CheckMate 77T: Phase III study comparing neoadjuvant nivolumab (NIVO) plus chemotherapy (chemo) vs neoadjuvant placebo plus chemo followed by surgery and adjuvant NIVO or placebo for previously untreated, resectable stage II–IIIb NSCLC

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Background
Neoadjuvant (neoadj) NIVO + chemo provides efficacy benefit vs chemo in patients (pts) with resectable NSCLC. However, the efficacy of perioperative NIVO + chemo has not been evaluated in phase 3 studies. Here, we report prespecified interim analysis results from CheckMate 77T, a randomized, double-blind, phase 3 study evaluating neoadj NIVO + chemo followed by surgery and adj NIVO (NIVO + chemo/NIVO) compared with neoadj placebo + chemo followed by surgery and adj placebo (chemo/PBO) in resectable stage II–IIIb NSCLC.

Methods
Adults with untreated resectable stage IIA (>4 cm)–IIIB (N2) NSCLC (AJCC v8), EGFR/ALK wild-type, and ECOG PS ≤1 were stratified by tumor histology, PD-L1 expression, and disease stage, and randomized 1:1 to NIVO 360 mg Q3W + platinum-doublet chemo (4 cycles) followed by surgery and adj NIVO 480 mg Q4W (1 y), or placebo Q3W + platinum-doublet chemo (4 cycles) followed by surgery and adj placebo Q4W (1 y). Primary endpoint was EFS (RECIST v1.1 per BICR). Secondary endpoints were pCR and MPR (both per BIPR), OS, and safety.

Results
Baseline characteristics were balanced between arms (NIVO + chemo/NIVO, n = 229; chemo/PBO, n = 232). At a minimum follow-up of 15.7 mo, NIVO + chemo/NIVO significantly improved EFS vs chemo/PBO (median [95% CI], not reached [28.9 mo–not reached] vs 18.4 mo [13.6–28.1]; HR [97.36% CI], 0.58 [0.42–0.81]; P = 0.00025). NIVO + chemo/NIVO also improved pCR rates (25.3% vs 4.7%; odds ratio, 6.64 [95% CI, 3.40–12.97]) and MPR rates (35.4% vs 12.1%; odds ratio: 4.01 [2.48–6.49]) vs chemo/PBO. Definitive surgery rates were 78% vs 77% in the NIVO + chemo/NIVO vs chemo/PBO arms; of these, 89% vs 90% were R0 resections, respectively. Grade 3–4 treatment-related AEs were 32% and 25% in the NIVO + chemo/NIVO and chemo/PBO arms; surgery-related AEs were 12% and 12%, respectively.

Conclusions
CheckMate 77T met its primary endpoint with a statistically significant and clinically meaningful improvement in EFS with neoadj NIVO + chemo followed by surgery and adj NIVO vs chemo/PBO in pts with resectable NSCLC. No new safety signals were noted with the NIVO + chemo/NIVO regimen.

Clinical trial identification
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Disclosure

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