A PHASE 2 STUDY OF DURVALUMAB COMBINED WITH CHEMOTHERAPY AND STEREOTACTIC BODY RADIOTHERAPY (SBRT) IN PATIENTS WITH OLIGOMETASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) (SABRCURE TRIAL)

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Background Immunotherapy +/- chemotherapy is currently the standard of care for metastatic NSCLC, but strategies to expand the benefit are still needed. Oligometastatic NSCLC is a state of limited disease in which widespread metastasis has not yet evolved. Locally radiotherapy achieves prolonged progression-free survival and overall survival in a small proportion of well selected oligometastatic NSCLC patients1. Preliminary evidence suggests high dose fractionated radiotherapy, such as SBRT, in combination with systemic immunotherapy has a synergistic effect and may enhance survival2. Durvalumab (PD-L1 antibody) is approved as consolidation therapy for unresectable, locally advanced NSCLC who have not progressed following chemoradiotherapy. These findings support further investigation of durvalumab + SBRT combinations in oligometastatic NSCLC who received standard systematic therapy.

Methods SABRCURE is an open-label, phase 2 study evaluating the efficacy and safety of durvalumab combined with SBRT and chemotherapy in oligometastatic stage IV NSCLC. Key eligibility criteria include no more than 5 metastatic lesions in up to 3 organs, EGFR/ALK/ROS1 wild type, no previous systemic therapy or brain metastases. Forty patients will be enrolled and receive durvalumab 1500mg + platinum-doublet chemotherapy every 3 weeks for 4 cycles, and then durvalumab 1500mg every 4 weeks monotherapy until disease progression or up to 24 months. Patient without progression after 4 cycles durvalumab + chemotherapy will receive stereotactic body radiotherapy. SBRT will be started within 2 weeks after chemotherapy completion and administered to primary lesion and all known metastatic lesions, with a total dose of 50-60Gy in 10 fractions. The primary endpoint is progression free survival (PFS) per RECIST v1.1. Secondary end points are objective response rate (ORR), overall survival (OS), safety and treatment failure pattern. This study was funded by AstraZeneca China.

Trial Registration NCT04255836

REFERENCES

Ethics Approval This study was approved by Cancer Hospital of the University of Chinese Academy of Sciences Ethics Committee.

Consent Written informed consent was obtained from the patient for publication of this abstract.