



Aardvark Therapeutics Reports Exploratory Data from the Terminated HERO and Open-Label Extension Trials

October 23, 2026

- ***HERO trial terminated early (67 of 90 planned participants randomized); all efficacy data are considered exploratory***
- ***HQ-CT scores fell by Week 2 of dose escalation on ARD-101 and returned to near baseline within two weeks of stopping treatment, with less rebound on placebo***
- ***OLE participants switching from placebo to ARD-101 saw a further reduction in HQ-CT scores by Day 28***
- ***ARD-101 was well tolerated; most adverse events mild to moderate***
- ***FDA lifted full clinical hold on ARD-101; Company plans to request FDA meeting to align on new Phase 3 trial design and expects to resume PWS clinical activities in 2027***
- ***Conference call and webcast today at 8:00 a.m. ET***

SAN DIEGO, Oct. 23, 2026 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark or the Company) (Nasdaq: AARD), a clinical-stage biopharmaceutical company developing novel, small-molecule therapeutics designed to suppress hunger for the treatment of Prader-Willi syndrome (PWS) and metabolic diseases, today reported exploratory efficacy data from its previously terminated Phase 3 Hunger Elimination or Reduction Objective (HERO) trial and open-label extension (OLE) trial. As previously announced, Aardvark unblinded the data accumulated across both the HERO trial and OLE trial to assess the totality of available efficacy and safety data to inform the path forward for ARD-101.

"Though the HERO trial was stopped early and the current partial data are not sufficient to draw definitive conclusions, we believe these exploratory efficacy and safety data are directionally consistent and give us confidence in the continued development of ARD-101 for the treatment of PWS. We look forward to continuing to work closely with the FDA and plan to request a meeting to align on the design of a new Phase 3 trial intended to support a future marketing application, with the important goal of delivering this potential treatment option to patients in need," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "Hyperphagia is one of the most challenging aspects of PWS for patients and their families, and we believe there remains a significant need for additional treatment options that can meaningfully reduce the constant, life-limiting hunger that defines this disease."

A summary of the available dataset from the Phase 3 HERO trial and OLE trial can be found below. The HERO trial randomized 67 of the planned 90 participants and was terminated early. As such, all efficacy data are considered exploratory.

- At week two of dose escalation on ARD-101, a modest reduction in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) score versus placebo was observed in the HERO trial.
- Upon discontinuation of ARD-101, the average HQ-CT score of the ARD-101 treatment group returned to near baseline, while the placebo-treated group had less rebound toward baseline.
- In the OLE cohort, participants who switched from placebo to ARD-101 had an observed average reduction of 6 points in HQ-CT score.
- A similar pattern was observed for caregiver and clinician outcome measures, assessed by Caregiver Global Impression and Clinician Global Impression Severity scores, respectively.
- ARD-101 was generally well tolerated, with most adverse events being mild to moderate.
- One cardiac serious adverse event was observed in the HERO trial at 800 mg twice daily (BID) in a participant who was also taking pitolisant, a CYP2D6 substrate. The U.S. Food and Drug Administration (FDA) concurred that this event is related to a drug-drug interaction.

Aardvark plans to resume dosing of ARD-101 in patients with PWS at a dose lower than the 800 mg BID dose studied in the Phase 3 HERO trial and OLE trial, pending discussion with the FDA. The Company plans to request a meeting with the FDA to align on its Phase 3 program, with the goal of advancing ARD-101 toward potential regulatory approval.

As previously [announced](#) on October 22, 2026, the FDA has lifted the clinical hold on the Company's Investigational New Drug application for ARD-101 for the treatment of hyperphagia in PWS.

Conference Call and Webcast

The Company will host a live conference call and webcast for investors to discuss data from the HERO and OLE trials today, October 23, 2026, at 8:00 a.m. ET. To access the live webcast, participants may register [here](#). To access the subsequent archived recording of this event, please visit the Investors section of Aardvark's [website](#).

About ARD-101

ARD-101 is an oral, small-molecule therapeutic designed to stimulate the release of gut-peptide hormones through activation of bitter taste receptors. ARD-101 is being developed as a treatment for hyperphagia associated with Prader-Willi Syndrome, a rare genetic disorder characterized by insatiable hunger.

About Aardvark Therapeutics, Inc.

Aardvark is a clinical-stage biopharmaceutical company developing novel, small-molecule therapeutics designed to suppress hunger for the treatment of Prader-Willi Syndrome and metabolic diseases. Hunger, which is the discomfort from not having eaten recently, is a distinct neural signaling pathway separate from appetite, the reward-seeking desire for food. Our programs explore therapeutic applications in hunger-associated indications and potential complementary uses with anti-appetite therapies. For more information, visit www.aardvarktherapeutics.com.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." These statements include, but are not limited to, statements concerning: Aardvark's business strategy, product candidates, the path forward for ARD-101, including the anticipated resumption of dosing of ARD-101 in patients with PWS and anticipated doses to be used in future trials, the timing for resuming clinical activities, and Aardvark's planned engagement with the FDA regarding its Phase 3 program and the potential for any future Phase 3 trial to support a future marketing application or regulatory approval, as well as plans and objectives of management for future operations. The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the FDA may not agree with Aardvark's proposed Phase 3 program or may require additional studies; the timing of resuming dosing and activating clinical sites; the risk of additional safety findings, including risks related to cardiac safety and drug-drug interactions; limitations in interpreting data from the HERO trial and its OLE trial, which were terminated early and were not powered to assess efficacy; the risk of unfavorable clinical trial results; the risk that results from earlier clinical trials and preclinical studies may not necessarily be predictive of future results; the risk that Aardvark may use its capital resources sooner than expected; and other risks and uncertainties, including the factors described under the "Risk Factors" section of Aardvark's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the Securities and Exchange Commission on August 11, 2026. When evaluating Aardvark's business and prospects, careful consideration should be given to these risks and uncertainties. Any forward-looking statements contained in this press release are based on the current expectations of Aardvark's management team and speak only as of the date hereof, and Aardvark specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise, unless required by law.

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