



ArriVent Announces Cancer Cell Publication Highlighting Firmonertinib in EGFR PACC-Mutant Non-Small Cell Lung Cancer

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NEWTOWN SQUARE, Pa., Oct. 19, 2026 (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 the publication of FURTHER Phase 1b (FURMO-002; NCT05364073) results of firmonertinib in *Cancer Cell*, highlighting the preclinical and clinical findings supporting its potential, if approved, as the first oral, chemotherapy-free targeted therapy for treatment-naïve patients with advanced EGFR PACC-mutant non-small cell lung cancer (NSCLC).

EGFR PACC-mutant NSCLC is one of the largest underserved patient populations within EGFR-driven lung cancer. Accounting for approximately 12% of EGFR-mutant tumors, these patients currently have no established targeted standard of care, and are typically treated with therapies that were not designed for their unique biology, resulting in limited clinical benefit. This longstanding treatment gap underscores the significant opportunity for a targeted therapy purpose-built for EGFR PACC mutations.

"The publication demonstrated that firmonertinib's unique molecular structure fits the EGFR PACC mutations very well, so this TKI has a unique potential high anti-tumor activity for this lung cancer patient population," said Xiuning Le, MD, Ph.D., associate professor of Thoracic/Head and Neck Medical Oncology at the University of Texas MD Anderson Cancer Center, Houston, Texas. "Now the preclinical findings translated to prospective clinical trial data, resulting in robust confirmed response and progression-free survival. We believe this is very encouraging to EGFR PACC-mutant NSCLC patients."

"We believe firmonertinib has the potential to change the treatment paradigm for EGFR PACC-mutant NSCLC, and these findings give us a strong foundation for our global Phase 3 ALPACCA trial," said Bing Yao, Ph.D., CEO of ArriVent. "We continue to enroll patients in our global Phase 3 ALPACCA trial as we seek to address this area of high unmet medical need where there is no current standard of care."

Key Highlights for Firmonertinib from the Publication Include:

- **Enhanced in vitro potency vs. osimertinib:** Firmonertinib's unique trifluoroethoxy side chain creates additional contact points for binding to PACC-mutated EGFR's kinase domain.
- **Robust, durable clinical activity:** 43% (160 mg) and 68% (240 mg) confirmed overall response rate (ORR), with 11.1- and 16.0-months median progression free survival (PFS), both by blinded independent central review (BICR), respectively in front-line EGFR PACC-mutant NSCLC.
- **Meaningful intracranial activity:** 47% (8/17) confirmed intracranial ORR, including 41% complete responses among 17 patients with baseline brain metastases.
- **ctDNA clearance correlated with outcomes:** 80% of evaluable patients achieved complete molecular response by cycle 3, with higher ORR (70% vs. 20%) and longer median PFS (15.1 vs. 3.0 months) than those without clearance.
- **Manageable, consistent safety profile:** Treatment-related adverse event rates were consistent with firmonertinib's safety profile in prior clinical studies.

Based on these and other findings, ArriVent is evaluating firmonertinib versus investigator's choice of osimertinib or afatinib as first-line treatment for patients with locally advanced or metastatic EGFR PACC-mutant NSCLC (FURMO-006; NCT07185997).

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. Firmonertinib is approved in China for first-line advanced non-small-cell lung cancer (NSCLC) patients with EGFR exon 19 deletion or L858R mutations, with previously treated locally advanced or metastatic NSCLC with EGFR T790M mutation, both known as EGFR classical mutations, as well as for with exon 20 insertion mutations who have experienced disease progression during or after platinum-containing chemotherapy, or who are intolerant to platinum-containing chemotherapy.

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 and in a global Phase 3 study in first line NSCLC patients with EGFR PACC mutations (ALPACCA; NCT07185997).

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 α C-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 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.

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 business strategy, our plans, activity of firmonertinib compared to available therapies, including osimertinib, the intracranial activity of firmonertinib, the adverse event profile of firmonertinib, anticipated timing and results of the global pivotal Phase 3 study of firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR PACC mutations and in view of our evaluation of the full dataset of the pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, and our determination of the appropriate development path for firmonertinib, and our estimates of the incidence in that indication, 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, 2025, filed with the Securities and Exchange Commission on March 5, 2026 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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