AriBio Completes Treatment Phase of Global Phase 3 POLARIS-AD Trial of AR1001 for Early Alzheimer's Disease

Pivotal Phase 3 registration trial advances to database lock and analysis;
Topline results expected in Q4'26;
Results planned for presentation at CTAD 2026

SEONGNAM-SI, SOUTH KOREA, August 3, 2026 /EINPresswire.com/ -- AriBio Co., Ltd., a clinical-stage biopharmaceutical company developing novel therapies for neurodegenerative diseases, today announced the completion of Treatment Phase of POLARIS-AD, its global Phase 3 registration trial evaluating AR1001 in patients with early Alzheimer's disease.

The completion of the treatment phase marks the completion of the final safety visit for the last patient in the study and represents a key milestone in the clinical trial process. With patient participation in the main 52-week study now complete, POLARIS-AD has advanced to the final stages of data cleaning, validation, database lock, and statistical analysis.

POLARIS-AD enrolled 1,535 patients with early Alzheimer's disease across approximately 230 clinical trial sites in 13 countries, including the United States, Europe, South Korea, and China. The study was conducted according to the planned protocol and timeline, with 1,348 participants completing the 52-week dosing by the end of June 2026. The last treated patient completed the scheduled four-week post-treatment safety follow-up visit on July 27, 2026.

AriBio is currently conducting data-cleaning and validation activities for clinical data collected from study sites worldwide. Following final review of data queries, and safety information, the company plans to proceed with database lock and pre-specified statistical analyses.

The company plans to announce topline efficacy and safety results from the 52-week study once data analysis is complete. Detailed Phase 3 results are planned for presentation at the Clinical Trials on Alzheimer's Disease conference, CTAD 2026, to be held in Boston beginning November 16, 2026.

"We are pleased to have completed this large-scale global Phase 3 trial involving 1,535 patients across 13 countries as planned," said Jai-Jun Choung, Ph.D., Chief Executive Officer of AriBio. "AR1001 has now reached an important stage where its clinical value will be evaluated through data. Our immediate priority is to complete database lock and statistical analysis with the

highest focus on data integrity and analytical accuracy."

AriBio also continues to evaluate AR1001 in the ongoing long-term open-label extension phase of POLARIS-AD. Following completion of the 52-week main study, 95.5 percent of eligible participants entered the optional extension study - a high retention rate with more than 1,250 participants currently receiving treatment and undergoing follow-up assessments. The extension study is scheduled to conclude in July 2027 and is expected to provide additional long-term safety and efficacy data to support future regulatory and commercialization planning.

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. 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, once-daily oral small molecule being 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 currently being evaluated.

About AriBio Co., Ltd.
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.

James Rock
Chief Clinical Officer, AriBio Co., Ltd.
jimrock@aribiousa.com
