CTIM-14

Early safety data from a randomized, multicenter, double-blind, phase 2b study of IGV-001, an autologous cell immunotherapy, versus placebo, in newly diagnosed glioblastoma (ndGBM)

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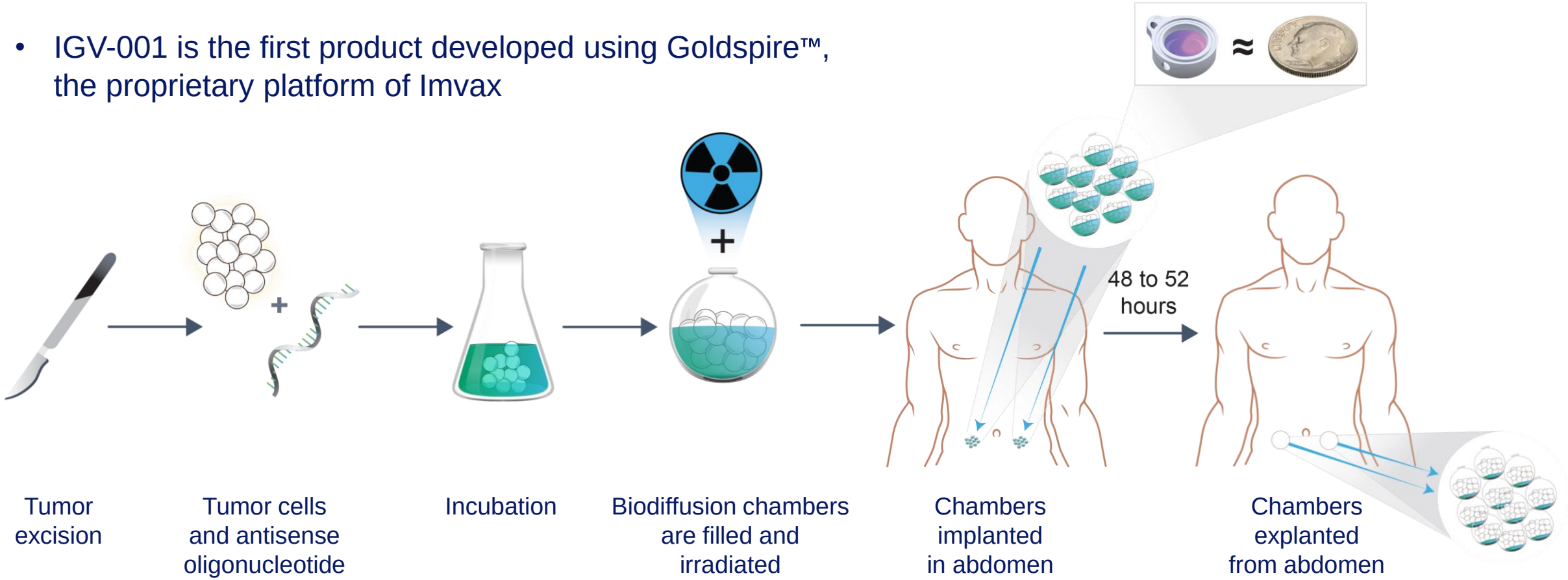
Imvax's Goldspire Process

- IGV-001 is the first product developed using Goldspire™, the proprietary platform of Imvax



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

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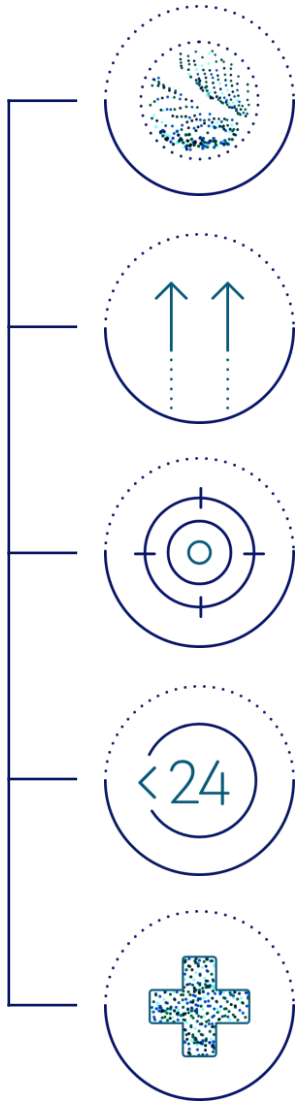
Goldspire Platform has Multiple Advantages



