ArriVent BioPharma Reports Third Quarter 2024 Financial Results

November 14, 2024

Robust firmonertinib monotherapy activity in front-line EGFR PACC mutant NSCLC including in patients with brain metastases

Top-line pivotal data from global Phase 3 FURVENT trial for firmonertinib in front-line NSCLC harboring EGFR exon 20 insertion mutations expected 2025

Cash and cash equivalents of $282.9 million as of September 30, 2024

NEWTOWN SQUARE, Pa., Nov. 14, 2024 (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 reported financial results for the third quarter ended September 30, 2024, and highlighted recent Company progress.

"Our lead clinical program of firmonertinib in non-small cell lung cancer (NSCLC) is strongly advancing with encouraging potential to expand across EGFR mutant types. In September, we announced compelling monotherapy data for firmonertinib from our FURTHER study supporting rapid and robust anti-tumor activity across EGFR PACC mutations building on the strong activity observed in patients with EGFR exon 20 insertion mutations," said Bing Yao, Chairman and Chief Executive Officer of ArriVent. "Importantly, the high activity in tough to treat patients with central nervous system (CNS) metastases or compound mutations points to firmonertinib as a promising candidate for front-line patients with PACC mutations. Collectively, the broad activity in EGFR PACC mutations, the high responses in the CNS, and consistent, manageable safety profile across trials reinforces the promise firmonertinib holds to address unmet needs across the spectrum of EGFR mutant NSCLC."

Dr. Yao continued, "We expect several near-term catalysts for our firmonertinib program including initiating dose expansion for the combination study in classical EGFR mutant NSCLC with SHP2 inhibitor ICP-189 in the fourth quarter of the year, an update on the Phase 1b PACC study and plans for our potential registration study in the first half of 2025, and topline pivotal data from our global Phase 3 FURVENT study in front-line EGFR exon 20 mutant NSCLC in 2025. With our strong balance sheet and operating runway into 2026, we are well-positioned to execute across our near-term catalysts."

Third Quarter 2024 and Recent Highlights

Firmonertinib

- **Positive proof-of-concept data in EGFR PACC mutant NSCLC.** In September, ArriVent presented interim FURTHER Phase 1b clinical data for first-line firmonertinib monotherapy in patients with EGFR PACC mutant NSCLC during the Presidential Symposium at the 2024 annual World Conference on Lung Cancer and hosted a virtual webinar. In what we believe to be the first clinical dataset testing an EGFR inhibitor in a randomized defined population of EGFR PACC mutant NSCLC, firmonertinib demonstrated robust systemic and CNS anti-tumor activity with a manageable safety profile consistent with previous trials.

Upcoming Milestones

- **Dose expansion for SHP2 inhibitor combination.** Initiation of dose expansion cohort for the ongoing Phase 1b trial evaluating firmonertinib in combination with SHP2 inhibitor ICP-189 by InnoCare in patients with classical EGFR mutations expected in the fourth quarter of 2024.

- **EGFR PACC pivotal study plan.** Data from the FURTHER Phase 1b (NCT05364043) trial continues to mature for first-line firmonertinib monotherapy in patients with EGFR PACC mutant NSCLC. ArriVent expects to provide an update on EGFR PACC plans in the first half of 2025.

- **Selection of next-generation antibody drug conjugate (ADC) candidate.** ArriVent and its partner, Aarvik Therapeutics, Inc., continue to make progress, including initiating CMC activities, on selecting a multi-target multivalent ADC candidate for the treatment of solid tumors in the ARR-002 program, and expect to complete selection of a candidate that will be advanced into IND enabling studies in late 2024 or early 2025.

- **Top-line pivotal Phase 3 data in 2025.** Firmonertinib is currently being studied as a monotherapy in the pivotal, global Phase 3 FURVENT trial (NCT05607550) evaluating

firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations with topline data expected in 2025.

Third Quarter 2024 Financial Results

- As of September 30, 2024, the Company had cash and cash equivalents of $282.9 million, which is expected to fund operations into 2026. Net cash used in operations was $54.1 million and $40.9 million for the nine months ended September 30, 2024 and 2023, respectively.
- Research and development expenses were $58.9 million and $44.9 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in expense was primarily due to increased headcount and clinical expense related to firmonertinib.
- General and administrative expenses were $11.8 million and $6.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in expense was primarily due to expenses related to expanding the infrastructure necessary for operating as a public company.
- Net loss was $59.9 million and $48.1 million for the nine months ended September 30, 2024 and 2023, respectively.

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 (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 1b study, which includes a cohort evaluating firmonertinib in patients with EGFR PACC mutations (FURTHER; NCT05364043). 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.

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, anticipated clinical milestones, including dose expansion of ICP-189 in combination with firmonertinib, the study plan for a pivotal study of firmonertinib in patients with NSCLC EGFR PACC mutations, top-line pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, and the selection of an ADC clinical candidate, 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, 2023, filed with the Securities and Exchange Commission on March 28, 2024 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.

ARRIVENT BIOPHARMA, INC.

BALANCE SHEETS
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 282,855	$ 150,389
Prepaid expenses and other current assets	9,543	9,579
Total current assets	292,398	159,968
Right of use assets – operating leases	187	291
Deferred offering costs	—	2,732
Other assets	126	107
Total assets	$ 292,711	$ 163,098
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,646	$ 4,532
Accrued expenses	10,359	6,952
Operating lease liabilities	157	140
Total current liabilities	15,162	11,624
Operating lease liabilities, net of current amount	56	177
Total liabilities	15,218	11,801
Series A convertible preferred stock $0.0001 par value, 150,000,000 shares authorized; 150,000,000 shares issued and outstanding at December 31, 2023	—	149,865
Series B convertible preferred stock $0.0001 par value, 147,619,034 shares authorized; 147,619,034 shares issued and outstanding at December 31, 2023	—	154,625
Stockholders' equity (deficit):		
Preferred stock $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock $0.0001 par value, 200,000,000 shares authorized; 33,694,355 and 2,745,480 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	—
Additional paid-in capital	495,190	4,652
Accumulated deficit	(217,700)	(157,845)
Total stockholders' equity (deficit)	277,493	(153,193)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 292,711	$ 163,098

ARRIVENT BIOPHARMA, INC.

STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 20,088	$ 14,280	$ 58,841	$ 44,874
General and administrative	4,144	2,436	11,762	6,598
Total operating expenses	24,232	16,716	70,603	51,472
Operating loss	(24,232)	(16,716)	(70,603)	(51,472)

Interest income	3,668	2,315	10,748	3,332
Net loss	$ (20,564)	$ (14,401)	$ (59,855)	$ (48,140)
Share information:				
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (5.52)	$ (1.95)	$ (24.69)
Weighted-average shares of common stock outstanding, basic and diluted	33,581,810	2,607,192	30,720,711	1,949,597

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