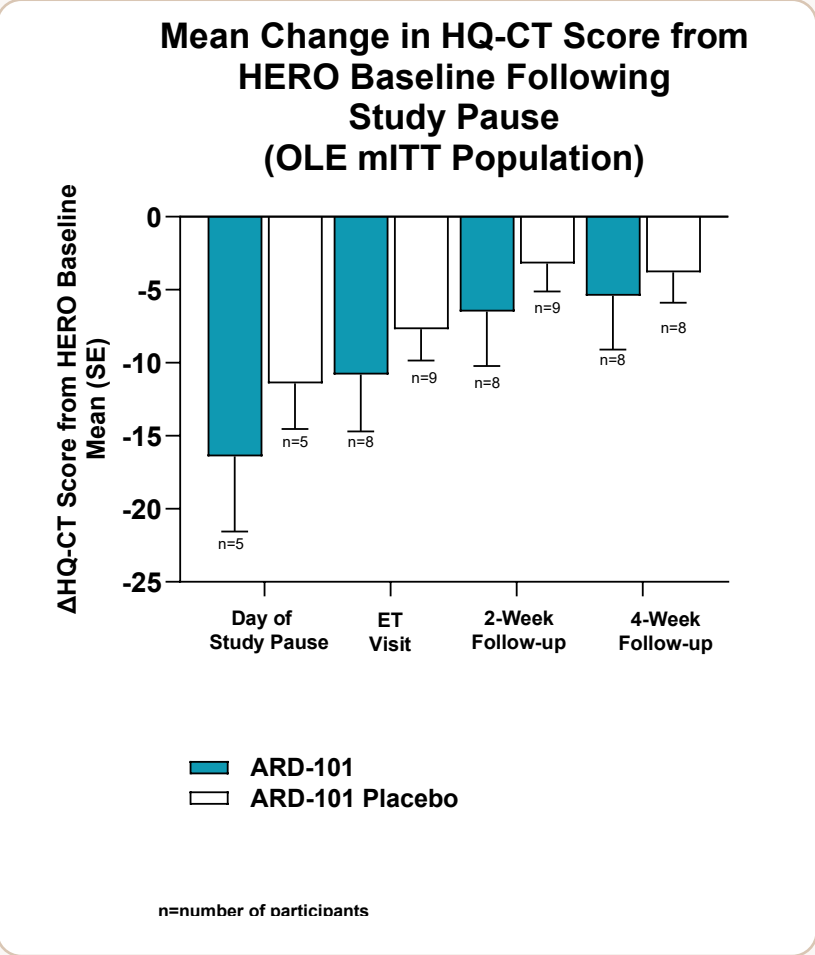


Baseline mean CGI-S score:
ARD-101=4.8
Placebo=4.9

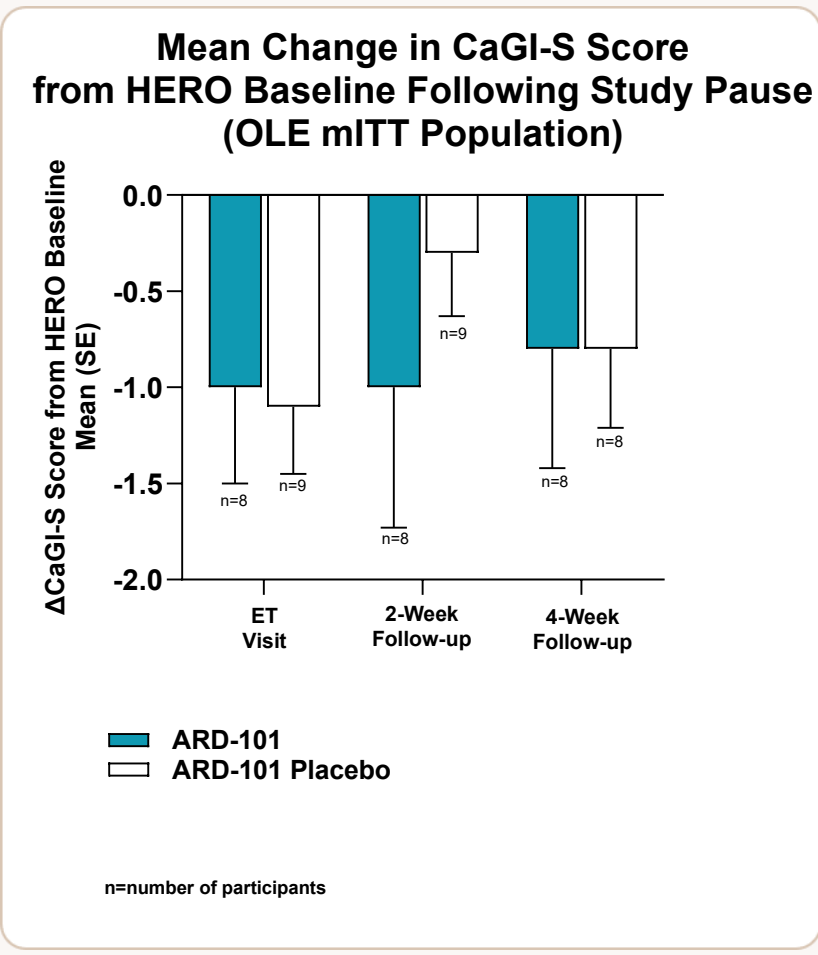
Mean time from last dose [Mean(Min-Max)]: Early Term Visit [(9 days(1-31)], 2-Week Follow Up Visit [24 days(13-52)], 4-Week Follow Up Visit [39 days(22-68)]