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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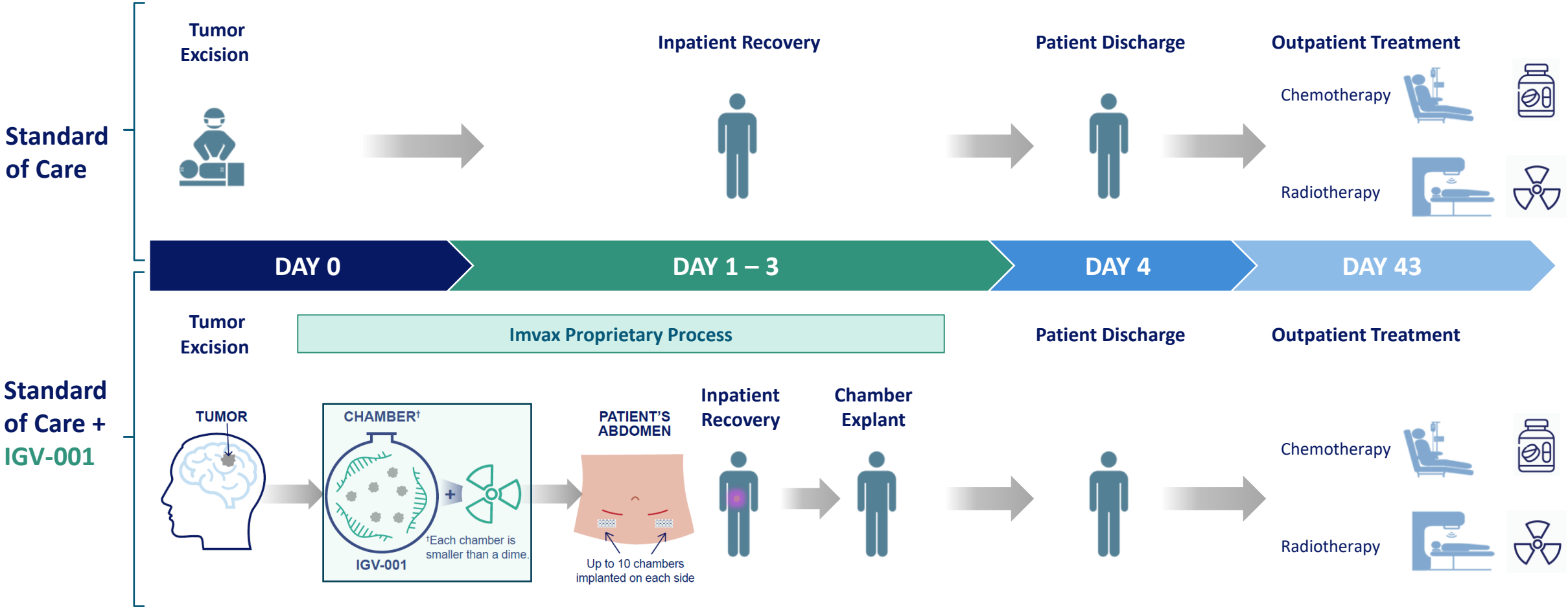
Goldspire Fits Seamlessly into GBM Standard of Care

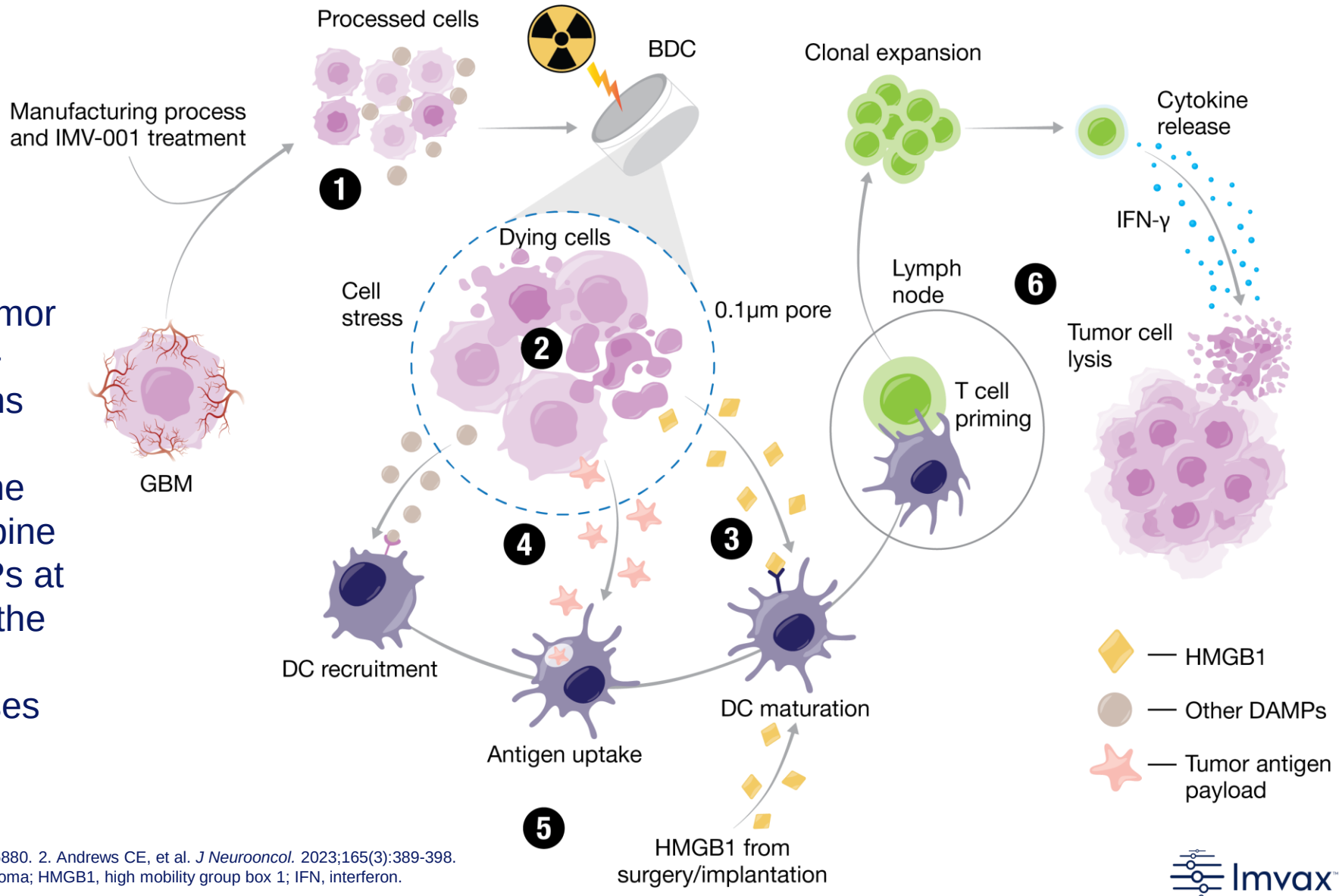
Phase 2 trial for newly-diagnosed GBM fully enrolled



