PEPN2415; A Phase I Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of AZD1390 (NSC# 852149, IND# 172675) when Combined with Focal Radiation in Pediatric Patients with High Grade Glioma

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- For the dose escalation phase, patients must be ≥ 12 months and < 18 years of age at the time of study enrollment. - For the disease expansion phase, patients must be ≥ 12 months and < 22 years of age at the time of study enrollment. - Patients with newly diagnosed primary High-Grade Glioma, Diffuse Midline Glioma or Diffuse Intrinsic Pontine Glioma who are eligible to receive 54-59.4 Gy fractionated radiation at 1.8 Gy/day. - Patients must have had histologic verification of malignancy at original diagnosis except in patients with DIPG.

Exclusion Criteria:

- Patients who are pregnant or breast-feeding. - Patients who are currently receiving another investigational drug. - Patients receiving prior therapy for any cancer diagnosis (including radiation) is not allowed with the exception of surgery and/or corticosteroids. - Patients who are currently receiving other anti-cancer agents are not eligible with the exception of corticosteroids. - Anti-GVHD agents post-transplant: Patients who are receiving anti-graft-versus-host disease post bone marrow transplant.

Conditions & Interventions

Interventions:
Drug: ATM Kinase Inhibitor AZD1390, Procedure: Biospecimen Collection, Procedure: Magnetic Resonance Imaging, Radiation: Radiation Therapy, Other: Survey Administration
Conditions:
Cancer
Keywords:
Focal Radiation, HGG, High Grade Glioma, Pediatric, Phase I

More Information

Description: The primary purpose of this study is to define the recommended Phase 2 dose of AZD1390 when given in combination with radiation for pediatric supratentorial and infratentorial high-grade gliomas. The toxicities, safety profile and pharmacokinetic profile of AZD1390 in this setting will also be assessed.
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Phase: PHASE1
IRB Number: STUDY00025588