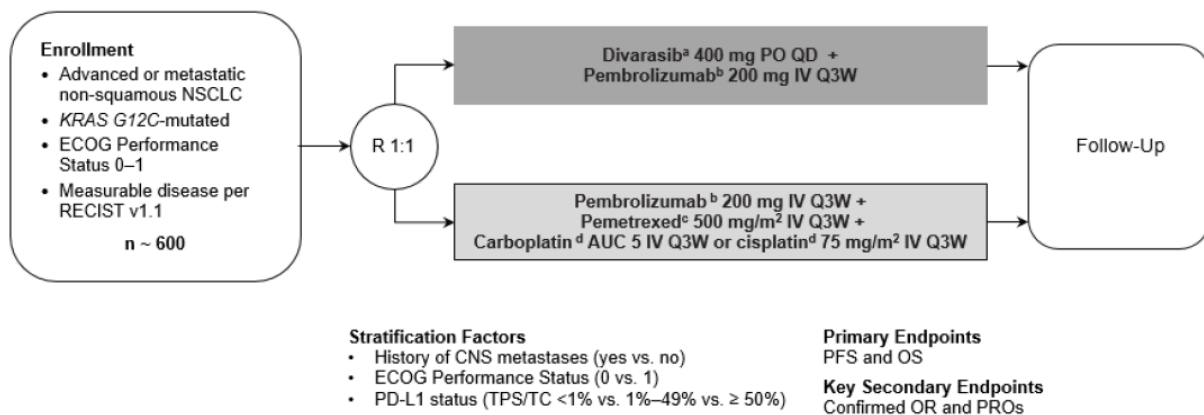


## Krascendo 2

### A Study Evaluating the Efficacy and Safety of Divarasib and Pembrolizumab Versus Pembrolizumab and Pemetrexed and Carboplatin or Cisplatin in Participants With Previously Untreated, KRAS G12C-Mutated, Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (Krascendo 2)

This is the trial summary as assessed on [clinicaltrials.gov](https://clinicaltrials.gov). You can check this on this direct link: [Study Details | NCT06793215 | A Study Evaluating the Efficacy and Safety of Divarasib and Pembrolizumab Versus Pembrolizumab and Pemetrexed and Carboplatin or Cisplatin in Participants With Previously Untreated, KRAS G12C-Mutated, Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer | ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT06793215)

#### Trial design



#### Inclusion criteria

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Histologically or cytologically confirmed diagnosis of advanced or metastatic non squamous NSCLC that is not eligible for curative surgery and/or definitive chemoradiotherapy
- Measurable disease, as defined by RECIST v1.1
- No prior systemic treatment for advanced or metastatic NSCLC
- Documentation of the presence of a KRAS G12C mutation
- Documentation of known PD-L1 expression status in tumor tissue
- Availability of a representative tumor specimen
- Adequate end-organ function
- Eligible to receive a platinum-based chemotherapy regimen

#### Exclusion Criteria Related to NSCLC:

- Known concomitant second oncogenic driver with available targeted treatment
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Spinal cord compression not definitively treated with surgery and/or radiation or previously diagnosed and treated spinal cord compression without

evidence that disease has been clinically stable for  $\geq 2$  weeks prior to randomization

- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once a month or more frequently)

#### **Exclusion Criteria Related to Current or Prior Treatments:**

- Any anti-cancer systemic therapy, including hormonal therapy, within 21 days prior to randomization, or is expected to require any other form of antineoplastic therapy while in the study
- Radiation therapy including palliative RT to bone metastases within 2 weeks prior to randomization and RT to the lung  $>30\text{Gy}$  within 6 months prior to randomization
- Prior treatment with KRAS G12C inhibitors or pan-KRAS/RAS inhibitors
- Treatment with systemic immunosuppressive or immunostimulatory medications, including CD137 agonists and immune checkpoint inhibitors
- Current treatment with medications that are well known to prolong the QT interval
- Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to randomization
- Prior allogeneic stem cell or solid organ transplantation

#### **Exclusion Criteria Related to General Health:**

- History of malignancy other than NSCLC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death (e.g., 5-year overall survival [OS] rate  $>90\%$ ), such as adequately treated carcinoma in situ of the cervix, non melanoma skin carcinoma, localized prostate cancer, ductal breast carcinoma in situ, or Stage I uterine cancer
- Individuals with chronic diarrhea, short bowel syndrome or significant upper gastrointestinal surgery including gastric resection, a history of inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis) or any active bowel inflammation (including diverticulitis), malabsorption syndrome, conditions that would interfere with enteral absorption
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on the screening chest computed tomography scan
- Significant cardiovascular disease within 3 months prior to screening