GBM, glioblastoma.

The IGV-001 Manufacturing Assembly and 6-Stage Mechanism of Action[1,2]

- IGV-001 can induce cellular stresses on GBM cells in the product, resulting in immunogenic cell death and consequent antitumor immunity[1]
- Antigens from dying/dead tumor cells, IMV-001, and damage-associated molecular patterns (DAMP) immune stimulators diffuse from the BDCs into the surrounding tissue and combine with locally generated DAMPs at the implantation site to train the immune system to generate tumor-specific T-cell responses that reduce/eliminate tumor burden[1,2]

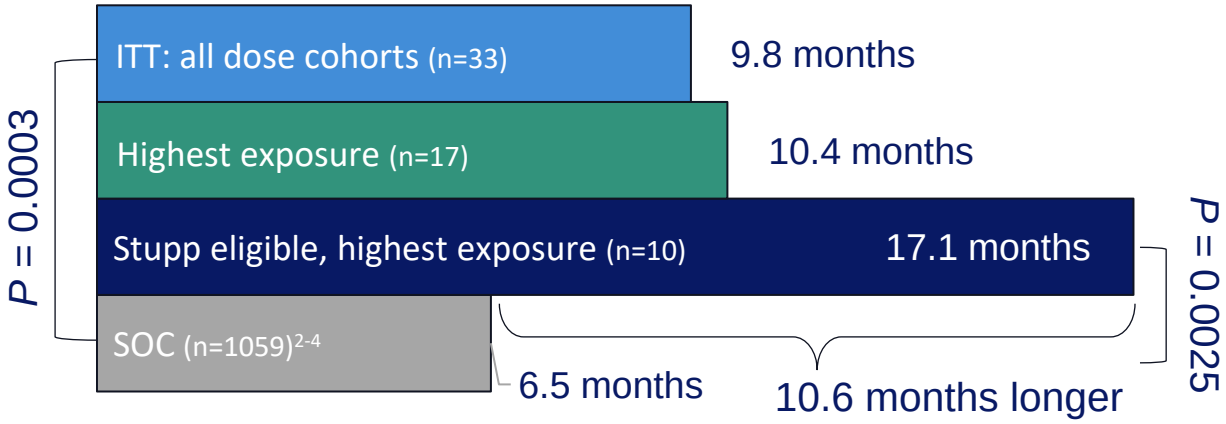


1. Cultrara C, et al. *J Immunother Cancer.* 2023;11(8):e006880. 2. Andrews CE, et al. *J Neurooncol.* 2023;165(3):389-398.
BDC, biodiffusion chamber; DC, dendritic cell; GBM, glioblastoma; HMGB1, high mobility group box 1; IFN, interferon.

