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Checkmate 77T: A phase 3 trial of neoadjuvant nivolumab (NIVO) plus chemotherapy (chemo) followed by adjuvant NIVO in resectable early-stage NSCLC.

Checkmate 77T: A phase III trial of neoadjuvant nivolumab (NIVO) plus chemotherapy (chemo) followed by adjuvant NIVO in resectable early-stage non-small cell lung cancer (NSCLC)

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ABSTRACT

Background: Although surgery for early NSCLC is potentially curative, 5-year overall survival (OS) rates for patients with stage IIA–IIIB NSCLC are historically <50%, representing a population of high unmet need. Conventional neoadjuvant or adjuvant chemo provides a 5% absolute improvement in OS at 5 years. A rational approach to improve survival in these patients is to eradicate micrometastatic disease and potentially induce anti-tumor immunity to minimize the risk of relapse with peri-operative regimens including NIVO, a fully human anti-programmed cell death 1 antibody. Early phase trials indicate the potential of NIVO-based regimens to deepen pathological responses and extend survival in this setting (Reuss JE et al, ASCO 2019. Abstract 8524; Cascone T et al, ASCO 2019. Abstract 8504; Provencio M et al, WCLC 2019. Abstract OA13.05). Phase 2 single-arm NADIM trial (NCT03081689) demonstrated a major pathological response (MPR) rate of 83% with neoadjuvant NIVO + chemo followed by adjuvant NIVO in patients with resectable stage IIIA NSCLC (Provencio M et al, WCLC 2019. Abstract OA13.05). These results require validation in a large randomized controlled study. CheckMate 77T (NCT04025879), a phase 3, randomized, double-blind trial, evaluates neoadjuvant NIVO + chemo followed by adjuvant NIVO in resectable early stage NSCLC.

Design: Approximately 452 patients aged ≥18 years with resectable stage IIA–IIIB (T3N2 only) NSCLC, ECOG performance status ≤1, and available lung tumor tissue will be enrolled at 111 sites globally. Patients with EGFR/ALK mutations, brain metastasis, prior systemic anti-cancer treatment or radiotherapy, and autoimmune disease are excluded. Patients will be randomized to neoadjuvant NIVO + platinum-based doublet chemo followed by surgery and adjuvant NIVO, or neoadjuvant placebo + platinum-based doublet chemo followed by surgery and adjuvant placebo. The primary endpoint is event-free survival, assessed by blinded independent central review. Secondary endpoints include OS, pathological complete response and MPR assessed by blind independent pathological review, safety and tolerability. Start date was Sept. 2019; estimated primary completion date is May 2023.

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