

# Imvax Corporate Overview

A unique platform for personalized, whole tumorderived immunotherapies with compelling clinical data in glioblastoma

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June 2024

### Imvax: Goldspire Platform Provides Broad Oncology Opportunity; Initial Focus on Glioblastoma Supported by Compelling Early Clinical Data

- Imvax's Goldspire<sup>™</sup> platform is a personalized therapy inducing antitumor immunity using a patient's own tumor cells
  - Platform has applicability across a broad range of solid tumors
  - Strong patent portfolio covering use of biodiffusion chambers (BDCs) to treat GBM
- Streamlined manufacturing is efficiently scalable to commercial volumes and yields low cost of goods

 IGV-001: registration-enabling Phase 2b study for the treatment of patients with ndGBM<sup>1</sup>



GBM represents a multi-billion dollar opportunity in an area of significant unmet need



IGV-001's compelling Phase 1b data<sup>2</sup> demonstrated a more than doubling of PFS, OS and 5-yr survival vs. current SOC



Full enrollment in potentially registrationenabling Phase 2b study completed in May 2024



#### **Track Record of Execution and Near-Term Data Readout**



Demonstrated compelling Phase 1b clinical data in glioblastoma<sup>1</sup>



Completed enrollment for Phase 2b clinical study



Established in-house GMP manufacturing supplying registration-enabling Phase 2b study



Recently closed \$57 million financings provide funding through upcoming data readout



Generated robust preclinical data extending the Goldspire platform to other indications



Received Orphan Drug designation and Fast Track designation from FDA for IGV-001



Published mechanism-of-action paper in *The Journal for ImmunoTherapy of Cancer*<sup>2</sup>



Data from Phase 2b clinical trial anticipated in mid-2025





### **GBM** is a Large and Poorly Served Patient Population<sup>1</sup>



GBM is the **most common** malignant tumor of the brain and central nervous system

- Approximately 14,000 newly diagnosed patients in the U.S. annually
- Conservative assumptions translate to a \$4-\$5 billion peak sales opportunity in the U.S. alone



GBM patients are underserved with no recent innovation

- No change to standard of care since establishment of Stupp protocol<sup>2</sup> in 2005
- Fewer than 7% of GBM patients survive to five years after diagnosis
- Overall survival of ~ 16 months with existing standard of care therapy





### Phase 1b Study in ndGBM Demonstrated Compelling Efficacy Across Broad Spectrum of Patients with Favorable Safety Profile<sup>1</sup>

- 33 patients randomized to receive varying number of BDCs over different time periods
- Broad inclusion criteria resulted in enrollment of difficult to treat patients
- Statistically significant PFS and OS benefits compared to historical standard of care
  - Particularly at higher doses and when the Stupp Inclusion/Exclusion criteria are applied
  - Even more compelling in the MGMT+ subgroup of patients

- Favorable safety profile observed
  - Adverse events largely procedure related and addressed during the study

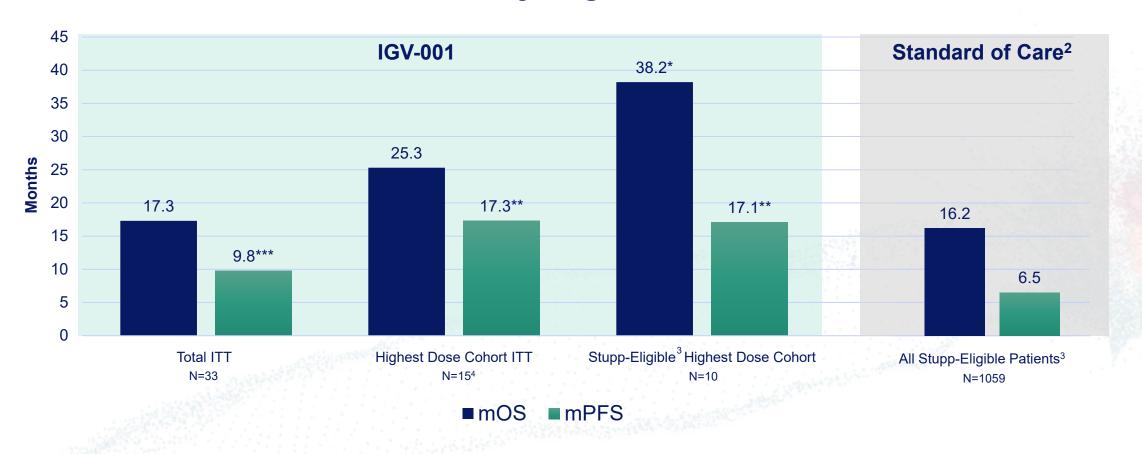
Number of chambers and length of implantation				
	24 hours	48 hours		
10 chambers	N = 6	N = 5		
20 chambers	N = 5	N = 17*		

