



# HERO: Phase 3 Trial for Treatment of Hyperphagia in PWS

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PWS National Conference

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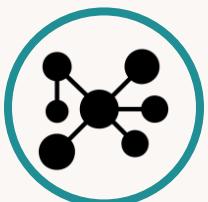
# Aardvark Therapeutics



Established in **2017** in California San Diego, United States



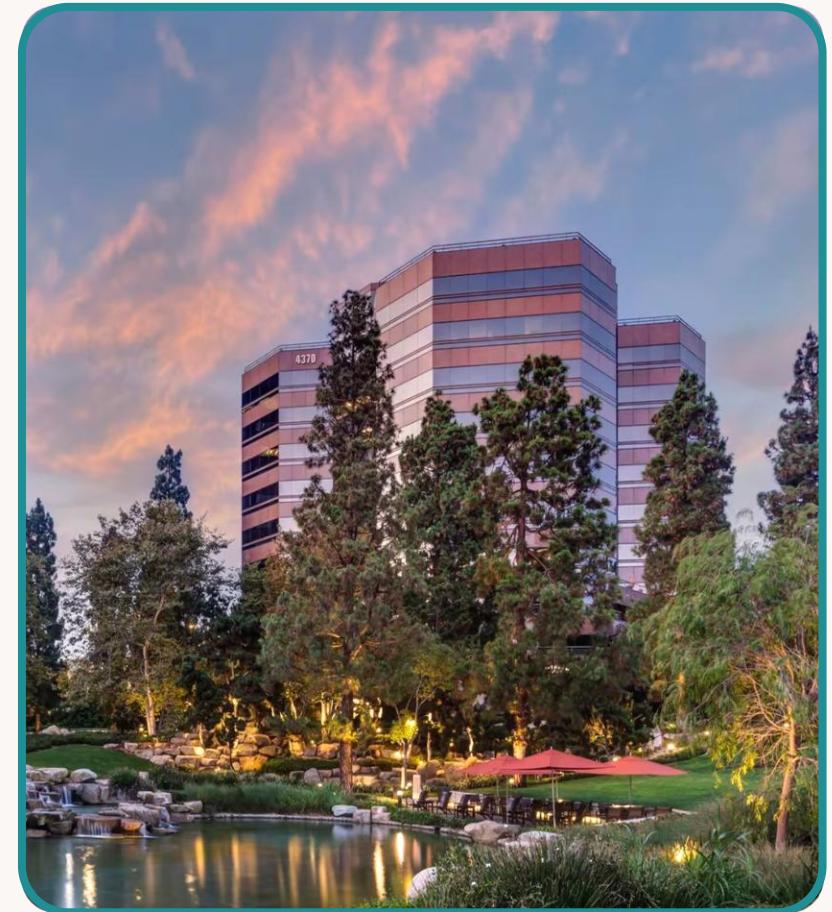
Clinical-stage biopharmaceutical company developing novel, small-molecule therapies designed to **reduce hunger and treat metabolic diseases**



Studying **ARD-101, an oral investigational drug for hunger (hyperphagia) in PWS**



