


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

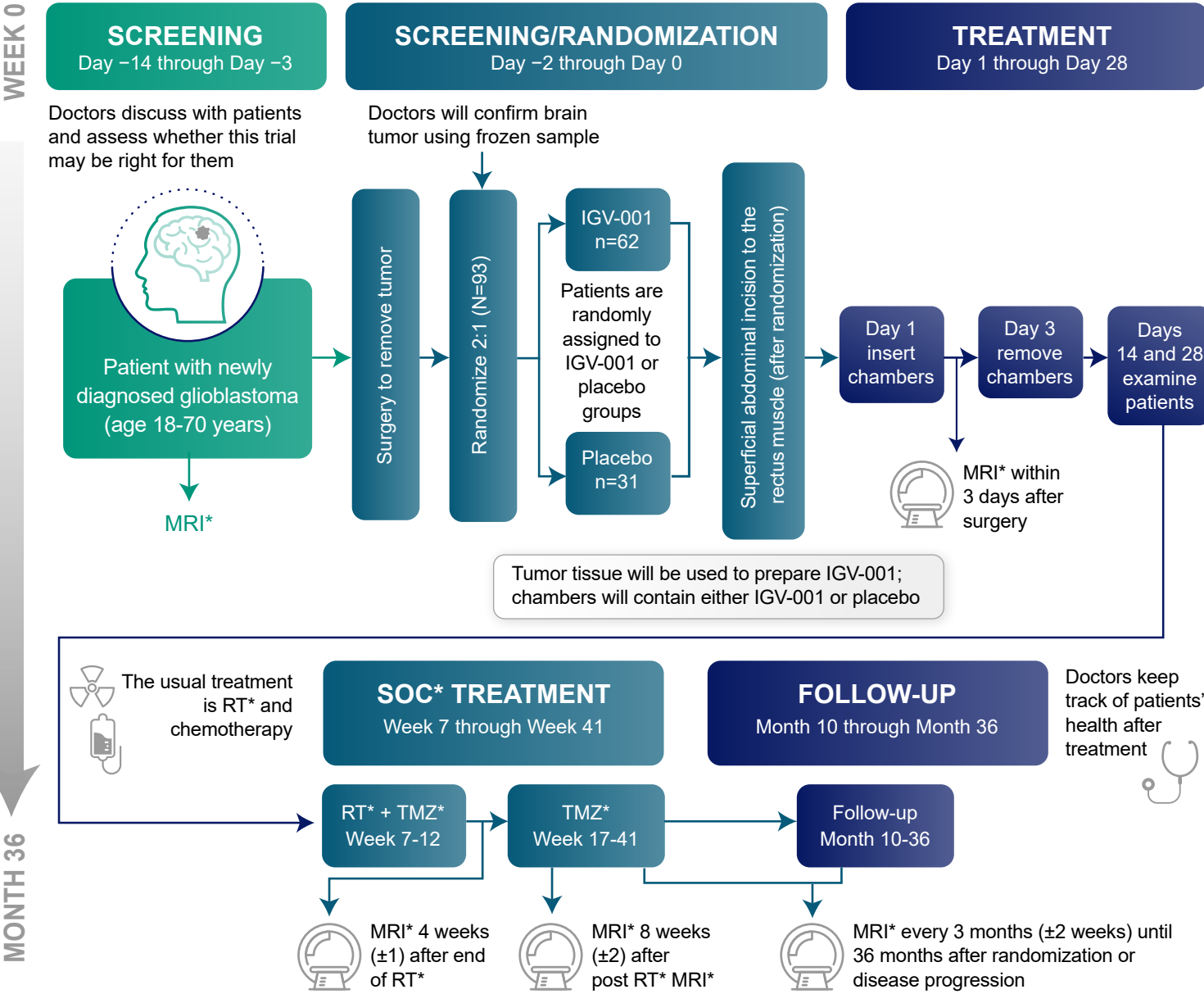
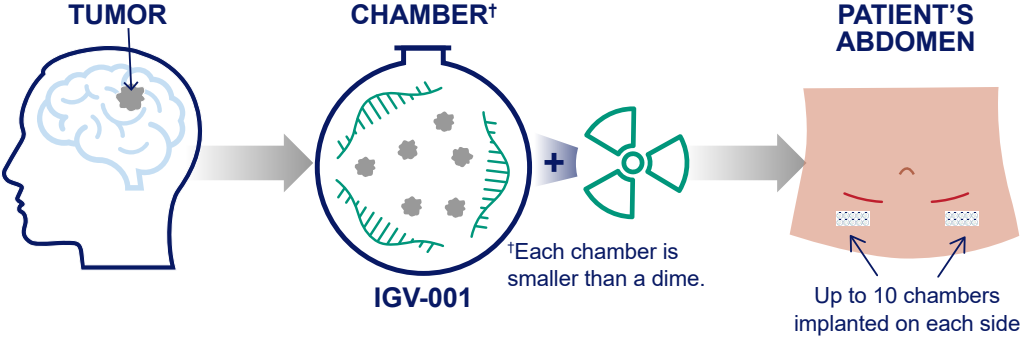
Survival overall

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



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.

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**
Invax, Inc.

 **ClinicalTrials.gov identifier**
NCT04485949

 **Protocol number**
14379-201

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)



CRITERIA

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.