CLINICAL TRIAL ANNOUNCEMENT

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

Official Title: A Phase 2, Open-label Study of ABI-009 (nab-Rapamycin) in Bevacizumab-naive 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

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
PNI/JWCI/Aadi Bioscience

Saint John’s Health Center