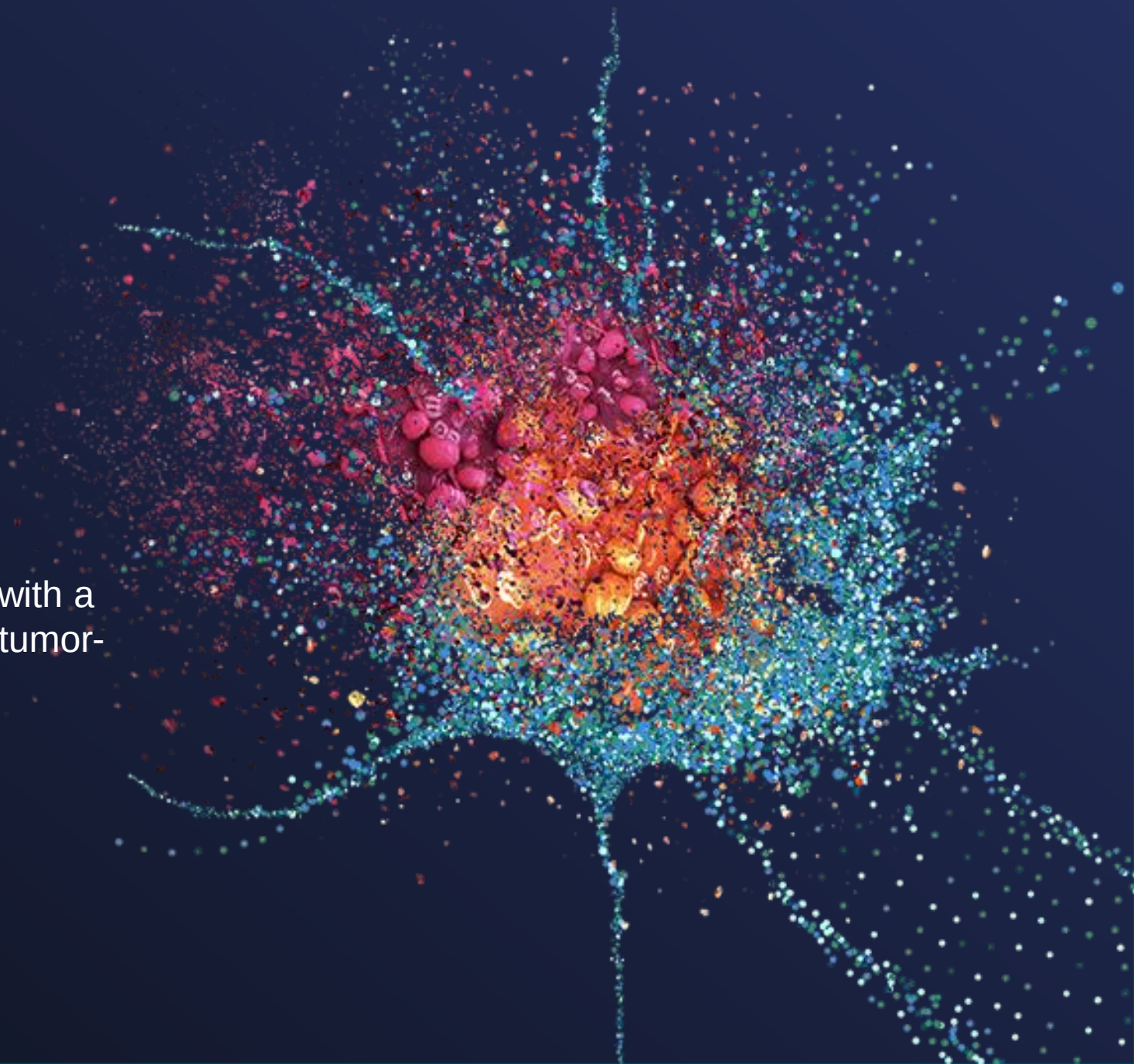
Imvax™

Imvax Corporate Overview

A clinical-stage biotechnology company with a unique platform for personalized, whole tumor-derived immunotherapies



September 2023

Imvax: A late-stage oncology opportunity

- Lead asset to treat newly-diagnosed GBM (ndGBM) currently in Phase 2b
  - Seeking to build on groundbreaking Phase 1b data
  - Potential to file for approval on completion of the trial
  - Full enrollment expected in 1st half of 2024
  - High unmet need in GBM with no improvements in last two decades could result in multibillion dollar market opportunity
- Imvax Goldspire™ platform is a personalized therapy that aims to induce antitumor immunity using a patient's own tumor cells; applicability across multiple solid tumor types
- Additional IND filing planned for endometrial cancer in 2024
- Seasoned leadership team with deep biopharma development and commercialization experience

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Recent accomplishments and near-term milestones

- [x] IND approved & initiated Phase 2b clinical trial; 20 sites activated and enrolling
- [x] Published mechanism-of-action paper in *The Journal for ImmunoTherapy of Cancer*
- [x] Established in-house GMP manufacturing currently supplying Phase 2b trial
- [x] Generated robust preclinical data extending the Goldspire platform to other indications
- [ ] 2024 IND filing for endometrial cancer
- [ ] Full enrollment in 1H 2024