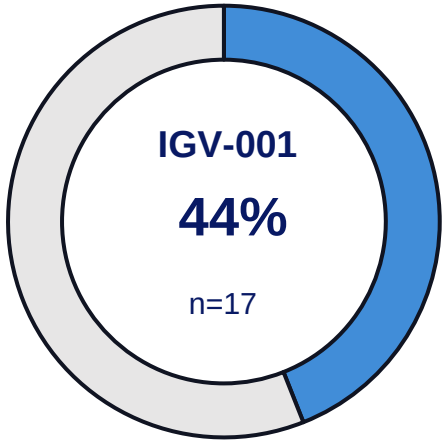
IGV-001 Was Well Tolerated in a Phase 1b Study (NCT02507583)[1] With an Exposure-Response Relationship

The median PFS and OS compared favorably with SOC arms of published studies[2-4]

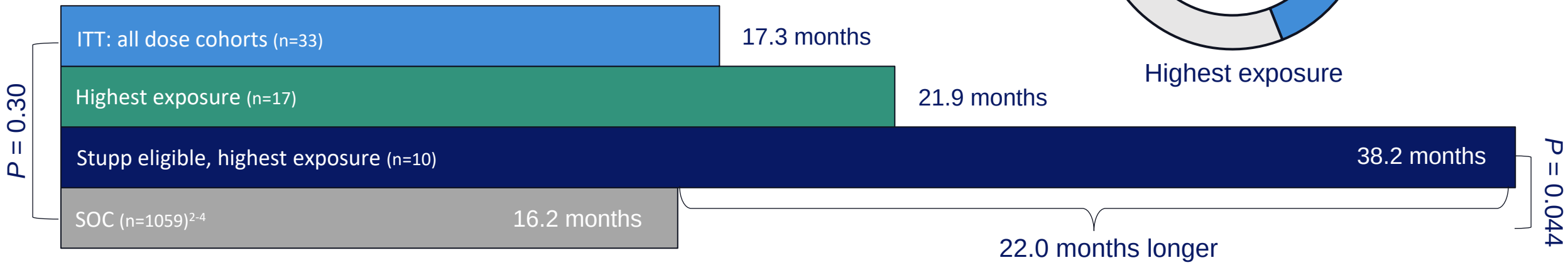
Median PFS



2-year OS



Median OS



1. Andrews, DW, et al. *Clin Cancer Res.* 2021;27(7):1912-1922. 2. Chinot OL, et al. *N Engl J Med.* 2014;370(8):709-722. 3. Gilbert MR, et al. *N Engl J Med.* 2014;370(8):699-708. 4. Stupp R, et al. *Lancet Oncol.* 2009;10(5):459-466.

OS, overall survival; PFS, progression-free survvial; SOC, standard of care.

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IGV-001 Phase 1b Study Conclusions

- IGV-001 is a personalized, autologous cancer cell-based immunotherapy
- IGV-001 was safe and mediated potential efficacy in patients with newly diagnosed GBM especially in those receiving the highest IGV-001 exposure
- These findings led to the initiation of a follow-up Phase 2b study (NCT04485949)

Andrews, DW, et al. *Clin Cancer Res.* 2021;27(7):1912-1922

GBM, glioblastoma.

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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

Protocol Number: 14379-201

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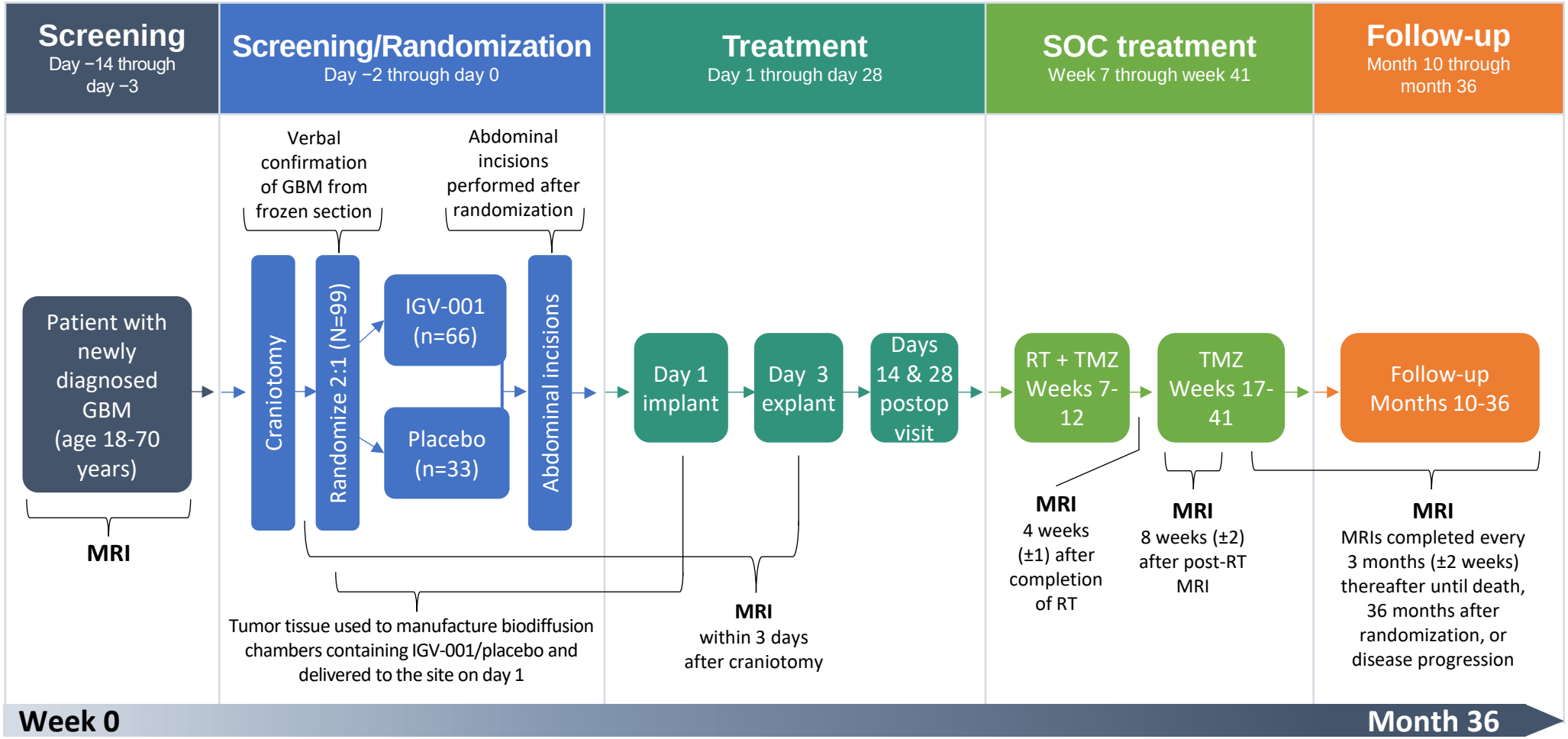
Phase 2b Study Design and Periods



