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

Imvax®

Andrews DW, et al. *Clin Cancer Res.* 2021;27(7):1912-1922.
Clinical Study Report (14379-102), Version 1.0 (15 Sep 2020).

Points of Interest

SAFETY and CLINICAL IMPROVEMENTS

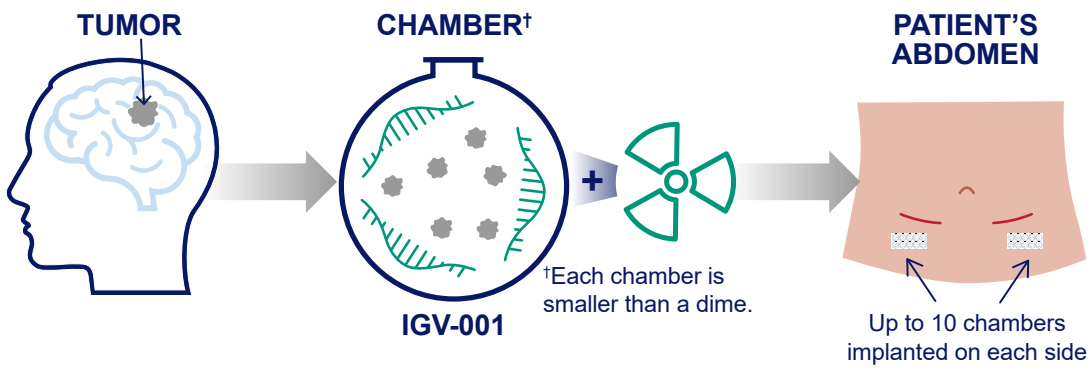
Included in Trial

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**[a] 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



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*

SOC

After treatment with IGV-001, patients went on to standard treatment (or SOC)* with **RADIATION AND TEMOZOLOMIDE** (an FDA*-approved treatment for glioblastoma)

SAFETY

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

EFFICACY

10.6 MONTHS LONGER

Patients who received IGV-001 at the highest level lived on **AVERAGE 10.6 MONTHS LONGER** without worsening of disease than other patients from past studies who received only SOC (historical control group)

22 MONTHS LONGER

Patients who received IGV-001 at the highest level lived on **AVERAGE 22 MONTHS LONGER** versus the historical control group

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.

Version 2 | Aug 1, 2023