

## 2. Non-Technical Project Summary

**TITLE OF PROJECT:** A Phase I, Open Label Safety Study of Allogeneic Glioblastoma Tumor Cell Lines Mixed with Allogeneic Fibroblasts Genetically Modified to Secrete GM-CSF in Patients with Glioblastoma Multiforme or Anaplastic Astrocytoma. Immune Response Corp, Carlsbad, California

Standard therapy for patients with the most common types of brain tumor, called *malignant gliomas*, consists of surgery to remove as much tumor as possible, followed by radiation therapy alone, or in combination with medications, called chemotherapy. Despite treatment, most patients with the most severe form of glioma called *glioblastoma multiforme* eventually develop recurrent disease with an average life span of 9 to 11 months from the time of diagnosis, or 18 to 24 months of life for patients with a less malignant form, anaplastic astrocytoma. Effective treatment options if the tumor comes back are rarely curative.

In recent years, immunotherapy, similar to vaccination against diphtheria, polio or tetanus, has become a major focus for a new approach to the treatment of cancer. Active immunotherapy involves the use of either the patient's own, or another patient's tumor cells, altered in some way to increase their ability to stimulate the immune system; these are then administered to patients. Previous studies using tumor cells secreting a hormone called GM-CSF, which further activates immunity, have shown potential benefit in several different types of cancer by inducing specific anti-tumor immune responses with minimal side effects.

The purpose of this early phase study is to determine *safety* and evidence for *immune response* in patients with two of the most deadly forms of brain who will receive the new Glioma Cancer Vaccine. This vaccine consists of cells from three different human brain tumors that have been grown in the laboratory. These are then mixed with another cell type grown from the skin which has been genetically altered to makes high levels of the hormone GM-CSF, which can stimulate the immune system further. A mixture of three cell lines is used to provide a wider range of immunity than would be found on a single brain tumor.

Patients will be monitored for safety, side effects and for specific immune responses to their own tumors and the tumor cells contained within the vaccine. The time to tumor recurrence and length of life will also be monitored