Primary Endpoint: PFS

Secondary Endpoint: OS

GBM, glioblastoma; MRI, magnetic resonance imaging; N, number of patients; OS, overall survival; PFS, progression-free survival; RT, radiotherapy; SOC, standard of care; TMZ, temozolomide.

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Phase 2b Study Endpoints

Primary	Secondary	Tertiary	Exploratory	Safety
PFS in the ITT population (with sensitivity analyses performed in the PP population)	OS in the ITT population (with sensitivity analyses performed in the PP population)	Time to definitive deterioration of Karnofsky Performance Scale Score	Change in QOL in the ITT from baseline to beginning of RT and concurrent TMZ, based on 2 questionnaires : • EORTC-QLQ-C30 • QLQ-BN20	Safety and tolerability
		PFS and OS within 2 subgroups: • MGMT+ • MGMT–	ORR in the subset of patients with MRD based on the RANO criteria by central blinded radiology review, as documented on the baseline MRI scan (ie, the first post-operative MRI performed within 3 days post-craniotomy)	
		PFS and OS within the histology subgroups: • WHO Grade 3 diffuse astrocytic glioma • WHO Grade 3 IDH wild-type • WHO Grade 3 with molecular features of GBM • WHO Grade 4 • WHO Grade 4 GBM	Determination of independent prognostic factors by multivariate analysis of PFS and OS, amongst: • Treatment arm • Age group • MGMT methylation status • Extent of resection	
			Markers of immune response: • Change in levels of immune response markers from baseline to disease progression • Correlation between immune response markers and efficacy endpoints	
			Tumor mutational burden by NGS	

GBM, glioblastoma; ITT, intent-to-treat; MGMT, O^6-methylguanine-DNA methyl-transferase; MRI, magnetic resonance imaging; NGS, next-generation sequencing; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PP, per-protocol; QOL, quality of life; RANO, Response Assessment in Neuro-Oncology; RT, radiotherapy; TMZ, temozolomide; WHO, World Health Organization.

