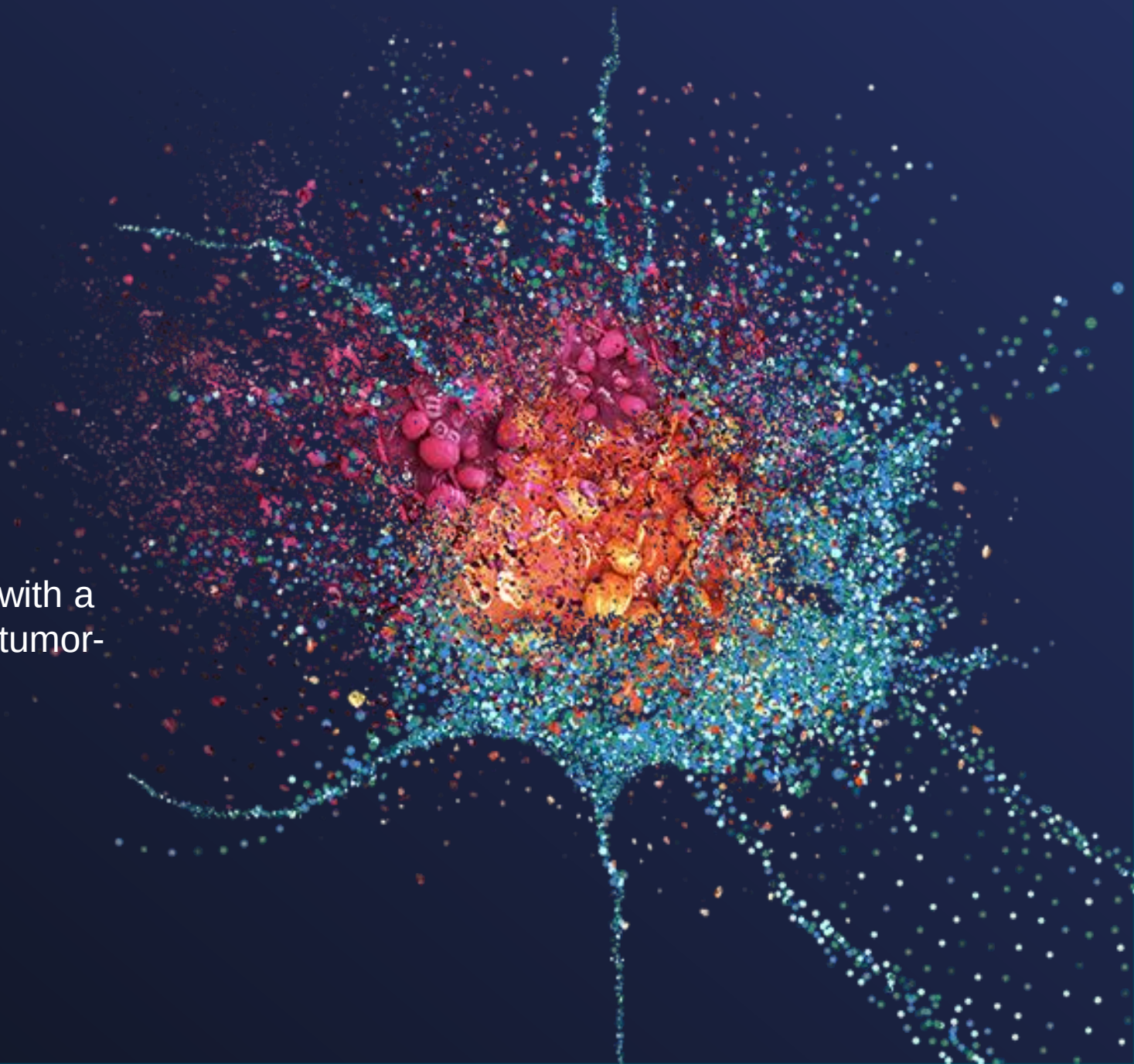
Imvax™

Imvax Corporate Overview

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



June 2023

Imvax: A late-stage oncology opportunity

- The Imvax Goldspire™ platform is a personalized therapy that aims to induce antitumor immunity using a patient's own tumor cells plus a molecule called IMV-001
- 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
- Additional IND planned for endometrial cancer in 2023
- Established GMP manufacturing capabilities at Imvax
- Projected $2B - $3B global peak sales in ndGBM and up to $3B in other pipeline assets
- Seasoned leadership with deep biopharma development and commercialization experience

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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 and CS, 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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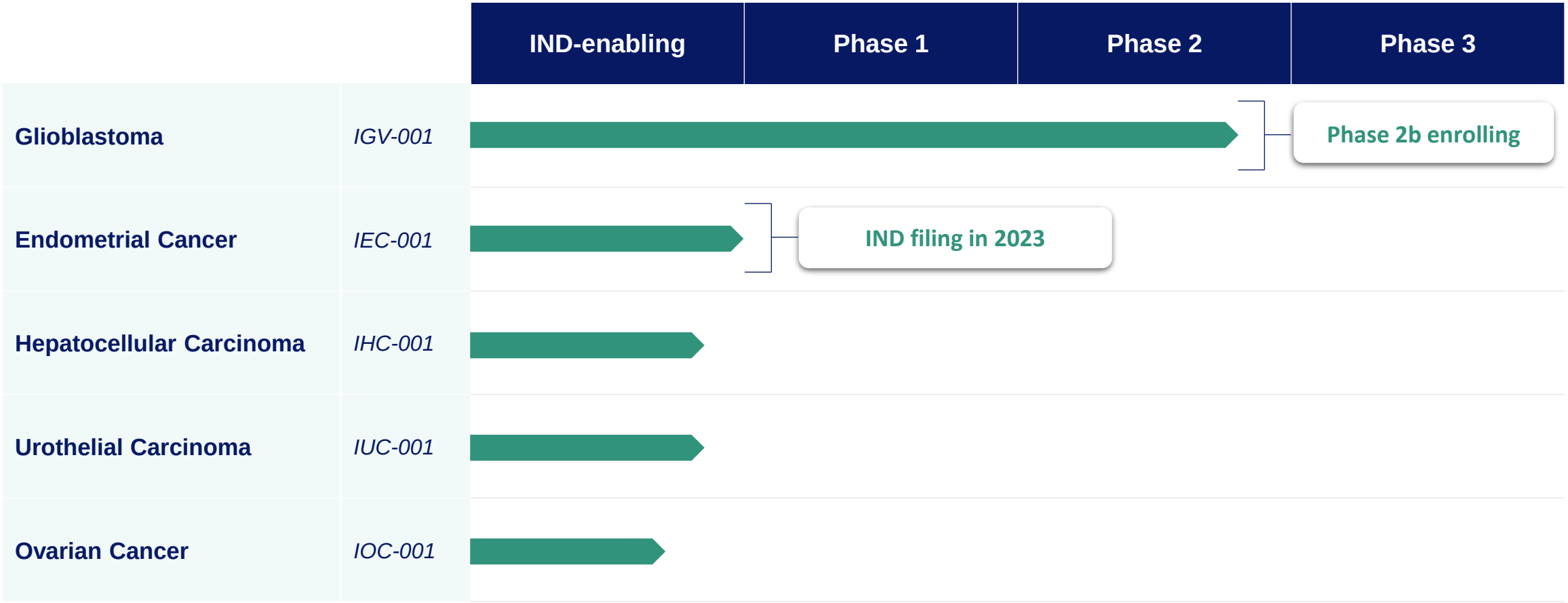
Imvax's Goldspire pipeline: Focused on solid tumor types



