



# AIVITA Newly Diagnosed Glioblastoma (GBM) Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic at UC Irvine, and the Neuro-Oncology Brain Tumor Program

**Study Title:** PHASE II TRIAL OF AV-GBM-1 (AUTOLOGOUS DENDRITIC CELLS LOADED WITH AUTOLOGOUS TUMOR ASSOCIATED ANTIGENS) AS ADJUNCTIVE THERAPY FOLLOWING PRIMARY SURGERY PLUS CONCURRENT CHEMORADIATION IN PATIENTS WITH NEWLY DIAGNOSED GLIOBLASTOMA

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## What is the study?

The purpose of this study is to determine whether an investigational immunotherapy will lengthen survival without harmful effects in patients newly diagnosed with glioblastoma cancer. The immunotherapy, AV-GBM-1, consists of a patient's own dendritic cells (a type of immune cell) loaded with a patient's own tumor associated antigens (proteins that are made by their cancer cells), and is injected under the skin of the arm or leg.

## How long will my participation last?

This study includes 8 study treatment visits over a period of 24 weeks. After you complete the study treatment, you will have follow up visits every 3 months for up to 3 years, or for the rest of your life, or until study closure.

## How can I take part in this trial?

At UC Irvine, we will enroll approximately 40 adult subjects with newly diagnosed glioblastoma.

Please note this may not be a complete list of eligibility criteria.

### **Main Inclusion Criteria**

- 18-70 years of age
- Grade 4 malignant glioma (glioblastoma or gliosarcoma) diagnosis

- Agree to provide tumor tissue and have a leukapheresis (white blood cell collection) procedure
- About to begin primary chemoradiation therapy

## How does it work?

The intent is to make a patient's immune response better at fighting the existing tumor and to increase survival. The treatment is given once a week for three weeks, and then once a month for five months, for up to a total of 8 doses.

## Where is the study conducted?

At the University of California, Irvine Medical Center located in Orange, CA.

## Will I be compensated?

You will not be compensated for your participation in this research study.

## For more information please contact:

**UC Irvine Alpha Stem Cell Clinic**

949-824-3990 or [stemcell@uci.edu](mailto:stemcell@uci.edu)