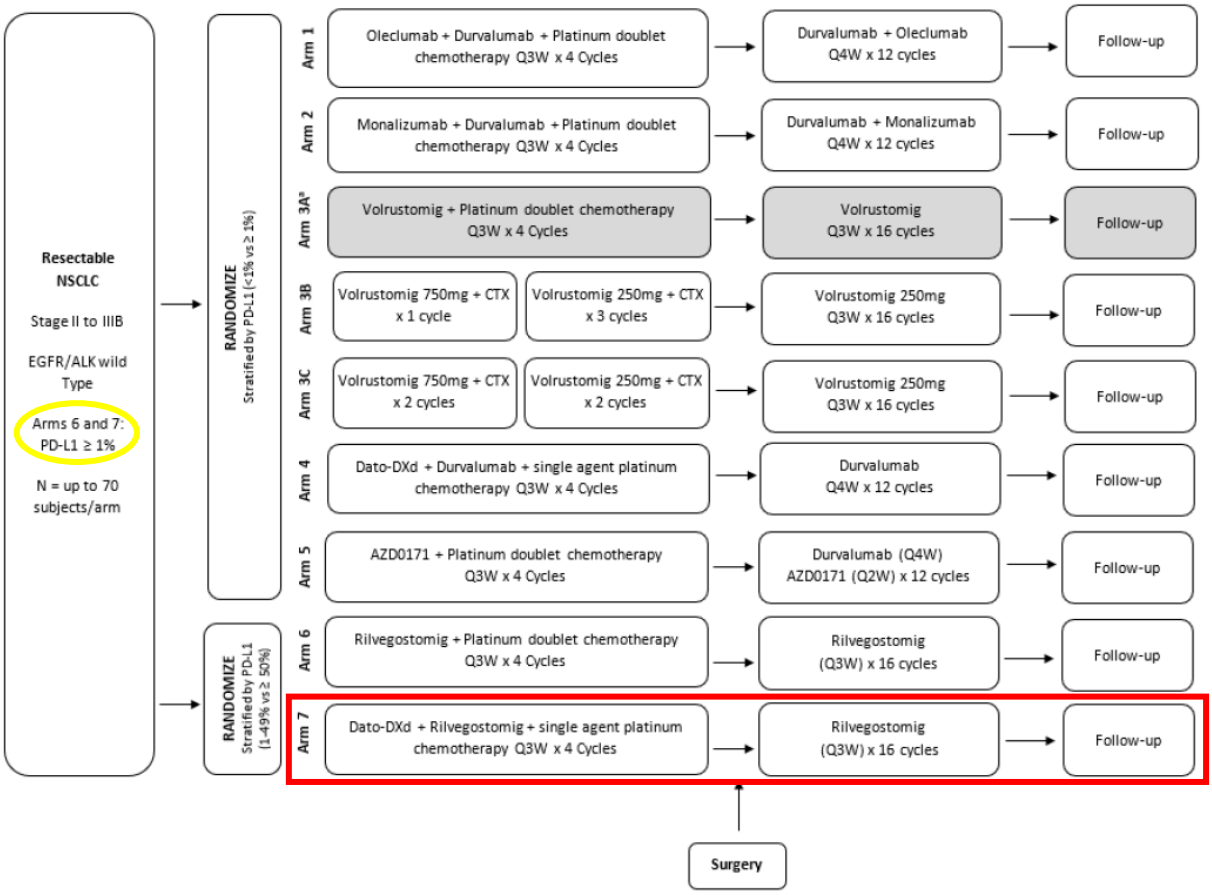
Neocoast-2

A Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) Non-small Cell Lung Cancer

This is the trial summary as assessed on clinicaltrials.gov. You can check this on this direct link: [Study Details | Neoadjuvant and Adjuvant Treatment in Resectable Non-small Cell Lung Cancer | ClinicalTrials.gov]

Trial design



Inclusion criteria

1. Newly diagnosed NSCLC patients with resectable disease (Stage IIA to Stage IIIB).
2. WHO or Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
3. Adequate organ and bone marrow function.
4. Provision of tumour samples (newly acquired or archival tumour tissue [≤ 6 months old]) to confirm Programmed death-ligand 1 (PD-L1) status, epidermal growth factor receptor (EGFR), or anaplastic lymphoma kinase (ALK) status.
5. Adequate pulmonary function.

Exclusion criteria

6. Participants with sensitising EGFR mutations or ALK translocations.
7. Participants with baseline PD-L1 expression status <1% (Arms 6 and 7 only).
8. Active or prior documented autoimmune or inflammatory disorders.
9. Uncontrolled intercurrent illness, uncontrolled hypertension, unstable angina pectoris, uncontrolled cardiac arrhythmia, active bleeding diseases, serious chronic gastrointestinal conditions associated with diarrhoea, or psychiatric illness/social situations that would limit compliance with study requirement.
10. History of another primary malignancy.
11. Participants with small-cell lung cancer or mixed small-cell lung cancer.
12. History of active primary immunodeficiency.
13. History of non-infectious interstitial lung disease (ILD) ILD/pneumonitis that required steroids, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening.
14. Participants who have preoperative radiotherapy treatment as part of their care plan.
15. Participants who require or may require pneumonectomy, segmentectomies, or wedge resections, as assessed by their surgeon at baseline, to obtain potentially curative resection of primary tumour.
16. QTcF (QT interval corrected by Fridericia's formula) interval ≥ 470 ms.
17. Any medical contraindication to treatment with chemotherapy as listed in the local labelling.
18. Participants with moderate or severe cardiovascular disease.
19. Any concurrent chemotherapy, investigational product, biologic, or hormonal therapy for cancer treatment.