Development of IGV-001 For the Treatment of Newly Diagnosed Glioblastoma

For more information:
www.imvax.com
Advancing a New Approach to Personalized Cancer Immunotherapy

Imvax Pipeline: Focused on Solid Tumors

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>IND enabling</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
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</thead>
<tbody>
<tr>
<td>Glioblastoma</td>
<td>IGV-001</td>
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<tr>
<td>Endometrial cancer</td>
<td>IEC-001</td>
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<td>Hepatocellular carcinoma</td>
<td>IHC-001</td>
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<td>Urothelial cancer</td>
<td>IUC-001</td>
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<tr>
<td>Ovarian cancer</td>
<td>IOC-001</td>
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IGV-001, IEC-001, IHC-001, IUC-001, IOC-001 are investigational products and have not been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority.
Imvax’s Goldspire™ Process

1. Tumor excision
2. Tumor cells and antisense oligonucleotide
3. Incubation
4. Biodiffusion chambers are filled and irradiated
5. Chambers implanted in abdomen
6. Chambers explanted from abdomen

- Complete manufacturing in less than a day
- Implanted once for 48 hours, then explanted
Advantages of the Goldspire™ Platform

- Captures full immune-related signals
- Avoids off-target effects
- Fits into standard of care
- Activates broad immune response
- Overnight tissue processing

Immune Response Attacks Tumors on Multiple Fronts

1. **IMMUNOGENIC CELL DEATH**
   - Tumor cells
   - IMV-001 antisense oligonucleotide
   - IGV-001 plus radiation causes tumor cell death in the chambers that are implanted, leading to immune response

2. **APCs ACTIVATED**
   - Antigens and IMV-001 antisense oligonucleotide pass through the chamber’s small pores and are picked up by cells of the immune system (APCs)

3. **T CELLS PRIMED**
   - Activated APCs reach sentinel lymph nodes and prime local T cells against the tumor

4. **T CELLS SLOW DOWN CANCER GROWTH AND KILL TUMOR CELLS**
   - The T cells find the tumor and cause tumor cell death, getting the immune system ready to guard against future tumors
1. Tumor cells treated with IMV-001 antisense are placed in biodiffusion chambers (BDCs) and irradiated
2. Tumor cells undergo stress leading to immunogenic cell death (ICD)
3. ICD results in production of high mobility group box 1 (HMGB1) and damage-associated molecular patterns (DAMPs) which are released from stressed/dying cells inside the BDCs and from the surrounding damaged tissue at the abdominal implantation site
4. Simultaneously, ICD results in a tumor antigen payload (<0.1 μm in size) being released from the BDCs
5. Dendritic cells (DCs) are recruited by DAMPs adjuvanticity and mature upon tumor antigen uptake
6. DC-primed T cells undergo clonal expansion, and tumor-antigen specific T cells kill tumor cells

This figure was created with BioRender.com and then further modified.

Imvax’s Goldspire™ Platform
Fits Seamlessly Into Standard-of-care Treatment for Newly Diagnosed Glioblastoma

**STANDARD OF CARE**

<table>
<thead>
<tr>
<th>Tumor removed</th>
<th>Inpatient recovery</th>
<th>Patient discharge</th>
<th>Outpatient treatment</th>
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<tr>
<td><img src="image" alt="Tumor removed" /></td>
<td><img src="image" alt="Inpatient recovery" /></td>
<td><img src="image" alt="Patient discharge" /></td>
<td><img src="image" alt="Chemotherapy" /> <img src="image" alt="Radiotherapy" /></td>
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**IGV-001 + STANDARD OF CARE**

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<td>IMV-001 antisense oligonucleotide</td>
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<td><img src="image" alt="Patient discharge" /></td>
<td><img src="image" alt="Chemotherapy" /> <img src="image" alt="Radiotherapy" /></td>
</tr>
<tr>
<td><img src="image" alt="Tumor removed" /></td>
<td><img src="image" alt="&lt;1 day manufacturing process" /> <img src="image" alt="Chambers implanted" /> <img src="image" alt="Chambers removed" /> <img src="image" alt="48 hours" /></td>
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**IMVAX’S GOLDSPIRE™ PLATFORM**

- **DAY 0**
- **DAYS 1-3**
- **DAY 4**
- **DAY 43**

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Phase 2b study of IGV-001 in newly diagnosed glioblastoma is enrolling (NCT04485949)
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

*Each chamber is smaller than a dime.

Up to 10 chambers implanted on each side

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*

After treatment with IGV-001, patients went on to standard treatment (or SOC)* with radiation and temozolomide (an FDA*-approved treatment for glioblastoma)

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

SAFETY

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) medical management.

10.6 MONTHS LONGER

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

22 MONTHS LONGER

EFFICACY

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

Sponsor | ClinicalTrials.gov identifier | Protocol number
Imvax, Inc. | NCT04485949 | 14379-201

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.

*TUMOR

CHAMBER*

*Each chamber is smaller than a dime.

IGV-001

PATIENT’S ABDOMEN

Up to 10 chambers implanted on each side.

*AE, adverse event; SOC, standard of care.
OBJECTIVES

PRIMARY OBJECTIVE
Survival without worsening of disease

SECONDARY OBJECTIVE
Survival overall

SAFETY OBJECTIVE
Safety and tolerability

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

*RT, radiotherapy; SOC, standard of care; TMZ, temozolomide.

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

*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.
Patients are randomly assigned to IGV-001 or placebo groups.

**SCREENING**
Day −14 through Day −3

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

**SCREENING/RANDOMIZATION**
Day −2 through Day 0

Patients are randomly assigned to IGV-001 or placebo groups.

**SOC* TREATMENT**
Week 7 through Week 41

The usual treatment is RT* and chemotherapy.

**TREATMENT**
Day 1 through Day 28

Superficial abdominal incision to the rectus muscle (after randomization).

**FOLLOW-UP**
Month 10 through Month 36

Doctors keep track of patients’ health after treatment.

**WEEK 0**

**MONTH 36**

Doctors will confirm brain tumor using frozen sample.

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

The usual treatment is RT* and chemotherapy.

*MRI, magnetic resonance imaging; N, number of patients; RT, radiotherapy; SOC, standard of care; TMZ, temozolomide.
For more information:

imvax.com/patients-families  clinicaltrials.gov/study/NCT04485949