

A Phase I Study of BAY3498264 Given Together With Sotorasib in Participants Who Have Advanced Solid Cancers With Specific Genetic Changes Called KRASG12C Mutation

NCT06659341

Status	RECRUITING
Phase	Phase 1
Sponsor	Bayer
Enrollment	104 participants

Key Eligibility Criteria

Inclusion (6)

- Histologically confirmed solid tumor malignancy with documented KRAS^{G12C} mutation as assessed by an appropriately accredited laboratory.
 - Documented disease progression after treatment with at least 1 prior standard of care (SoC) systemic therapy other than a G12C inhibitor for locally advanced or metastatic disease, and with no further standard treatment options available, or when standard treatment options are not acceptable and this study is a reasonable option.
 - Participants whose access to SoC therapies is limited due to regional access, refusal, intolerance, or eligibility may participate.
 - Prior G12C inhibitor treatment is permitted. Participants receiving prior G12C inhibitor therapy must have documented disease progression after treatment, or have discontinued that treatment due to intolerance.
 - Adequate archival formalin-fixed paraffin-embedded tumor tissue available (preferably no older than 6 months, obtained after the last targeted therapy). If archival material is not available, a fresh tumor biopsy should ideally be obtained if safe and feasible.
- ... and 1 more (see full listing online)

Exclusion (14)

- \- Active central nervous system (CNS) tumors including metastatic brain disease, at the time of screening.
 - 'Active' is defined as untreated brain lesions (new or progressing) or symptomatic brain lesions (as determined by the investigator).
 - Participants who have received treatment (e.g. surgery or radiotherapy) for brain metastases ending at least 4 weeks before the start of study intervention may be eligible if, at the point of study entry:
 - i. their condition is considered stable by the investigator.
 - ii. they have no residual neurological symptoms (Grade ≥ 2).
 - iii. a follow-up Magnetic resonance imaging (MRI) scan during the screening period shows no progression or new lesions.
 - iv. they do not need systemic corticosteroids to treat symptoms of brain metastasis.
- ... and 9 more (see full listing online)

Locations (10 total)

Border Medical oncology - Albury Wodonga Regional Cancer Centre, Albury, New South Wales, Australia
Macquarie University Hospital - Oncology Department, Macquarie Park, New South Wales, Australia
Peninsula and Southeast Oncology, Frankston, Victoria, Australia
... and 7 more locations

<https://clinicaltrials.gov/study/NCT06659341>

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