



ArriVent Announces Program Update from the Phase 3 FURVENT Trial of Firmonertinib in First-Line EGFR Exon 20 Insertion Mutant NSCLC

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NEWTOWN SQUARE, Pa., Oct. 06, 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 that the FURVENT (NCT05607550) Phase 3 trial evaluating firmonertinib monotherapy in patients with previously untreated, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) harboring EGFR exon 20 insertion mutations did not meet its primary endpoint of progression free survival (PFS) by blinded independent central review (BICR). Clinical benefit was observed with secondary endpoints such as PFS by investigator's assessment and confirmed objective response rate by BICR. Although not yet mature, a trend toward an improvement in overall survival was also observed. The safety profile observed in FURVENT was consistent with previous clinical studies of firmonertinib, with no new safety signals identified.

"These disappointing results are not what we hoped for, particularly for the patients with EGFR exon 20 insertion-mutant NSCLC who urgently need more effective treatment options," said Bing Yao, Ph.D., Chairman, Chief Executive Officer of ArriVent. "While the safety profile observed with firmonertinib was consistent with previous clinical studies, FURVENT did not show a meaningful improvement in PFS over chemotherapy by BICR in this study. We are deeply grateful to the patients, investigators and clinical teams who made this program possible and are evaluating the full FURVENT dataset as we determine the most appropriate development path for firmonertinib."

Key Results from the Phase 3 FURVENT Trial

The FURVENT key results are summarized below.

	Firmonertinib 240mg Median PFS (months)	Firmonertinib 160mg Median PFS (months)	Control Median PFS (months)	p-value (240mg vs. control)	HR (95% CI) 240mg vs Control	HR (95% CI) 160mg vs Control	Confirmed ORR 240mg	Confirmed ORR 160mg	Confirmed ORR control
BICR	11.0 months	8.4 months	9.5 months	0.0654	0.75 (0.55, 1.02)	0.91 (0.67, 1.25)	60%	35%	33 %
Investigator's Assessment	11.1 months	8.3 months	7.1 months		0.61 (0.46, 0.81)	0.86 (0.65, 1.14)	61%	41%	28%

The safety profile observed in FURVENT was consistent with previous clinical studies of firmonertinib, with no new safety signals identified. Treatment-emergent adverse events (TEAE) Grade ≥ 3 were 52% with firmonertinib 240mg, 53% with firmonertinib 160mg, and 55% with the control arm. Treatment-related adverse events (TRAE) Grade ≥ 3 were 26% with firmonertinib 240mg, 22% with firmonertinib 160mg, and 40% with the control arm.

About FURVENT

FURVENT (NCT05607550) 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 RECIST 1.1. Secondary endpoints include overall survival (OS), PFS by investigator's assessment, confirmed objective response rate by BICR, and in patients with brain metastases at baseline, 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.

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 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; 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 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, our evaluation of the full FURVENT dataset, and our determination of the appropriate development path for firmonertinib, 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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