PEPN2411; DT2216 (NSC#850950, IND# 170973) in combination with irinotecan for children, adolescents and young adults with relapsed or refractory solid tumors: A Phase 1 study with Phase 2 feasibility cohort for fibrolamellar carcinoma

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Phase 1: Relapsed & refractory solid tumor. Age: Patients between ≥ 1 year and ≤ 21 years of age at the time of study. Diagnosis: Patients with recurrent/refractory solid tumors excluding primary central nervous system tumors. Disease Status: Patients must have either measurable or evaluable disease. - Phase 2: Fibrolamelar carcinoma. Age: Patients between ≥ 1 year and ≤ 39 years of age at the time of study enrollment. Diagnosis: Patients with (FLC), which must include genomic confirmation of the DNAJB1:PRKACA fusion performed at a CLIA-certified laboratory. Disease Status: Patients must have measurable disease.

Exclusion Criteria:

- Pregnant or breast-feeding women. - Concommitant meds: Corticosteroids, Investigational Drugs, Anti-cancer Agents, Anti-GVHD agents post-transplant, CYP-450 Interactions. - Patients with lymphoma. - Patients who have an uncontrolled infection.

Conditions & Interventions

Conditions:
Bone, Joint & Muscle, Cancer, Children's Health

More Information

Description: Primary Aims 1. To estimate the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of DT2216 in combination with intravenous irinotecan in patients with recurrent/refractory solid tumors. 2. To define and describe the toxicities of DT2216 in combination with irinotecan administered on this schedule in patients with recurrent/refractory solid tumors and patients with fibrolamellar carcinoma (FLC). 3. To characterize the pharmacokinetics of DT2216 in combination with irinotecan in patients with recurrent/refractory solid tumors and patients with fibrolamellar carcinoma (FLC). 4. To preliminarily define antitumor activity of DT2216 in combination with irinotecan in patients with recurrent/refractory solid tumors (within the confines of a Phase 1 study) and in patients with recurrent/refractory FLC.
Study Contact: Allison Fullenkamp - fulle631@umn.edu
Principal Investigator: Robin Williams
Phase: PHASE1
IRB Number: STUDY00025703