

Testing How the Body Responds to the Drug CBX-12 in Patients With Advanced Solid Cancers

NCT05691517

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	35 participants

Key Eligibility Criteria

Inclusion (30)

- Patients must have histologically confirmed solid tumors with metastatic disease that have progressed after ≥ 1 line of prior therapy
 - Patients must have measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version (v)1.1, with at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded for non-nodal lesions and short axis for nodal lesions) as ≥ 20 mm (≥ 2 cm) by chest x-ray or as ≥ 10 mm (≥ 1 cm) with CT scan, MRI, or calipers by clinical exam)
 - Patients must have a tumor site amenable to biopsy
 - Age ≥ 18 years of age
 - Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (Karnofsky $\geq 60\%$)
- ... and 25 more (see full listing online)

Exclusion (7)

- Patients must have recovered from clinically-significant adverse-events of their most recent cancer immunotherapy to grade 1 or less (with the exception for alopecia or lymphopenia)
 - Eligibility of subjects receiving any medications or substances with the potential to affect the activity of CBX-12 or exatecan will be determined following review of their cases by the Principal Investigator
 - Patients who are receiving any other investigational agents
 - Patients taking medication known to prolong the QT interval, or receiving any medications or substances that are strong CYP3A4 or CYP1A2 inhibitors or inducers, and sensitive substrates of CYP3A or CYP2B6 with a narrow therapeutic index are ineligible, if they cannot be transferred to alternative medication. Patients on substrates of OATP1B1 and OATP1B3 should be excluded unless they can be transferred on alternative medication. Because the lists of these agents are constantly changing, it is important to regularly consult a frequently-updated medical reference. As part of the enrollment/informed consent procedures, the patient will be counseled on the risk of interactions with other agents, and what to do if new medications need to be prescribed or if the patient is considering a new over-the-counter medicine or herbal product
 - History of allergic reactions attributed to compounds of similar chemical or biologic composition to CBX-12 (e.g., other topoisomerase I inhibitors) or the inactive ingredients in the drug product
- ... and 2 more (see full listing online)

Locations (1 total)

National Cancer Institute Developmental Therapeutics Clinic, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT05691517>

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