**HERO global phase 3 study now enrolling**



# Overview: Oral ARD-101 for Treatment of Hyperphagia in PWS

## Unique Investigational Approach to Reducing Hunger:

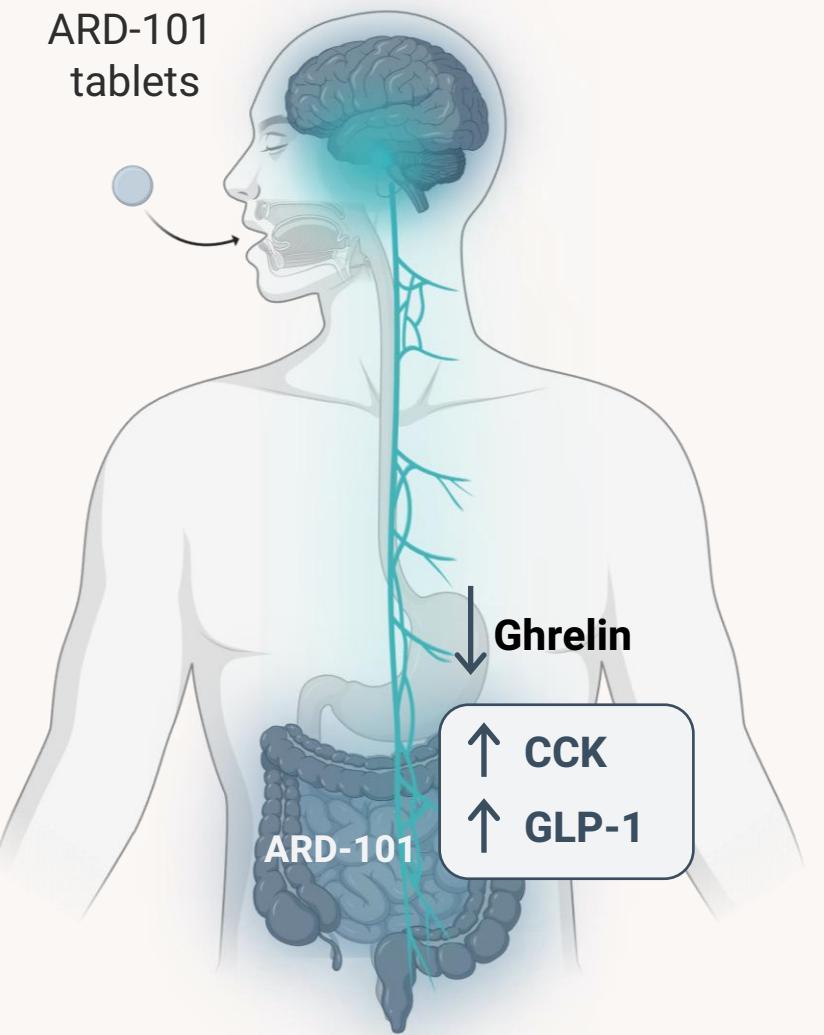
- Administered orally, ARD-101 binds to taste receptors (TAS2R) in the gut stimulating the release of several gut hormones, including the satiety hormone CCK, with the potential to restore the gut-brain pathway of hunger control impaired in PWS
- A gut-restricted drug, potentially minimizing toxicities

## Phase 2 Findings Guided Phase 3 Trial Design:

- Reduction in hyperphagia, anxiety, and food-seeking behaviors observed in several individuals with PWS (ages 17 years and older) treated at well-tolerated ARD-101 doses

## HERO Phase 3 – Global Trial of ARD-101 for hyperphagia in PWS:

- Individuals with PWS ages 13 and older receive either ARD-101 tablets or placebo for 12 weeks, to be followed by open-label extension study with all participants receiving ARD-101

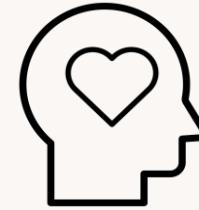
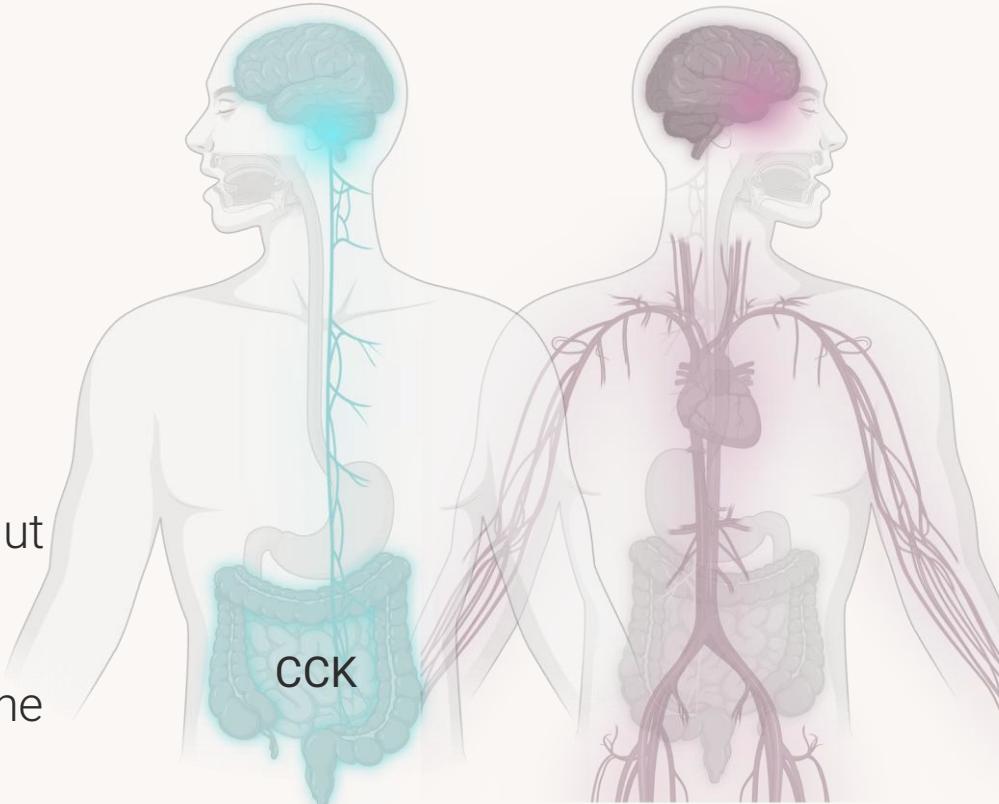


