ArriVent Announces First Patient Dosed in Global Pivotal Phase 3 ALPACCA Trial Evaluating Firmonertinib for First-Line Treatment of EGFR PACC Mutant Non-Small Cell Lung Cancer

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- *Firmonertinib has the potential to redefine first-line treatment in this underserved population as a once daily, oral, brain-penetrant, chemo-free monotherapy*
- *ALPACCA pivotal trial is designed to support potential accelerated and full regulatory approvals*

NEWTOWN SQUARE, Pa., Dec. 22, 2025 (GLOBE NEWSWIRE) -- ArriVent BioPharma, Inc. (Company or ArriVent) (Nasdaq: AVBP), a clinical-stage company dedicated to accelerating the global development of innovative biopharmaceutical therapeutics, today announced that the first patient has been dosed in the global pivotal Phase 3 ALPACCA study evaluating firmonertinib monotherapy for first-line treatment of EGFR PACC mutant non-small cell lung cancer (NSCLC). Firmonertinib is an oral, once daily, highly brain-penetrant and broadly active mutation-selective EGFR inhibitor.

“Initiation of our pivotal Phase 3 ALPACCA trial marks an important milestone in our strategy to expand the global reach of firmonertinib,” said Bing Yao, Ph.D., Chairman and Chief Executive Officer of ArriVent. “Patients with EGFR PACC mutant NSCLC currently have limited treatment options and represent a clear unmet medical need. With a well-characterized safety profile and broad clinical systemic and central nervous system (CNS) activity in patients, we believe firmonertinib is strongly positioned to bring meaningful innovation to NSCLC patients with PACC mutations and the potential to become a cornerstone therapy across the EGFR mutant spectrum.”

PACC mutations represent a distinct and underserved population of EGFR mutant NSCLC, with limited approved first-line targeted therapies and historically poor outcomes. The ALPACCA (FURMO-006) randomized, global Phase 3 study is evaluating firmonertinib 240 mg once daily versus investigator’s choice of osimertinib or afatinib in first-line patients with EGFR PACC mutant NSCLC. The primary endpoints are overall response rate (ORR) and progression-free survival (PFS) by blinded independent central review (BICR). The 240 mg dose of firmonertinib was selected for pivotal development based on compelling data showing a 16-month median PFS and a confirmed 68% ORR by BICR in the FURTHER trial. The ALPACCA study is designed to support potential global registration with endpoints for accelerated and full approval pathways. We estimate that the global ex-China annual incidence of NSCLC patients with EGFR PACC mutations to be approximately 42,000 patients and the US annual incidence to be approximately 6,200 patients.

About ArriVent

ArriVent is a clinical-stage biopharmaceutical company dedicated to the identification, development, and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. ArriVent seeks to utilize its team’s deep drug development experience to maximize the potential of its lead development candidate, firmonertinib, and advance a pipeline of novel therapeutics, such as next-generation antibody drug conjugates, through approval and commercialization.

About Firmonertinib

Firmonertinib is an oral, highly brain-penetrant, and broadly active mutation-selective epidermal growth factor receptor (EGFR) inhibitor active against both classical and uncommon EGFR mutations, including PACC and exon 20 insertion mutations. In March 2021, firmonertinib was approved in China for first-line advanced non-small-cell lung cancer (NSCLC) with EGFR exon 19 deletion or L858R mutations and for patients with previously treated locally advanced or metastatic NSCLC with EGFR T790M mutation, otherwise known as EGFR classical mutations.

Firmonertinib was granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation for the treatment of patients with previously untreated locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations. Firmonertinib was also granted U.S. FDA Orphan Drug Designation for the treatment of NSCLC with EGFR mutations or human epidermal growth factor receptor 2 (HER2) mutations or HER4 mutations.

Firmonertinib is currently being studied in a global Phase 3 trial for first-line NSCLC patients with EGFR exon 20 insertion mutations (FURVENT; NCT05607550) and in a global Phase 3 study in first line NSCLC patients with EGFR PACC mutations (ALPACCA).

About EGFR mutant NSCLC

Globally, lung cancer is the leading cause of cancer-related deaths among men and women. NSCLC is the predominant subtype of lung cancer, accounting for approximately 85% of all cases. Mutational activation of the EGFR is a frequent and early event in the development of NSCLC. EGFR mutations are divided into classical and uncommon. EGFR exon 20 insertion mutations are a group of uncommon EGFR mutations and constitute approximately 9% of all EGFR mutations. PACC mutations are another group of uncommon EGFR mutations and represent approximately 12% of all EGFR mutations. Patients with NSCLC whose tumors harbor uncommon EGFR mutations have significantly lower life expectancy with available therapies and represent an area of unmet medical need.

About EGFR PACC mutations

P-loop and αC-helix compressing (PACC) EGFR mutations are a distinct set of approximately 70 mostly missense activating mutations within the kinase domain of EGFR. They are similar to Exon 20 insertion mutations in narrowing the drug binding pocket to affect tyrosine kinase inhibitor activity. PACC mutations are diagnosed through commercially available NGS and most PCR tests. Patients with PACC mutations have limited treatment options, and there is no broadly utilized standard of care treatment for first-line PACC mutant patients.

About FURVENT

FURVENT is a global, pivotal, 3 arm Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients

with exon 20 insertion mutations being conducted jointly with our partner Allist. The FURVENT clinical trial is designed to assess the safety and efficacy of firmonertinib administered at either 160 mg or 240 mg, once-daily with each dose being compared to platinum-based chemotherapy with pemetrexed, the current first-line standard of care. The primary endpoint of this study is PFS by BICR per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. Secondary endpoints in patients with brain metastases at baseline include brain-specific CNS overall response rate (CNS-ORR) and CNS-PFS by modified RECIST (mRECIST). The study enrolled 398 patients globally, including from sites in the United States, Europe and certain Asian countries including Japan and China. An interim analysis for this study has not been performed and there is no plan to perform such analysis given the expected timing of top-line data.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, estimates of our addressable market, activity of firmonertinib compared to available therapies, anticipated clinical milestones, our expectation that ALPACCA may support potential global registration and may facilitate accelerated and full approval pathways, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Forward-looking statements are based on ArriVent's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties that are described more fully in the section titled "Risk Factors" in our annual report on Form 10-K for the fiscal year ended December 31, 2024, filed with the Securities and Exchange Commission on March 3, 2025 and our other filings with the Securities and Exchange Commission. Forward-looking statements contained in this press release are made as of this date, and ArriVent undertakes no duty to update such information except as required under applicable law.

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