Aardvark Therapeutics Announces Voluntary Pause of Phase 3 HERO Trial in Prader-Willi Syndrome

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SAN DIEGO, Feb. 27, 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 it is voluntarily pausing the Phase 3 Hunger Elimination or Reduction Objective (HERO) trial. The HERO trial is a Phase 3 randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of ARD-101 as a treatment for hyperphagia in patients with Prader-Willi Syndrome (PWS).

The decision by Aardvark to voluntarily pause the HERO (NCT06828861) and open-label extension (NCT07197034) trials was based on reversible cardiac observations at above target therapeutic doses found during routine safety monitoring in a healthy volunteer study. Aardvark is conducting a comprehensive review of the data to inform next steps. Out of an abundance of caution, the company has voluntarily paused ongoing enrollment and dosing in the HERO trial during this evaluation.

“The safety of every patient in our clinical studies is our highest priority, so we will thoroughly evaluate the signals seen at higher than therapeutic doses of ARD-101 in a healthy volunteer study,” said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. “We are committed to advancing the ARD-101 clinical program and we are evaluating optimal therapeutic dosing levels to support its progress. We will continue to collaborate closely with the FDA and scientific and clinical experts, and we greatly appreciate our partnership with the PWS community as we determine next steps for this program.”

Based on the ongoing activities in the ARD-101 program, Aardvark no longer anticipates announcing topline data from the HERO trial in the third quarter of 2026 and expects to provide further guidance in the second quarter of this year.

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).

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 review of the data from the healthy volunteer study, the expected timeline for announcing topline data from the Phase 3 HERO trial, potential next steps for ARD-101, and Aardvark’s expected timing for providing further guidance. 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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