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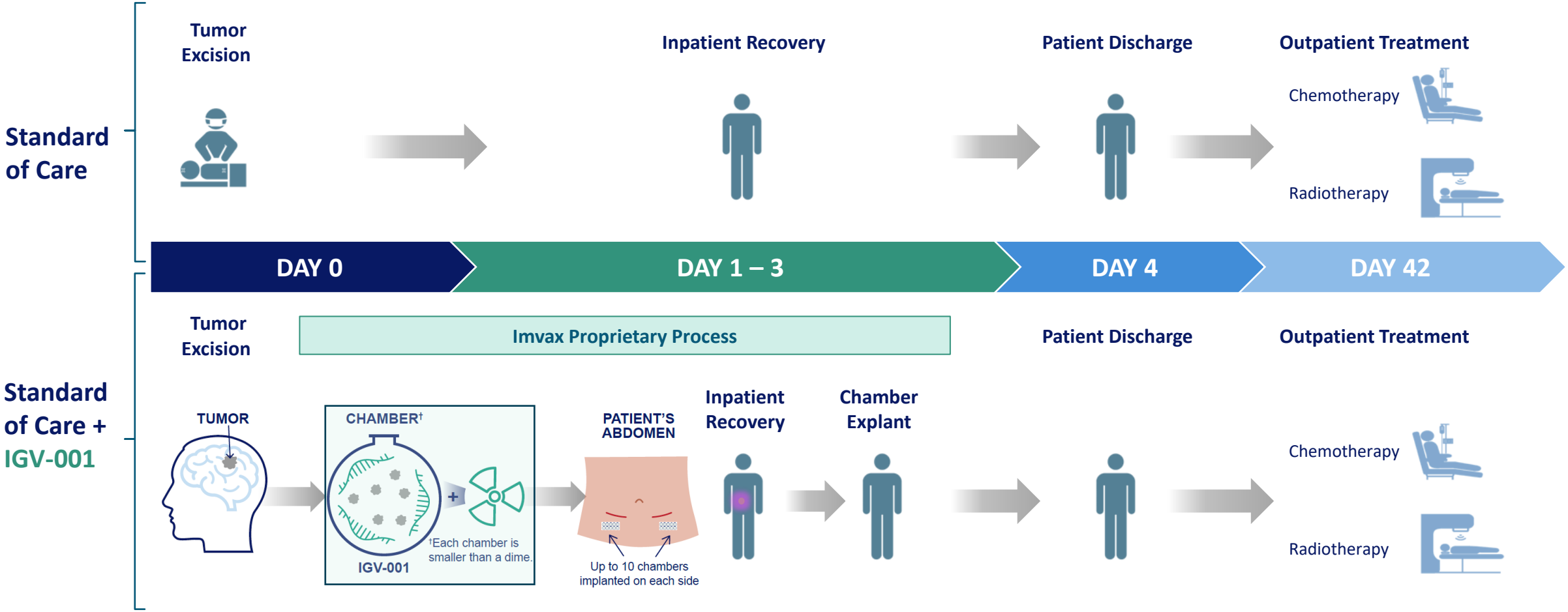
Lead Program: GBM

GBM Program Overview

- GBM is the most common malignant tumor of the brain and CNS
- Newly-diagnosed GBM patients have median overall survival (OS) or life expectancy of approximately 16 months, and less than 7% of GBM patients survive to five years after diagnosis
    - Standard of care 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 approach fits seamlessly into GBM standard of care (SOC)
- Strong patent position exclusively licensed from Thomas Jefferson University

