



ArriVent's Topline Pivotal Phase 3 FURVENT Data for Firmonertinib in First-Line NSCLC EGFR Exon20 Insertion Mutations is Projected to be Early 2026

July 21, 2025

Enrollment in FURVENT was completed in Q1 2025

Firmonertinib received FDA Breakthrough Therapy Designation in this patient population

NEWTOWN SQUARE, Pa., July 21, 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 topline firmonertinib monotherapy data from the global pivotal FURVENT Phase 3 (NCT05607550) study in first-line EGFR exon20 insertion mutant non-small cell lung cancer (NSCLC) is projected to be in early 2026. The primary endpoint will assess progression free survival (PFS) by blinded independent central review (BICR) per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. In the first quarter of 2025, the study completed enrollment across global sites.

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 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.

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). In addition, firmonertinib is also being studied in a clinical combination study targeting advanced or metastatic NSCLC patients with EGFR classical mutations, in partnership with Beijing InnoCare Pharma Tech Co., Ltd.

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 future results of operations, business, activity of firmonertinib compared to available therapies, anticipated clinical milestones, including the timing of top-line pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, 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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