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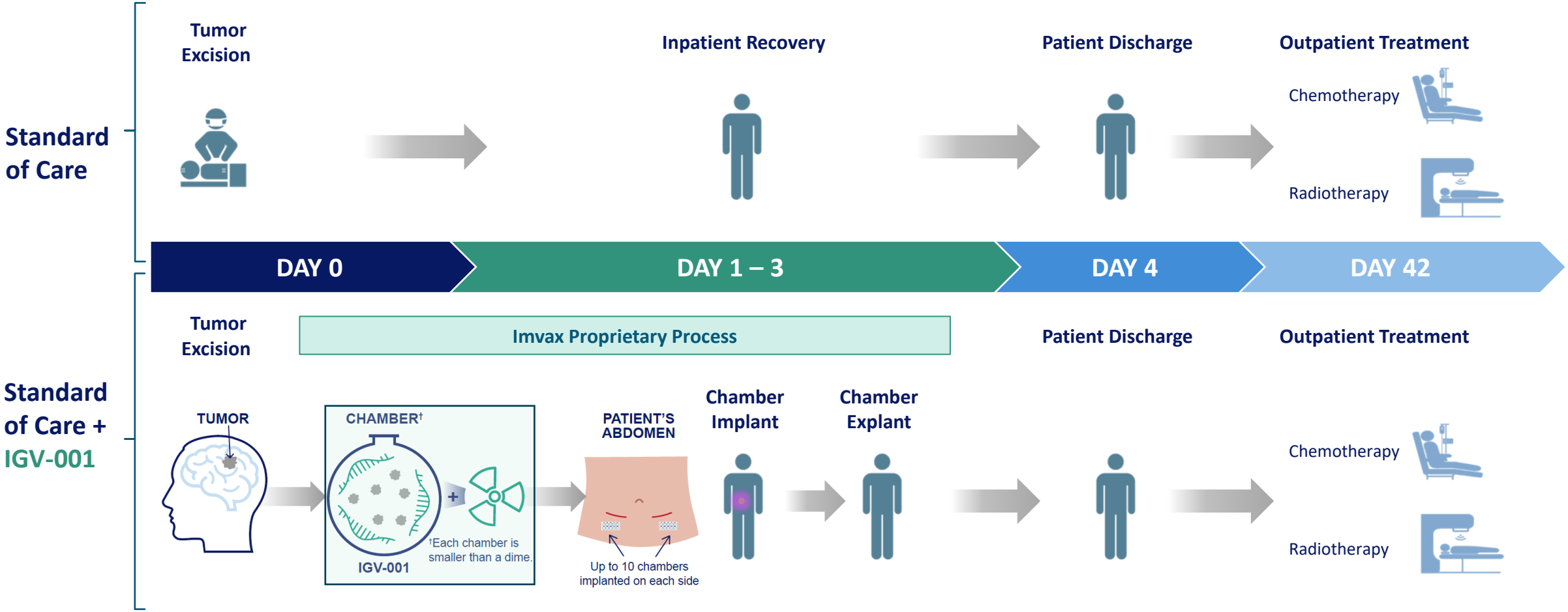
Lead Program: GBM

GBM Program Overview

- GBM is the most common malignant tumor of the brain and CNS
- ndGBM patients have median overall survival (OS), or life expectancy, of approximately 16 months, with less than 7% of GBM patients survive to five years after diagnosis
    - Standard of care (SOC) treatment is surgery followed by radiotherapy and chemotherapy
- Orphan Drug Designation granted by FDA; approximately 14,000 newly diagnosed patients in the US annually
    - Underserved market with no recent innovation
- Imvax therapeutic approach fits seamlessly into GBM SOC
- Strong patent portfolio covering use of biodiffusion chambers (BDCs) in combination with irradiated tumor cells and antisense to treat GBM
    - Exclusively licensed from Thomas Jefferson University

Goldspire fits seamlessly into GBM standard of care

Currently enrolling Phase 2b trial for Newly-Diagnosed GBM



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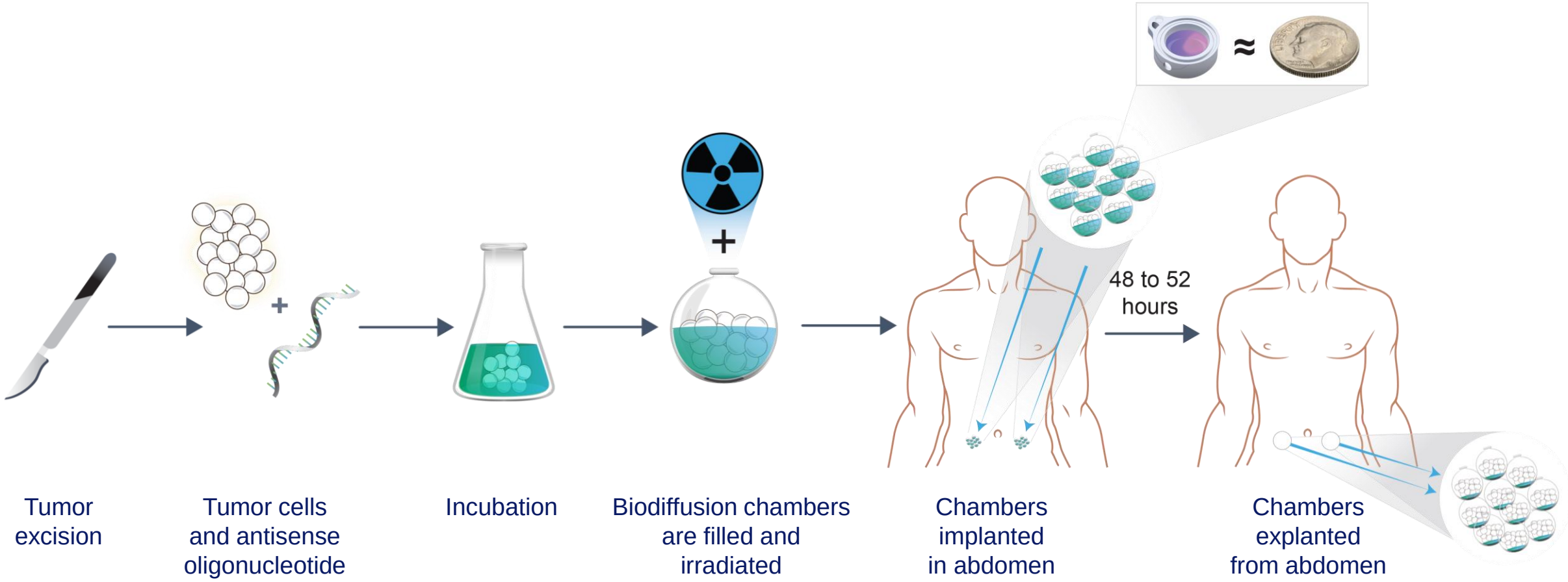
Imvax's Goldspire process



