



Aardvark Therapeutics Announces FDA Has Lifted the Clinical Hold on ARD-101 for the Treatment of Prader-Willi Syndrome and Will Host Webcast to Review the Available Exploratory Phase 3 HERO/OLE Data

October 22, 2026

Clinical development of ARD-101 for hyperphagia in Prader-Willi Syndrome (PWS) may resume

Aardvark will host a webcast to review available dataset from the terminated Phase 3 HERO trial and OLE trial on Friday, October 23, 2026, at 8:00 a.m. EST

SAN DIEGO, Oct. 22, 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 announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Company's Investigational New Drug application for ARD-101 for the treatment of hyperphagia in PWS.

"We are pleased that the FDA has lifted the clinical hold on ARD-101, allowing us to continue advancing our clinical development program," said Tien Lee, M.D., Founder and Chief Executive Officer of Aardvark. "With strong alignment and collaboration with the FDA, we completed the work necessary to allow for the resumption of clinical studies. People living with PWS and their families continue to face profound unmet need, and we look forward to working with the FDA as we advance ARD-101."

On February 27, 2026, Aardvark voluntarily paused dosing in the Phase 3 Hunger Elimination or Reduction Objective (HERO) trial and its open-label extension (OLE) trial following reversible electrocardiogram (ECG) changes observed during routine safety monitoring in a separate study in healthy volunteers. In May 2026, the FDA placed a clinical hold on the HERO trial and OLE trial. In alignment with the FDA, the Company conducted a thorough ECG study in additional healthy volunteers and an in vitro cardiac sodium channel (NaV1.5) study. No cardiac events were observed in the recently completed ECG study at ARD-101 doses of 200 mg and 400 mg twice daily.

Aardvark plans to resume clinical development of ARD-101 in patients with PWS following additional anticipated engagement and alignment with the FDA on the Phase 3 trial design. 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.

Conference Call and Webcast

The Company will host a live conference call and webcast for investors to discuss data from the terminated HERO and OLE trials tomorrow, October 23, 2026, at 8:00 AM ET. To access the live conference call, participants may register [here](#). To access the live webcast and 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 (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, the path forward for ARD-101, including the anticipated resumption of the clinical development of ARD-101 and any further engagement and alignment with the FDA prior to such resumption, 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; 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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