Cleveland Clinic

Temodar & ABT-888 CC669/NABTT 0801

Full Title
A Phase I/II Trial of Temozolomide and ABT-888 in Subjects with Newly Diagnosed Glioblastoma Multiforme

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Objectives
Primary Objective - To determine the MTD of ABT-888 in subjects with newly diagnosed glioblastoma when given during radiation therapy with concurrent and adjuvant TMZ.

Secondary Objectives:
1) To assess the toxicity associated with these two treatment regimens.
2) To assess and describe the pharmacokinetics of ABT-888 in these two treatment regimens.

Phase II Safety and Efficacy:

1) To estimate overall survival for adult subjects with newly diagnosed GBM treated with ABT-888 at the MTD during RT with concurrent and adjuvant TMZ.
2) To estimate the frequency of toxicity associated with this treatment regimen.

Eligibility
Inclusion
- 18 yrs or older
- Histologically supratentorial grade IV GBM
- KPS = >/= 60
- Hematolgic, renal and liver function acceptable range (refer to protocol – page 11)
- Adequate contraception (refer to page 11)
- MMSE = >/= 15
- Dose Esc/PH II only: No prior RT, chemo, immunotherapy or biologic agent or hormonal therapy for brain tumor
- Dose Esc/PH II only: Recovered from immediate post-op period
- Dose Esc/PH II only: stable corticosteroid at least 5 days
- Dose Esc/PH II only: Gad MRI or contrast CT w/in 14 days of start
- Dose Esc/PH II only: If biopsy or resection of new tumor, begin no sooner than 1wk post surgery

Exclusions
- Serious concurrent infection or medical illness
- Life expectancy expected < 3 months
- Pregnant or breast-feeding
- Receiving concurrent therapy for tumor
- concurrent or prior malignancy
- Taking EIADs w/in 10 days of start
- Known seizure disorder, uncontrolled or seizures occurring >/= 3 x wk over past month
- PH II only: Received Gliadel wafers
- Dose Esc phase only: Received Gliadel wafers ARE eligible