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Neoadjuvant nivolumab monotherapy for high-risk clinical stage I non-small cell lung cancer: A phase II POTENTIAL study

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Background

There is limited evidence regarding neoadjuvant/adjuvant therapy for stage I non-small cell lung cancer (NSCLC).

Methods

A multicenter phase II trial (POTENTIAL) evaluated the safety and efficacy of neoadjuvant nivolumab in patients with clinical stage I (ver. 8) NSCLC at high risk of recurrence. The study included patients with histologically or cytologically confirmed stage I NSCLC and a pure solid tumor with no ground-glass opacity component or a solid component measuring 2-4 cm on preoperative high-resolution computed tomography. Patients with known EGFR mutation, ALK translocation, or ROS-1 translocation were excluded. Nivolumab (240 mg/body) was administered intravenously as neoadjuvant therapy every 2 weeks for 3 cycles. Lobectomy and lymph node dissection were then performed. The primary endpoint was pathologic complete response (pCR) rate as assessed by central review with a threshold of 10%.

Results

Fifty-two patients were evaluated and all patients underwent surgical resection. The primary endpoint was met with a pCR rate of 23.1% (12/52, 95% confidence interval (CI) 12.5-36.8%). The major pathologic response rate was 46.2% (24/52, 95% CI 32.2-60.5%). No new safety signals or treatment-related deaths were observed. With a median follow-up of 33.7 months, the 2-year relapse-free survival rate was 88.0% and the 2-year overall survival rate was 93.8%.

Conclusions

Neoadjuvant nivolumab demonstrated safety and efficacy in high-risk clinical stage I NSCLC.

Legal entity responsible for the study

Hiroshima University.

Funding

Ono Pharma.

Disclosure

Y. Tsutani: Financial Interests, Personal, Advisory Board: AstraZeneca, Chugai, Ono; Financial Interests, Personal, Writing Engagement: Taiho; Financial Interests, Personal, Invited Speaker: BMS, MSD, Takeda, Novartis, Eli Lilly, Medi-Phydics, JB, CSL-Behring, Johnson and Johnson, Covidien; Financial Interests, Personal, Steering Committee Member: AstraZeneca; Financial Interests, Institutional, Research Grant: Chugai, Boehringer Ingelheim, Taiho, Daiichi Sankyo, Medtronic, JB, Otsuka, Kirin, Abbott. M. Tsuboi: Financial Interests, Personal, Invited Speaker, Lecture: Johnson & Johnson Japan; Financial Interests, Personal, Advisory Board, Lectures, Advisory boards: AstraZeneca KK, Chugai Pharmaceutical CO.,LTD, MSD; Financial Interests, Personal, Invited Speaker, Lectures: Eli Lilly Japan, Bristol Myers Squibb KK, Taiho Pharma, Medtronic Japan, ONO Pharmaceutical CO.,LTD, Daiichi Sankyo company limited; Financial Interests, Personal, Advisory Board, Advisory boards: Novartis, MiREXS; Financial Interests, Institutional, Research Grant: Boehringer Ingelheim Japan, MSD, AstraZeneca

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