- Complete manufacturing in less than a day
- Implanted <u>once</u> for 48 hours, then explanted

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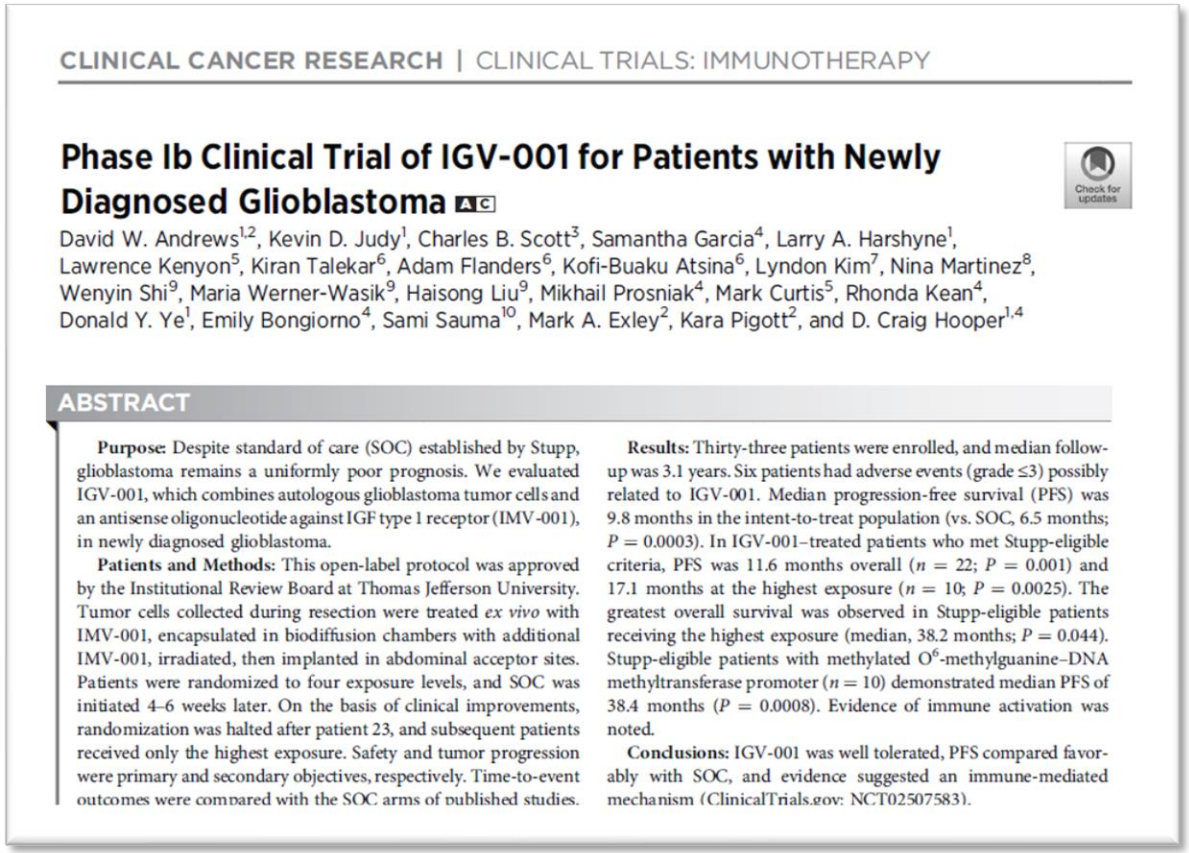
Phase 1b results published in peer-reviewed *Clinical Cancer Research* in April 2021

- Phase 1b trial of IGV-001 in patients with newly-diagnosed glioblastoma
- Primary and secondary objectives were safety and tumor progression
- Broad inclusion criteria resulted in enrollment of difficult to treat patients
- 33 patients randomized to receive varying number of BDCs and/or differing lengths of exposure

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

* 15 patients if two patients with bihemispheric/multicentric disease excluded



CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

Phase Ib Clinical Trial of IGV-001 for Patients with Newly Diagnosed Glioblastoma

David W. Andrews[1,2], Kevin D. Judy[1], Charles B. Scott[3], Samantha Garcia[4], Larry A. Harshyne[1], Lawrence Kenyon[5], Kiran Talekar[6], Adam Flanders[6], Kofi-Buaku Atsina[6], Lyndon Kim[7], Nina Martinez[8], Wenyin Shi[9], Maria Werner-Wasik[9], Haisong Liu[9], Mikhail Prosniak[4], Mark Curtis[5], Rhonda Kean[4], Donald Y. Ye[1], Emily Bongiorno[4], Sami Sauma[10], Mark A. Exley[2], Kara Pigott[2], and D. Craig Hooper[1,4]

ABSTRACT

Purpose: Despite standard of care (SOC) established by Stupp, glioblastoma remains a uniformly poor prognosis. We evaluated IGV-001, which combines autologous glioblastoma tumor cells and an antisense oligonucleotide against IGF type 1 receptor (IMV-001), in newly diagnosed glioblastoma.

