ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)Non Small Cell Lung Carcinoma

A Study of Alectinib, Entrectinib, or Vemurafenib Plus Cobimetinib in Participants With Stages I-III Non-Small Cell Lung Cancer With ALK, ROS1, NTRK, or BRAF v600E Molecular Alterations

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT04302025 ML41591

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

NAUTIKA1: Multicenter, Phase II, Neoadjuvant and Adjuvant Study of Multiple Therapies in Biomarker-Selected Patients With Resectable Stages IB-III Non-Small Cell Lung Cancer

Trial Summary:

This trial will evaluate the efficacy and safety of various therapies in patients with Stage IB, IIA, IIB, IIIA, or selected IIIB resectable and untreated non-small cell lung cancer (NSCLC) tumors that meet protocol-specified biomarker criteria

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT04302025 ML41591
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

Inclusion Criteria for Neoadjuvant Therapy:

- Pathologically documented NSCLC:
- Newly diagnosed early-stage NSCLC stages IB, IIA, IIB, IIIA, or selected IIIB (T3N2 only) NSCLC of squamous or non-squamous histology. Staging should be based on the 8th edition of the American

Joint Committee on Cancer (AJCC)/Union Internationale Contre le Cancer (UICC) NSCLC staging system.
- T4 primary NSCLC will be allowed only on the basis of size. Invasion of the diaphragm, mediastinum, heart, great vessels, trachea, recurrent laryngeal nerve, esophagus, vertebral body, carina, and separate tumor nodules in a different ipsilateral lobe is not permitted.
- All patients will undergo clinical staging using CT and PET scanning, as well as brain imaging using MRI. Invasive mediastinal staging by either mediastinoscopyor endo- bronchial ultrasonography is highly encouraged for patients with radiographically suspected mediastinal nodal disease (ie, N2) but not mandated if the CT or PET scans showed no evidence of N2 disease.
- Molecular testing results from CLIA-certified laboratories and showing at least one of the following abnormalities: ALK fusion, ROS1 fusion, NTRK1/2/3 fusion; BRAF V600 mutation (enrollment closed); RET fusion (enrollment closed), PD-L1, KRAS G12C expression in # 1% tumor cells as determined by FDA-approved test.
- Measurable disease, as defined by RECIST v1.1
- NSCLC must have a solid or subsolid appearance on CT scan and cannot have a purely ground glass opacity appearance. For subsolid lesions, the tumor size (i.e., clinical T stage) should be measured based on the solid component only, exclusive of the ground glass opacity component.
- Evaluated by the attending surgeon prior to study enrollment to verify that the primary tumor and any involved lymph nodes are technically completely resectable and verify that the participant is medically operable
- Adequate pulmonary function to be eligible for surgical resection with curative intent
- Adequate cardiac function to be eligible for surgical resection with curative intent
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Adequate hematologic and end-organ function
- Negative hepatitis B surface antigen (HBsAg) test at screening for cohort
- Negative total hepatitits B core antibody (HBcAb) test at screening for cohort, or positive total HBcAb test followed by a negative hepatitis B virus (HBV) DNA test at screening
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening
- Male participants must be willing to use acceptable methods of contraception
- Female participants of childbearing potential must agree to use acceptable methods of contraception

Inclusion Criteria for Adjuvant Therapy (TKI Cohorts and KRAS G12C cohort [if continuing on Divarasib]):

- Participants whose tumors lack radiographic progression
- ECOG Performance Status of 0 or 1
- Adequate hematologic and end-organ function

Exclusion Criteria:

- NSCLC that is clinically T4 by virtue of mediastinal organ invasion or Stage IIIB by virtue of N3 disease
- Any prior therapy for lung cancer, including chemotherapy, targeted therapy, immunotherapy, or radiotherapy, within 2 years
- Participants with prior lung cancer
- Major surgical procedure within 28 days prior to Cycle 1, Day 1
- Malignancies other than the disease under study within 3 years prior to Cycle 1, Day 1, with the exception of patients with a negligible risk of metastasis or death and with expected curative outcome
- Treatment with an investigational agent for any condition within 4 weeks prior to Cycle 1, Day 1
- Participants known to be positive for HIV are excluded if they meet any of the following criteria: CD4+ T-cell count of <350 cells/microliters; detectable HIV viral load; history of an opportunistic infection within the past 12 months; on stable antiretroviral therapy for <4 weeks

- Severe infection within 4 weeks prior to initiation of study treatment, including but not limited to hospitalization for complications of infections, or any active infection that, in the opinion of the investigator, could impact participant safety
- Pregnant or lactating, or intending to become pregnant during the study