<sup>\*</sup> Includes two patients with bihemispheric/multicentric disease



### Phase 1b Efficacy Data<sup>1</sup>: Compelling Across Broad Spectrum of Patients

#### **Patients with Newly Diagnosed Glioblastoma**

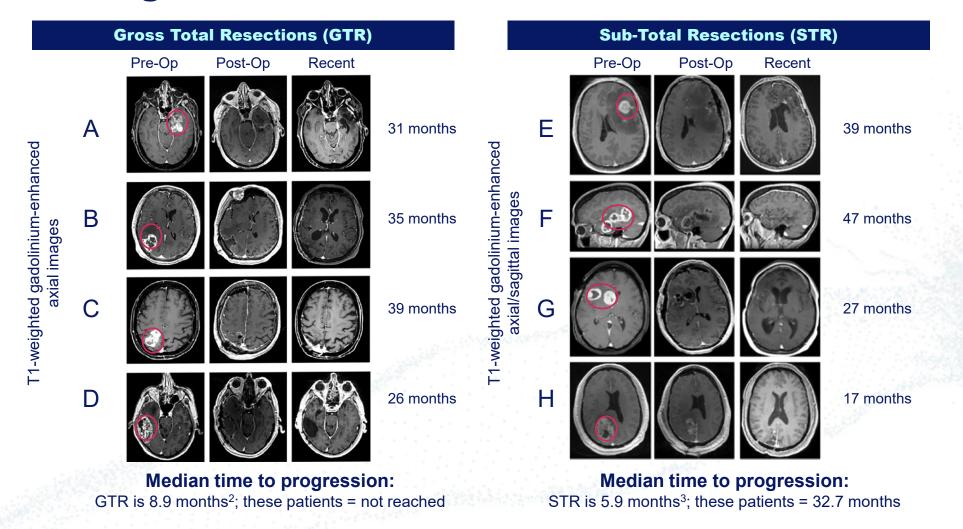




<sup>1</sup> Andrews, D.W., et al. Clin Cancer Res. 2021;27(7):1912-1922 2 SOC data only available for age cut < vs.> 60 in Stupp; Stupp et al. Lancet Oncol 10: 459-466

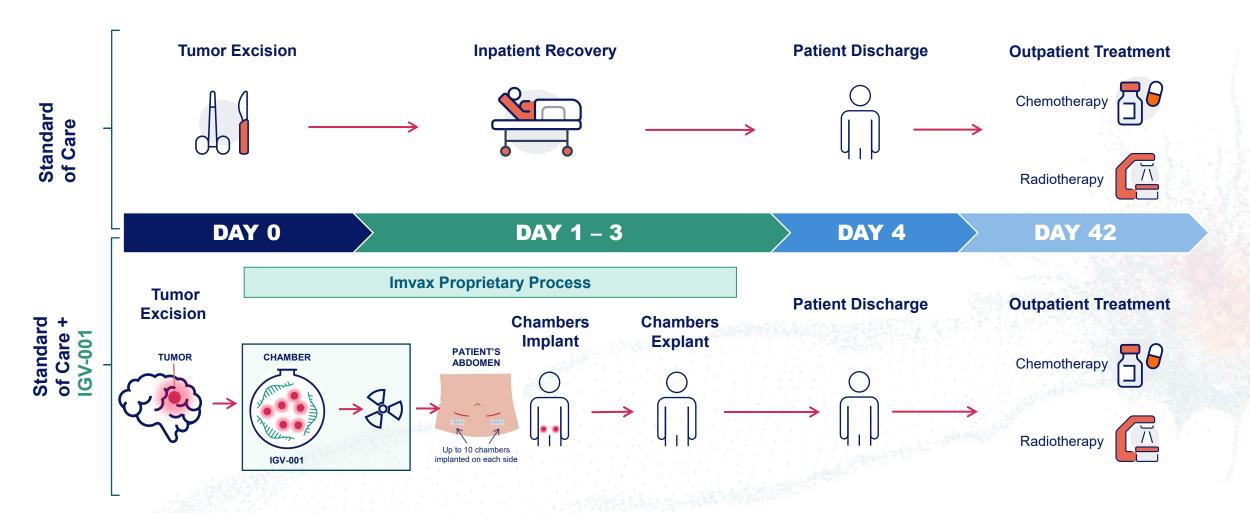
Stupp-Eligible excludes >/U yrs old and extensive intracrania
 Excludes two patients with bihemispheric/multicentric disease.