Patients and Methods: This open-label protocol was approved by the Institutional Review Board at Thomas Jefferson University. Tumor cells collected during resection were treated *ex vivo* with IMV-001, encapsulated in biodiffusion chambers with additional IMV-001, irradiated, then implanted in abdominal acceptor sites. Patients were randomized to four exposure levels, and SOC was initiated 4–6 weeks later. On the basis of clinical improvements, randomization was halted after patient 23, and subsequent patients received only the highest exposure. Safety and tumor progression were primary and secondary objectives, respectively. Time-to-event outcomes were compared with the SOC arms of published studies.

Results: Thirty-three patients were enrolled, and median follow-up was 3.1 years. Six patients had adverse events (grade ≤3) possibly related to IGV-001. Median progression-free survival (PFS) was 9.8 months in the intent-to-treat population (vs. SOC, 6.5 months; $P = 0.0003$). In IGV-001–treated patients who met Stupp-eligible criteria, PFS was 11.6 months overall ($n = 22$; $P = 0.001$) and 17.1 months at the highest exposure ($n = 10$; $P = 0.0025$). The greatest overall survival was observed in Stupp-eligible patients receiving the highest exposure (median, 38.2 months; $P = 0.044$). Stupp-eligible patients with methylated O^6-methylguanine–DNA methyltransferase promoter ($n = 10$) demonstrated median PFS of 38.4 months ($P = 0.0008$). Evidence of immune activation was noted.

Conclusions: IGV-001 was well tolerated, PFS compared favorably with SOC, and evidence suggested an immune-mediated mechanism (ClinicalTrials.gov: NCT02507583).

https://clincancerres.aacrjournals.org/content/27/7/1912

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Phase 1b study met safety endpoints

Efficacy data compelling across broad spectrum of patients

Patients with Newly Diagnosed Glioblastoma				
	IGV-001 Phase 1b Study			Standard of Care[1]
Groups	**Total ITT**	**Highest Dose Cohort ITT**	**Stupp-Eligible[2] Highest Dose Cohort**	**All Stupp-Eligible Patients[2]**
Patients (n)	(n=33)	(n=15)[3]	(n=10)	(n=1,059)
mOS	17.3 months	25.3 months	38.2** months	16.2 months
mPFS	9.8* months	17.3** months	17.1** months	6.5 months

- No concerns regarding **safety** profile of product; AEs largely procedural related and addressed during the trial
- ***Statistically significant*** **PFS and survival benefits** compared to SOC seen particularly at higher exposures ITT and when the Stupp Inclusion/Exclusion criteria are applied and even more significant in the MGMT+ subgroup of patients

Note: figures based on May 1, 2020 data cut-off. * $p < 0.05$, ** $p < 0.01$, and *** $p < 0.001$

