A Phase 1/2 Study of the Oral RET Inhibitor LOXO-292 in Pediatric Patients with Advanced RET-Altered Solid or Primary Central Nervous System Tumors; Protocol Number: LOXO-RET-18036 (J2G-OX-JZJJ)

Status: Recruiting

Eligibility Criteria

Sex: All
Age Group: 6 months to 21 years old

Inclusion Criteria:

Advanced or metastatic solid or primary CNS tumor which has failed standard of care therapies Evidence of an activating RET gene alteration in the tumor and/or blood Measurable or non-measurable disease Karnofsky (participants 16 years and older) or Lansky (participants younger than 16) performance score of at least 50 Participant with primary CNS tumors or cerebral metastases must be neurologically stable for 7 days prior and must not have required increasing doses of steroids within the last 7 days Adequate hematologic, hepatic and renal function. Ability to receive study drug therapy orally or via gastric access Willingness of men and women of reproductive potential to observe conventional and effective birth control

Exclusion Criteria:

Major surgery within two weeks prior to planned start of LOXO-292 Clinically significant, uncontrolled cardiac, cardiovascular disease or history of myocardial infarction within 6 months prior to planned start of LOXO-292 Active uncontrolled systemic bacterial, viral, fungal or parasitic infection Clinically significant active malabsorption syndrome Pregnancy or lactation Uncontrolled symptomatic hyperthyroidism or hypothyroidism (i.e. the participant required a modification to current thyroid medication in the 7 days before start of LOXO-292) Uncontrolled symptomatic hypercalcemia or hypocalcemia Known hypersensitivity to any of the components of the investigational agent, LOXO-292 or Ora-Sweet® SF and OraPlus®, for participants who will receive LOXO-292 suspension Prior treatment with a selective RET inhibitor(s) (including investigational selective RET inhibitor[s])

Conditions & Interventions

More Information

Description: This is an open-label, multi-center, Phase 1/2 study of oral LOXO-292 in pediatric patients with an activating RET alteration and an advanced solid or primary CNS tumor.
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Phase: Phase 1/Phase 2
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