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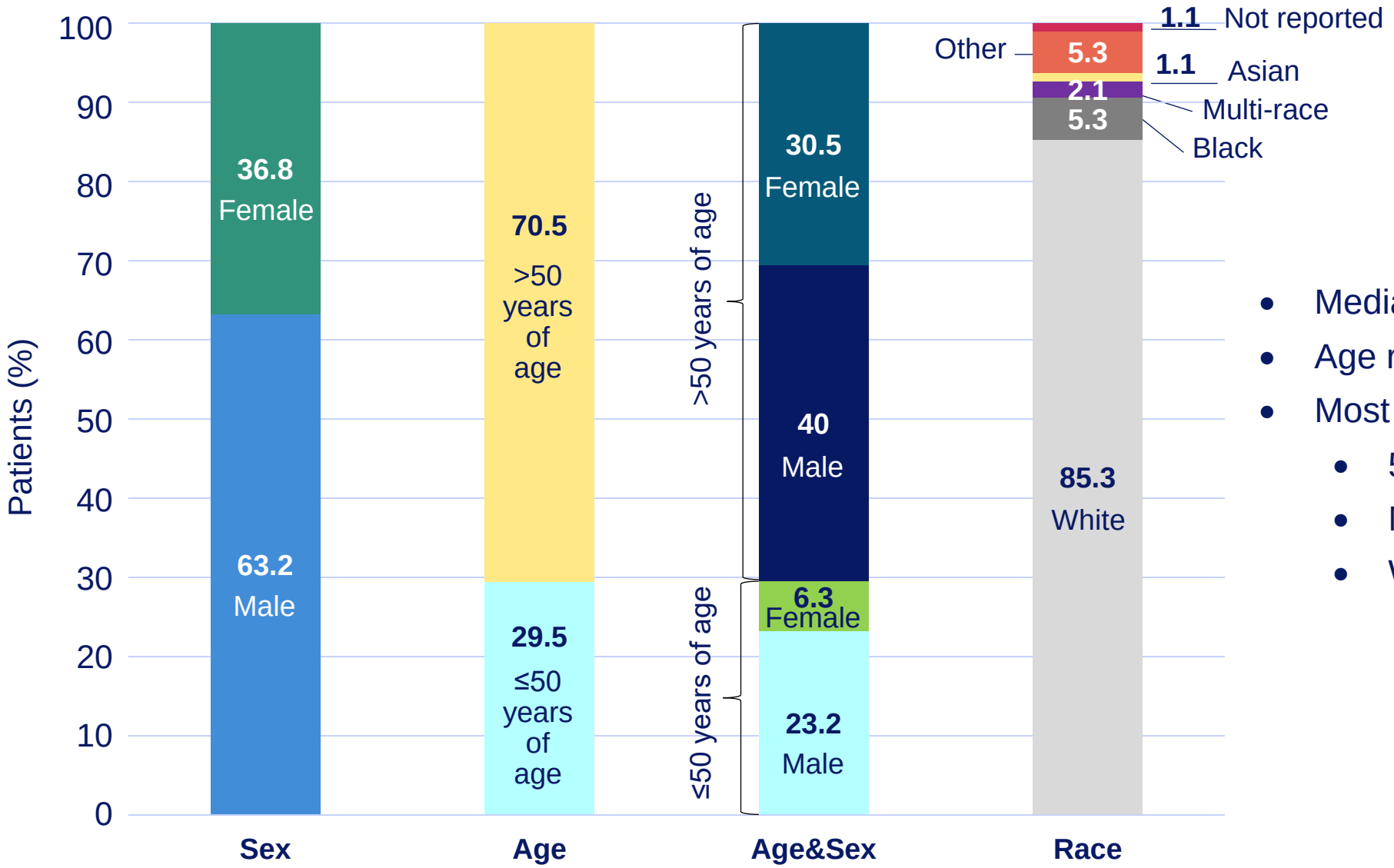
Baseline Demographic Characteristics (Safety Population, N=95)



- Median age: 60.0 years
- Age range: 24-70 years
- Most randomized patients were:
  - 51-70 years of age (70.5%)
  - Male (63.2%)
  - White (85.3%)

Data cutoff: 14 July 2024.

