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.
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