PACIFIC NEUROSCIENCE INSTITUTE℠

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

CLINICAL TRIAL ANNOUNCEMENT

Phase I /II Trial to Evaluate **Isatuximab** in Patients with **Advanced Malignancies**

For more information, contact the Neuro-Oncology Clinical Trial Team at:
Neuro.Oncology@jwci.org
310-829-8265

Clinical Trial Investigators

Garni Barkhoudarian, MD
Jose Carrillo, MD
Daniel Kelly, MD
Santosh Kesari, MD, PhD,
Steven O'Day, MD
Marlon Garzo Saria, PhD, RN

Clinical Trial Team

Jaya Mini Gill, RN, BSN
Jaya.Gill@providence.org
310-582-7437

Annie Heng, RN, BSN
Annie.Heng@providence.org
310-582-7457

Hanh Nguyen, CRA
NguyenThuyH@jwci.org
310-582-7434

Sponsor

Sanofi Aventis, R&D

Saint John's Health Center
PROVIDENCE Health & Services

Official Title:
A Phase 1/2 open-label, multi-center, safety, preliminary efficacy and pharmacokinetic (PK) study of isatuximab (SAR650984) in combination with atezolizumab or isatuximab alone in patients with advanced malignancies

The purpose of this study is to assess the safety profile and response rate of isatuximab in combination with atezolizumab in participants with advanced malignancies such as glioblastoma (GBM), squamous cell carcinmona of head and neck (SCCHCC), hepatocellular carcinoma (HCC), and epithelial ovarian cancer (EOC).

Isatuximab an anti-CD38 monoclonal antibody that binds selectively to a unique epitope on the human surface antigen CD38. Isatuximab kills tumor cells via multiple biological mechanisms; antibodydependent cellular-mediated cytotoxicity, antibody-dependent cellular-mediated phagocytosis, complement-dependent cytotoxicity and direct induction of apoptosis (pro-apoptosis) without crosslinking.

Atezolizumab is a humanized immunoglobulin G1 mAb that targets PD-L1 and inhibits the interaction between PD-L1 and its receptors, PD-1 and B7-1 (also known as CD80), both of which function as inhibitory receptors expressed on T cells. Therapeutic blockade of PD-L1 binding by atezolizumab has been shown to enhance the magnitude and quality of tumor-specific T cell responses, resulting in improved anti-tumor activity.

Monoclonal antibodies that block the PD-1/PD-L1 axis have changed the landscape of cancer therapy. This study designed to explore whether isatuximab may contribute to reshaping the tumor immuneenvironment and will enhance the activity of established anti-PD-L1 therapy.

Key Inclusion Criteria:

- Histologically confirmed diagnosis of advanced malignancy
- At least one measurable lesion for HCC, SCCHN, EOC (per RECIST 1.1)
- For GBM: Documentation of PD or first recurrence

Key Exclusion Criteria:

- Active brain metastases or leptomeningeal metastases
- Prior treatment with an agent (approved or investigational) that blocks CD38
- Prior treatment with an agent (approved or investigational) that blocks the PD-