



NYSE AMERICAN: IGC



# Safe Harbor

The matters discussed in this presentation include forward-looking statements about the business prospects of IGC Pharma, Inc. Forward-looking statements are often preceded by words such as believes, expects, anticipates, plans, will, goal, may, intends, assumes, or similar expressions. Forward-looking statements reflect management's current expectations as of the date of this conference call and involve certain risks and uncertainties. The forward-looking statements are based on assumptions that we have made in light of our industry experience and our perceptions of historical trends, current conditions, expected future developments, and other factors that we believe are appropriate under these circumstances.

As with any projection or forecast, they are inherently susceptible to uncertainty and changes in circumstances. IGC Pharma, Inc.'s actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors and the forward-looking statements are not guarantees of performance. Some of the factors that could cause future results to materially differ from recent results or those projected in forward-looking statements are included in our filings with the Securities and Exchange Commission (the "SEC"), such as our Annual Report on form 10-K filed with the SEC and subsequent filings on Form 10Q. We are under no obligation and expressly disclaim any obligation to update or alter the forward-looking statements, whether as a result of such changes, new information, subsequent events, or otherwise.

# **Highlights**

- Diversified pipeline containing multiple patent protected Alzheimer's Disease (AD) candidates and new GLP-1 candidates
- IGC-AD1 near-term opportunity with Phase 2 CALMA trial in agitation – the only natural THC-based investigational drug candidate currently undergoing FDA trials
- Long-term opportunity with new IGC-AD1 trial in 2025 investigating potential to halt and modify Alzheimer's

# **Highlights**

- Leading artificial intelligence partnerships
- Poised for growth with industry headwinds from Complementary & Alternative Medicine (CAM) Market
- Vertically Integrated manufacturing and production facilities
- Clean capital structure

## IGC is Well Positioned in Two Large Addressable Markets

Alzheimer's Therapeutics Market<sup>1</sup>

\$15.2B<sup>1</sup>

Market Size in 2030

19.99%

CAGR 2023- 2030

**\$4.2B**Market Size in 2022

Complementary and Alternative Medicine Market<sup>1</sup>

\$1.2T<sup>2</sup>

Market Size in 2033

25%

CAGR 2024- 2033

\$123.8B

Market Size in 2023

<sup>&</sup>lt;sup>1</sup> Grandview Research

<sup>&</sup>lt;sup>2</sup> Precedence Research

# **Our Pipeline**

Asset   Precli	inical   Phase II   Phase III   Phase III	Milestones
IGC-AD1 Targe	ets NPS and AD pathology	Interim Phase 2 data available
LMP-platform	Targets NPS and AD pathology	Bio Equivalence to IGC-AD1 2025
TGR-platform	Targets Aβ plaques (Early- Moderate AD)	Tox study 2025
IGCM-platform	Targets Plaques and GLP-1	Tox study 2025
IGCC-platform	Targets Tau, 1A, 1B and 1C target GLP-1 and GIP	Tox study 2025

# **Protected Intellectual Property**

Target	Description	Patent Applications	<b>US Patents</b> Granted	Foreign Patents Granted	
(IGC-AD1)	Composition & Method for treating CNS Disorders.	7	1		
(IGC-AD1)	Composition & Method for treating CNS Disorders.	8	1	1	
(TGR-63)	Naphthalene Monoimide Derivatives with ability to impact Aß protein build-up.	6			
(IGC-1C)	Naphthalene Monoimide Derivatives with ability to impact Tau aggregation and neurofibrillary tangle formation	1			
(IGC-M3)	Naphthalene Monoimide Derivatives with ability to impact Aß plaque buildup and neurofibrillary tangle formation	4			In-house patents and applications
Cancer (Naphthalene Dimdes)	Naphthalene diimide Derivatives with ability to self-assemble molecular interactions for biological and nonbiological systems		1	1	Patents and applicat acquired through exc
(IGC-LMP)	Composition, Synthesis & Medical use of Hybrid Molecule	1			license agreements
Epilepsy	Composition & Method for treating Seizures in humans & Cats/Dogs.	2	2		
Eating Disorders	Natural formulation with Cyproheptadine for treating Cachexia & Eating Disorders.	1	1		
Stuttering & Tourette Syndrome	Formulation for Treating Stuttering & Symptoms of Tourette Syndrome.	1			
Pain	Formulation containing Cobalamin and method for pain management.	1	2	2	

We have filed 32 patent applications, which are distributed among the US, Canada, Europe, Colombia, India, Mexico, Brazil, and Hong Kong.

