ArriVent Biopharma Announces First Patient Enrolled in Global Phase 1b Trial of Furmonertinib in Advanced or Metastatic Non-Small Cell Lung Cancer with EGFR or HER2 Mutations

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Furmonertinib granted Fast Track Designation in this indication by the U.S. Food and Drug Administration

ArriVent Biopharma, Inc., dedicated to accelerating the global development of innovative biopharmaceutical therapeutics, today announced that the first patient has been enrolled in its Phase 1b trial of furmonertinib in patients with advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) or HER2 mutations, including exon 20 insertion mutations. Furmonertinib, an oral, irreversible, pan-EGFR mutant selective inhibitor—which has been shown to be highly brain penetrant—was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) in this indication.

"This is an important milestone for ArriVent as it represents the initiation of our Company's first clinical trial and the first global study for furmonertinib—a promising therapy for patients with NSCLC," said Stuart Lutzker, M.D., Ph.D., President of R&D at ArriVent. "Furmonertinib was initially developed and approved in China for EGFR T790M mutant NSCLC, and more recently was approved in China as a first-line treatment for classical EGFR mutant NSCLC by our partners Allist Pharmaceuticals, who continue to advance its development in other indications including EGFR exon 20 insertion mutant NSCLC."

Continued Dr. Lutzker: "In parallel to the important clinical research ongoing by our partners in China, we look forward to further developing furmonertinib globally in a broad spectrum of EGFR and HER2 mutant NSCLC patients, including those with brain metastases, which occurs in 50-60% of patients during the course of their disease. With this FDA designation, we will be able to expedite the development and regulatory review process of furmonertinib, and if successful, deliver this EGFR inhibitor as a meaningful treatment option for the thousands of patients impacted by this serious and life-threatening disease."

The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

About Furmonertinib

Furmonertinib is an oral, small molecule, highly brain-penetrant, pan-EGFR mutant inhibitor that targets both classical (exon 19 deletion and L858R) and atypical EGFR mutations, including exon 20 insertion mutations as well as HER2 exon 20 insertion mutations. Furmonertinib is approved in China as an anticancer therapy for EGFR T790M NSCLC patients, and more recently, as a first-line treatment for classical EGFR mutant NSCLC patients. Furmonertinib is being developed in China by Allist Pharmaceuticals and in the rest of the world by ArriVent Biopharma.

About EGFR mutant NSCLC

Globally, lung cancer is the leading cause of cancer-related deaths among men and women. Non-small cell lung cancer (NSCLC) is the predominant subtype of lung cancer, accounting for approximately 85% of all cases. Mutational activation of the epidermal growth factor receptor (EGFR) is a common and early event in the development of NSCLC and is present in approximately 32% of NSCLC patients. The most common EGFR activating mutations are exon 19 deletions and a point mutation in exon 21 (L858R), which together are termed classical EGFR mutations and account for approximately 67% of all the EGFR mutations. 31% of EGFR activating mutations are termed atypical EGFR mutations of which exon 20 insertion mutations constitute 9% of EGFR activating mutations overall.

About the Phase 1b Clinical Trial

The furmonertinib Phase 1b, open-label, multi-center, dose-escalation and dose-expansion study is designed to evaluate the safety, pharmacokinetics, and preliminary antitumor activity of furmonertinib in patients with advanced or metastatic NSCLC with activating EGFR or HER2 mutations, including Exon 20 insertion mutations. Patients will be enrolled into two stages: Stage 1 (Dose Escalation and Backfill Cohorts) and Stage 2 (Dose Expansion). For more information about the trial, please visit clinicaltrials.gov (NCT05364073).

About ArriVent Biopharma

ArriVent is dedicated to accelerating the global development of innovative biopharmaceutical products. With a deep and global network, ArriVent seeks to access unique and best-in-class drug candidates at various development stages, including those coming from China and other emerging biotech hubs. Through strategic collaborations with innovative biopharma companies, ArriVent aims to globalize medicines for patients with unmet medical need in a broad range of diseases, with an initial focus in oncology.

For additional information, visit www.arrivent.com.

Media

Amy Bonanno, Managing Director, Solebury Trout

abonanno@soleburytrout.com

914-450-0349