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Poster Session

A phase II exploratory trial of adebrelimab in combination with chemotherapy and concurrent radiotherapy as a first-line treatment for oligo-metastatic extensive-stage small-cell lung cancer.

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Background: Oligometastasis of extensive-stage small-cell lung cancer (ES-SCLC) is an intermediate state between local and extensive metastasis, characterized by reduced metastatic potential and a limited number of metastatic sites, which makes local treatment of each lesion possible. Multiple clinical studies have shown that adding local therapy to standard systemic therapy can improve the prognosis of patients with oligometastatic disease. The PD-L1 inhibitor adebrelimab combined with chemotherapy has become one of the standard regimens for first-line treatment of ES-SCLC. Based on these, we hypothesize that in patients with oligometastatic ES-SCLC at risk of early progression, the early addition of chest radiotherapy and stereotactic radiotherapy (SBRT) for metastatic lesions to first-line treatment with adebrelimab combined with chemotherapy may be expected to achieve local control, thereby improving survival benefits. **Methods:** This is a prospective, single-arm, multicenter, phase II exploratory trial. Patients will be eligible if they are 18 to 75 years of age; have histopathologically or cytologically confirmed ES-SCLC with the number of metastatic lesions of $\leq$ 5 and organ metastasis of $\leq$ 3 (i.e. oligometastases); have an ECOG PS of 0-1; and have no previous systemic treatment. The treatment period in this trial is subdivided into induction therapy, concurrent chemoradiotherapy, and consolidation and maintenance therapy. In the induction setting, patients will receive two 3-week cycles of adebrelimab (20 mg/kg on day 1), carboplatin (AUC of 5 mg/mL per min on day 1)/cisplatin (75 mg/m^2 on day 1), and etoposide (100 mg/m^2 on days 1-3). Patients who achieve partial response or stable disease after induction therapy will then receive concurrent chemoradiotherapy, of which chemotherapy regimen is the same as the induction setting. Radical IMRT radiotherapy (2.5-3 Gy/f, total dose 45-55 Gy) will be performed for the primary tumor in the chest and lymph node region, and SBRT radiotherapy will be given to metastatic lesions. Prophylactic cranial irradiation is optional. After the end of chemoradiotherapy, patients will receive 1-2 cycles of consolidation treatment with the same regimen as induction treatment, followed by adebrelimab monotherapy (20 mg/kg on day 1, q3w) as maintenance treatment until disease progression, intolerance toxicity, or up to 2 years of adebrelimab. The total cycle number of chemotherapy is 4-6. The primary endpoint is progression-free survival (PFS), and secondary endpoints are objective response rate, duration of response, overall survival (OS), 6-month and 1-year PFS rates, 1-year and 2-year OS rates, and safety. The trial is under recruitment, and a total of 62 patients are planned to be enrolled. Clinical trial information: NCT06177925. Research Sponsor: Jiangsu Hengrui Pharmaceuticals Co., Ltd.