ForPatients
by Roche

Non Small Cell Lung Carcinoma

A Study to Evaluate the Efficacy and Safety of Divarasib Compared With Investigator's Choice of Immunotherapy or Observation in Participants With Resected Stage II-III KRAS G12C-Positive Non-Small Cell Lung Cancer (NSCLC)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07541170 2025-524263-21-00 BO45885

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:

A Phase III, Randomized, Open-label Study Evaluating the Efficacy and Safety of Divarasib Compared With Investigator's Choice of Immunotherapy or Observation in Patients With Resected Stage II-III KRAS G12C-Positive Non-small Cell Lung Cancer

Trial Summary:

The main purpose of this study is to evaluate the efficacy of divarasib compared with investigator's choice of immunotherapy (pembrolizumab or nivolumab) or observation in participants with resected Kirsten rat sarcoma viral oncogene homolog glycine 12 to cysteine (KRAS G12C)-positive Stage II-IIIB NSCLC, regardless of tumor programmed death-ligand 1 (PD-L1) status, who have not achieved pathologic complete response (pCR) following neoadjuvant chemoimmunotherapy.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Histological or cytological diagnosis of clinical Stage II-IIIB NSCLC of either non-squamous or squamous histology
- Participants must have had complete resection of NSCLC
- Prior treatment with neoadjuvant immune checkpoint inhibitor (pembrolizumab or nivolumab) in combination with histology-based platinum-based doublet chemotherapy
- Participants must be randomized within 12 weeks of their surgery date
- No evidence of disease recurrence or metastatic disease
- Documentation of the presence of a KRAS G12C mutation

Exclusion Criteria:

- Participants who achieve pCR following neoadjuvant treatment
- Prior treatment with a KRAS inhibitor or any other anti-cancer therapy not otherwise specified in the protocol
- Prior treatment with radiation therapy for NSCLC, with the exception of localized symptom-directed radiation prior to surgical resection
- Resolved Grade 3 or greater immune-related AE or unresolved Grade 2 or greater immune-related AE from neoadjuvant immunotherapy
- Active or history of autoimmune disease or immune deficiency
- Significant cardiovascular disease