Goldspire fits seamlessly into GBM standard of care

Currently enrolling Phase 2 trial for Newly-Diagnosed GBM



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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 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 25 US sites
- 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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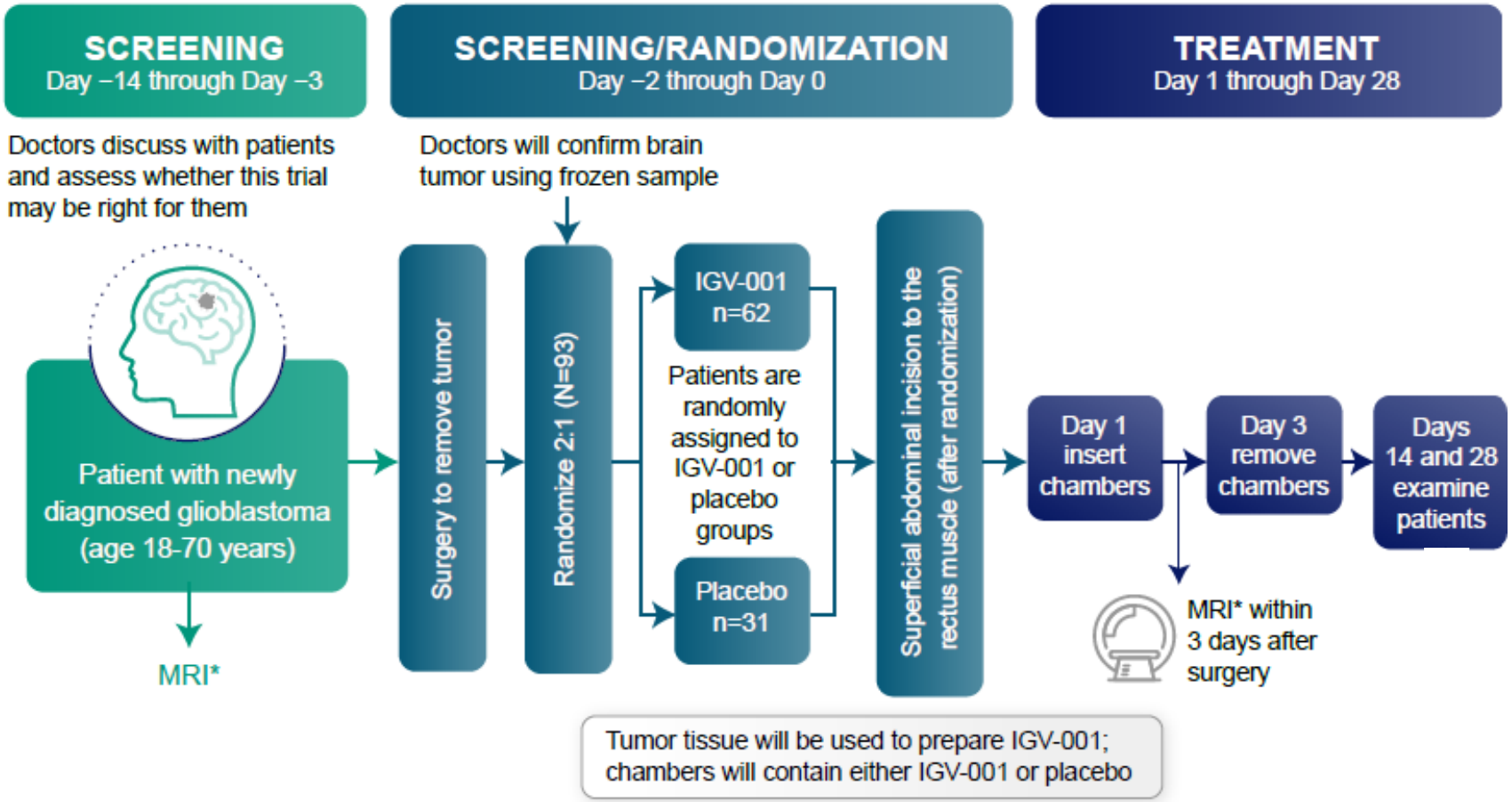
Phase 2b clinical trial design



- Patients receive Standard of Care (SOC) treatment
  - Weeks 6-12: radiotherapy and chemotherapy (temozolomide)
  - Weeks 17-41: chemotherapy alone
- Follow-up period: patients monitored from months 10 to 36

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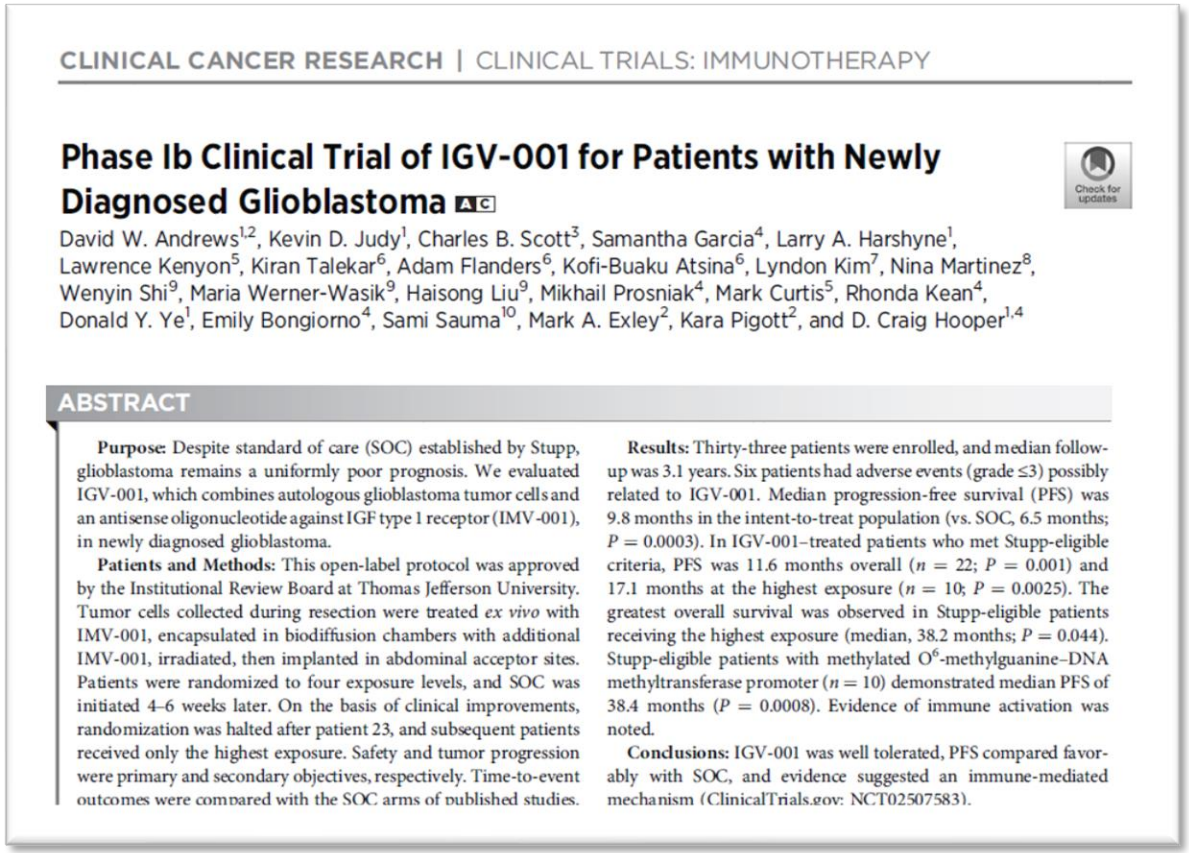
Phase 1b results published in peer-reviewed *Clinical Cancer Research* in April 2021

