

JDQ E (Novartis)

This is Phase Ib/II, multicenter, open-label adaptive platform study of JDQ443 with select therapies in patients with advanced solid tumors harboring the KRAS G12C mutation.

This is the trial summary as assessed on clinicaltrials.gov on 25/10/2022.

Minor changes in the protocol may occur. You can check this on this direct link: <https://clinicaltrials.gov/ct2/show/NCT05358249>

Trial Design:

ARM	INTERVENTION
Experimental: JDQ + trametinib	JDQ - KRAS inhibitor (PO) Trametinib - MEK inhibitor (PO)
Experimental: JDQ + ribociclib	JDQ - KRAS inhibitor (PO) Ribociclib - CDK4/6 inhibitor (PO)

Inclusion criteria:

Dose Escalation:

- Patients with advanced (metastatic or unresectable) KRAS G12C mutant solid tumors who have received standard of care therapy or are ineligible to receive such therapy.

Phase II:

- Patients with advanced (metastatic or unresectable) KRAS G12C mutant non-small cell lung cancer who have received platinum-based chemotherapy regimen and immune checkpoint inhibitor therapy, unless patient was ineligible to receive such therapy
- Patients with advanced (metastatic or unresectable) KRAS G12C mutant colorectal cancer who have received fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, unless patient was ineligible to such therapy.

All patients:

- ECOG performance status of 0 or 1.
- Patients must have a site of disease amenable to biopsy and be a candidate for tumor biopsy according to the treating institution's guidelines.

Exclusion criteria:

- Tumors harboring driver mutations that have approved targeted therapies, with the exception of KRAS G12C mutations
- Prior treatment with a KRAS G12C inhibitor is excluded for patients in a subset of groups in Phase II.
- Active brain metastases, including symptomatic brain metastases or known leptomeningeal disease
- Clinically significant cardiac disease or risk factors at screening

- Insufficient bone marrow, hepatic or renal function at screening Other protocol-defined inclusion/exclusion criteria may apply