

PLX038 in CNS Tumors

A research study for **adults** with primary central nervous system (CNS) tumors containing changes in the *MYC* or *MYCN* genes.



+ Objective

National Cancer Institute (NCI) researchers are conducting an investigational study of patients with primary CNS tumors.

This study seeks to find the optimal dose of the investigational drug PLX038 and will provide information on how this study drug affects CNS tumors containing changes (amplifications) in the *MYC* or *MYCN* genes.

What the research study involves:

- Receive the investigational drug treatment intravenously every 3 weeks for a maximum of 10 cycles
- Optional tumor biopsies for some participants
- Full physical and neurological examination
- Health and symptoms questionnaires
- Imaging studies
- Study of tumor tissue from prior surgeries
- Your samples used for tumor genetic testing
- All tests, procedures, and medications provided within the NIH Clinical Center (CC) at no cost
- No compensation is provided

This study is conducted at the NIH CC in Bethesda, Maryland. The principal investigator is Marta Penas-Prado, M.D., of the NCI Center for Cancer Research's Neuro-Oncology Branch at NIH.

You can participate if you:

- Are age 18 or older
- Have a diagnosis of:
 - Recurrent or progressive primary CNS tumor (with or without *MYC* or *MYCN* amplification) – Phase 1 only
 - Newly diagnosed *MYCN*-amplified ependymoma post-surgery and radiation – Phase 2 only
 - Recurrent or progressive primary CNS tumor containing *MYC* or *MYCN* amplification, including ependymoma, medulloblastoma, and others
- Are able to care for yourself
- Can self-report symptoms and physical function as determined by assessment of clinical team
- Have tumor tissue available for central review and confirmation of diagnosis
- Have no prior history of photon craniospinal radiation
- Are not pregnant (if breastfeeding, you must stop at the start of treatment until 6 months post-treatment)
- Have adequate organ, marrow, and physical function as determined by assessment of clinical team



Questions?

Contact us at **(240) 760-6010** or
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clinicaltrials.gov ID: NCT06161519