

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: 6 Months to 21 Years old

This study is NOT accepting healthy volunteers

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

Interventions:

Drug: LOXO-292

Conditions:

Medullary Thyroid Cancer, Infantile Myofibromatosis, Infantile Fibrosarcoma, Papillary Thyroid Cancer, Soft Tissue Sarcoma

Keywords:

Loxo, LOXO-292, KIF5B-RET, M918T, CCDC6-RET, RET-PTC1, NCOA4-RET, RET-PTC, RET-PTC3, RET-PTC4, PRKAR1A-RET, RET-PTC2, GOLGA5-RET, RET-PTC5, ERC1-RET, KTN1-RET, RET-PTC8, HOOK3-RET, PCM1-RET, TRIM24-RET, RET-PTC6, TRIM27-RET, TRIM33-RET, RET-PTC7, AKAP13-RET, FKBP15-RET, SPECC1L-RET, TBL1XR1-RET, BCR-RET, FGRF1OP-RET, RFG8-RET, RET-PTC9, ACBD5-RET, MYH13-RET, CUX1-RET, KIAA1468-RET, FRMD4A-RET, SQSTM1-RET, AFAP1L2-RET, PPFIBP2-RET, EML4-RET, PARD3-RET, G533C, C609F, C609G, C609R, C609S, C609Y, C611F, C611G, C611S, C611Y, C611W, C618F, C618R, C618S, C620F, C620R, C620S, C630R, C630Y, D631Y, C634F, C634G, C634R, C634S, C634W, C634Y, K666E, E768D, L790F, V804L, V804M, A883F, S891A, R912P, CLIP1-RET, Y806C, RET fusion, RET alteration, RET mutation, RET rearrangement, RET translocation, Neoplasms by Site, Neoplasms, Non-Small Cell Lung Cancer, Lung Neoplasms, Carcinoma, Non-Small-Cell Lung, Cancer of Lung, Cancer of the Lung, Lung Cancer, Neoplasms, Lung, Neoplasms, Pulmonary, Pulmonary Cancer, Pulmonary Neoplasms, Respiratory Tract Neoplasms, Lung Diseases, Respiratory Tract Diseases, Carcinoma, Bronchogenic, Bronchial Neoplasms, Medullary Thyroid Cancer, Papillary Thyroid Cancer, Thyroid Diseases, Thyroid Neoplasms, Cancer of the Thyroid, Cancer of Thyroid, Neoplasms, Thyroid, Thyroid Adenoma, Thyroid Cancer, Thyroid Carcinoma, Endocrine System Diseases, Endocrine Gland Neoplasms, Head and Neck Neoplasms, Thoracic Neoplasms, CNS tumor, Primary CNS tumor, Colonic Neoplasms, Cancer of Colon, Cancer of the Colon, Colon Cancer, Colon Neoplasms, Colonic Cancer, Neoplasms, Colonic, Malignant tumor of Breast, Mammary Cancer, Mammary Carcinoma, Human, Mammary Neoplasm, Human, Neoplasms, Breast, Tumors, Breast, Human Mammary Carcinoma, Malignant Neoplasm of Breast, Breast Carcinoma, Breast Tumors, Cancer of the Breast, Breast Neoplasms, Breast Cancer, RET Inhibitor, MTC, NSCLC, Soft tissue sarcoma, Infantile Myofibromatosis, Infantile Fibrosarcoma

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.

Contact(s): Allison Fullenkamp - fulle631@umn.edu

Principal Investigator: Emily Greengard

Phase: Phase 1/Phase 2

IRB Number: STUDY00008874

System ID: NCT03899792

Thank you for choosing StudyFinder. Please visit <http://studyfinder.umn.edu> to find a Study which is right for you and contact sfinder@umn.edu if you have questions or need assistance.