ORR was 84.3%; estimated 4-year OS rate after completion of 35 cycles of pembrolizumab (ie, approximately 6 years after randomization) was 61.8%. Among 33 patients who received second-course pembrolizumab, ORR was 15.2%.

Conclusions With 5 years of follow-up, first-line pembrolizumab monotherapy continued to show substantial clinical benefit with higher 5-year OS rates, and durable response over chemotherapy in patients with PD-L1-positive, locally advanced/metastatic NSCLC without EGFR/ALK alterations. First-line pembrolizumab remains a standard of care in patients with PD-L1 TPS ≥1%, as underscored by these long-term results.

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Trial Registration ClinicalTrials.gov, NCT02220894

Ethics Approval The protocol and all amendments were approved by the appropriate ethics committee at each center, the study was conducted in accordance with the standards of Good Clinical Practice and in compliance with the Declaration of Helsinki. Patients provided written informed consent before enrollment.

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