### Radiographic Responses in Phase 1b Study Show Meaningful Delay to Disease Progression<sup>1</sup>





#### **Goldspire Platform Fits Seamlessly into GBM Standard of Care**



### Phase 2b Study Fully Enrolled in 1H 2024

- Phase 2b study seeks to build on groundbreaking Phase 1b results
  - Randomized, placebo-controlled Phase 2b study assessing IGV-001 in patients with ndGBM postcraniotomy
  - Study compares one-time treatment of IGV-001 plus SOC (radiotherapy + temozolomide) vs. placebo plus SOC
- PFS is the primary efficacy endpoint and OS is a key secondary endpoint

- Study fully enrolled in 13 months
  - Enrolled ~ 100 patients across 19 US sites with 2:1 randomization
  - Strong adoption by the clinical trial sites
- Potential PFS readout in mid-2025 followed by OS in mid-2026
- Phase 2b study represents a potential path to accelerated approval in ndGBM



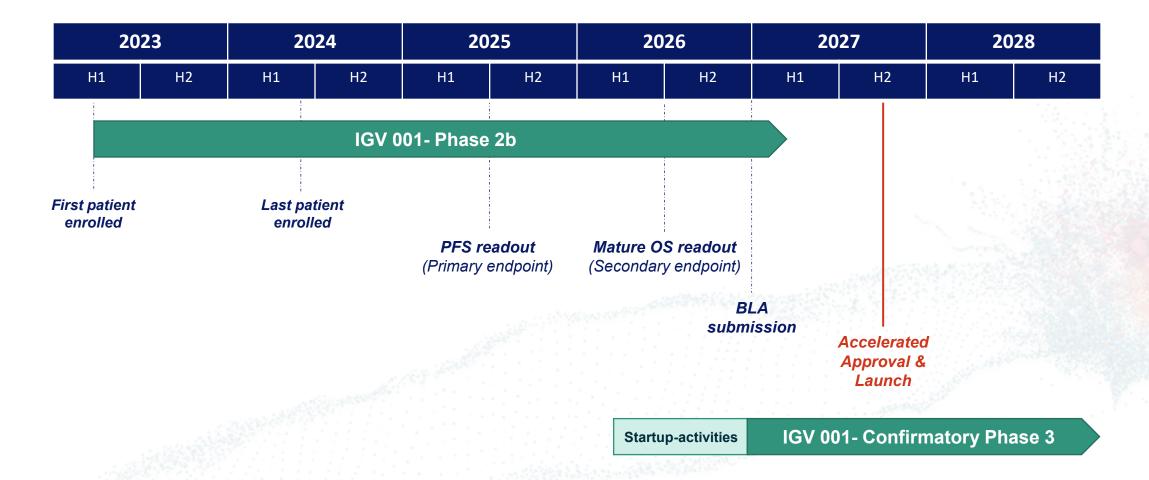
### Clinician Demand is High for Even Modest Efficacy Improvements in ndGBM

- Stupp 2005 trial resulted in the most recent major advance in treatment of ndGBM
  - Improvement in median PFS from 5.0 to 6.9 months
  - Improvement in median OS from 12.1 to 14.6 months
- Imvax Phase 1b trial resulted in median PFS of 17.1 months and median OS of 38.2 months in Stupp-eligible patients at the highest dose
  - 5-year survival of 15% is more than double historical survival rates

Improving PFS by at least 3.5 months in the Phase 2b trial would be clinically meaningful for providers and patients



