ArriVent Announces Positive Interim Firmonertinib Monotherapy Data From Global Phase 1b Study in EGFR PACC Mutant Non-Small Cell Lung Cancer and Plans to Advance into a Global Pivotal Study

June 23, 2025

16.0 months median progression free survival (mPFS) with firmonertinib 240 mg by blinded independent central review (BICR) in first-line patients

Robust central nervous system (CNS) activity; 41% (7/17) confirmed complete response (CR) and 53% confirmed overall response (ORR) in CNS evaluable disease patients by BICR in overall cohort

Enrollment of first patient in a randomized, global pivotal Phase 3 (ALPACCA) study in first-line PACC patients expected in the second half of 2025

ArriVent to host virtual webinar today at 8 am ET

NEWTOWN SQUARE, Pa., June 23, 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 encouraging additional follow up 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 and a clinical development update for the firmonertinib program for the treatment of EGFR PACC mutant NSCLC. ArriVent plans to host a virtual webinar today June 23, 2025 at 8 am ET. To register for the event, please click here.

“We are encouraged by the strong progression-free survival and durable systemic responses with long term firmonertinib treatment in frontline patients with EGFR PACC mutant NSCLC. Moreover, the generally well-tolerated safety profile is consistent with what has been clinically established,” said Bing Yao, Ph.D., Chairman and Chief Executive Officer of ArriVent. “We believe these Phase 1b findings support the advancement of firmonertinib towards a registration study for EGFR PACC mutant NSCLC, with potential for accelerated approval. We expect to enroll the first patient in the second half of 2025 in our randomized, global pivotal ALPACCA Phase 3 trial.”

Stuart Lutzker, M.D., Ph.D., Co-Founder and President of R&D of ArriVent added, “Patients with PACC mutant NSCLC represent an underserved population. We believe the interim median progression free survival of 16 months observed in the FURTHER study is clinically meaningful, and together with the compelling CNS activity and favorable safety profile underscore the potential of firmonertinib to address unmet needs across patients with PACC mutations as a once daily oral, chemo-free monotherapy.”

Key Highlights of Interim Data:

- **Clinically Meaningful Progression Free Survival and Durable Responses**
  - 16.0 months mPFS with firmonertinib 240 mg by BICR with 12.5 months median follow up
    - Majority of patients treated at 240 mg remain on study after 1 year
  - 14.6 months median duration of response with firmonertinib 240 mg by BICR
  - 68.2% and 43.5% confirmed ORR by BICR at 240mg and 160mg dose levels, respectively
    - Confirmed responses at first tumor assessment in the majority of patients
  - 41% (7/17) CNS confirmed CR and 53% (n = 9/17) CNS confirmed ORR in CNS evaluable disease patients by BICR
- **Consistent Safety Profile with No New Safety Signals**
  - Generally well-tolerated and manageable safety profile maintained over longer treatment duration (median follow up of 12.5 months)
  - Most frequent treatment-related adverse events (TRAEs) include diarrhea, hepatic enzyme elevation, rash, stomatitis, and dry skin
  - Safety profile consistent with EGFR-TKI class and initial firmonertinib Phase1b PACC

and FURTHER data

Development Update – Firmonertinib for the Treatment of EGFR PACC Mutations

- ALPACCA (FURMO-006), the first randomized global Phase 3 study in first-line NSCLC in patients across PACC mutations designed with extensive regulatory input
- Trial design enables potential for both accelerated and full approval
- Firmonertinib 240 mg selected as the optimal dose for pivotal Phase 3 development
- Enrollment of first patient in ALPACCA (FURMO-006) is expected in the second half of 2025

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 (formerly furmonertinib) 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 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. Food and Drug Administration Orphan Drug Designation for the treatment of non-small cell lung cancer with epidermal growth factor receptor (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 1b study, which includes a cohort evaluating firmonertinib in patients with EGFR PACC mutations (FURTHER; NCT05364073). 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.

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, activity of firmonertinib compared to available therapies, anticipated clinical milestones, including the top-line pivotal global Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, expansion of firmonertinib into a pivotal trial for 1L EGFR PACC mutant NSCLC and the timing of the first patient enrolled in such study, participation in the global Phase 3 registrational study of firmonertinib in adjuvant uncommon mutant NSCLC, anticipated IND filings for ADC candidates, 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.

Contact:
Joyce Allaire
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com