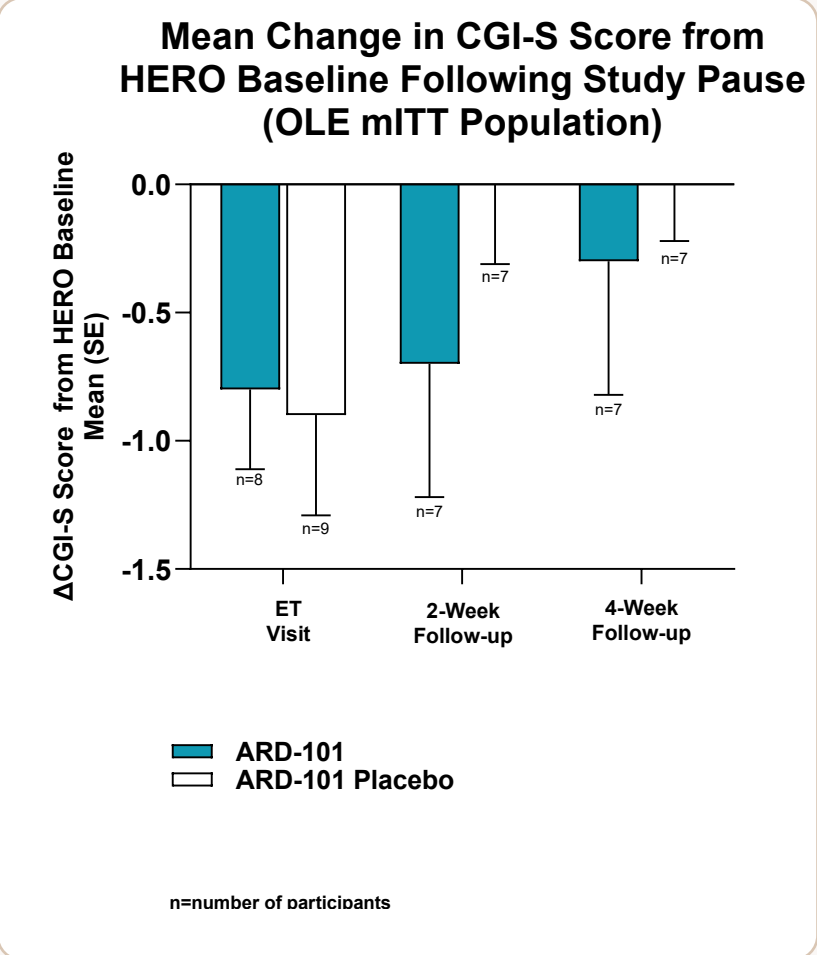
OLE Mean Change in HQ-CT, CaGI-S, CGI-S Scores Following Study Pause (OLE mITT Population; N=19)