### PFS Readout in mid-2025 Could Trigger BLA Submission Activities





### **Goldspire Platform Provides Multiple Benefits**







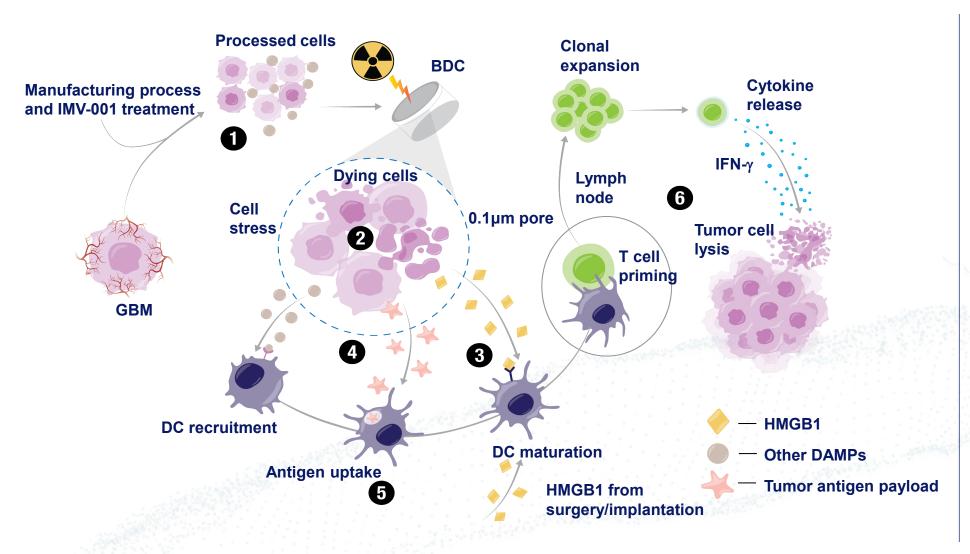




#### **Goldspire Platform has Advantages Over Traditional Cell Therapy**

		Cell therapy	Imvax process
Clinical	Product delivery time	~30 days	~1–2 days
	Hospital stay	~10 – 14 days on average	~2–3 days (fits within SOC)
	Additional requirements	Conditioning therapy for optimal efficacy	N/A
	Main safety concerns	Lymphodepletion, cytokine release syndrome, patients with weakened immune systems	Implant and explant procedures
Manufacturing	Processing time	7–9 days	~0.5 days
	Shipping logistics	Transporting cells (requires prior preservation)	Transporting live tissue
	Time to new facility	4-5 years	~2.5 years
Financial	Capital requirements	~\$400–500M / facility	~\$50M / facility (3 regional facilities required)
	COGS	Higher (extended manufacturing timeline, cost to prior preserve, raw materials to grow cells)	Lower (expedited manufacturing turnaround, low cost of raw materials)
	Gross margin	Lower	Higher

### **IGV-001 Manufacturing Process and Mechanism of Action**



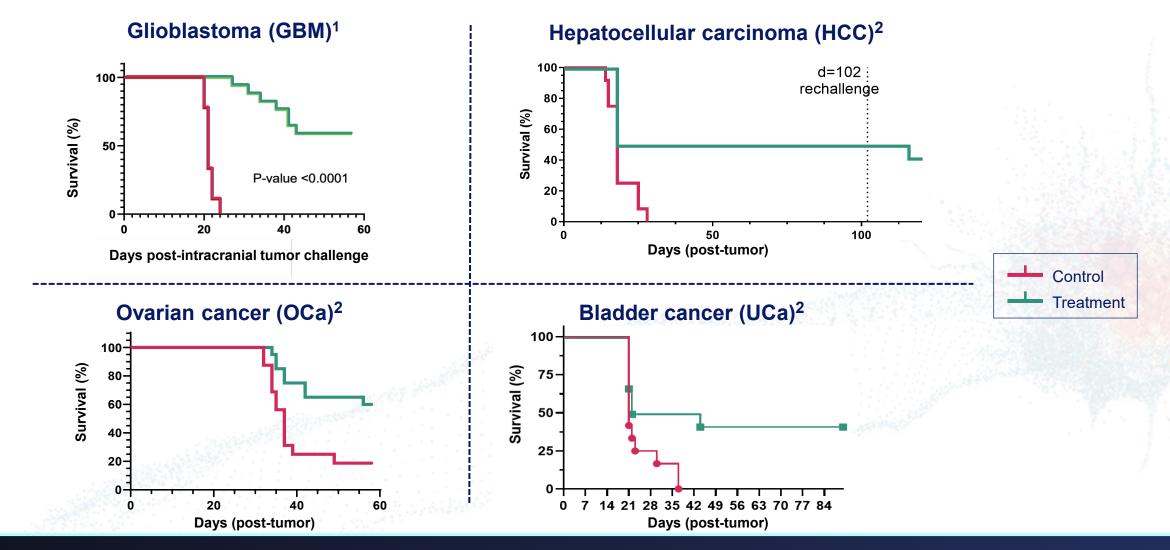
- . Tumor cells treated with IMV-001 antisense are placed in BDCs and irradiated
- Tumor cells undergo stress leading to ICD
- 3. ICD results in production of HMGB1 and DAMPs which are released from stressed/dying cells inside the BDCs and from the surrounding damaged tissue at the abdominal implantation site
- Simultaneously, ICD results in a tumor antigen payload (<0.1 μm in size) being released from the BDCs
- DCs are recruited by DAMPs adjuvanticity and mature upon tumor antigen uptake
- 6. DC-primed T cells undergo clonal expansion, and tumorantigen specific T cells kill tumor cells