# Primary Target: Therapeutic Treatment for Agitation in Alzheimer's

**Agitation:** excessive motor activity, verbal aggression, or physical aggression impairing personal relationships, social functioning, and/or daily activities

**Agitation** starts early in AD and increases in severity as the disease progresses

40-80% of Alzheimer's patients suffer from agitation

#### Agitation is associated with:

- Higher admission rate to assisted living facilities
- Higher use of medications
- Long-term hospitalization
- Higher mortality

# The Only "Treatment" Option Today

#### **REXULTI®** (brexpiprazole)

- A repurposed, atypical antipsychotic with a black box warning
- Costing patients
   \$17,000 per year with a
   6-10 week onset of action



#### **BREXPIPRAZOLE BLACK BOX WARNING:**

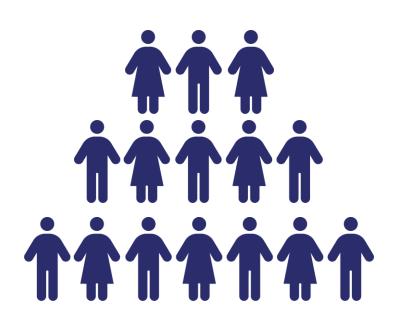
INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS

#### **Our Solution**

#### **IGC-AD1**

- A natural patent-protected compound in Phase 2B trials
- The **FIRST** compound that relies on low doses of THC, a cannabinoid, and another compound as active pharmaceutical ingredients ("API")
- The ONLY natural THC-based investigational drug candidate currently undergoing FDA trials

# **IGC-AD1 Phase 2 CALMA Trial: Ongoing**



The study targets completion by 146 participants

Currently enrolled or completed: 50 patients

Multicenter, Double Blind, Randomized, Placebo-Controlled Trial

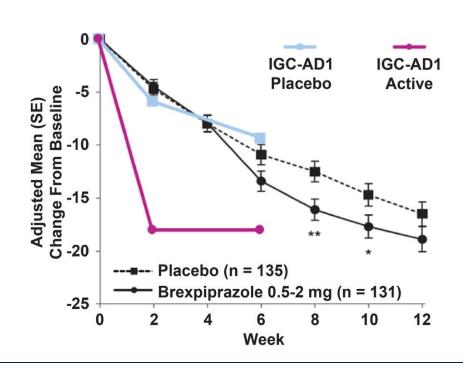
#### **Objectives:**

Evaluate the safety and efficacy of IGC-AD1 on agitation in AD at week 2 and week 6

#### **Key Inclusion Criteria:**

- Diagnosis of probable AD using the NIA-AA criteria
- Clinically significant agitation using a score ≥4 in NPI agitation domain

# Phase 2 Interim Results Indicate Drug Could Outperform Current Approved Therapy



- Brexpiprazole has limited effect at week 2
- Brexpiprazole starts to show effect at week 6

- CMAI score: Cohen-Mansfield Agitation Inventory, a clinical tool used to assess and quantify agitation levels
- In this study, patients who took IGC-AD1 showed a statistically significant improvement vs placebo in agitation over 6 weeks

CMAI Least Squared mean change from baseline at EOT comparing active and placebo groups A) IGC-AD1 1ml BID trial (NCT05543681) and Brexpiprazole trial 0.5 to 2 mg flexible doses trial (NCT01922258). \* p<0.05, \*\* p<0.05, \*\* p<0.001; Mixed Model of Repeated Measures. SE: Standard Error; CMAI: Cohen-Mansfield Agitation Inventory.

## Adverse Events: IGC-AD1 vs. Brexpiprazole

#### **Brexpiprazole Trial**

- ~6% participants had SAEs
- 5% participants had AEs leading to discontinuation
- 7 deaths reported, 6 in the active group and 1 in placebo

#### **IGC-AD1** Trial to date

- **№ No SAEs** reported up to 6 weeks
- No AEs leading to discontinuation
- No deaths

1. Data obtained from: Otsuka Pharmaceutical Company. (2023, April). BREXPIPRAZOLE FOR THE TREATMENT OF AGITATION ASSOCIATED WITH ALZHEIMER'S DEMENTIA SPONSOR BRIEFING DOCUMENT. https://www.fda.gov/media/167068/download

