Phase 2b Clinical Trial of IGV-001 for Patients With Newly Diagnosed Glioblastoma

Phase 2b Trial to Further Assess the Safety and Efficacy of IGV-001

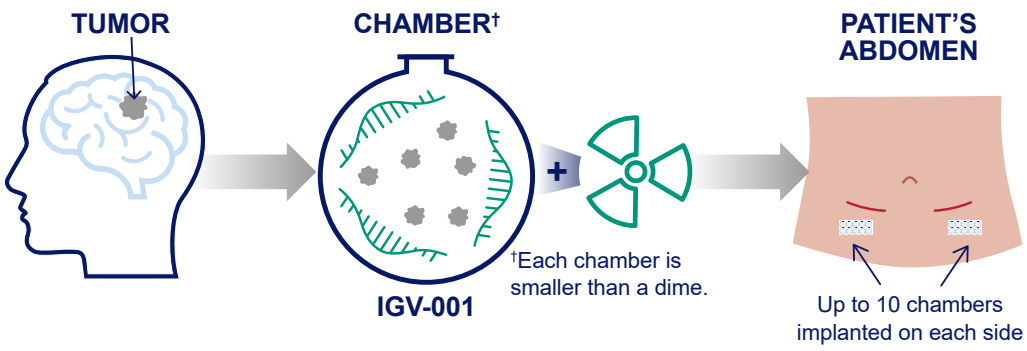
ClinicalTrials.gov identifier: NCT04485949

OBJECTIVES

- **PRIMARY OBJECTIVE**: Survival without worsening of disease
- **SECONDARY OBJECTIVE**: Survival overall
- **SAFETY OBJECTIVE**: Safety and tolerability

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 placed in chamber



WEEK 0

SCREENING
Day −14 through Day −3

Doctors discuss with patients and assess whether this trial may be right for them

Patient with newly diagnosed glioblastoma (age 18-70 years)

MRI*

SCREENING/RANDOMIZATION
Day −2 through Day 0

Doctors will confirm brain tumor using frozen sample

Surgery to remove tumor

Randomize 2:1 (N=93)

- IGV-001 n=62
- Placebo n=31

Patients are randomly assigned to IGV-001 or placebo groups

Superficial abdominal incision to the rectus muscle (after randomization)

TREATMENT
Day 1 through Day 28

- Day 1 insert chambers
- Day 3 remove chambers
- Days 14 and 28 examine patients

MRI* within 3 days after surgery

Tumor tissue will be used to prepare IGV-001; chambers will contain either IGV-001 or placebo

MONTH 36

The usual treatment is RT* and chemotherapy

SOC* TREATMENT
Week 7 through Week 41

- RT* + TMZ* Week 7-12
- TMZ* Week 17-41

FOLLOW-UP
Month 10 through Month 36

- Follow-up Month 10-36

Doctors keep track of patients' health after treatment

- MRI* 4 weeks (±1) after end of RT*
- MRI* 8 weeks (±2) after post RT* MRI*
- MRI* every 3 months (±2 weeks) until 36 months after randomization or disease progression

Phase 1b Trial Results [Andrews DW, et al. *Clin Cancer Res.* 2021;27(7):1912-1922]

SAFETY

IGV-001 was generally well tolerated

15% had mild or non–life-threatening AEs* related to the cut in the abdomen where the chambers were placed

9% had mild or non–life-threatening AEs that may have been caused by IGV-001

EFFICACY

Patients who received IGV-001 and SOC* in past studies lived, on average, longer than those in earlier studies who received only SOC*

10.6 MONTHS LONGER without worsening of disease

22 MONTHS LONGER overall

*AE, adverse event; MRI, magnetic resonance imaging; N, number of patients; RT, radiotherapy; SOC, standard of care; TMZ, temozolomide.

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FACTSHEET: Phase 2b Clinical Trial of IGV-001 for Patients With Newly Diagnosed Glioblastoma

Imvax®

Protocol title

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Phase 2b Study to Assess the Safety and Efficacy of IGV-001, an Autologous Cell Immunotherapy With Antisense Oligonucleotide (IMV-001) Targeting IGF-1R, in Newly Diagnosed Patients With Glioblastoma

Sponsor
Imvax, Inc.

ClinicalTrials.gov identifier
NCT04485949

Protocol number
14379-201

CRITERIA

Key Inclusion Criteria

Patients who take part in the trial* must:

- Have newly diagnosed glioblastoma
- Be 18 to 70 years of age
- Have a KPS score ≥70 (unable to work but able to care for themselves overall)

Key Exclusion Criteria

Patients are not allowed to participate* in the trial if they have:

- A tumor that is on both sides of the brain
- Had previous surgery or anticancer treatment for glioblastoma
- Glioblastoma that came back
- Another cancer† while having glioblastoma or within the last 3 years that is not cured
- A weakened immune system (example: HIV, HBV, HCV) or an autoimmune disorder (example: Crohn's disease)
- Heart disease or history of heart issues

STUDY DESIGN

SCREENING: Patients will have screening procedures completed between Day -14 to Day -2 (up to 16 days)

RANDOMIZATION: Patients are randomly assigned 2:1 to treatment with IGV-001 or placebo

TREATMENT: Patients receive study treatment (IGV-001 or placebo) during Days 1-28

SOC TREATMENT: Patients receive usual treatment (SOC) of RT and chemotherapy (TMZ) during Weeks 7-12, then chemotherapy alone during Weeks 17-41

FOLLOW-UP: Doctors keep track of patients' health during Months 10-36

*Additional criteria apply. Please refer to protocol 14379-201 for full inclusion and exclusion criteria. †Patients can participate if they had some skin cancers, superficial bladder cancer (cancer that was only on the surface of the lining of the bladder), or carcinoma in situ (cancer that had not spread) of the cervix or breast that had been cured.

HIV, human immunodeficiency virus; HBV, hepatitis B virus; HCV, hepatitis C virus; IGF-1R, insulin-like growth factor 1 receptor; KPS, Karnofsky Performance Scale; RT, radiotherapy; SOC, standard of care; TMZ, temozolomide.

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