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Updated safety and efficacy results of SHR-1316 combined with chemotherapy and sequential chest radiotherapy as first-line therapy for extensive-stage small cell lung cancer (ES-SCLC) from a phase II trial.

Dawei Chen, Aiqin Gao, Wei Huang, Qian Shao, Xiangjiao Meng, Xiaoyong Tang, Pinliang Zhang, Xudong Hu, Yan Zhang, Jun Guo, Lei Fu, Wei Zhao, Changhong Zhao, Jiajia Yuan, Jinming Yu, Linlin Wang; Shandong Cancer Hospital, Shandong University, Jinan, China; Shandong Cancer Hospital and Institute, Jinan, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Science, Jinan, Shandong, China; Jiangsu Hengrui Pharmaceuticals Co. Ltd, Shanghai, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Science, Jinan, China

Background: CAPSTONE-1 study showed that SHR-1316 (PD-L1 antibody) combined with first-line chemotherapy could prolong overall survival in patients (pts) with ES-SCLC. Previous studies have shown that radiotherapy could potentially promote tumor antigen presentation and reverse immunosuppressive microenvironment in tumor. The purpose of this study was to explore the efficacy and safety of SHR-1316 combined with chemotherapy and sequential chest radiotherapy as first-line therapy for ES-SCLC. **Methods:** Key inclusion factors were 18-75 years old, histologically or cytologically confirmed ES-SCLC, ECOG performance status 0-1, no previous systematic treatment. Pts included in this study received 4~6 cycles of SHR-1316 (20mg/kg, D1, q3w) combined with EP/EC (cisplatin, 75mg/m^2, D1-3, q3w or carboplatin, AUC = 5, D1, q3w and etoposide, 100mg/m^2, D1-5, q3w), sequentially SHR-1316 combined with chest radiotherapy (≥3Gy*10f or ≥2Gy*25f, involved-field irradiation), and then entered the maintenance treatment stage until disease progression or intolerable side effects. The main endpoints included objective response rate (ORR), disease control rate (DCR), progression-free survival (PFS) and safety. **Results:** From October 2020 to January 2023, 63 pts with ES-SCLC were enrolled and received at least one dose of SHR-1316, 33 of them have received chest radiotherapy. The median age was 63 (range: 38-75), and most pts were male (53, 84.1%), former smokers (42, 66.7%) with an ECOG performance status 1 (60, 95.2%). At baseline, 24 (38.1%) pts were diagnosed with brain metastasis and 19 (30.2%) pts had liver metastasis. At the data cutoff date, the average number of treatment cycles was 6.9, 17 pts remained on treatment. 55 pts had at least one post-treatment tumor assessment. 41 pts achieved a confirmed partial response, and 12 pts had stable disease. The confirmed ORR and DCR were 74.5% and 96.4%, respectively. The median PFS was 7(CI: 4.3~9.7) months. Adverse events (AEs) occurred in 47 (74.6%) pts. Grade 3 or 4 AEs occurred in 35 (55.6%) pts. The most common grade 3 or 4 AEs included neutropenia (27, 42.9%), leukopenia (13, 20.6%), lymphocytopenia (5, 7.9%), pneumonia (4, 6.3%), anemia (3, 4.8%), and thrombocytopenia (2, 3.2%). **Conclusions:** SHR-1316 combined with chemotherapy and sequential chest radiotherapy as first-line therapy for ES-SCLC showed promising efficacy and acceptable safety. It is worthy of further clinical exploration. Clinical trial information: NCT04562337. Research Sponsor: None.