Testing the Combination of Two Anti-cancer Drugs, Peposertib (M3814) and Tuvusertib (M1774) for Advanced Solid Tumors

NCT05687136

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (25)

- Patients must have histologically confirmed solid malignancy that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective.
- For the dose escalation and dose expansion phases, patients must have genomic (tumor next-generation sequencing \[NGS\], circulating tumor deoxyribonucleic acid \[ctDNA\], fluorescence in situ hybridization \[FISH\], etc.) or immunohistochemical evidence of inactivating ATM mutations, MYC amplification, mutation of FBXW7, CCNE1 amplification, SWI/SNF member mutation (ARID1A, PBRM1, SMARCA4, ARID2, ARID1b, SMARCB1, SMARCA2, SS18), and ATRX/DAXX. Mutations may be germline or somatic. All mutations/alterations must be approved by the overall principal investigator (PI). Other SWI/SNF mutations may be considered after discussion with the overall PI.
- Progression on at least one prior standard therapy.
- Age \>= 18 years. Because no dosing or adverse event data are currently available on the use of peposertib (M3814) in combination with tuvusertib (M1774) in patients \< 18 years of age, children are excluded from this study.
- Life expectancy \> 3 months.

... and 20 more (see full listing online)

Exclusion (17)

- Patients who have received immunotherapy within 21 days of Cycle 1 Day 1.
- Patients who have received therapeutic radiation therapy within 21 days, or palliative radiation therapy within 7 days, of Cycle 1 Day 1.
- Patients who have undergone major surgery within 21 days of Cycle 1 Day 1.
- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities \> Grade 1) with the exception of alopecia, controlled endocrine toxicity (e.g., hypothyroidism), and cutaneous toxicity which will be permitted at Grade 2.
- Patients who are receiving any other investigational agents.

... and 12 more (see full listing online)

Locations (6 total)

National Cancer Institute Developmental Therapeutics Clinic, Bethesda, Maryland, United States
National Institutes of Health Clinical Center, Bethesda, Maryland, United States
Massachusetts General Hospital Cancer Center, Boston, Massachusetts, United States
... and 3 more locations