PACIFIC NEUROSCIENCE INSTITUTE℠

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

For more information, contact the Neuro-Oncology Clinical Trial Team at:
neuro.oncology@jwci.org
310-829-8265

Clinical Trial Investigators

Achal S. Achrol, MD

Garni Barkhoudarian, MD

Daniel Kelly, MD

Santosh Kesari, MD, PhD,

Steven O'Day, MD

Marlon Garzo Saria, PhD, RN

Clinical Trial Team

Najee Boucher, CRA
najee.boucher@providence.org
310-582-7460

Jaya Gill, RN, BSN
jaya.gill@providence.org
310-582-7437

Annie Heng, RN, BSN
HengA@jwci.org
310-582-7457

Tiffany Juarez, PhD
Tiffany.Juarez@jwci.org
310-449-5225

Anand Moses, CRA
MosesA@jwci.org
310-582-7097

Sponsor

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PROVIDENCE Health & Services

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.

Recently, a novel treatment using a device—tumor treating fields (Optune®) – in addition to standard TMZ/RT —> TMZ has been shown to significantly improve both progression-free and overall survival in newly diagnosed GBM patients. Treatment has been approved by the FDA as an option and standard of care. This study will combine Marizomab + Temozolomide + Optune™ in patients entering the Adjuvant Treatment phase.

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 with Optune™: All AEs resulting from surgery must have resolved to NCI-CTCAE (v. 4.03) Grade ≤ 1; for patients assigned to Optune™, they are excluded if they are < 22 years of age or have an implanted medical device
- 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