

A Phase 1b/2 Study of Abemaciclib in Combination with Irinotecan and Temozolomide (Part A) and Abemaciclib in Combination with Temozolomide (Part B) in Pediatric and Young Adult Patients with Relapsed/Refractory Solid Tumors and Abemaciclib in Combination with Dinutuximab, GM-CSF, Irinotecan, and Temozolomide in Pediatric and Young Adult Patients with Relapsed/Refractory Neuroblastoma (Part C). Protocol Number: I3Y-MC-JPCS

Status: Recruiting

Eligibility Criteria

Age: Not specified

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Parts A and B only: participants must be less than or equal to 18 years of age and with any relapsed/refractory malignant solid tumor (excluding lymphoma), including central nervous system tumors, that have progressed on standard therapies - Part C only: participants must be less than (<) 21 years of age and with first relapse/refractory neuroblastoma and with any relapsed/refractory malignant solid tumor (excluding lymphoma), including central nervous system tumors, that have progressed on standard therapies Parts A, B & C: - participants must have discontinued all previous treatments for cancer or investigational agents and must have recovered from the acute effects to Grade = < 1 at the time of enrollment - able to swallow and/or have a gastric/nasogastric tube

Exclusion Criteria:

- received allogenic bone marrow or solid organ transplant - diagnosed and/or treated additional malignancy within 3 years prior to enrollment that may affect the interpretation of results, with the exception of curatively treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin, and/or curatively resected in situ cervical and/or breast cancers - pregnant or breastfeeding

Conditions & Interventions

Conditions:

Cancer

Keywords:

Refractory Solid Tumor, Relapsed Solid Tumor

More Information

Description: The study's purpose is to see if the drug abemaciclib is safe and effective in combination with temozolomide and irinotecan (Part A) and abemaciclib in combination with temozolomide (Part B) in pediatric and young adult participants with relapsed/refractory solid tumors.

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IRB

Number: STUDY00013998

System ID: 33902

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