AriBio Announces Completion of Dosing in POLARIS-AD Global Phase 3 Trial of AR1001 for Early Alzheimer's Disease

Readout from the pivotal global Phase 3 trial of 1,535 participants is expected later in 2026

SAN DIEGO, CA, UNITED STATES, June 30, 2026 /EINPresswire.com/ -- AriBio Co., Ltd. today announced that the last patient has completed dosing in POLARIS-AD (NCT05531526), the pivotal global Phase 3 clinical trial evaluating AR1001, an investigational, disease-modifying, once-daily oral treatment candidate for early Alzheimer's disease.

POLARIS-AD enrolled 1,535 participants across approximately 230 clinical sites in 13 countries, including the United States, Canada, the United Kingdom, the European Union, South Korea and China. The first patient was dosed in December 2022 in the United States, and the final patient completed the 52-week treatment period on June 29, 2026. A total of 1,348 participants completed 52 weeks of treatment.

Participants are now proceeding to the final study safety visit, which will enable final data collection, data cleaning, database lock, and analysis. The company expects to report topline results from POLARIS-AD later in 2026.

"Completion of dosing in POLARIS-AD is an important milestone for AriBio and reflects the commitment of the patients, caregivers, investigators, clinical sites, partners and employees who supported this global study," said Jai Jun Chung, Ph.D., Chief Executive Officer of AriBio. "The need for innovative Alzheimer's disease treatment options remains critical, particularly therapies that may be disease-modifying, safer, convenient and scalable for patients, caregivers and healthcare systems. We look forward to completing the analysis process with rigor and transparency as we prepare to report topline results."

"Leading POLARIS-AD from AriBio's U.S. office in San Diego has been an extraordinary effort," said James Rock, Chief Clinical Officer of AriBio. "It is inspiring when teams come together with a shared focus on testing meaningful therapies that may improve patients' lives and clinical outcomes. Completing dosing in a 1,535-participant global Alzheimer's disease trial across 13 countries reflects the strength and commitment of our teams, investigators, participants and their families. We are deeply grateful for their support and are now focused on ensuring that the final data review, database lock and analyses are completed to the highest standards."

AR1001 is an investigational, disease-modifying, once-daily oral small molecule and a potent, blood-brain barrier-penetrant phosphodiesterase-5 (PDE5) inhibitor. POLARIS-AD is a randomized, double-blind, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of AR1001 in patients with early Alzheimer's disease over 52 weeks of treatment. The study includes clinical, functional, and biomarker assessments intended to support marketing applications across multiple countries.

The trial demonstrated exceptional tolerability, high compliance, and strong participant interest for a large, long-duration Alzheimer's disease study, with a low discontinuation rate of 12.2% during the 52-week treatment period. In addition, 95.5% of participants who completed the main study elected to enter the optional long-term extension study, representing more than 1,250 participants. The extension study is expected to continue through July 2027 and is intended to provide longitudinal efficacy and safety information.

About POLARIS-AD:

POLARIS-AD is a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating AR1001 in patients with early Alzheimer's disease (NCT05531526). The study enrolled 1,535 participants across approximately 230 clinical sites in 13 countries. Participants received AR1001 or placebo for 52 weeks, with clinical, functional, and biomarker assessments conducted during the treatment period. A total of 1,348 participants completed the 52-week treatment period. Eligible participants completing the main study had the option to continue in a long-term extension study.

About AR1001:

AR1001 is an investigational, disease-modifying, once-daily oral small molecule developed by AriBio for Alzheimer's disease and other neurodegenerative disorders. AR1001 is a potent, blood-brain barrier-penetrant PDE5 inhibitor designed to modulate NO–cGMP signaling and address multiple biological pathways implicated in Alzheimer's disease, including cerebral perfusion, neuroprotection, neuroinflammation and tau phosphorylation. AR1001 is being evaluated in the global Phase 3 POLARIS-AD trial for early Alzheimer's disease. AR1001 has not been approved by the U.S. Food and Drug Administration or any other regulatory authority, and its safety and efficacy have not been established.

About AriBio:

Founded in 2010, AriBio Co., Ltd. is a clinical-stage biotechnology company focused on developing therapies for neurodegenerative diseases and other areas of high unmet medical need. The company's lead program, AR1001, is being developed as an investigational oral treatment candidate for Alzheimer's disease. AriBio is also advancing additional programs in dementia and related neurological disorders.

Forward-Looking Statements:

This press release contains forward-looking statements, including statements regarding the development of AR1001, the timing of topline results from POLARIS-AD, the potential clinical, regulatory and commercial prospects of AR1001, AriBio's future development and commercialization plans, the expected continuation and completion of the long-term extension study, and AR1001's potential mechanism of action and therapeutic profile. Forward-looking statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied. These risks and uncertainties include, but are not limited to, risks related to clinical trial conduct, data collection and analysis, regulatory review, safety and efficacy outcomes, manufacturing, commercialization, partnerships, market acceptance and other factors. AR1001 is an investigational product and has not been approved for marketing by any regulatory authority. AriBio undertakes no obligation to update forward-looking statements except as required by applicable law.

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