1 SOC data only available for age cut < vs.> 60 in Stupp; Stupp et. al. Lancet Oncology 10: 459-466 (2009)

2 Stupp-Eligible excludes >70 yrs old and extensive intracranial disease in both hemispheres or multi-centric disease

3. Excludes two patients with bihemispheric/multicentric disease

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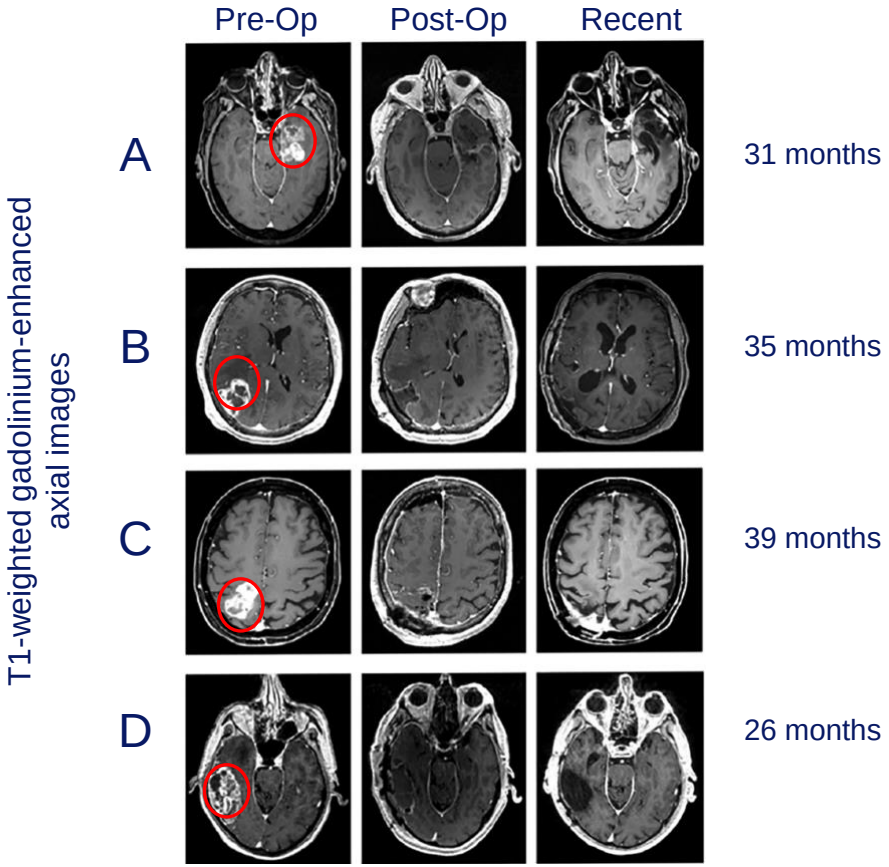
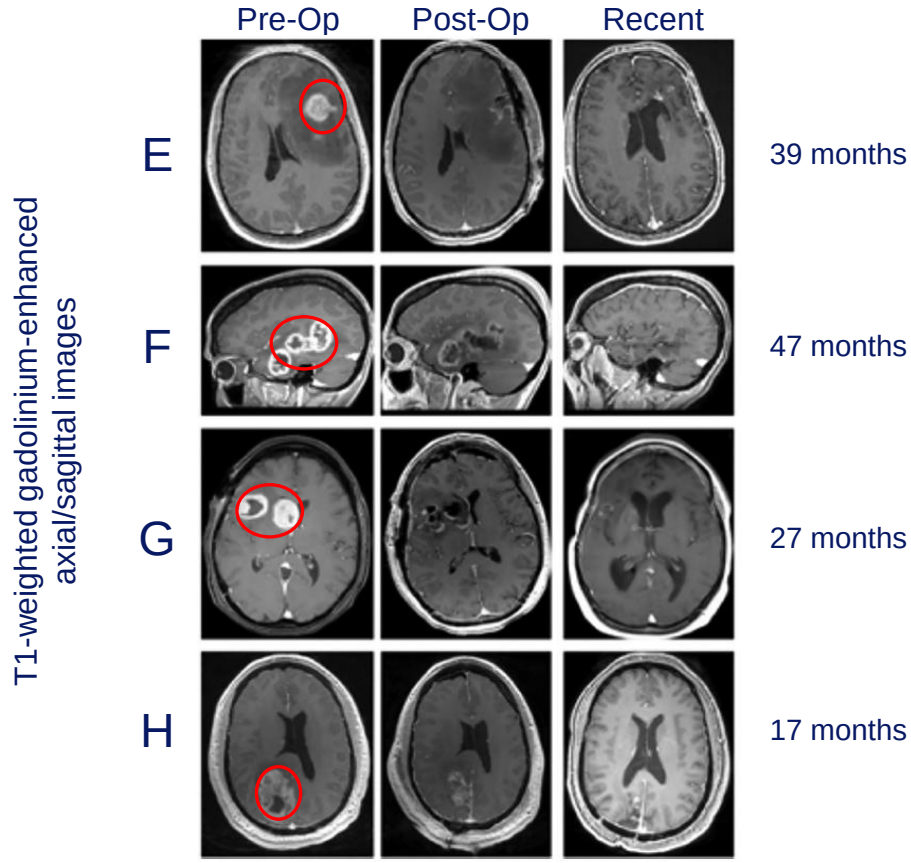
Radiographic responses in Phase 1b study show meaningful delay to disease progression

Gross Total Resections (GTR)



Median time to progression:
GTR is 8.9 months[1]; these patients = not reached

Sub-Total Resections (STR)



Median time to progression:
STR is 5.9 months[2]; these patients = 32.7 months

1 Chaichana KL et. al. (2014) World Neurosurgery 82: 257-265
2 Fukui A et. al. (2017) World Neurosurgery 98: 73-80

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Phase 2b clinical trial underway

- Imvax's GBM program seeks to build on groundbreaking Phase 1b data
- Randomized, multicenter, double-blind, placebo-controlled, Phase 2b study to assess IGV-001 in newly diagnosed patients with glioblastoma post-craniotomy
- Compares efficacy of a one-time treatment with IGV-001 (20 chambers for 48 hours) plus SOC GBM therapy (radiotherapy + temozolomide) with SOC GBM therapy alone
- 93 patients will be randomized 2:1 (IGV-001 + SOC vs SOC) at up to 20 US sites; full enrollment expected in 1st half of 2024
- Primary efficacy endpoint: progression free survival (PFS)
- Secondary efficacy endpoints to include overall survival (OS) and time to definitive deterioration of Karnofsky Performance Scale (KPS)
- Potential PFS data in 2Q 2025 and then OS follow-up in mid-2026