- 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 chambers 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 AC

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**	
Patients (n)	(n=33)	(n=15)	(n=10)	(n=1,059)
mOS	17.3 months	25.3 months	38.2** months	16.2 months
OS24†	39%	50%	60%	30%
PFS6	86%	85%	90%	56%
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.
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

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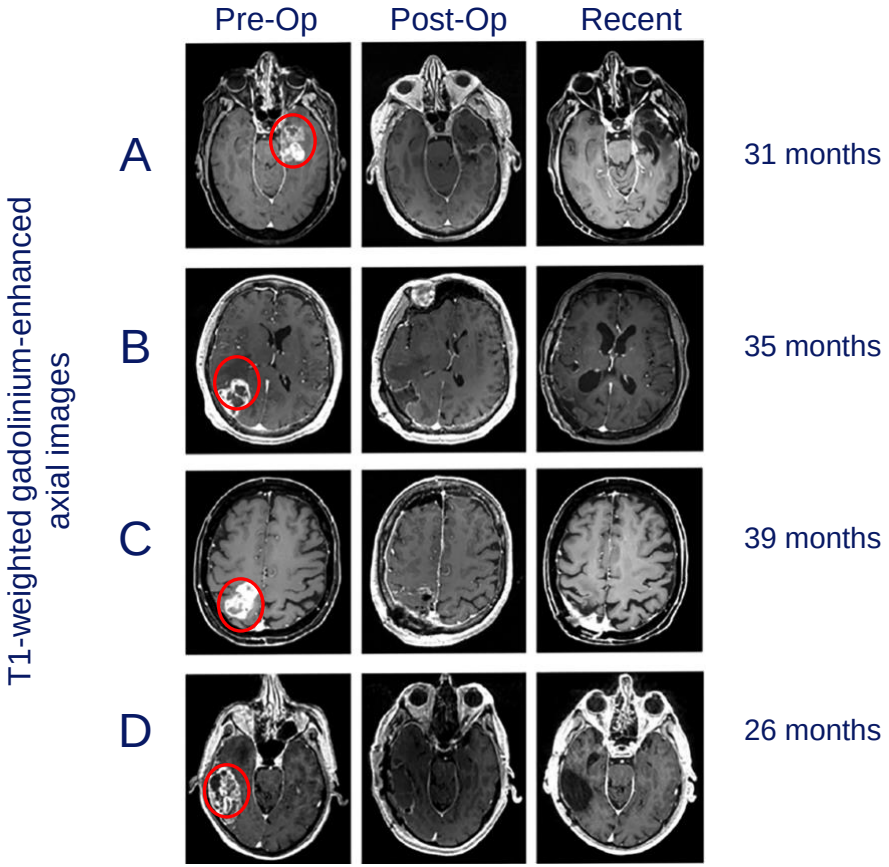
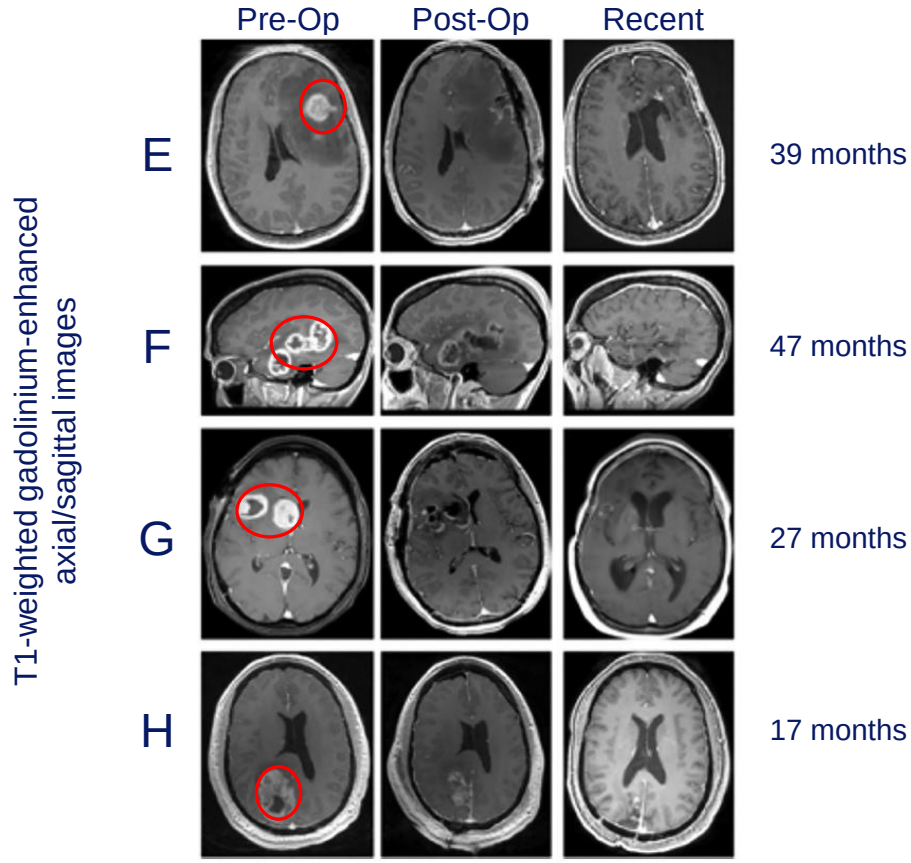
Radiographic responses in Phase 1b study show meaningful delay to disease progression

