Phase 1b Clinical Trial of IGV-001 for Patients With Newly Diagnosed Glioblastoma


**Points of Interest**

**SAFETY and CLINICAL IMPROVEMENTS**

**Included in Trial**

Adults with newly diagnosed Glioblastoma

**Treatment**

IGV-001 is a personalized therapy that aims to induce antitumor immunity; it includes the patient’s own glioblastoma tumor cells plus a molecule called IMV-001

Tumor cells and IMV-001 were mixed after surgery outside the body in either 10 or 20 SMALL CHAMBERS† that underwent radiation to prevent the growth of tumor cells. Soon afterwards, the chambers were put into the PATIENT’S ABDOMEN for 24 or 48 hours

**SAFETY**

**STUDY DETAILS**

Early-stage phase 1b trial in which all patients knew they were receiving IGV-001

23 PATIENTS were initially assigned randomly to receive 1 of 4 different levels of IGV-001 to test the safety of each level

10 MORE PATIENTS received IGV-001 at the highest level (20 chambers for 48 hours)

Patients who had the highest level of IGV-001 also had good clinical improvements with only mild or not life-threatening AEs*

**EFFICACY**

IGV-001 was generally well tolerated, without immune-related adverse events typical of other immunotherapies

15% OF PATIENTS had mild or not life-threatening AEs related to the cut in the abdomen where the chambers were placed. These AEs were addressed with standard medical management

9% OF PATIENTS had mild or not life-threatening AEs that may have been caused by IGV-001. These AEs were addressed with observation or standard medical management

**NEXT STEPS**

Doctors will be testing IGV-001 in a later-stage phase 2b trial

This will compare IGV-001 with placebo in a greater number of patients with glioblastoma (NCT04485949)

*AE, adverse event; FDA, United States Food and Drug Administration; SOC, standard of care.

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†Each chamber is smaller than a dime. Up to 10 chambers implanted on each side.