# Hunger vs. Appetite: Distinct Neural Pathways



## Hunger

- **Penalty avoidance:**  
*Need* to eat
- Mediated by local gut hormones like **CCK**
- Signaling through the **Gut-Brain Axis**



## Appetite

- **Reward-based:**  
*Desire* to eat
- Mediated by circulating hormones like **GLP-1**
- Targeted systemically through the **bloodstream**

CCK, cholecystokinin; GLP-1, glucagon-like peptide-1



# Oral ARD-101: Reduced Hunger in Prior Phase 2 PWS Study



ARD-101 was tested in PWS patients (ages 17 and older) in a 28-day study



Hunger was measured using the HQ-CT (Questionnaire to measure hunger in PWS)

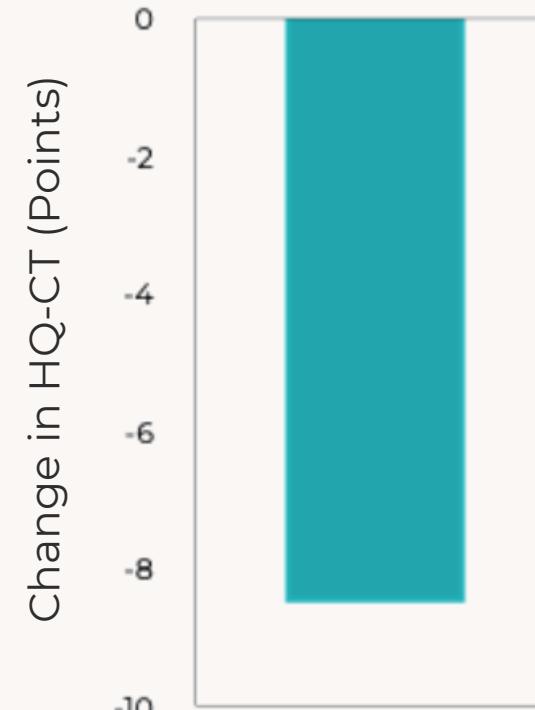


Participants experienced an average reduction in hunger behavior while on treatment



Early signs of improved fat and muscle balance

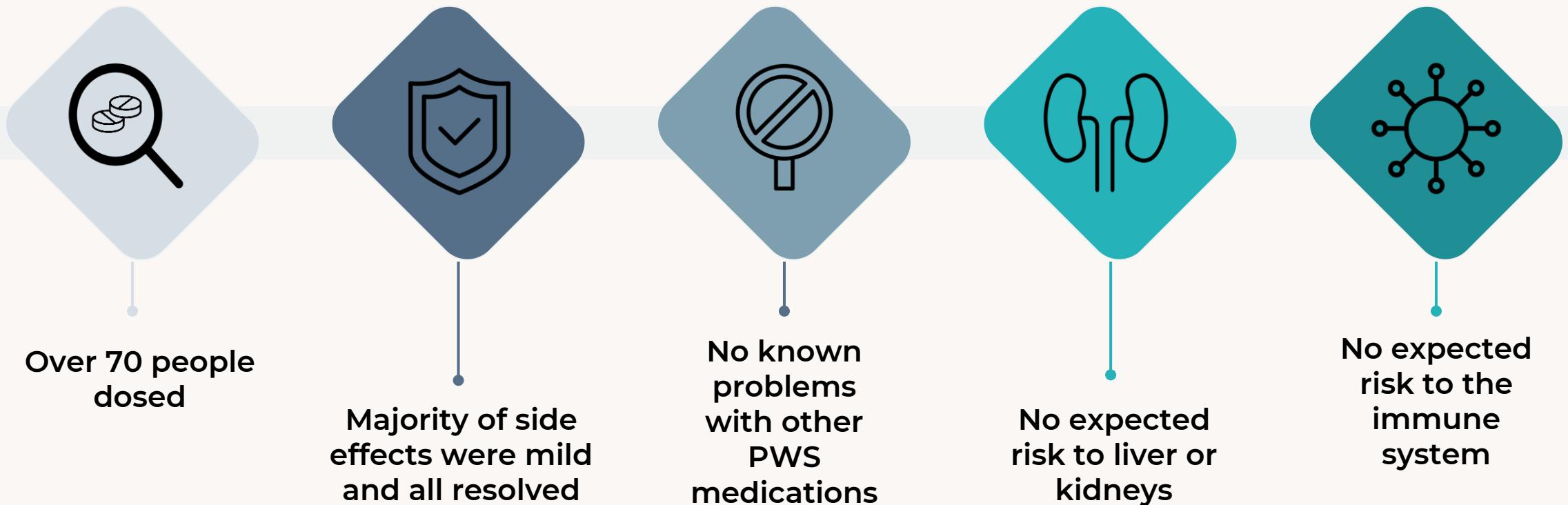
## Average Change in Hunger and Food-Seeking Behavior During 28-Day Study<sup>(1)</sup>