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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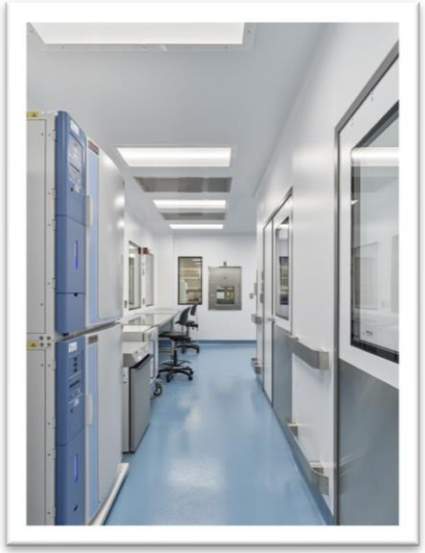
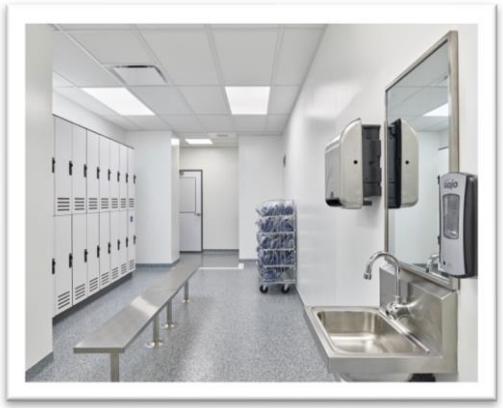
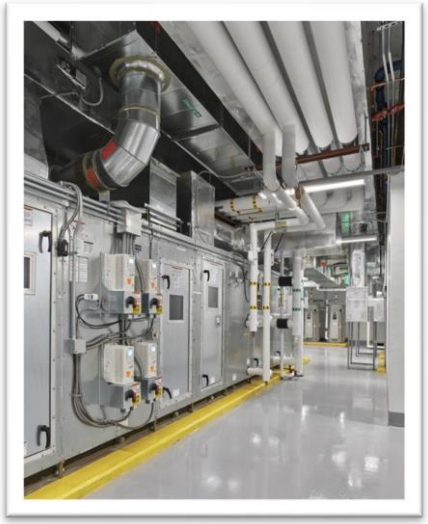
Proprietary in-house manufacturing to support clinical activity and early commercialization







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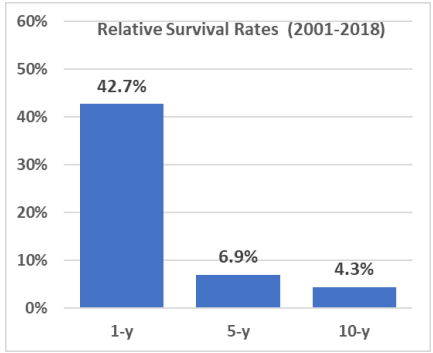
Path to market

Newly diagnosed GBM is an indication with very high unmet need

- Most common malignant brain & CNS tumor[1]
- 6.9% of patients survive 5-years post diagnosis[1]
- Limited progress despite advances in many cancers

- Estimated 14,490 US cases in 2023[1]
- 80-85% patients undergo craniotomy[2,3]



- Stupp protocol remains SOC
  Limited adoption of TTFs[4]
- mPFS in Stupp trial was 6.9m[5]

IGV-001 could be eligible for accelerated approval if the ongoing Phase 2b trial reflects the strong PFS and OS results from the earlier Phase 1b trial

PFS (primary endpoint) readout planned for 2025 → OS (secondary endpoint) readout planned for 2026 → Potential US market entry in 2027

TTFs: tumor treating fields.

[1]Ostrom QT, et al. *Neuro Oncol.* 2022 Oct 5;24(Suppl 5):v1-v95. doi: 10.1093/neuonc/noac202. PMID: 36196752; PMCID: PMC9533228; [2]Annavarapu S, et al. *CNS Oncol.* 2021 Sep 1;10(3):CNS76. doi: 10.2217/cns-2021-0007. Epub 2021 Aug 11. PMID: 34378977; PMCID: PMC8461754; [3]Skaga E, et al. *Neurooncol Adv.* 2021 Feb 26;3(1):vdab008. doi: 10.1093/noajnl/vdab008. PMID: 33665615; PMCID: PMC7914075; [4]Mehta M, et al. *Crit Rev Oncol Hematol.* 2017 Mar;111:60-65. doi: 10.1016/j.critrevonc.2017.01.005. Epub 2017 Jan 22. PMID: 28259296; [5]Stupp R, et al. *N Engl J Med.* 2005 Mar 10;352(10):987-96. doi: 10.1056/NEJMoa043330. PMID: 15758009.

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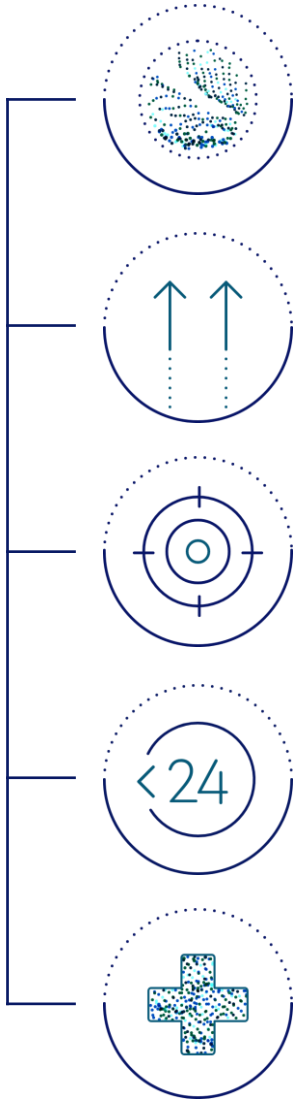
Imvax’s Goldspire Platform

