Arrivent Presents the Final Analysis of Firmonertinib Monotherapy Data from Global Phase 1b Study in EGFR PACC Mutant Non-Small Cell Lung Cancer at the 2025 World Conference on Lung Cancer

September 9, 2025

- *16.0 months median progression free survival (mPFS) with firmonertinib 240 mg by blinded independent central review (BICR) in first-line patients*
- *Confirmed overall response rate (cORR) 68.2% and duration of response (DOR) 14.6 months by BICR in first-line patients*
- *Confirmed CNS (central nervous system) responses with firmonertinib including complete responses (CRs) by BICR*
- *Firmonertinib rapidly decreased or cleared PACC circulating tumor DNA (ctDNA) in frontline patients across PACC mutation types (frequent, less frequent and compound PACC) consistent with broad PACC activity*
- *Enrollment of the first patient in the global pivotal Phase 3 ALPACCA study in first-line EGFR PACC mutant non-small cell lung (NSCLC) cancer expected in the second half of 2025*

NEWTOWN SQUARE, Pa., Sept. 09, 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 presented positive final proof-of-concept data from the randomized global Phase 1b FURTHER trial for first-line firmonertinib monotherapy in patients with non-small cell lung cancer (NSCLC) harboring EGFR PACC mutations at the IASCLC 2025 annual World Conference on Lung Cancer (WCLC), in Barcelona, Spain.

“Our 16-month prolonged progression free survival with once daily oral firmonertinib monotherapy has been maintained with 16.5 months of median follow up and we are particularly encouraged by the CNS responses including CNS complete responses” said Bing Yao, Ph.D., Chairman and Chief Executive Officer of ArriVent. “Together this data reinforces the potential of firmonertinib to address key unmet needs in the global EGFR mutant NSCLC treatment landscape. Additionally, the rapid clearance of PACC ctDNA in frontline patients observed across a broad range of PACC mutations, including those with frequent, less frequent and compound PACC mutations, is consistent with the broad activity of firmonertinib in PACC mutant NSCLC. We expect to enroll the first patient in our global registrational ALPACCA Phase 3 trial in frontline PACC patients in the second half of the year.”

Key Highlights of Longer-term Final Analysis Data for Firmonertinib Monotherapy:

- **Maintained Clinically Meaningful PFS and Durable Responses**
  - 16.0 months mPFS with firmonertinib once daily 240 mg by BICR, with majority of patients remaining on study
  - 14.6 months median duration of response with firmonertinib 240 mg by BICR
  - 68.2% and 43.5% confirmed ORR by BICR at 240 mg and 160 mg, respectively
    - Confirmed responses at first tumor assessment in the majority of patients
    - Responses across a wide range of EGFR PACC mutations including most frequent (G719X, S768I), less frequent (E709X, V774M) and compound mutations
  - 42.9% (6/14) CNS confirmed ORR and 35.7% (5/14) CNS confirmed CRs in CNS evaluable disease front-line patients by BICR
- **Safety Profile Continues to be Consistent with No New Safety Signals**
  - Generally well-tolerated and manageable safety profile maintained over longer treatment duration
  - Most frequent treatment-related adverse events include diarrhea, hepatic enzyme elevation, rash, stomatitis, and dry skin

- No new safety findings with further follow up and safety profile remains consistent with EGFR-TKI class

- **Rapidly Decreased or Cleared PACC ctDNA in Frontline Patients**
  - 82% (9/11) and 79% (11/14) ctDNA clearance in frontline PACC patients treated with firmonertinib at 240 mg and 160 mg, respectively, in patients with detectable PACC ctDNA at baseline
  - Consistent decreases in ctDNA across different PACC mutations were observed including in patients with frequent, less frequent and compound mutations

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). 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 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. Topline data expected in early 2026. An interim analysis for this study has not been performed and there is no plan to perform such analysis.

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, cash runway, estimates of our addressable market, activity of firmonertinib compared to available therapies, duration of firmonertinib therapy in NSCLC patient populations, anticipated clinical milestones, the timing of, and results of, top-line pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, the timing of potential enrollment of the first patient in the global pivotal Phase 3 ALPACCA study of firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR PACC 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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