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

CLINICAL TRIAL ANNOUNCEMENT

A Phase I Dose Escalation and CNS Pharmacokinetic Study of the ErbB Family Inhibitor Afatinib in Patients with Recurrent or Progressive Brain Cancer

This study is a Phase I dose escalation and CNS pharmacokinetic study of the ErbB family inhibitor **afatinib** in patients with recurrent or progressive brain cancer. It is an open-label, single institution, 3+3 dose escalation study to describe the safety and tolerability of afatinib in patients with brain cancer having failed prior therapy and to determine the recommended phase II dose.

Eligible patients will receive **afatinib** in treatment cycles of 28 days that will consist of **afatinib** administered orally by mouth once every four days. Patients will be assigned to the dose level open at the time of their enrollment. Patients will continue dosing of **afatinib** until disease progression, unacceptable toxicity, withdrawal of consent, or treating physician determines it is in their best interest to stop.

Afatinib (BIBW2992; Gilotrif®) is a small molecule, selective and irreversible ErbB family blocker. In preclinical models it effectively inhibits EGFR, HER2 and HER4 phosphorylation resulting in tumour growth inhibition and regression of established subcutaneous tumours derived from four human cell-lines known to co-express ErbB receptors.

Key Inclusion Criteria:

- Histologically or radiologically confirmed diagnosis of brain cancer of any kind including: glioblastoma (GBM), anaplastic astrocytoma (AA), anaplastic oligodendroglioma (AO), anaplastic mixed oligoastrocytoma (AMO), low grade gliomas, brain metastases, meningiomas, leptomeningeal metastases, chordomas, pituitary tumors, and medulloblastomas
- Failed prior standard therapy
- Age ≥ 18 years
- Karnofsky Performance Status ≥ 60%

Exclusion Criteria:

- Insufficient time from prior therapy to study entry
- Current or anticipated use of enzyme-inducing anti-epileptic drugs
- Major surgery within 4 weeks before starting study treatment or scheduled for surgery during the projected course of the study

Please feel free to contact the clinical trial team to learn more about this study.

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