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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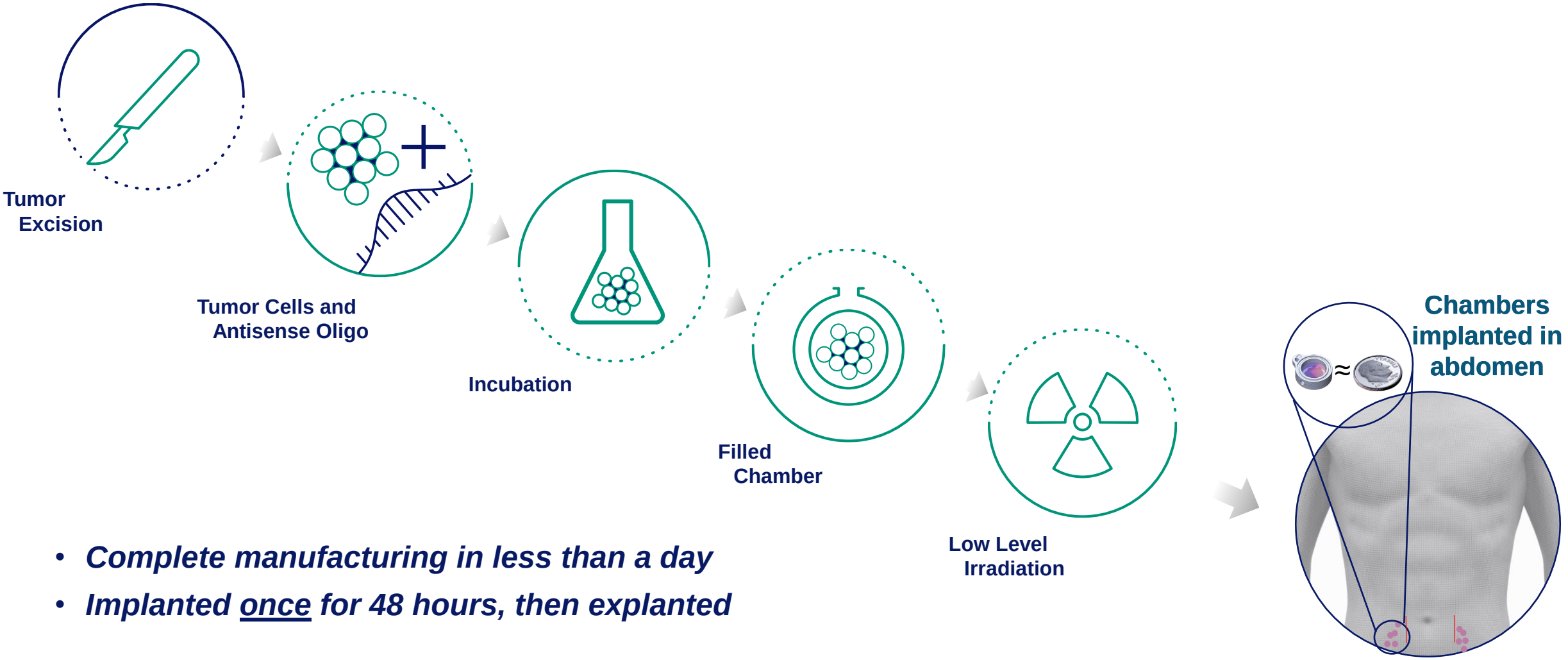
Imvax's Goldspire process



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

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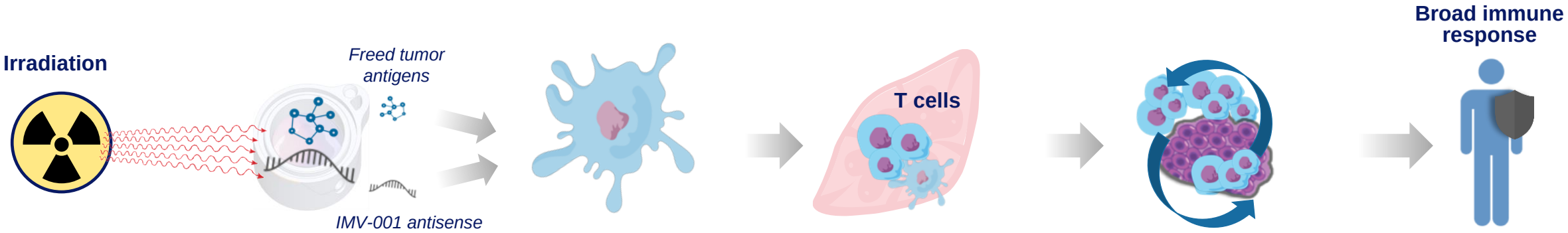
Immune response effectively attacks tumors on multiple fronts



1 Immunogenic cell death

IGF1R is overexpressed in malignant cells, where it promotes cell survival and tumor progression. The use of IMV-001 (antisense oligonucleotide against IGF1R), radiation and implantation within small specialized chambers induces immunogenic cell death during the short implantation in the body.

2 APCs activated

The full tumor antigen signature diffuses out of the chamber's micropores and is picked up by local 'antigen presenting cells' (APC).

Free IMV-001 also diffuses out of the chambers and serves as a second layer of immune stimulation for local APCs.

3 T cells primed

Activated APCs migrate to local draining lymph nodes, where they prime T cells against the tumor antigens. Implanting the chambers remote from immuno-suppressed tumor-draining lymph nodes elicits an optimal immune response

4 T cells impair proliferation and kill tumors

Resulting antigen-specific T cells migrate to tumor site and provide anti-tumor cytotoxicity. These T cells also produce IFNγ, which inhibits tumor cell proliferation and activates other immune cells.