# **Preclinical Data Support Platform in Broad Range of Solid Tumors**

Tumor	Model Status	
Glioblastoma	Compelling activity, additional combo activity	
Ovarian	Compelling durable activity	
Hepatocellular carcinoma	Compelling durable activity, rechallenge data	
Bladder	Compelling durable activity	
Pancreatic ductal adenocarcinoma	Modest statistical benefit to date	
Colorectal carcinoma	Modest statistical benefit to date	

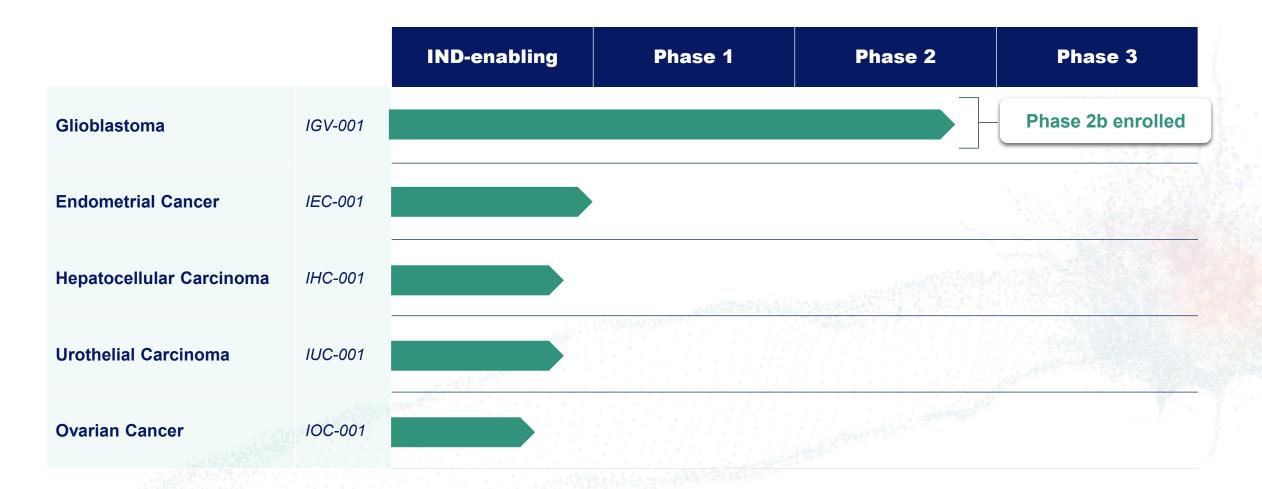


# In Vivo Data Demonstrate Extended Survival in Multiple Animal Models



#### **Imvax's Goldspire Pipeline:**

**GBM Opportunity Unlocks Potential in Broad Range of Solid Tumors** 





#### **Financing Overview**

- Over \$200 million raised to date to support
  - Late-stage clinical trial for IGV-001 in GBM
  - Buildout and validation of in-house GMP manufacturing facility
  - Validation of technology across numerous solid tumor indications
- Current cash runway into late 2025
- Key institutional investors include:



















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