Phase 1/2 Study to Evaluate Palbociclib (IBRANCE®) in Combination With Irinotecan and Temozolomide and/or in Combination with Topotecan and Cyclophosphamide in Pediatric Patients With Recurrent or Refractory Solid Tumors Protocol No.: ADVL1921/A5481092

Status: Recruiting

Eligibility Criteria

Age: Not specified

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- 2 years to 20 years of age - confirmed relapsed or refractory solid tumor (including CNS tumors but not lymphomas) - recovered to CTCAE Grade 1 or less, or to baseline, from any non-hematological acute toxicities of prior surgery, chemotherapy, immunotherapy, radiotherapy, differentiation therapy or biologic therapy, with the exception of alopecia - serum/urine pregnancy test (for all girls 8 or older) negative at screening and at the baseline visit - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- prior irradiation to >50% of the bone marrow - major surgery within 4 weeks prior to study entry. Surgical biopsies or central line placement are not considered major surgeries - patients with known symptomatic brain tumors or brain metastases and require steroids, unless they have been on a stable or on a decreasing steroid dose for >14 days - fertile male patients or female patients of childbearing potential who are unwilling or unable to follow contraceptive requirements - pregnant or breastfeeding women - additional exclusion criteria apply (study staff will review)

Conditions & Interventions

Conditions:
Cancer
Keywords:
Medulloblastoma, Neuroblastoma, Rhabdoid Tumor, Rhabdomyosarcoma, Solid Tumors, Ewing Sarcoma

More Information

Description: This is a Phase 1/2 multicenter, open-label study to evaluate palbociclib in combination with either irinotecan (IRN) and temozolomide (TMZ) or topotecan (TOPO) and cyclophosphamide (CTX) chemotherapy in children, adolescents and young adults with recurrent or refractory solid tumors. The study consists of a non-randomized Phase 1 portion for recurrent or refractory solid tumors followed by potential non- randomized tumor specific cohort(s) and a randomized, Phase 2 portion for recurrent or refractory EWS.
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