Phase 1 Dose-escalating Study of MM-398 (Irinotecan Sucrosofate Liposome Injection) Plus Intravenous Cyclophosphamide in Recurrent or Refractory Pediatric Solid Tumors

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 months to 20 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Histologically or cytologically-confirmed Ewing sarcoma, rhabdomyosarcoma, neuroblastoma, or osteosarcoma
- Disease progression after prior therapy in locally advanced or metastatic setting
- Measurable or evaluable disease based on the Response Evaluation Criteria in Solid Tumors (RECIST v1.1) criteria
- Age 12 months to <21 years
- Adequate bone marrow reserves, hepatic function, and renal function
- Recovered from effects of any prior surgery or cancer therapy
- Patients 18 years or older will provide written consent. A parent or legal guardian of a patient <18 years of age will provide informed consent and patients 11 to 18 years of age will provide written assent or as per participating institutional policy.

Exclusion Criteria:

- Clinically significant gastrointestinal disorders
- NYHA Class III or IV congestive heart failure, ventricular arrhythmias or uncontrolled blood pressure
- Active infection or unexplained fever
- Known hypersensitivity to any of the components of MM-398 or other liposomal products
- Recent Investigational therapy
- Pregnant or breast feeding; females of child-bearing potential must test negative for pregnancy at the time of enrollment

Conditions & Interventions

Interventions:
DRUG: MM-398 (Irinotecan Sucrosofate Liposome Injection) plus cyclophosphamide
Conditions:
Recurrent or Refractory Solid Tumors, Ewing Sarcoma, Rhabdomyosarcoma, Neuroblastoma, Osteosarcoma
Keywords:
pediatric, MM-398, cyclophosphamide, irinotecan

More Information

Description:
This is a Phase 1 study of the combination of two drugs: MM-398 and Cyclophosphamide. The goal is to find the highest dose of MM-398 that can be given safely when it is used together with the chemotherapy drug Cyclophosphamide.

Contact(s): - cancer@cchmc.org
Phase: PHASE1
System ID: NCT02013336

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