8503 **Oral Abstract Session**

Surgical outcomes from the phase 3 CheckMate 816 trial: Nivolumab (NIVO) + platinum-doublet chemotherapy (chemo) vs chemo alone as neoadjuvant treatment for patients with resectable non-small cell lung cancer (NSCLC).

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Background: CheckMate 816 (NCT02998528) is a randomized phase 3 study of neoadjuvant NIVO + chemo vs chemo in resectable NSCLC. The study met its first primary endpoint, demonstrating significantly improved pathological complete response (pCR) with neoadjuvant NIVO + chemo. Here we report key surgical outcomes from the study. **Methods:** Adults with stage IB ($\geq$ 4 cm)–IIIA (per AJCC 7th ed) resectable NSCLC, ECOG PS $\leq$ 1, and no known *EGFR*/*ALK* alterations were randomized to NIVO 360 mg + platinum-doublet chemo Q3W or chemo Q3W for 3 cycles (n = 179 each). Definitive surgery was to be performed within 6 weeks of treatment. Primary endpoints are pCR (defined as 0% viable tumor cells in lung and lymph nodes) and event-free survival; both are evaluated by blinded independent review. Feasibility of surgery and surgery-related adverse events (AEs) are exploratory endpoints. **Results:** Baseline characteristics were comparable between arms; 64% of patients (pts) were stage IIIA. Definitive surgery rates were 83% with NIVO + chemo (n = 149) vs 75% with chemo (n = 135). Reasons for cancelled surgery were disease progression (12 and 17 pts, respectively), AEs (2 pts/arm), or other scenarios (14 and 19 pts, respectively; including pt refusal, unresectability, poor lung function). Minimally invasive surgery rates were 30% and 22%, and conversion from minimally invasive to open surgery rates were 11% and 16% for NIVO + chemo and chemo, respectively. Lobectomy was performed in 77% vs 61% of pts, and pneumonectomy in 17% and 25% for NIVO + chemo vs chemo, respectively. AEs were responsible for delays of surgery in 6 pts in the NIVO + chemo arm and 9 pts in the chemo arm. An R0 resection was achieved in 83% vs 78% of pts and median residual viable tumor (RVT) cells in the primary tumor bed were 10% vs 74% for NIVO + chemo vs chemo. There was no increase in median (Q1, Q3) duration of surgery and length of hospitalization between NIVO + chemo vs chemo (184 [130, 252] vs 217 [150, 283] min; and 10.0 [7, 14] vs 10.0 [7, 14] days, respectively). Any-grade and grade 3–4 surgery-related AEs were reported in 41% vs 47% and 11% vs 15% of the NIVO + chemo vs chemo arms, respectively. Grade 5 surgery-related AEs were reported in 2 vs 0 pts in the NIVO + chemo vs chemo arms; 0 vs 3 pts died due to treatment-related AEs, respectively. **Conclusions:** In CheckMate 816, neoadjuvant NIVO + chemo did not impede the feasibility and timing of surgery, nor the extent or completeness of resection vs chemo alone; treatment was tolerable and did not increase surgical complications. NIVO + chemo led to increased depth of pathological response. The surgical outcome data from CheckMate 816 along with significant improvement in pCR support NIVO + chemo as a potential neoadjuvant option for patients with stage IB to IIIA resectable NSCLC. Clinical trial information: NCT02998528. Research Sponsor: Bristol Myers Squibb.