# Secondary Target: IGC-AD1 as a Disease Modifying Treatment

~400 million

Asymptomatic with AD pathology in their brains<sup>1</sup>

50 million

Diagnosed with AD worldwide<sup>2</sup>

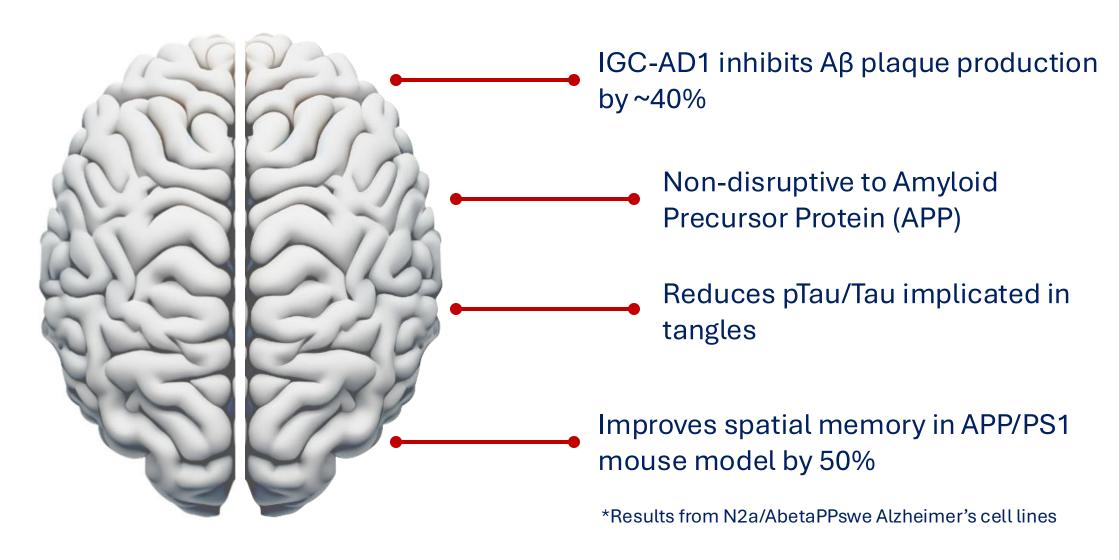
7 million

Americans currently living with AD<sup>2</sup>

<sup>1</sup>Baylor University, October 2024

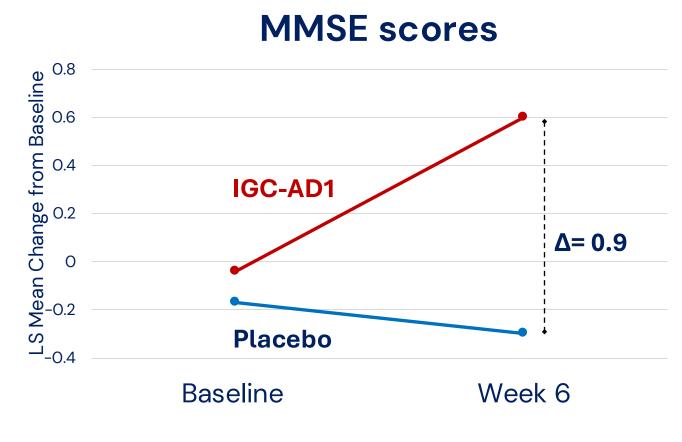
<sup>2</sup>2024 Alzheimer's disease facts and figures. Alzheimer's Dement. 2024 May;20(5):3708-3821. doi: 10.1002/alz.13809. Epub 2024 Apr 30. PMID: 38689398; PMCID: PMC11095490

#### **Our Preclinical Data**



J. Pineal. Res. 2011, 51, 75-86; J. Alzheimer's disease 2014, 42, 973-984; Int. J. Mol. Sci. 2022, 23, 2757; Int. J. Mol. Sci. 2022, 23, 4253

# Phase 2 Mini Mental State Exam (MMSE) Interim Results



- MMSE, 30-point test, assess global cognitive status.
- It is widely used to detect cognitive impairment
- No negative impact on cognitive performance compared to placebo
- ✓ P value may be influenced by the small sample size and the adjustments for baseline scores, site variations, and visits.

Mean change (CI 95%)	Active	Placebo	Difference	Adjusted mean difference (95% CI))	p value
Scores	0.6 (-0.50, 1.71)	-0.3 (-1.23, 0.64)	0.9 (-0.56, 2.36)	0.515 (-0.497, 1.526)	0.319

## Revenue Projections for Agitation in Alzheimer's

	North America And Europe			
Item	Adoption	Adoption	Adoption	
Individuals with AD	15 million	15 million	15 million	
Agitation in AD (76%)	11 million	11 million	11 million	
% adoption of IGC-AD1	3%	5%	10%	
Monthly Price of drug	\$700	\$700	\$700	
Estimated	\$2.7B	\$4.6B	\$9.2B	
Revenue	\$2.7D	34.0D	<b>↓7.∠D</b>	







