Aardvark Therapeutics Announces FDA Submission and IRB Approval of Amended Trial Protocol for Lead Candidate ARD-101, Expanding Eligibility in Phase 3 Study of Prader-Willi Syndrome

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Protocol Expansion Broadens Phase 3 HERO Trial Eligibility Criteria to Include Children Ages 7+ in the United States

SAN DIEGO, Feb. 10, 2026 (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, today announced that Institutional Review Board (IRB) approval has been granted in the United States for an amended protocol to its ongoing Phase 3 HERO pivotal clinical trial evaluating ARD-101 for the treatment of hyperphagia in individuals with Prader-Willi Syndrome (PWS). The amended protocol, submitted to the U.S. Food and Drug Administration (FDA), lowers the minimum age of eligibility for trial participation from 10 to 7 years old.

This protocol amendment reflects Aardvark's continued focus on reducing barriers to participation and expanding access for those affected by PWS, a rare genetic disorder characterized by chronic hyperphagia. By expanding enrollment to younger children who meet eligibility criteria, the HERO trial may better capture the potential impact of ARD-101 in the PWS population.

"We are very pleased to report this important protocol expansion, which allows us to broaden the patient population for our Phase 3 HERO trial to include children as young as 7 years of age in the U.S.," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "Hyperphagia may begin early in life for some individuals with PWS, and it presents a persistent burden for patients and caregivers. Expanding eligibility reflects our commitment to addressing the urgent need in the PWS community for a differentiated therapy and we aim to ensure broad and equitable access."

Dr. Lee added, "Enrollment in HERO is progressing steadily and remains on track to report topline data in the third quarter of 2026. We believe these data will further inform our understanding of ARD-101's potential role as a differentiated therapeutic approach for the treatment of hyperphagia associated with PWS."

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 U.S., 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. All participants who complete the 12-week clinical trial will have the option to participate in an Open Label Extension trial. More information about the study can be found at www.heroforpws.com.

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 Prader-Willi Syndrome (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 (PWS) 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 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, 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, the potential for younger patients to benefit from early intervention, the potential that the change in eligibility criteria will allow Aardvark to better capture the potential impact of ARD-101 or increase enrollment in 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.

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