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

Dawei Chen, Bing Zou, Xiangjiao Meng, Wei Huang, Qian Shao, Xiaoyong Tang, Jun Guo, Xudong Hu, Yan Zhang, Lei Fu, Yuan Jiajia, Jinming Yu, Linlin Wang; Shandong Cancer Hospital Affiliated to Shandong University, Jinan, China; Department of Radiation Oncology, Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Science, Jinan, China; Shandong Cancer Hospital and Institute, Jinan, China; Shandong Cancer Hospital, Shandong University, Jinan, China; Shandong Cancer Hospital, Jinan, China; Jiangsu Hengrui Pharmaceuticals Co.,Ltd, Shanghai, China

Background: Impower133 and CASPIAN studies showed that PD-L1 antibody combined with first-line chemotherapy could prolong the overall survival. 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 (PD-L1 antibody) 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. Patients (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; 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 PFS, ORR and safety. **Results:** From October 2020 to December 2021, 31 pts with ES-SCLC received at least one dose of SHR-1316. The median age was 64 (range: 37-75) with 25(80.6%) male, 22(71%) former smokers and 31 (100%) ECOG performance status 1. 17 (54.8%) pts were with brain metastasis, 8 (25.8%) pts with liver metastasis, 8 (25.8%) pts with kidney/adrenal metastasis, 7(22.6%) pts with bone metastasis. At the data cutoff date, 15 pts remained on treatment, the average number of treatment cycles was 5.19. 24 pts had at least one 1 post-treatment tumor assessment. The median PFS was 7.56 months, the confirmed ORR and DCR in all pts were 50% (12/24) and 87.5% (21/24), respectively. The confirmed ORR and DCR in pts with brain metastasis were 38.5% (5/13) and 76.9% (10/13), and were 63.6% (7/11) and 100% (11/11) in pts without brain metastasis. In pts received chest radiotherapy, the confirmed ORR and DCR were 80% (8/10) and 100% (10/10). During the study period, 23 (74.2%) pts had adverse drug reactions, and 16 (51.6%) pts had grade 3 or 4 adverse drug reactions, including 12 (38.7%) neutropenia 8 (25.8%) leukopenia, 2 (6.5%) thrombocytopenia, 2 (6.5%) anemia, 1(3.2%) lymphocytopenia, 1(3.2%) amylase increased. No grade 5 adverse drug reaction was observed. **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: Jiangsu Hengrui Pharmaceuticals Co. Ltd.