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Ensartinib as adjuvant therapy in patients (pts) with stage IB–IIIB ALK-positive (ALK+) non-small cell lung cancer (NSCLC) after complete tumor resection: The phase III randomized ELEVATE trial

D. Yue[1], M. Huang[2], P. Song[3], Y. Chen[4], B. Li[5], J. Fu[6], J. Guo[7], C. Cheng[8], Q. Chen[9], S. Xu[10], H. Liu[11], F. Lv[12], J. Hu[13], K. Jiang[14], W. Mao[15], F. Ye[16], B. Shen[17], L. Ding[18], Y. Lu[19], C. Wang[20]

[1] Lung Cancer Dept, TMUCIH - Tianjin Medical University Cancer Institute and Hospital, Tianjin, China, [2] Division of Thoracic Tumor Multimodality Treatment, Cancer Center, West China Hospital, Sichuan University, Chengdu, China, [3] Oncology Department, Shandong Cancer Hospital Affiliated to Shandong University, Jinan, China, [4] Thoracic Surgery, Hunan Cancer Hospital, Changsha, China, [5] Department of Thoracic Surgery, Second Hospital of Lanzhou University, Lanzhou, China, [6] Thoracic Surgery, The First Affiliated Hospital of Xi'an Jiaotong University, Xi'an, China, [7] Department of Cardiothoracic Surgery, The First Affiliated Hospital of Guangxi Medical University, Nanning, China, [8] Thoracic Surgery Department, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, China, [9] Department of Thoracic Surgery, Cancer Hospital of the University of Chinese Academy of Sciences/ Zhejiang Cancer Hospital, Hangzhou, China, [10] Thoracic Surgery Department, 3rd Affiliated Hospital of Harbin Medical University, Harbin, China, [11] Department of Thoracic Surgery, Cancer Hospital of Dalian University of Technology, Liaoning Cancer Hospital & Institute, Shenyang, China, [12] Department of Thoracic Surgery, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China, [13] Department of Thoracic Surgery, The First Affiliated Hospital of Medical School of Zhejiang University, Hangzhou, China, [14] Department of Thoracic Surgery, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology/ Cancer Center Union Hospital, Wuhan, China, [15] Thoracic Surgery, Jiangxi Cancer Hospital, Nanchang, China, [16] Medical Oncology Dept., The First Affiliated Hospital of Xiamen University, Xiamen, China, [17] Department of Medical Oncology, Jiangsu Cancer Hospital, Nanjing, China, [18] Headquarters, Betta Pharmaceuticals Co., Ltd. - Headquarters, Hangzhou, China, [19] Division of Thoracic Tumor Multimodality Treatment and Department of Radiation Oncology, Cancer Center, West China School of Medicine/West China Hospital of Sichuan University, Chengdu, China[20] Department of Lung Cancer, TMUCIH - Tianjin Medical University Cancer Institute and Hospital, Tianjin, China

Background

Ensartinib is a 2G ALK tyrosine kinase inhibitor (TKI) that is recommended as a standard of care therapy for previously untreated advanced ALK+ NSCLC. Here, we report data from the prespecified interim analysis of ELEVATE trial, a double-blind, randomized, phase 3 study comparing adjuvant ensartinib vs placebo (PBO) for ALK+ NSCLC patients following resection and adjuvant chemotherapy.

Methods

Eligible pts were ≥18 years old, had an ECOG PS of 0/1 and completely resected, stage IB-IIIB(T3N2M0), ALK+ NSCLC (AJCC 8th edition), postoperative chemotherapy was allowed. Pts will be randomized 1:1 to receive once-daily 225 mg ensartinib or placebo for up to 2 years. The primary endpoint is disease-free survival (DFS); secondary endpoints are overall survival, safety, 3-year, and 5-year DFS rate.

Results

Between July 2022 and July 2024, 274 pts were randomized to treatment: ensartinib n=137, PBO n=137. Baseline characteristics were balanced across arms (ensatinib/PBO): stage IB 24.8/25.5%, stage II-IIIB 75.2/74.5%, female 66.4/61.3%, adjuvant chemotherapy 68.6/70.8%. At data cutoff (26 June 2025), the median follow-up was 22.1 months. In pts with stage II–IIIB disease, DFS HR was 0.20 (95% CI 0.11, 0.38; p<.0001); the 2-year DFS rate was 86.4% with ensartinib vs 53.5% with placebo. In the ITT population, DFS HR was 0.20 (95% CI 0.10, 0.37; p<.0001); the 2-year DFS rate was 87.3% with ensartinib vs 57.2% with PBO. Consistent DFS benefits were seen across subgroups. A clinically meaningful CNS-DFS benefit was observed in the ITT population (HR 0.22; 95% CI 0.08, 0.60). OS was immature (1% maturity) with 3/274 deaths (ensartinib n=1, PBO n=2) at DCO. The safety profile was consistent with the known safety profile of ensartinib.

Conclusions

Adjuvant ensartinib is the first ALK inhibitor to show a statistically significant and clinically meaningful improvement in DFS in pts with stage IB-IIIB (T3N2M0) ALK-positive NSCLC after complete tumor resection and adjuvant chemotherapy. Adjuvant ensartinib provides an effective new treatment strategy for these pts.

Clinical trial identification

NCT05341583.

Legal entity responsible for the study

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Disclosure

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