

A Study Evaluating the Efficacy and Safety of Divarasib Versus Sotorasib or Adagrasib in Participants With Previously Treated KRAS G12C-positive Advanced or Metastatic 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:

* Unequivocal histologically or cytologically confirmed diagnosis of metastatic or locally advanced NSCLC not amenable to treatment with surgical resection or combined chemoradiation * Disease progression during or after treatment with at least one prior systemic therapy but no more than three lines of prior systemic therapy in the advanced or metastatic setting * Measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 * Documentation of the presence of a KRAS G12C mutation * Availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in a paraffin block (preferred) or 10-15 (15 preferred) unstained, freshly cut, serial slides with an associated pathology report * Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 * Life expectancy of \geq 12 weeks

Exclusion Criteria:

* Known hypersensitivity to any of the components of divarasib, or sotorasib or adagrasib * Malabsorption syndrome or other condition that would interfere with enteral absorption * Known concomitant second oncogenic driver * Mixed small-cell lung cancer or large cell neuroendocrine histology * Known and untreated, or active central nervous system (CNS) metastases * Leptomeningeal disease or carcinomatous meningitis * Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures biweekly or more frequently * Any infection that, in the opinion of the investigator, could impact patient safety, or treatment with therapeutic oral or IV antibiotics within 14 days prior to Day 1 of Cycle 1 * Prior treatment with any KRAS G12C inhibitor or pan-KRAS/RAS inhibitor * More than 30 Gy of radiotherapy to the lung within 6 months of randomization * Uncontrolled tumor-related pain * Unresolved toxicities from prior anticancer therapy * History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death (e.g., 5-year OS rate \geq 90%), such as adequately treated carcinoma in situ of the cervix, nonmelanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer

Conditions & Interventions

Interventions:

DRUG: Divarasib, DRUG: Sotorasib, DRUG: Adagrasib

Conditions:

Non-small Cell Lung Cancer, KRAS G12C Lung Cancer

Keywords:

Advanced Non-Small Cell Lung Cancer, KRAS G12 Lung Cancer, Advanced Lung Cancer, Metastatic lung cancer, Divarasib, KRAS G12C Inhibitor, KRAS G12C Positive, KRAS Mutation, KRAS G12C Mutation, Lung Cancer Mutation

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06497556

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