Aardvark Therapeutics Announces First Patient Dosed in Australia in HERO Phase 3 Trial for Prader-Willi Syndrome

December 10, 2025

Multiple active sites and strong US enrollment continue to support Q3 2026 timing for topline data readout

Clinical trial sites in Canada and the United Kingdom have received regulatory clearance to enroll

All patients who have completed HERO trial to date have successfully enrolled and remain in the Open Label Extension trial

SAN DIEGO, Dec. 10, 2025 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark) (Nasdaq: AARD), a clinical-stage biopharmaceutical company focused on developing novel, small-molecule therapeutics to activate innate homeostatic pathways for the treatment of metabolic diseases, announced that the first patient has been dosed in Australia in its Phase 3 HERO pivotal clinical trial assessing ARD-101 for the treatment of hyperphagia in individuals with Prader-Willi syndrome (PWS). Additionally, regulatory clearance for enrollment by clinical trial sites in Canada and the United Kingdom has also been received. Based on strong enrollment in the US and continued progress in advancing the clinical trial internationally, the clinical trial continues to track towards a topline data readout in Q3 2026.

“We have seen very strong interest in the HERO trial within the patient community, which has been driving enrollment in the United States and in our newly opened Australia sites,” said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “In addition, all patients who have completed the 12-week clinical trial to date have enrolled in the Open Label Extension trial, which is an encouraging indicator of patient interest and engagement.”

US trial sites are actively enrolling, and sites in Australia started enrolling in November. Enrollment is expected to initiate shortly in Canada and the UK, where regulatory clearance has been received. At this time, Aardvark anticipates that it will not need to activate previously planned sites in the EU to fully enroll the HERO trial and meet its anticipated timeline for topline data readout in Q3 2026.

“It’s important to note that significant unmet needs continue to persist in the PWS community, and many families are eager for a therapy that could ameliorate the relentless hunger that is a hallmark of PWS,” added Manasi Jaiman, M.D., Chief Medical Officer of Aardvark.

About the HERO Trial
The Hunger Elimination or Reduction Objective (HERO) trial (NCT06828861) is a Phase 3 randomized, double-blind, placebo-controlled trial assessing ARD-101 for the treatment of hyperphagia in patients with Prader-Willi syndrome (PWS). Aardvark plans to enroll 90 patients in this clinical trial across the US, Australia, Canada, the United Kingdom, and South Korea. The primary endpoint is change in the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) score from baseline to Week 12. Secondary outcome measures include change in Caregiver Global Impression of Severity (CaGI-S) for hyperphagia in PWS patients and change in Clinical Global Impression of Severity (CGI-S) score for hyperphagia in PWS patients. Topline data is expected in the third quarter of 2026.

About ARD-101
ARD-101 is a gut-restricted small molecule agonist of select taste receptors (TAS2Rs) expressed on the luminal side of the intestine. As a potent bitter taste receptor pan-agonist, ARD-101 stimulates enteroendocrine cells of the digestive tract to release multiple gut-peptide hormones, including GLP-1 and the satiety hormone cholecystokinin (CCK), which activates gut-brain neurologic signaling to mediate hunger. ARD-101 has demonstrated an ability to reduce hunger when used alone or in combination with currently available GLP-1 therapies. The FDA has granted ARD-101 both Orphan Drug Designation and Rare Pediatric Disease Designation for PWS.

ARD-101 is being evaluated in the Phase 3 HERO trial for hyperphagia associated with PWS.

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. Our lead compound, oral ARD-101, is in Phase 3 clinical development for the treatment of hyperphagia associated with PWS, a rare disease characterized by insatiable hunger. Aardvark is also developing ARD-201, a planned fixed-dose combination of ARD-101 with a DPP-4 inhibitor, through two separate Phase 2 trials with a goal of addressing some of the limitations of currently marketed GLP-1 therapies for obesity and obesity-related conditions. For more information, visit 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, ongoing clinical trials, planned clinical trials, expected timing for data readouts and reporting interim, preliminary or topline results, likelihood of success, 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. Forward-looking statements in this press release include statements regarding ARD-101, including the expected timeline for receiving topline data from the Phase 3 HERO trial and the intended sites for conducting and completing enrollment for the trial. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to potential delays in the commencement, enrollment and completion of clinical trials; the risk that Aardvark may use its capital resources sooner than expected and that they may be insufficient to allow Aardvark to achieve its anticipated milestones; risks related to its dependence on third parties for manufacturing, shipping and production of drug product for use in clinical trials and preclinical studies; 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; 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 September 30, 2025 that Aardvark filed with the Securities and Exchange Commission on November 13, 2025. 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.

Contact:
Carolyn Hawley, Inizio Evoke Comms
(619) 849-5382
Carolyn.hawley@inizioevoke.com