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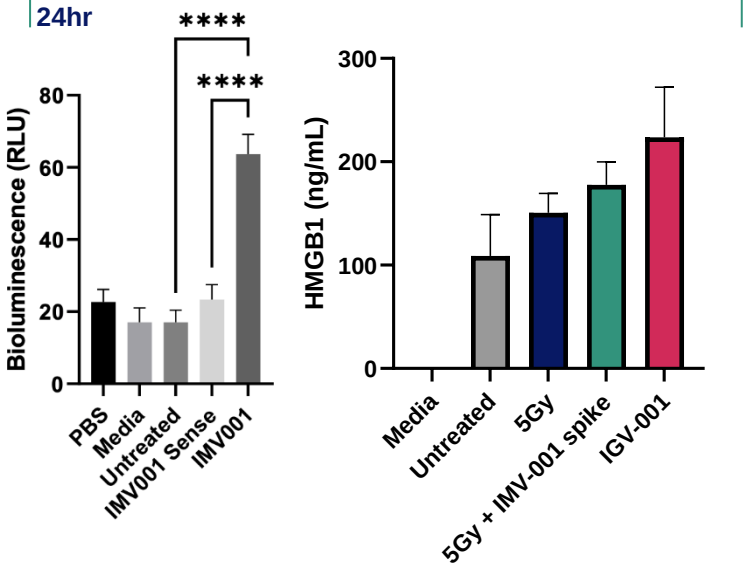
Preclinical data support multi-component mechanism of action

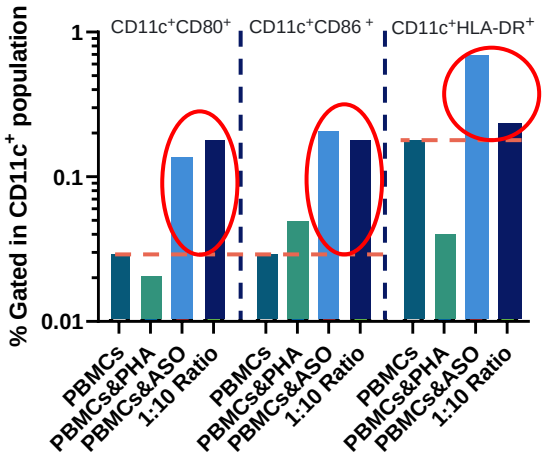
1 Immunogenic cell death

Tumor immunogenic cell death facilitates the induction of anti-tumor cellular immunity, in part due to the release of ATP (see below). Immunogenic cell death promotes the recruitment of APC and subsequent tumor antigen uptake.



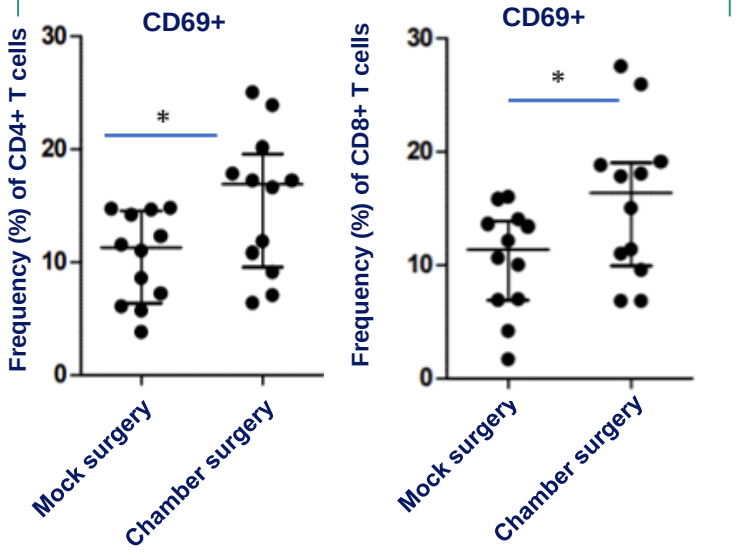
2 APCs activated

Increase in CD11c+ APC Dendritic-type cell activation and maturation induced by antisense.



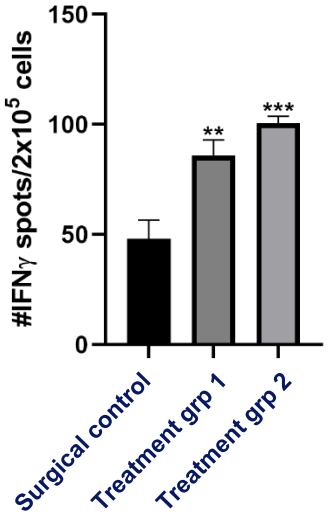
3 T cells primed

Increase in activated CD4 and CD8 T cells seen in treated mice.



4 T cells impair proliferation and kill tumors

Tumor antigen-specific IFNγ levels in PBMCs show significant rise in treated animals vs. controls. Treated mice show tumor shrinkage and extended survival.



* p < 0.05 ** p < 0.01 *** p < 0.001 **** p < 0.0001

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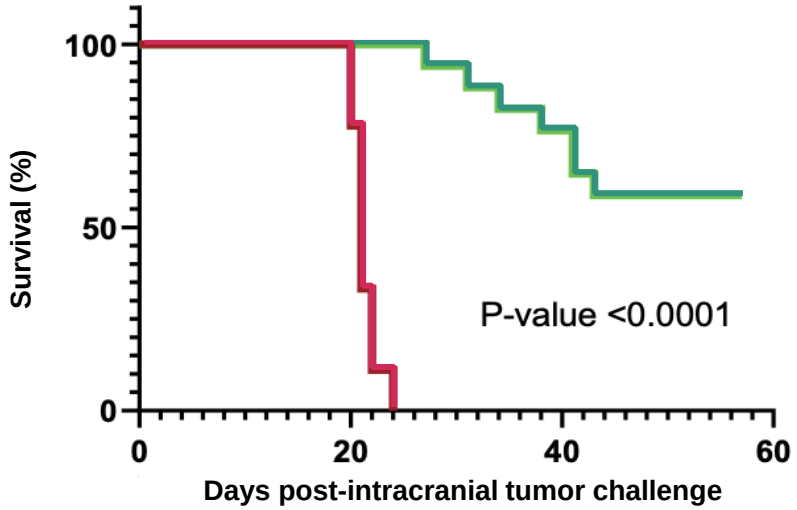
Pipeline in Solid Tumors

