Testing the Combination of the Anti-cancer Drugs ZEN003694 (ZEN-3694) and Talazoparib in Patients With Advanced Solid Tumors, The ComBET Trial

NCT05327010

Status	RECRUITING
Phase	Phase 2
Sponsor	National Cancer Institute (NCI)
Enrollment	88 participants

Key Eligibility Criteria

Inclusion (29)

- Patients must have histologically confirmed malignancy that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective
- Patients must have a tumor lesion that can be biopsied with 'low' or 'minimal' risk and at least one measurable disease site, as defined by Response Evaluation Criteria in Solid Tumors (RECIST) version (v) 1.1
- Note: Tumor lesions that are situated in a previously irradiated area may or may not be considered measurable
- Patients in cohorts 1, 2, and 4 should have at least one relevant mutation. Patients enrolled in cohorts 1-3 do not require that PARP inhibitor (i) be the immediate prior therapy to be eligible for the trial. Patients should sign a screening consent that will allow the review of local next generation sequencing (NGS) or equivalent Clinical Laboratory Improvement Amendment (CLIA)-certified assay results by MD Anderson's Precision Oncology Decision Support (PODS) team to ensure that the mutations are actionable. No variants of uncertain significance (VUS) will be allowed
- Patients in Cohort 1 must have (i) a germline or somatic mutation in BRCA1 or BRCA2; and (ii) must have received prior PARPi monotherapy or PARPi combination-therapy

... and 24 more (see full listing online)

Exclusion (16)

- Patients who are receiving any other investigational agents
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to ZEN003694 (ZEN-3694) or talazoparib
- Patients receiving any medications or substances that are strong inhibitors or inducers of CYP3A4 or P-gp, strong inhibitors of BCRP, sensitive substrates of CYP1A2, proton-pump-inhibitors (H2 antagonists are allowed), and herbal medications/preparations (vitamins are allowed) are ineligible. Strong inhibitors or inducers of CYP3A4 must be discontinued at least 7 days prior to the first dose of ZEN003694 (ZEN-3694). 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.
- Patients with uncontrolled intercurrent illness
- Patients with psychiatric illness/social situations that would limit compliance with study requirements

... and 11 more (see full listing online)

Locations (36 total)

City of Hope Comprehensive Cancer Center, Duarte, California, United States
City of Hope at Irvine Lennar, Irvine, California, United States
UC San Diego Moores Cancer Center, La Jolla, California, United States
... and 33 more locations