

Titolo:	V940-002 - A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer (INTerpath-002)
Patologia:	Polmone
Tipo di Studio:	Interventistico farmacologico
Fase:	3
Principali criteri di inclusione:	Has undergone margin negative, completely resected NSCLC, and has pathological Stage II, IIIA, IIIB (N2) squamous or nonsquamous TNM staging per AJCC Eighth Edition (Appendix 8). See Appendix 9 for preferred/recommended surgical resection including nodal sampling. Confirmation that either EGFR-directed or ALK-directed therapy is not indicated as primary therapy (historic data with respect to the index NSCLC under study of absence of tumor-activating EGFR mutations [ie, DEL19 or L858R] or ALK mutations, or as determined by either a local or the central laboratory). Note: If participant's tumor has a predominantly squamous histology, molecular testing for EGFR or ALK mutation is not required. Has NED before randomization. Disease-free status must be confirmed based on baseline radiological assessment as documented by contrast-enhanced chest/abdomen/pelvic CT (or MRI), contrast-enhanced brain MRI (or CT), and, if part of study site SOC, wholebody PET scan within 28 days prior to randomization. Has received at least one dose of adjuvant treatment with standard of care platinum doublet chemotherapy up to 4 cycles (or equivalent dose of platinum doublet chemotherapy).
Principali criteri di esclusione:	Received prior neoadjuvant therapy for their current NSCLC diagnosis. Received or is a candidate to receive radiotherapy for their current NSCLC diagnosis. Received prior treatment with another INT. Received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent, or with an agent directed to another stimulatory or coinhibitory T-cell receptor (eg, CTLA-4, OX- 40, CD137).
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