Preclinical data supports potential in broad range of solid tumors

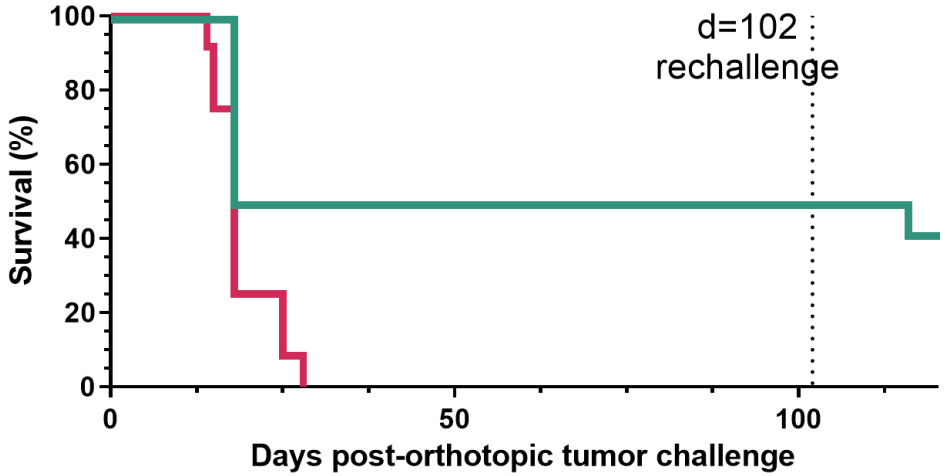
Tumor	Model Status
GBM	Compelling mono-activity, additional combo activity
Ovarian (OCa)	Compelling durable mono-activity
Hepatocellular carcinoma (HCC)	Compelling durable mono-activity, rechallenge data
Bladder (UCa)	Compelling durable mono-activity
Pancreatic ductal adenocarcinoma (PDAC)	Modest statistical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

In vivo data demonstrating extended survival in multiple animal models

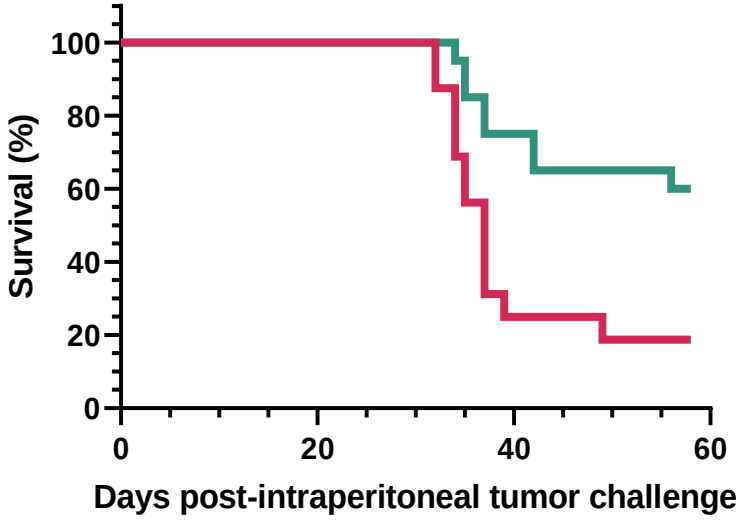
Glioblastoma (GBM)



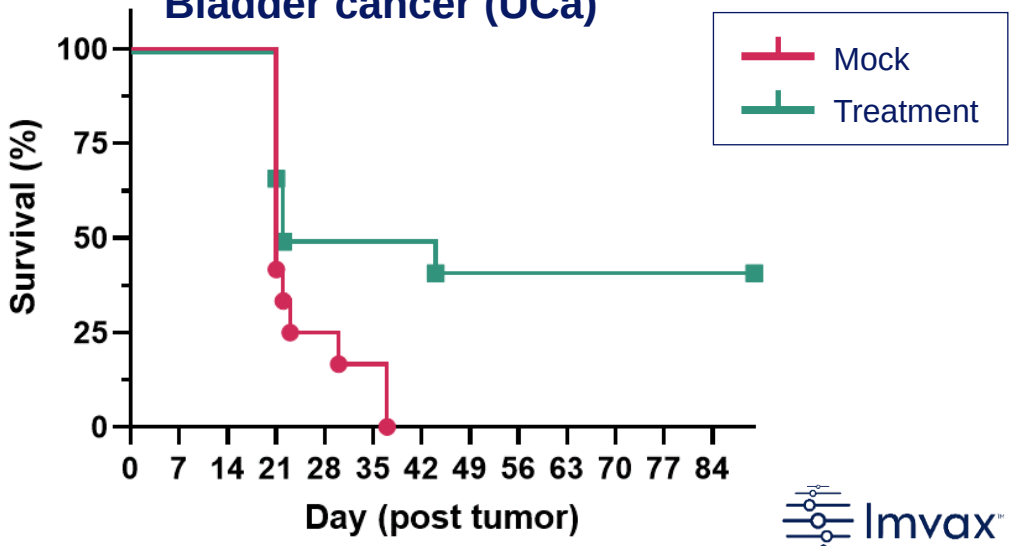
Hepatocellular carcinoma (HCC)



Ovarian cancer (OCa)



Bladder cancer (UCa)



Preclinical data provides MOA support and shows promise 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 use same chamber and antisense as human studies
- Well-tolerated, as in the clinic
- 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

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Imvax's Goldspire pipeline: Focused on solid tumor types

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Imvax: A late-stage oncology opportunity

- The Imvax Goldspire platform is a personalized therapy that aims to induce antitumor immunity using a patient's own tumor cells plus a molecule called IMV-001
- Lead asset to treat ndGBM currently in Phase 2b
  - Seeking to build on groundbreaking Phase 1b data
  - Potential to file for approval on completion of the trial
- Additional IND planned for endometrial cancer in 2023
- Established GMP manufacturing capabilities at Imvax
- Projected $2B - $3B global peak sales in ndGBM and up to $3B in other pipeline assets
- Seasoned leadership with deep biopharma development and commercialization experience

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