



A Window of Opportunity Trial of Mirdametinib plus Vorinostat for NF1 Associated, Malignant Peripheral Nerve Sheath Tumor; MPNST

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old This study is NOT accepting healthy

volunteers

Inclusion Criteria:

- Known Neurofibromatosis type 1 (NF-1) syndrome based on current diagnostic criteria Diagnosis of suspected MPNST by PET or MRI imaging Confirmation of histone H3 lysine 27 trimethylation-negative MPSNT by immunohistochemistry Twelve years of age or older
- •Complete blood count (CBC), platelet, liver and kidney function within institutional normal limits performed within 14 days of 1st dose of study drug Must be able to swallow capsules Females of childbearing potential must use highly effective contraception (see inclusion criteria section) from the time of study enrollment through 6 months after the last dose of vorinostat and mirdametinib Males with partners of childbearing potential must use highly effective contraception from the time of study enrollment through 3 months after the last dose of vorinostat Provides voluntary written consent prior to any study related activities, with parental/guardian consent and assent for those 12 to 17 years of age at enrollment

Exclusion Criteria:

- Pregnant or breastfeeding – females of childbearing potential must have a negative pregnancy test (serum and urine) within 7 days prior to the 1st dose of the study drugs - Significant cardiac disease - Ophthalmologic conditions - Radiation therapy or chemotherapy in the past year - Participants receiving systemic or ocular glucocorticoid therapy within 14 days prior to the first dose of study treatment

Conditions & Interventions

Interventions:

Drug: mirdametinib and vorinostat

Conditions:

Brain & Nervous System

More Information

Description: This is a small, Phase 0, window of opportunity study to provide human experience to support our pre-clinical data and gain preliminary information regarding the safety and tolerability of mirdametinib and vorinostat when given in combination.

Study Contact: Allison Fullenkamp - fulle631@umn.edu Principal Investigator: Christopher Moertel, MD

Phase: EARLY_PHASE1

IRB

Number: STUDY00022372

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.