HERO Baseline mean score:
ARD-101=25.0
Placebo=20.4



HERO Baseline mean CaGI-S score:
ARD-101=6.0
Placebo=5.2

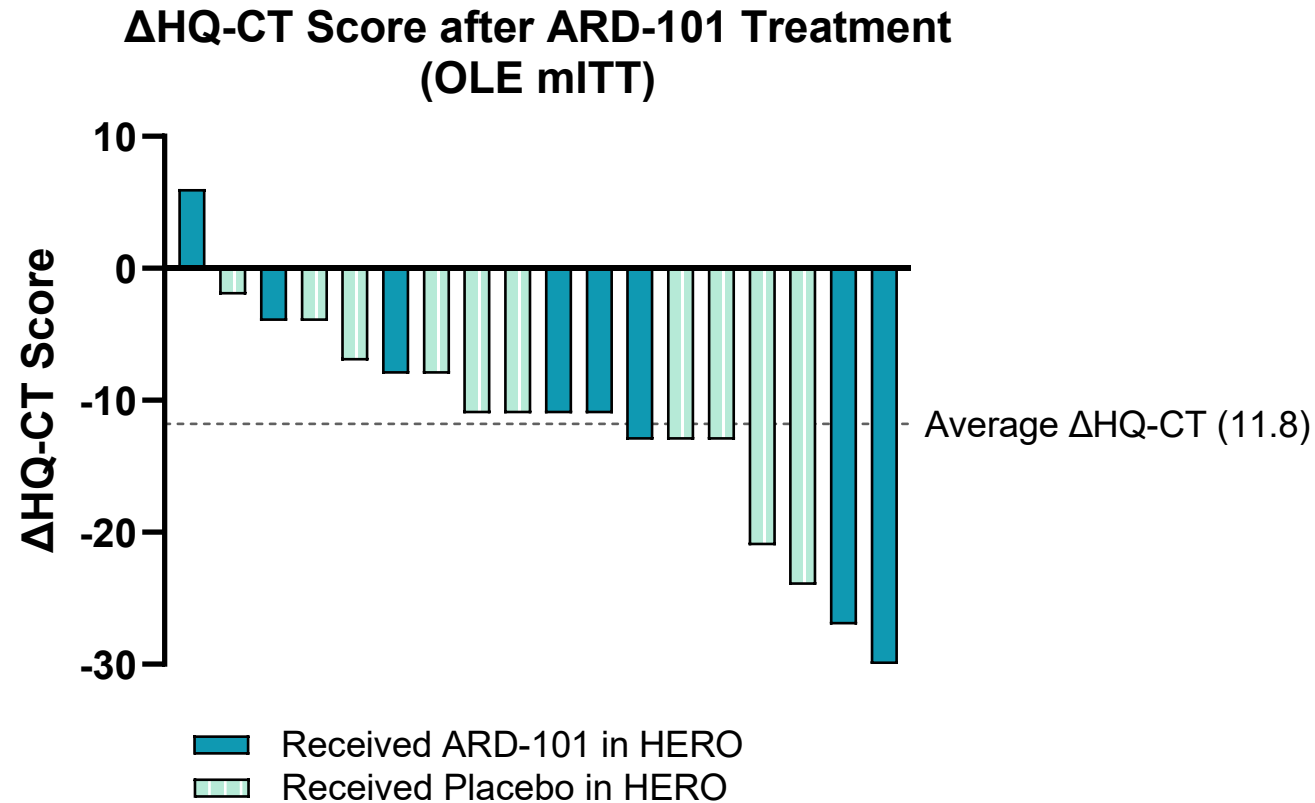


HERO Baseline mean CGI-S score:
ARD-101=5.1
Placebo=5.0

Mean time from last dose [Mean(Min-Max)]: Early Term Visit [7 days(1-26)], 2-Week Follow Up Visit [20 days(17-34)], 4-Week Follow Up Visit [35 days(31-47)]



Change in HQ-CT Score Waterfall (OLE mITT Population; N=19)*



Change from start of ARD-101 treatment

Change was calculated using baseline prior to ARD-101 treatment and ending with last score either prior to pause or within 4 days of the end of treatment date

*Total N=19 for mITT, 1 removed due to PD during 302 study (9 point increase of HQ-CT score in 302)