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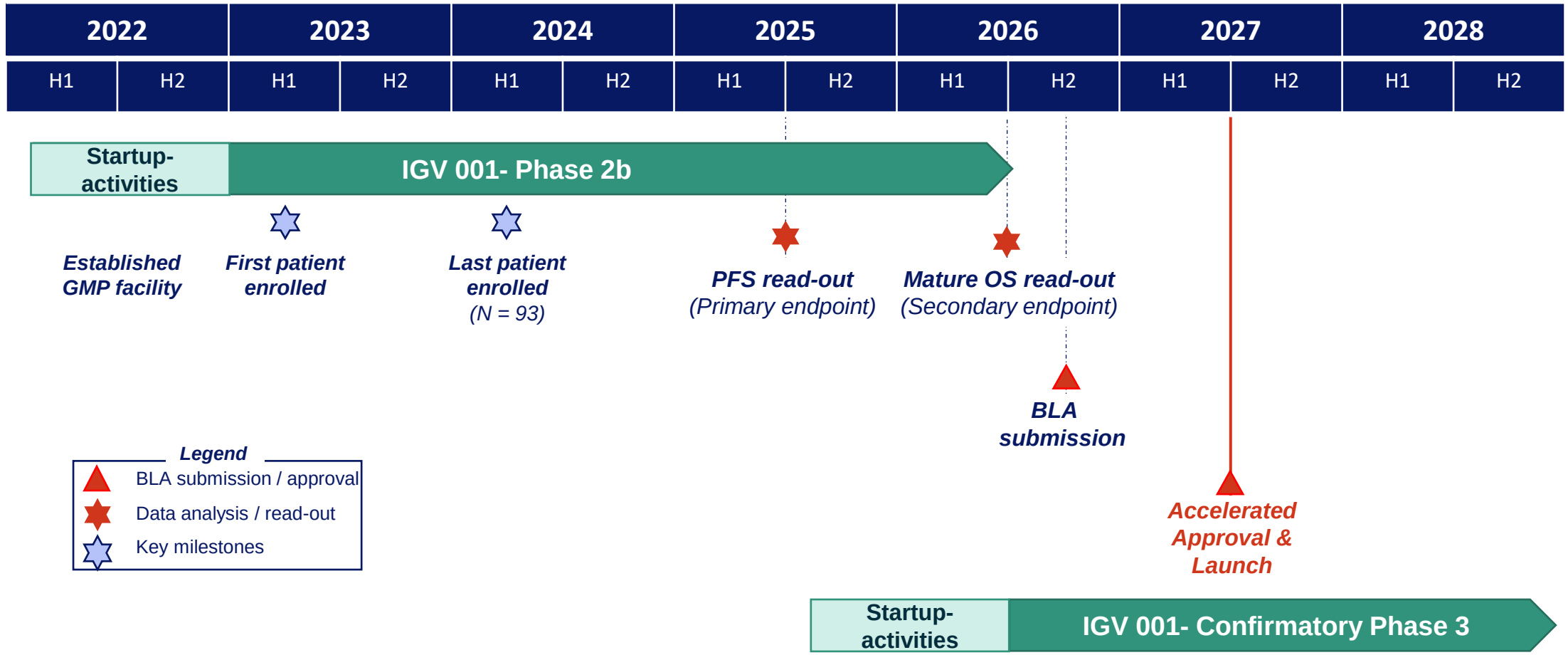
We are on track to complete Phase 2b enrollment in Q2 2024 and plan to file for accelerated approval in next ~3 years



Newly diagnosed GBM is an underserved market

There is a high unmet need …

… Imvax is uniquely positioned to meet it

Projected peak revenues over $2B

- **~25,000 new diagnoses** annually in the US/EU5
- **No recent innovation** despite advances in many other cancers

- **Unique and proprietary** platform
- IGV-001 **fits seamlessly** into current treatment paradigm
- **Potential pricing more than $200K** per patient
- **High margins** from efficient cell processing

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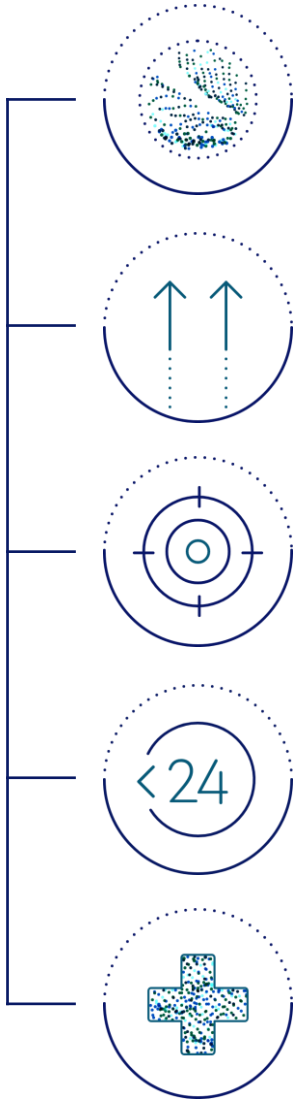
Imvax’s Goldspire Platform

A Powerful Approach to the Complexity
of Solid Tumors

Goldspire platform has multiple advantages



Full antigenic signature capture

Broad spectrum immune activation

No ‘off-target’ effects

Overnight tissue processing

Integrated into the ‘standard of care’

