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Phase II study of firmonertinib in patients with previously treated advanced/metastatic non-small cell lung cancer (mNSCLC) with EGFR exon 20 insertion (ex20ins) mutations

Y. Cheng[1], Y. Liu[1], Y. Yu[2], L. Wu[3], Y. Luo[3], X. Li[4], Z. Xiao[5], X. Ren[6], X. Wang[7], J. Lu[8], X. Dong[9], Z. Zhang[10], H. Lan[11], M. Sun[12], Y. Du[13], R. Yang[14], J. Wang[15], P. Cheng[16], Y. Jiang[17], Q. Zhao[17]

[1] Medical Oncology, Jilin Cancer Hospital, Changchun, China, [2] Respiratory Medicine, Harbin Medical University Cancer Hospital, Harbin, China, [3] Department of Thoracic Medicine, Hunan Cancer Hospital, Changsha, China, [4] Oncology Department, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China, [5] Department of Respiratory and Critical Care Medicine, Jiangxi Provincial People's Hospital, Nanchang, China, [6] Biotherapeutics Section, Tianjin Medical University Cancer Hospital, Tianjin, China, [7] Medical Oncology, Xuzhou Central Hospital, Xuzhou, China, [8] Medical Oncology, Nantong Tumor Hospital, Nantong, China, [9] Thoracic Oncology Department, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China, [10] Respiratory Oncology Department, Anhui Provincial Cancer Hospital, Hefei, China, [11] Oncology Department, Sichuan Provincial People's Hospital, Chengdu, China, [12] Oncology Department, Central Hospital Affiliated to Shandong First Medical University, Jinan, China, [13] Medical Oncology, The First Affiliated Hospital of Anhui Medical University, Hefei, China, [14] Medical Oncology, Yunnan Cancer Hospital, Kunming, China, [15] Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai, China, [16] Oncology Department, The First Affiliated Hospital of Nanyang Medical College, Nanyang, China[17] Clinical Development Department, Shanghai Allist Pharmaceuticals Co., Ltd., Shanghai, China

Background

Firmonertinib (firmo, also known as furmonertinib) is an oral third-generation EGFR inhibitor with broad activity and selectivity across EGFR mutations. Firmo has FDA breakthrough therapy designation and is being tested in a global randomized phase (Ph) III study in first-line (1L) *EGFR* ex20ins mutant NSCLC. Here, we report topline results from a Ph II trial conducted in previously treated NSCLC patients (pts) with *EGFR* ex20ins mutations (FURMO-003; NCT05466149).

Methods

FURMO-003 is a Ph II, multicenter, open-label study of firmo 240 mg QD. Eligible pts had advanced/mNSCLC with *EGFR* ex20ins mutations and received prior platinum-based therapy. Pts with clinically stable central nervous system (CNS) metastases were eligible. Primary endpoint was confirmed overall response rate (cORR) by blinded independent central review (BICR). Secondary endpoints included duration of response (DOR), progression-free survival (PFS), overall survival (OS) and safety.

Results

As of March 31, 2025, 71 pts were enrolled and treated (median age, 57.0 years; 50.7% female; 22.5% with CNS metastases; 76.1% ECOG PS 1; 1 median [1–3] lines of prior systemic therapy). Efficacy analysis included 70 pts, the cORR by BICR was 44.3%. The cORR was 47.0% if excluding 4 pts without measurable disease at baseline by BICR. The DCR was 90.0%. Median DOR was 8.3 months (mos). Median PFS and OS were 8.3 mos and 21.2 mos (32.9% death events), respectively. Treatment-related adverse events (TRAEs) occurring in ≥30% of pts included diarrhea (64.8%), anaemia (39.4%), blood creatinine increased (33.8%), and aspartate aminotransferase increased (31.0%). Grade 3–4 TRAEs were reported in 18 (25.4%) pts and 4 (5.6%) pts discontinued due to TRAEs.

Conclusions

Firmo demonstrates promising clinical activity and an acceptable safety profile in previously treated advanced/mNSCLC pts with *EGFR* ex20ins mutations in China. These results support firmo as a valuable treatment option for this pts population. Firmo is also under evaluation in a global, randomized Ph III trial for 1L NSCLC pts w/ex20ins (FURVENT; NCT05607550) and has completed enrollment.

Clinical trial identification

NCT05466149, NCT05607550.

Legal entity responsible for the study

The authors.

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Disclosure

Y. Jiang, Q. Zhao: Financial Interests, Personal, Full or part-time Employment: Shanghai Allist Pharmaceuticals Co., Ltd. All other authors have declared no conflicts of interest.