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

ClinicalTrials.gov identifier: NCT04485949

**OBJECTIVES**

**PRIMARY OBJECTIVE**
Survival without worsening of disease

**SECONDARY OBJECTIVE**
Survival overall

**SAFETY OBJECTIVE**
Safety and tolerability

**TREATMENT**

**Phase 1b Trial Results**

IGV-001 was generally well tolerated

<table>
<thead>
<tr>
<th></th>
<th>SAFETY</th>
<th>EFFICACY</th>
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<tbody>
<tr>
<td><strong>15%</strong></td>
<td>had mild or non–life-threatening AEs* related to the cut in the abdomen where the chambers were placed</td>
<td><strong>10.6 MONTHS LONGER</strong> without worsening of disease</td>
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<tr>
<td><strong>9%</strong></td>
<td>had mild or non–life-threatening AEs that may have been caused by IGV-001</td>
<td><strong>22 MONTHS LONGER</strong> overall</td>
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*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

**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

**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

**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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