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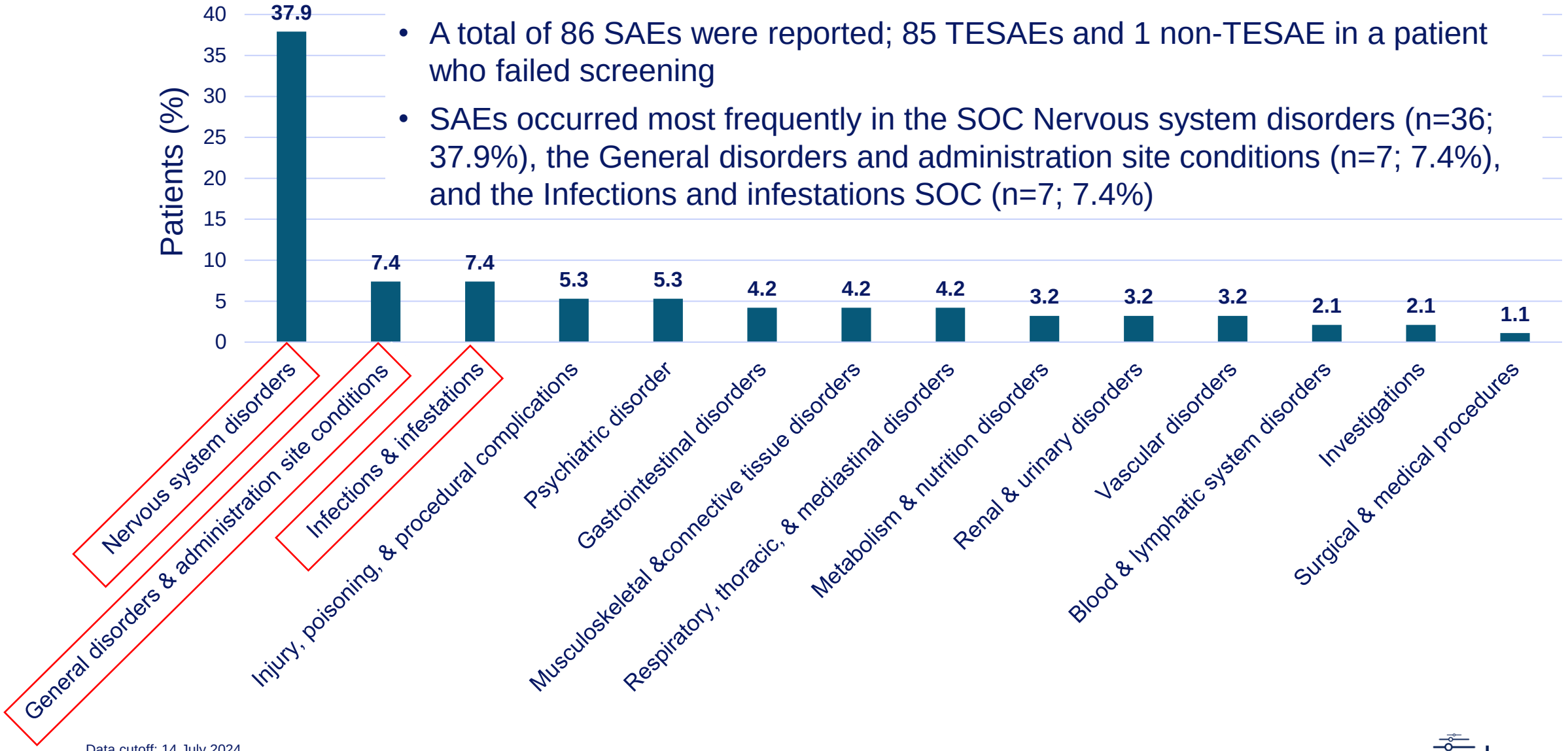
Patient Disposition

Parameter	Patients, n (%)
Patients randomized	99 (100)
Patients implanted with BDCs	95 (96.0)
Patients implanted with BDCs and with enough follow-up time to initiate treatment with concurrent RT and TMZ	94 (94.9)
Patients with enough follow-up time who initiated treatment with concurrent RT and TMZ[a]	84 (89.4)
Patients who discontinued treatment, n (%)[b]	36 (37.9)
Patients who discontinued the study, n (%)[b]	14 (14.7)

Data cutoff: 14 July 2024. [a]Percentages are calculated using the denominator of 94. [b]Percentages are calculated using the denominator of 95.
BDCs, biodiffusion chambers; RT, radiation; TMZ, temozolomide.

Early Blinded Safety: SAEs by SOC (Safety Population, N=95)



- A total of 86 SAEs were reported; 85 TESAEs and 1 non-TESAE in a patient who failed screening
- SAEs occurred most frequently in the SOC Nervous system disorders (n=36; 37.9%), the General disorders and administration site conditions (n=7; 7.4%), and the Infections and infestations SOC (n=7; 7.4%)

Data cutoff: 14 July 2024.
SAE, serious adverse event; SOC, system organ class; TESAE, treatment-emergent serious adverse event.

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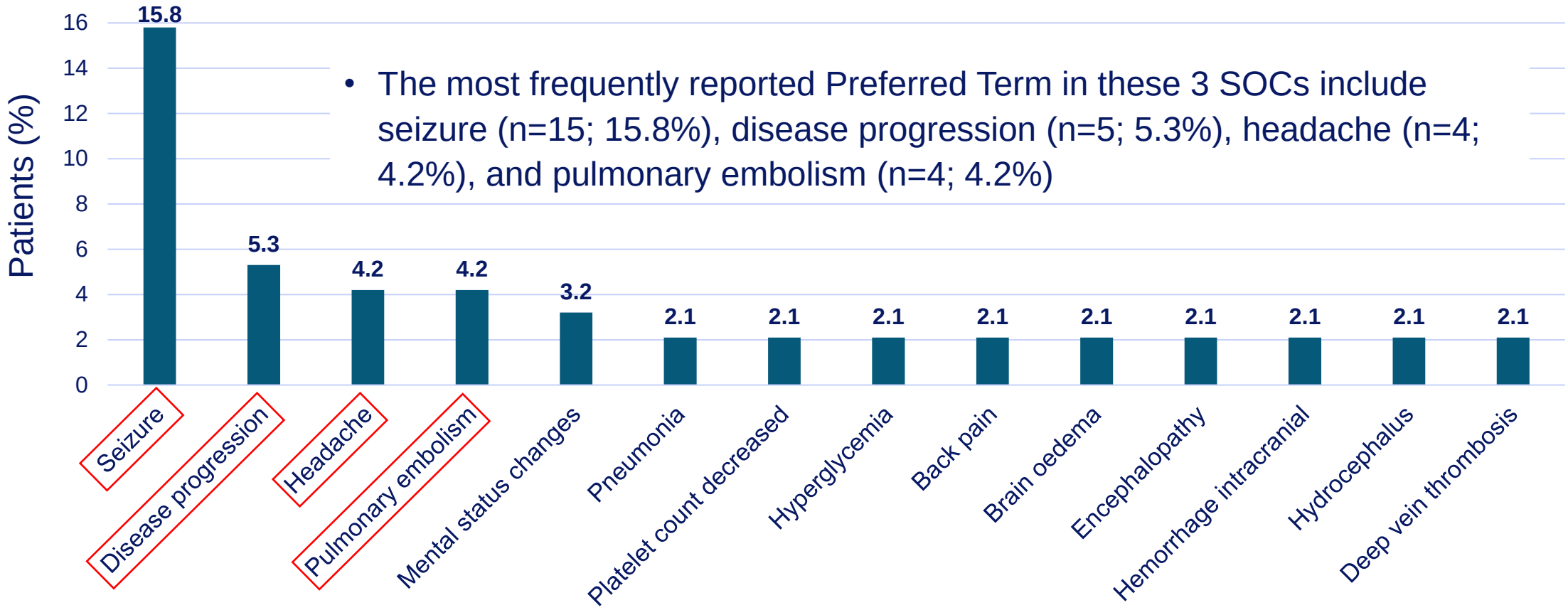
SAEs Occurring in ≥2 Patients (Safety Population, N=95)*



