A Study of First-Line Olomorasib (LY3537982) and Pembrolizumab With or Without Chemotherapy in Patients With Advanced KRAS G12C-Mutant Non-small Cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically or cytologically confirmed NSCLC with Stage IIIB-IIIC or Stage IV disease, not suitable for curative intent radical surgery or radiation therapy. * Part B and Safety Lead-In Part B: the histology of the tumor must be predominantly non-squamous (in line with pemetrexed label). * Must have disease with evidence of KRAS G12C mutation. * Must have known programmed death-ligand 1 (PD-L1) expression * Part A: Greater than or equal to (≥)50 percent (%). * Part B: 0% to 100%. * Must have measurable disease per RECIST v1.1. * Must have an ECOG performance status of 0 or 1. * Estimated life expectancy ≥12 weeks. * Ability to swallow capsules. * Must have adequate laboratory parameters. * Contraceptive use should be consistent with local regulations for those participating in clinical studies. * Women of childbearing potential must * Have a negative pregnancy test. * Not be breastfeeding during treatment

---

Exclusion Criteria:

* Have a documented additional validated targetable oncogenic driver mutation or alteration in genes such as epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), BRAF (V600E), human epidermal growth factor receptor 2 (HER2), MET (exon 14), ROS1, rearranged during transfection (RET), or neurotrophic tyrosine receptor kinase (NTRK)1/2/3. * Have had any of the following prior to randomization: \-- Prior systemic therapy (chemotherapy, immunotherapy, targeted therapy, or biological therapy) for advanced or metastatic NSCLC. \--- 1 cycle of standard-of-care treatment prior to study enrollment will be allowed for cases where immediate treatment is clinically indicated: * Have known active central nervous system metastases and/or carcinomatous meningitis. Exclusion Criteria for Participants receiving Pemetrexed and Platinum (Part B and Safety Lead-In Part B) * Have predominantly squamous cell histology for NSCLC * Only for participants with mild to moderate renal insufficiency: Unable to avoid aspirin, ibuprofen, or other nonsteroidal anti-inflammatory drugs (NSAIDs) two days before (5 days for long acting NSAIDs), day of, and two days after administration of pemetrexed * Is unable or unwilling to take folic acid or vitamin B12 supplementation.

Conditions & Interventions

Interventions:
DRUG: LY3537982, DRUG: Pembrolizumab, DRUG: Placebo, DRUG: Cisplatin, DRUG: Carboplatin, DRUG: Pemetrexed

Conditions:
Carcinoma, Non-Small-Cell Lung, Neoplasm Metastasis

Keywords:
Advanced Non-Small Cell Lung Cancer, KRAS G12 Lung Cancer, Advanced Lung Cancer, Metastatic Lung Cancer, KRAS G12C inhibitor, KRAS G12C Positive, KRAS Mutation, KRAS G12 Mutation, Lung Cancer Mutation, Olomorasib, Lung Diseases, Neoplastic Processes, Pathologic Processes, Neoplasm Metastasis, Non-Small Cell Lung Cancer, Non-Small Cell Lung Cancer (NSCLC), Antineoplastic Agents, Respiratory Tract Neoplasms, Thoracic Neoplasms, Neoplasms by Site, Neoplasms, Respiratory Tract Diseases, Carcinoma, Bronchogenic, Bronchial Neoplasms, Lung Neoplasms

More Information

Contact(s): Trial questions or participation questions: 1-877-CTLILLY (1-877-285-4559) or - LillyTrials@Lilly.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06119581
