Aardvark Therapeutics Plans to Unblind HERO and OLE Data to Inform Path Forward Following FDA Clinical Hold

May 14, 2026

SAN DIEGO, May 14, 2026 (GLOBE NEWSWIRE) -- Aardvark Therapeutics, Inc. (Aardvark or the Company) (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 the U.S. Food and Drug Administration (FDA) has placed a full clinical hold on its investigational new drug application (IND) for ARD-101 related to the Company's previously announced voluntary pause. The clinical hold applies to all ongoing clinical studies under the IND, including the Phase 3 HERO trial (AVK-101-301) evaluating ARD-101 for the treatment of hyperphagia in patients with Prader-Willi Syndrome (PWS) and the Phase 3 open-label extension (OLE) trial (AVK-101-302). The Company remains in active discussions with the FDA to support resolution of the clinical hold and determine a path forward for the ARD-101 program.

"We are continuing to work collaboratively with the agency to comprehensively evaluate the data and determine the best path forward for ARD-101," said Tien Lee, MD, Founder and Chief Executive Officer of Aardvark. "Patient safety will always be the highest priority for us, and we are deeply committed to the PWS community. We remain committed to advancing ARD-101 as a potential therapy for this underserved patient population."

In parallel with its ongoing engagement with the FDA, Aardvark intends to unblind the clinical data accumulated to date across both the HERO trial and the OLE trial to assess the totality of available efficacy and safety data and to support an informed determination of next steps for the ARD-101 program. As of February 27, 2026, Aardvark had dosed 68 patients in the randomized controlled HERO trial and 19 patients in the OLE trial.

As of March 31, 2026, Aardvark held $91.2 million in cash, cash equivalents and short-term investments, which the Company believes is sufficient to fund projected operations into mid-2027.

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 was being evaluated in the Phase 3 HERO trial 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 (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. 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, 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 the FDA clinical hold on ARD-101, Aardvark's anticipated cash runway, Aardvark's engagement with the FDA, Aardvark's planned unblinding and analysis of HERO and OLE trial data and Aardvark's future plans for its PWS and obesity programs. 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, recommencement, enrollment and completion of clinical trials and any additional actions that may be required following Aardvark's engagement with the FDA; 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; the possibility that the past track records of Aardvark and its personnel may not be repeated or indicative of future success; 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 March 31, 2026 filed with the Securities and Exchange Commission on May 7, 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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