ForPatients
by Roche

Solid TumorsCancer

Safety and Pharmacokinetics of Cobimetinib in Pediatric and Young Adult Participants With Previously Treated Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT02639546 2014-004685-25 GO29665

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase I/II, Multicenter, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of Cobimetinib In Pediatric and Young Adult Patients With Previously Treated Solid Tumors

Trial Summary:

This open-label, dose-escalation study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of cobimetinib in pediatric and young adult participants with solid tumors with known or potential kinase pathway activation for which standard therapy has proven to be ineffective or intolerable or for which no curative standard-of-care treatment options exist. The study will be conducted in two stages: a dose-escalation stage and an expansion stage at the recommended dose.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 6 Months & # 30 Years	No

Inclusion Criteria:

- For dose-escalation stage (tablets): age at study entry >= 6 years to < 18 years
- For dose-escalation stage (suspension): age at study entry >= 6 months to < 18 years. Participants <1 year of age will not be enrolled until >= 6 participants >= 1 year to < 18 years of age have received at

least one cycle of therapy with suspension and until safety and pharmacokinetic assessment of these participants have been conducted.
- For expansion stage: age at study entry to be >= 6 months (>=6 years if suspension is not available) to < 30 years. Participants >= 6 months to < 1 year of age may not be enrolled until >= 6 participants >= 1 year to < 18 years of age have received at least one cycle of therapy with suspension in the dose-escalation phase and until safety and pharmacokinetic assessment of these participants have been conducted.
- Tumor for which prior treatment has proven to be ineffective or intolerable or for which no standard therapy exists
- Tumor with known or expected RAS/RAF/MEK/ERK pathway involvement. Diagnosis must be one of the following tumor types:

Central nervous system gliomas, including high- and low-grade gliomas, and diffuse intrinsic pontine glioma (DIPG) Embryonal rhabdomyosarcoma and other non-rhabdomyosarcoma soft tissue sarcomas Neuroblastoma Melanoma Malignant peripheral nerve sheath tumor Rhabdoid tumors, including atypical teratoid/rhabdoid tumor (ATRT) NF1-associated tumor (including plexiform neurofibroma), schwannoma, or RASopathy-associated tumor that in the judgment of the investigator is life threatening, results in severe symptoms (including severe pain), or is in close proximity to vital structures

- Measurable disease as defined by mINRC, RANO criteria for HGG, RANO criteria for LGG, RECIST v1.1, or evaluable by nuclear medicine techniques, immunocytochemistry, tumor markers, or other reliable measures
- Availability of tumor tissue at study enrollment
- Lansky performance status or Karnofsky performance status of >= 50 percent
- Life expectancy >= 3 months
- Adequate hematologic, cardiac, and end-organ function
- Body weight must be >= 20 kilograms (kg) if suspension is not available

Exclusion Criteria:

- Pregnant or lactating women
- Close proximity in time to treatment with high-dose chemotherapy, stem-cell rescue, differentiation therapy, immunotherapy, thoracic or mediastinal radiotherapy, hormonal therapy, biologic therapy, herbal cancer therapy, hematopoietic growth factor, investigational therapy, or St. John's wort according to protocol-defined criteria prior to initiation of study drug
- Inability to swallow oral medications
- Impaired gastrointestinal absorption
- History or evidence of retinal pathology according to protocol-defined criteria, including serous retinopathy
- History of Grade >= 2 central nervous system (CNS) hemorrhage
- History of CNS hemorrhage within 28 days of study entry. This criterion may be waived at the investigator's request if the CNS hemorrhage was asymptomatic, with approval of the Medical Monitor
- Known active infection (excluding fungal infection of the nail beds) within 28 days prior to initiation of study drug that has not completely resolved
- Major surgical procedure or significant traumatic injury within 4 weeks prior to initiation of study drug, or anticipation of need for major surgical procedure during the course of the study
- Prior allogenic bone marrow transplantation or prior solid organ transplantation