PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

PHASE 1 TRIAL of **MARIZOMIB** with TEMOZOLOMIDE and RADIOTHERAPY in NEWLY DIAGNOSED BRAIN CANCER

Official Title: Phase 1b, Multicenter, Open-Label Study of Marizomib Combined With Temozolomide and Radiotherapy in Patients With Newly Diagnosed WHO Grade IV Malignant Glioma

This study is for newly diagnosed WHO Grade IV malignant glioma patients to determine whether an investigational drug known as **marizomib (MRZ)** will improve the treatment of newly diagnosed glioblastoma patients by delaying the growth of the cancer, reducing the size of the tumor, and/or improving survival.

Marizomib (MRZ) is a novel, second generation proteasome inhibitor that prevents the breakdown of proteins involved in signal transduction which blocks growth and survival of cancer cells.

Key Inclusion Criteria:

- Histologically confirmed newly diagnosed Grade 4 Malignant Glioma
- Karnofsky Performance Status (KPS) score ≥ 70%
- For Concomitant Treatment: Prior tumor resection or biopsy up to 8 weeks prior to first MRZ dose
- For Adjuvant Treatment: All AEs resulting from surgery must have resolved to NCI-CTCAE (v. 4.03) Grade ≤ 1
- Stable or decreasing dose of corticosteroids over 14 days prior to first MRZ dose
- For Concomitant Treatment: No prior treatment with MRZ or any other PIs, including BTZ, carfilzomib (CFZ), or ixazomib (IXZ)
- For Adjuvant Treatment: No prior treatment with BTZ, CFZ, or IXZ
- No investigational agent within 4 weeks prior to first dose of study drug
- Patients must be without seizures for at least 14 days prior to enrollment, and patients who receive treatment with AEDs must be on stable doses for at least 14 days prior to enrollment
- Absence of known HIV infection, chronic hepatitis B, or hepatitis C infection; absence of any other serious medical condition which could interfere with oral medication intake
- Patients with archival tumor tissue suitable for measurement of proteasome activity and biomarker status must give permission to access and test the tissue. Patients without archival tumor tissue are eligible for the Dose-Escalation stage, but not the Dose-Expansion stage of the study

For more information, contact the Neuro-Oncology Clinical Trial Team at:
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