PACIFIC NEUROSCIENCE INSTITUTE℠

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

CLINICAL TRIAL ANNOUNCEMENT

Study to Evaluate ABI-009 (*nab*-Rapamycin) in Patients with High Grade Glioma

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Sponsor

PNI/JWCI/Aadi Bioscience

Saint John's Health Center
PROVIDENCE Health & Services

Official Title: A Phase 2, Open-label Study of ABI-009 (*nab*-Rapamycin) in Bevacizumab-naïve Patients with Recurrent High-grade Glioma and in Patients with Newly Diagnosed Glioblastoma

ABI-009 (*nab*-rapamycin) - nanoparticle form of human albumin-bound rapamycin. The *nab* technology may enhance tumor penetration and accumulation via the albumin receptor-mediated (gp60) endothelial transcytosis. Albumin is highly soluble, has long plasma half-life, broad binding affinity, making it an ideal candidate for drug delivery. Importantly, albumin has been shown to be able to penetrate the blood-brain barrier (BBB) and highly accumulate in GBM. Therefore, albumin may facilitate the efficient delivery of nab-rapamycin into GBM tumors, making it a useful treatment option for GBM.

In patients with Newly diagnosed GBM, ABI-009 will be combined with standard of care Temozolomide and Radiation.

In patients with Recurrent High—grade Glioma, four cohorts will include: (1) ABI-009 as a single agent (2) ABI-009 + Temozolomide (3) ABI-009 + Bevacizumab and (4) ABI-009 + Lomustine .

Key Inclusion Criteria:

- Karnofsky Performance Status ≥ 70%.
- No investigational agent within 4 weeks prior to the first dose of study drug.
- Adequate hematological, renal, and hepatic function
- Patients must be without seizures for at least 14 days prior to enrollment
- If Newly Diagnosed: must have confirmed GBM, no prior treatment with mTOR inhibitors, and no prior local or systemic therapy for GBM
- If Recurrent: Must have histologic evidence of high grade glioma (WHO Grade 3 or 4), and no prior treatment with mTOR inhibitors or bevacizumab

Key Exclusion Criteria:

- Use of strong inhibitors and inducers of CYP3A4 within the 14 days prior to receiving the first dose of ABI-009