ORAL SESSION: SEMI-PLENARY SESSION

Phase II study of osimertinib in patients with plasma EGFR T790M positive advanced lung cancer (WJOG8815L/LPS)

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Background: Liquid biopsy (EGFR T790M mutation test with plasma sample) has become a clinical test that can be performed in clinical practice. However, there are no data directly investigating whether liquid biopsy correlates with the effectiveness of osimertinib. Therefore, liquid biopsy is approved only for the patients who cannot obtain tumor tissue sample. This study is a single arm Phase II study to confirm the effectiveness of osimertinib in subjects confirmed positive for T790M mutation by liquid biopsy.

Method: Eligibility included advanced non-small cell lung cancer (NSCLC) with EGFR sensitizing mutation, objective failure of standard treatment with first or second generation EGFR tyrosine kinase inhibitors (TKI), performance status 0 or 1. Plasma EGFR T790M mutation status was screened with Cobas EGFR mutation test v2 and Droplet Digital PCR. Patients were administered osimertinib 80mg/day until progression of disease. The primary endpoint was the response rate in advanced/metastatic NSCLC patients with plasma EGFR T790M+ confirmed with Cobas EGFR Mutation test v2.

Results: Between June 2016 and December 2017, 276 patients were screened in WJOG8815LPS study for EGFR T790M mutation with liquid biopsy. 73 patients were plasma EGFR T790M mutation positive, and 53 patients were enrolled in WJOG8815L study. The main analysis is scheduled for June 2018, and the final data will be presented in more detail at JSMO annual meeting 2018.

Conclusion: The WJOG8815L study will provide the first prospective data about the correlation between the liquid biopsy and the efficacy of treatment with Osimertinib. This information is valuable for deciding the future position of the liquid biopsy in clinical practice. (UMIN 000022076, 000022077).