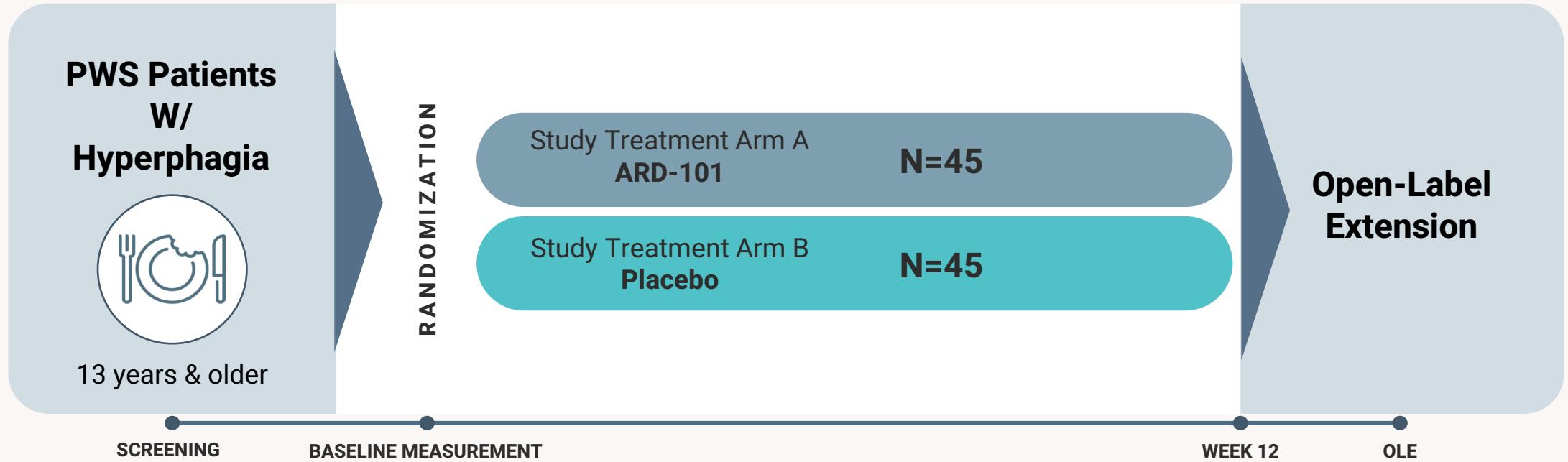
<sup>(1)</sup>Average change from baseline for participants using HQ-CT Version 9, only mean is plotted.