- The most frequently reported Preferred Term in these 3 SOCs include seizure (n=15; 15.8%), disease progression (n=5; 5.3%), headache (n=4; 4.2%), and pulmonary embolism (n=4; 4.2%)

Data cutoff: 14 July 2024. *The following AEs occurred in 1 patient each (1.1%): acute kidney injury, agitation, anemia, aphasia, asthenia, Bell's palsy, Clostridium difficile infection, delirium, depressed level of consciousness, diarrhea, dysphagia, epilepsy, extradural hematoma, fall, gait disturbance, hematoma evacuation, hemiparesis, hyponatremia, intestinal mass, ischemic stroke, Klebsiella sepsis, muscular weakness, musculoskeletal stiffness, nausea, nephrolithiasis, pancytopenia, paraparesis, partial seizures, postprocedural infection, procedural pain, renal hematoma, sepsis, third cranial nerve disorder, wound complication, wound dehiscence, and wound infection.
SAE, serious adverse event; SOC, system organ class.

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16 Reported Deaths (Safety Population, N=95)

- Overall, there were 16 (16.8%) deaths reported, regardless of causality:
- Two (2.1%) deaths occurred in patients ≤50 years of age and 14 (14.7%) deaths occurred in patients >50 years of age
- Nine (9.5%) deaths occurred in men and 7 (7.4%) deaths occurred in women
- There were 2 (2.1%) deaths due to SAEs:
  - 1 death was reported due to sepsis and the other was reported due to hypotension
  - These 2 SAEs were deemed not related to the blinded study product

Data cutoff: 14 July 2024.

Blinded Early Safety Data Summary

- Available data show that the nature, the severity, and the frequency of reported adverse events are strongly indicative of causal relationships to the Standard of Care and the patients' preexisting medical conditions and their natural complications
- The older population of patients, from 51 to 70 years old who represent twice the number of patients from 18 to 50 years old, seems to be experiencing 2x more SAEs, suggesting the possible role of age-related predisposing comorbidity factors
- Decision of two Independent Data Monitoring Committee (IDMC) meetings was to "continue the study as planned"
  - A final IDMC meeting is scheduled for December 2024

Blinded Early Safety Data Conclusions

- To date, in the ongoing phase 2b randomized study designed to assess the efficacy and safety of IGV-001 in patients with newly diagnosed GBM (NCT04485949), the review of the blinded safety data did not show any emerging risk and supports that there is no change to the benefit-risk profile of treatment with IGV-001 versus placebo

Overall, the benefit-risk profile remains positive and supports the continued development of IGV-001

GBM, glioblastoma.

Looking Ahead

- Phase 2b study seeks to build on groundbreaking Phase 1b results
  - Randomized, placebo-controlled Phase 2b study assessing IGV-001 in patients with ndGBM post-craniotomy
  - 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 the secondary efficacy endpoint
- Study fully enrolled in 13 months
  - Enrolled 99 patients across 20 US sites with 2:1 randomization
- Potential PFS data presentation in mid-2025 followed by OS in mid-2026

ndGBM, newly-diagnosed glioblastoma; OS, overall survival; PFS, progression-free survival; SOC, standard of care.

Thank you!

- We would like to thank the patients that have participated, or are participating, in IGV-001 clinical trials and their families, as well as the investigators and study personnel at participating sites

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