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

CLINICAL TRIAL ANNOUNCEMENT

Study of Immunotherapy in Newly Diagnosed GBM: Phase 3 Randomized, Double-blind, Controlled Study of ICT-107 in GBM

This is a double blind Phase III study where eligible subjects are randomized into two treatment arms following the SOC primary treatment with chemoradiation:

- Arm 1 will receive ICT-107 in combination with the standard of care, temozolomide (TMZ)
- Arm 2 will receive TMZ with a blinded control.

A 1:1 randomization will be employed, where ARM 1 will receive ICT-107 and Arm 2 will receive placebo control. All subjects must have glioblastoma tissue that has tumor assessment for MGMT methylation status prior to randomization (for stratification). Subjects will have had tumor resection and magnetic resonance imaging (MRI) prior to enrollment into the study. After signing of written informed consent and any required privacy compliance forms and screening, enrolled subjects will undergo large volume apheresis at the study site for collection of PBMCs.

Randomized subjects will receive 4 weekly administrations of subject-specific study therapy (ICT-107 or Control) during the Induction Phase. No TMZ will be given during the 4 week Induction Phase. Each study therapy injection will be delivered intradermally (axilla).

Inclusion Criteria:

- Subjects must understand and sign the study specific informed consent
- Subjects must be in primary remission
- Subjects should have < 1 cm3 disease by MRI within the previous 4 weeks (by central read)
- Subjects must be HLA-A2 positive by central lab
- Subjects must have adequate renal, hepatic and bone marrow function based on screening laboratory assessments. Baseline hematologic studies and chemistry and coagulation profiles must meet pre-specified criteria.
- Subjects must use effective contraceptive methods during the study and for three months following the last dose of study product, if of reproductive age and still retain fertility potential.
- Subjects must have at least one positive DTH skin response (more than 5 mm) to test item challenge prior to randomization.

Please feel free to contact the clinical trial team to learn more about this study.

For more information, please 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, FANA, FAAN

Steven O'Day, MD

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

Marlon Garzo Saria, PhD, RN, AOCNS, FAAN
SariaM@jwci.org

Sponsor

ImmunoCellular Therapeutics, Ltd.

Saint John's Health Center
PROVIDENCE Health & Services