# ARD-101 is Well-Tolerated Across Multiple Clinical Trials in Different Populations



# Currently Enrolling: HERO Phase 3 Trial Design

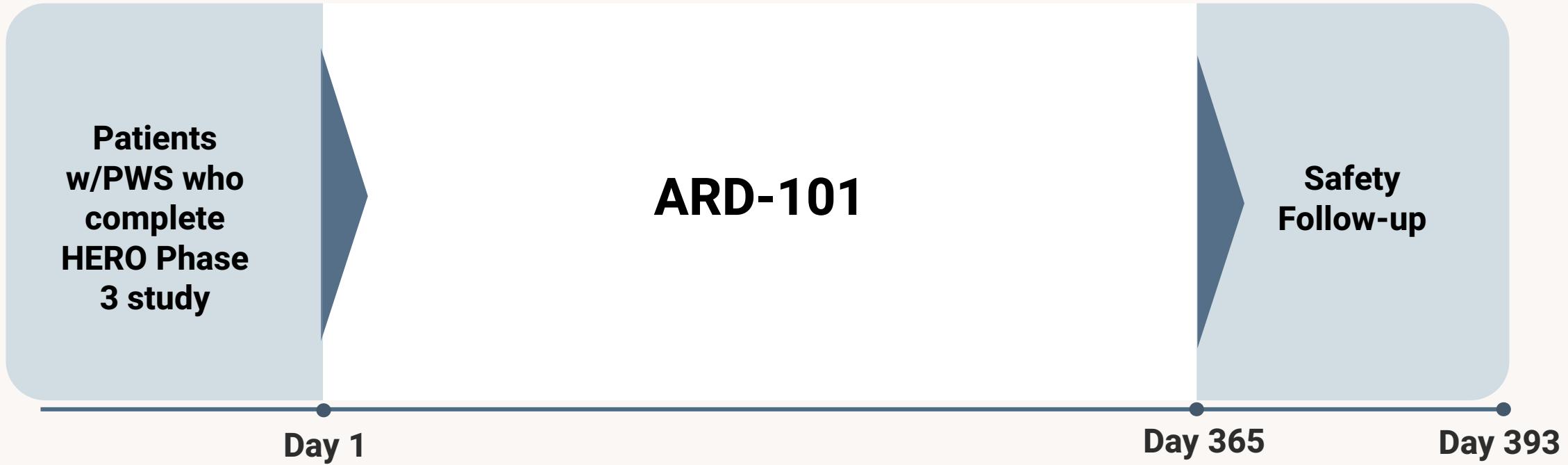


## EVALUATING

Change in Hyperphagia Questionnaire for Clinical Trials (HQ-CT 9) Score



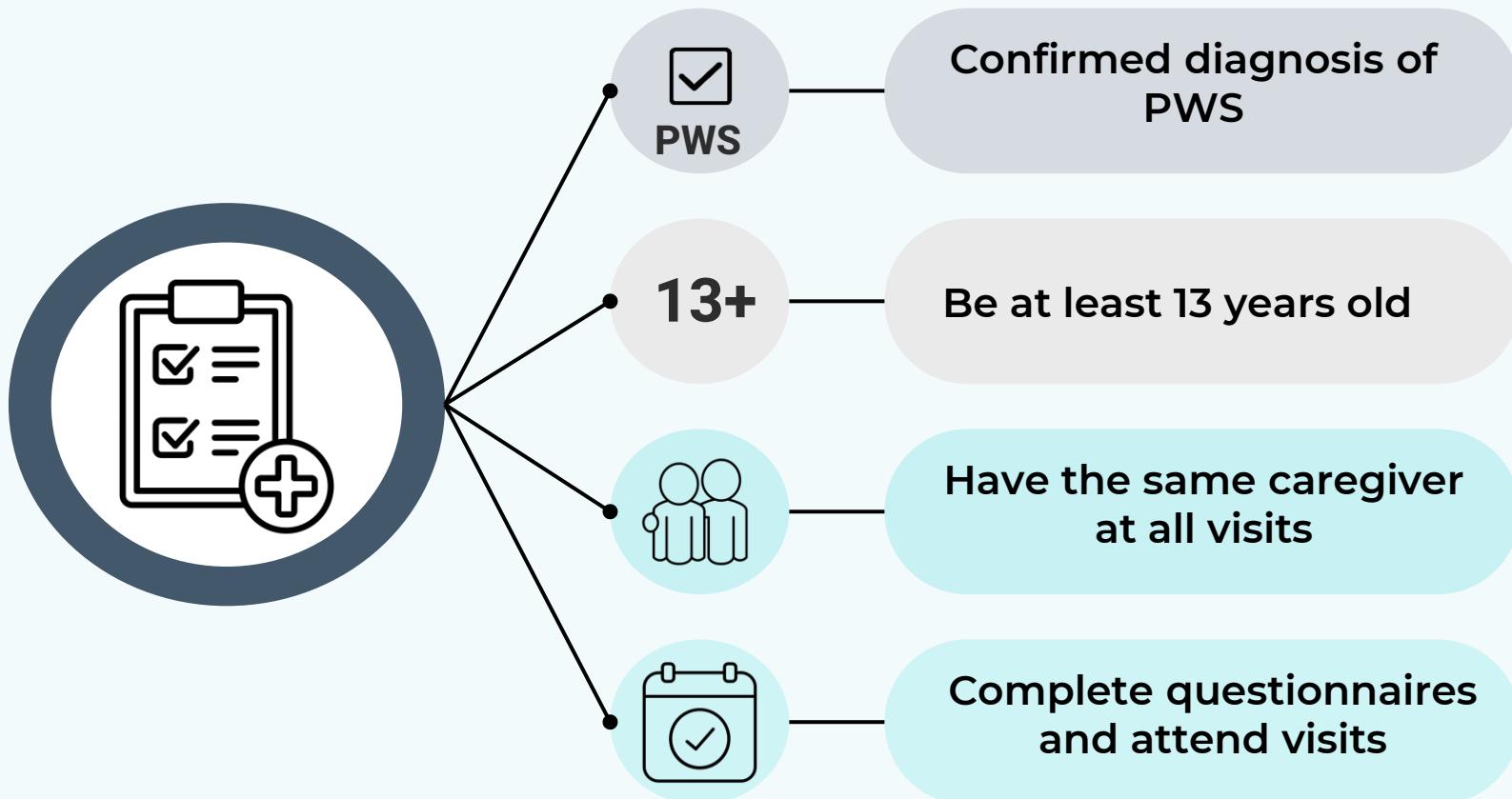
# HERO Open Label Trial Design



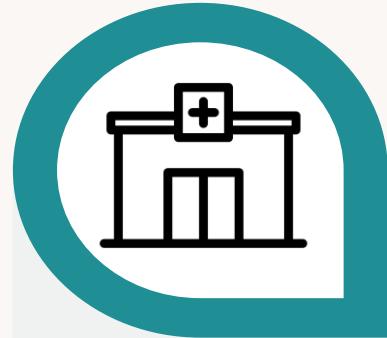
- Safety of taking ARD-101 in a long-term setting
- Change in Hyperphagia Questionnaire for Clinical Trials (HQ-CT 9) Score



# Requirements to Join the HERO Study



# HERO Study: Addressing Patient and Caregivers' Needs



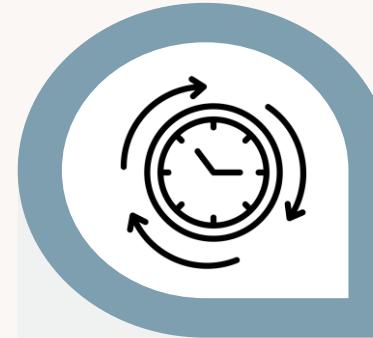
## Simple Schedule

4 clinic visits  
and 3  
telehealth  
check-ins



## Inclusive Design

No need to fast  
or skip meals  
for the study



## Stable Routine

Same caregiver  
throughout the  
study with  
minimal change  