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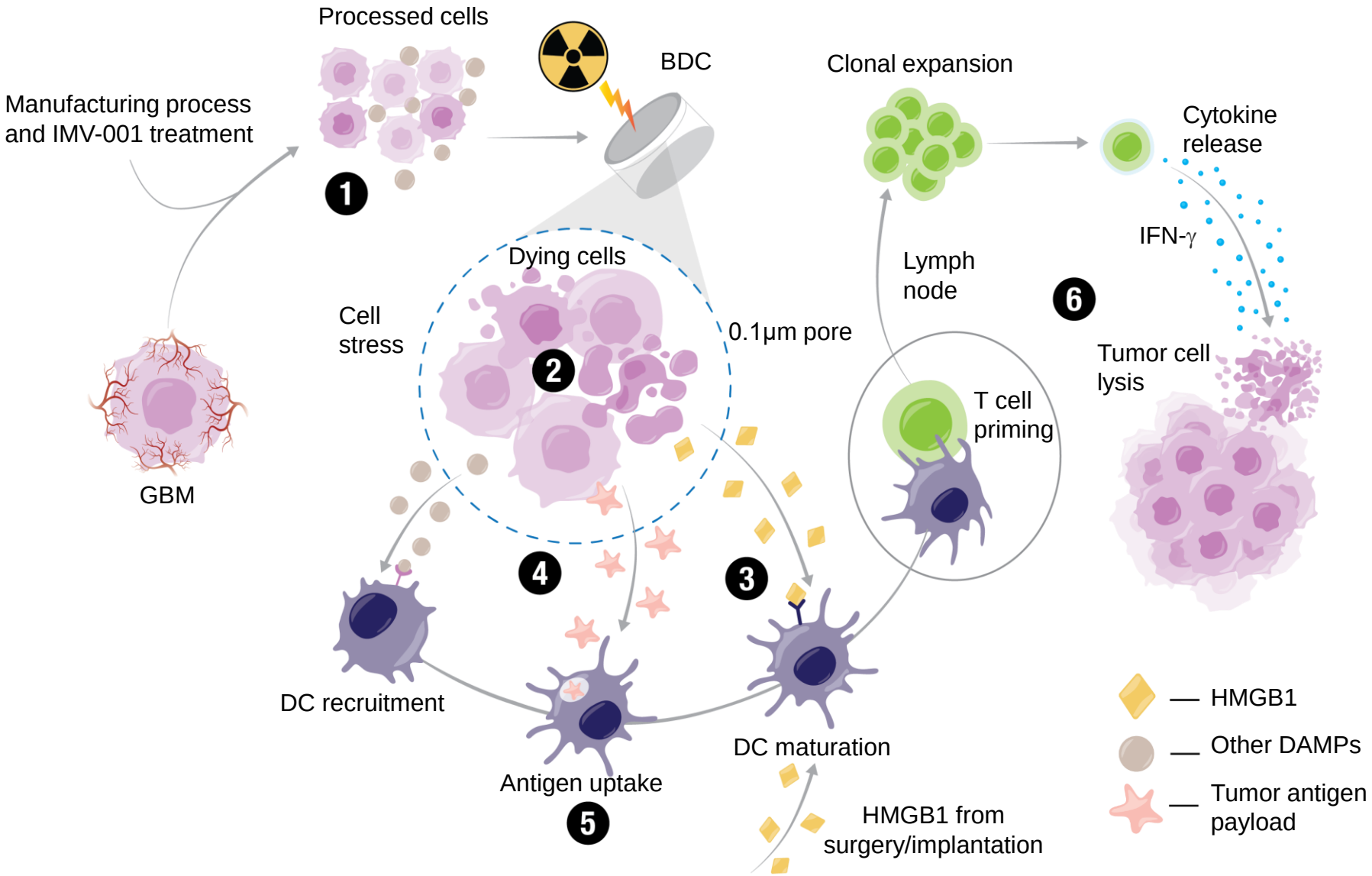
Manufacturing process and MoA of IGV-001



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

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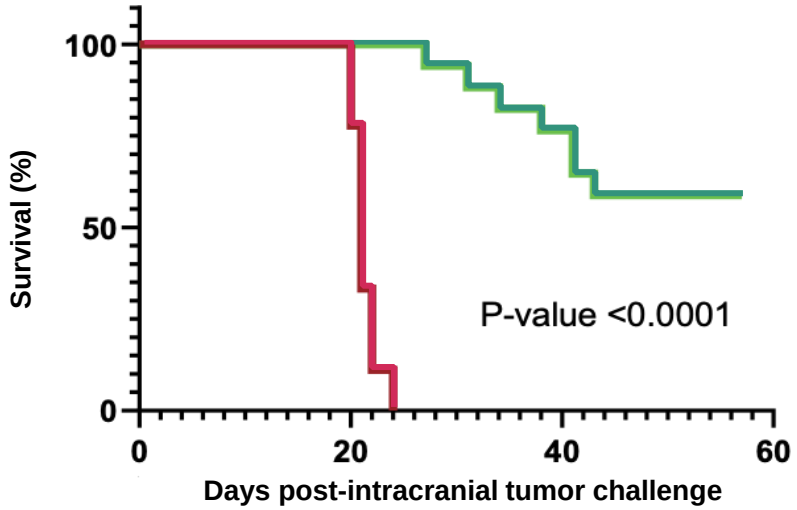
Preclinical data supports platform in a broad range of solid tumors

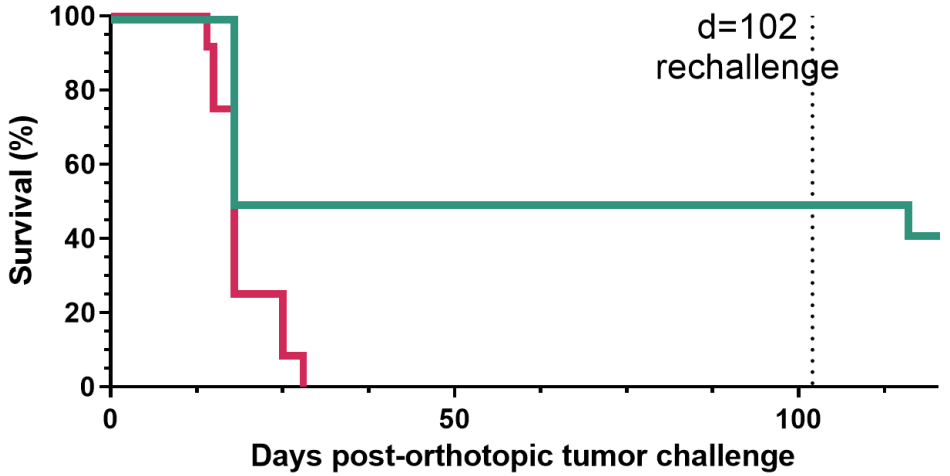
Tumor	Model Status
GBM	Compelling mono-activity, additional combo activity
Ovarian (OCa)	Compelling durable mono-activity
Hepatocellular carcinoma (HCC)	Compelling durable mono-activity, rechallenge data
Bladder (UCa)	Compelling durable mono-activity
Pancreatic ductal adenocarcinoma (PDAC)	Modest statistical benefit to date
Colorectal carcinoma (CRC)	Modest statistical benefit to date

