ArriVent Receives FDA Breakthrough Therapy Designation for Furmonertinib for First-Line Treatment of Advanced or Metastatic Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations

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ArriVent Biopharma, Inc., a clinical-stage company dedicated to accelerating the global development of innovative biopharmaceutical therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for furmonertinib for the treatment of patients with previously untreated, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations.

“Breakthrough Therapy designation is an important step forward in our development of furmonertinib and highlights its exciting potential as a first-line therapy for patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations,” said Bing Yao, Chairman, Co-founder and Chief Executive Officer of ArriVent.

Stuart Lutzker, Co-founder and President of R&D added: “This FDA designation underscores the encouraging clinical activity we have seen with furmonertinib in the FAVOUR study and reflects the critical need for effective and tolerable therapeutic options for these patients. We look forward to continuing our work with the agency as we progress our furmonertinib clinical development program in NSCLC, including our ongoing pivotal, global Phase 3 FURVENT trial evaluating furmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations.”

The Breakthrough Therapy designation was granted based on interim results from FAVOUR trial (NCT04858958), a Phase 1b, randomized, open-label, multi-center clinical trial evaluating the efficacy and safety of furmonertinib in patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations. FDA's Breakthrough Therapy designation is designed to expedite development and review of drugs intended to treat a serious or life-threatening condition for which preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapies. Interim results from the trial demonstrated furmonertinib has promising anti-tumor activity as a single agent with a well-tolerated safety profile in the first-line and previously treated patients. The pivotal Phase 3 FURVENT trial (NCT05607550) of furmonertinib for the treatment of first-line NSCLC with EGFR exon 20 insertion mutations is currently enrolling patients globally.

About ArriVent
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.

About Furmonertinib
Furmonertinib is a novel, oral, highly brain-penetrant, EGFR kinase inhibitor designed for broad activity and selectivity across EGFR mutations. Furmonertinib targets both classical (exon 19 deletion and L858R) and uncommon EGFR mutations, including exon 20 insertion mutations. 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. EGFR mutations occur in approximately 24% of NSCLC cases in the Americas and up to 50% in Asian populations. The most common EGFR mutations are exon 19 deletions and a point mutation in exon 21 (L858R), which together are termed classical EGFR mutations and account for approximately 70% of all EGFR mutations. The remaining EGFR mutations are termed uncommon EGFR mutations of which exon 20 insertion mutations constitute approximately 9% of all EGFR mutations. Patients with NSCLC whose tumors harbor uncommon EGFR mutations have significantly lower life expectancy.

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