to routine



## Travel & Lodging

We cover travel  
and lodging if  
needed



## Next Steps

After completion,  
participants can  
join another study  
where all get the  
investigational  
drug, ARD-101

# HERO: A Global Trial with 15 Sites Currently Enrolling



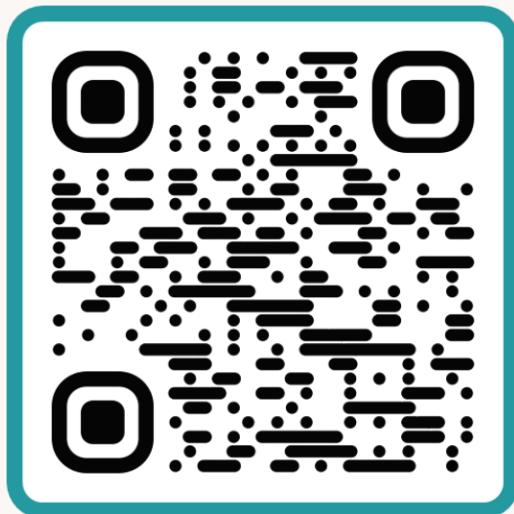
For the most current list of enrolling sites, refer to [clinicaltrials.gov](https://clinicaltrials.gov)



# Where to Find More Information About the HERO PWS Studies?

## HERO FOR PWS Website

<https://www.heroforpws.com/>



Scan for Dedicated Study Website

## HERO Phase 3 (Study ID: NCT06828861)



October 2025

## HERO Open Label Extension Study (Study ID: NCT07197034)



Scan for ClinicalTrials.Gov Listing Details



# ARD-101 in PWS: Strong Collaboration with PWS Foundations/Patient Advocacy Groups





# Thank you!

Thank you

Danke

Multumesc

Obrigado