In vivo data demonstrating extended survival in multiple animal models

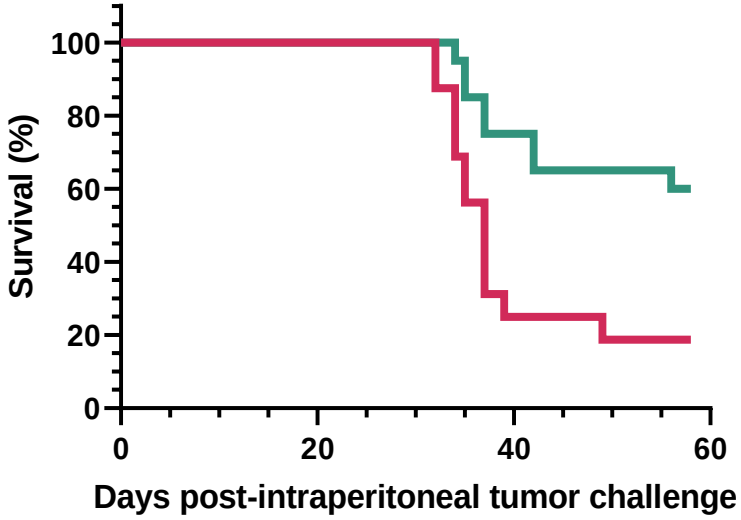
Glioblastoma (GBM)



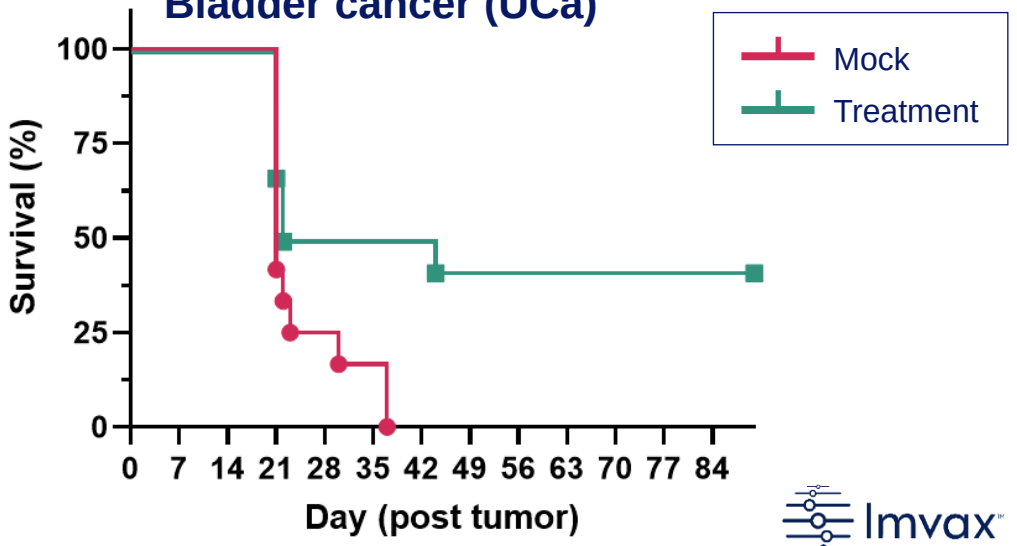
Hepatocellular carcinoma (HCC)



Ovarian cancer (OCa)



Bladder cancer (UCa)



Preclinical data supports MOA and potential in multiple solid tumors

- Powerful anti-tumor effects in multiple early/primary tumor models (GBM, HCC, UCA and ovarian) and modest benefit in PDAC
- Mouse models used same chamber device and antisense molecule as human studies
- Well-tolerated consistent with Ph 1b GBM results
- Immune response correlates across indications, including tumor antigen-specific IFNγ
- Increased activation markers in PBMCs exposed to IGV-001:
  - Increased Dendritic (antigen presenting) Cell activation and T cell memory markers

* Cultrara, et al. (2023) Journal for ImmunoTherapy of Cancer in press

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Imvax's Goldspire pipeline: Focused on solid tumor types

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Team that's been directly involved in development, approval and commercialization of multiple biological modalities

John Furey
CEO
- COO, Spark Tx
- SVP Global Operations, Baxalta
- VP Baxter & Pfizer

David Andrews
CMO, Founder
- Chief, Tumor Division, Dept of Neurosurgery, TJU
- Trained at NY Presbyterian & Memorial Sloan Kettering

Mark Exley
CSO
- VP, AgenTus (now MiNK)
- Co-Founder, NKT Tx
- Harvard & Manchester Faculty
- Current Honorary Academics

Sean Hemingway
COO
- SVP, Global Head of BioLife Plasma Services, Takeda
- SVP, Takeda Manufacturing

John Limongelli
CLO
- SVP, GC, Neos Therapeutics
- SVP, GC, Trevena

Diana Martine
Head of HR
- HR Director, Aramark
- Head of HR, Biocoat

Josh Muntner
CFO
- CFO, Mesoblast
- SVP, Bus Dev, ContraFect
- +15 yrs investment banking

Tyler Curiel
Scientific Advisor
- Prof of Med, Microbiology and Immunology at the Dartmouth Geisel School of Medicine

Shefali Agarwal
Scientific Advisor
- Pres & CEO, Onxeo
- Prev. EVP, CMDO Epizyme

Management
Non-Management

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