Accessible at an affordable price



#### **Next 18 months for IGC-AD1**

- 1. Data read out for completed Phase 2 trial as a treatment for Agitation in AD
- 2. Seek FDA approval with potential commercialization, through compassionate use
- 3. Complete partial toxicology studies for IGC-AD1 for chronic use

4. Establish IGC-AD1 as a diseasemodifying treatment



#### \$4B Valuation

\$300m, \$500m, 1.2B Valuation

#### Current valuation is ~ \$30m

~ \$30m Enterprise Value today

- Preclinical & Phase 1 safety completed
- Phase 2 Agitation ongoing with positive Interim data

#### Path to exponential value creation:

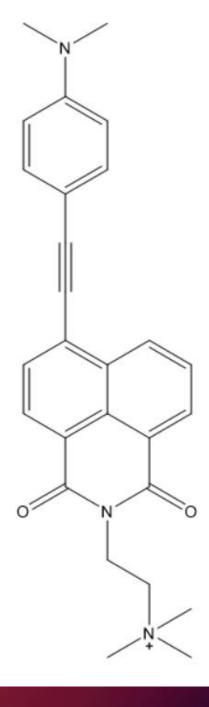
- Near-term clinical advancement
- Expanding market opportunity as disease modifying treatment
  - Complete Phase 2 for agitation
    - Achieve FDA-Breakthrough & or FastTrack Designation
    - Approval for early marketing based on compassionate use

- Complete one of two Phase 3s for agitation
- Positive results as a disease modifying treatment

2024

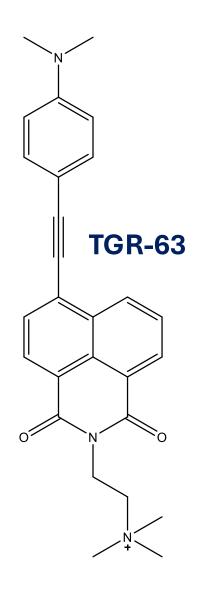
2026

2028



# **TGR Platform**

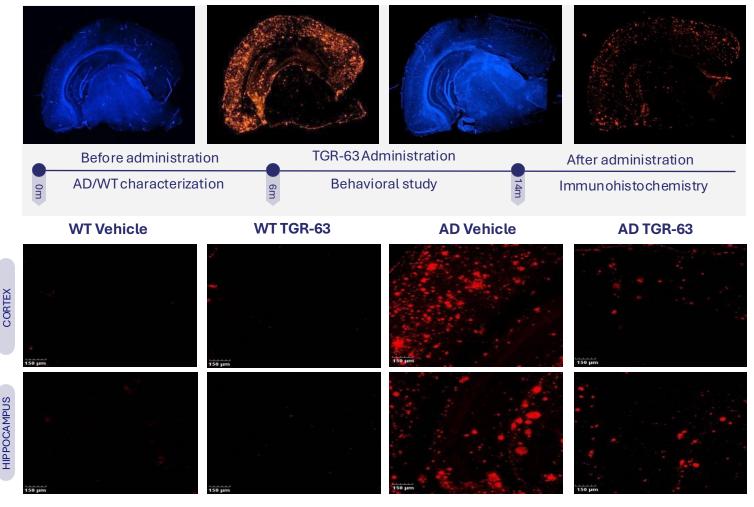
# TGR-63 Ameliorates Aβ Plaque



- IGC licensed TGR from India-based Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR)
- Preclinical data testing demonstrates TGR-63 holds potential to ameliorate plaque
- Behavioral tests with AD (APP/PS1) mice show that TGR-63 can:
  - Rescue neuronal cells from amyloid toxicity
  - Minimize learning deficiency, memory impairment and cognitive decline

### The Promise of TGR-63: Reduction of Plaque in Mouse Model

TGR-63 effectively reduced the amyloid burden in the mice cortex and hippocampus



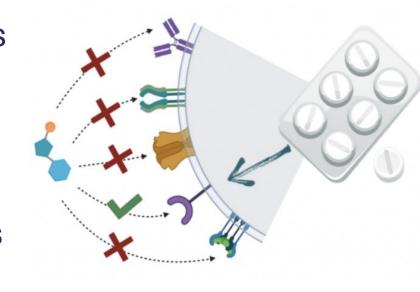
The brain tissue sections were immunostained with amyloid fibrils specific primary antibody (OC) and red fluorescent-labeled secondary antibody



#### Al Powered Model for Alzheimer's

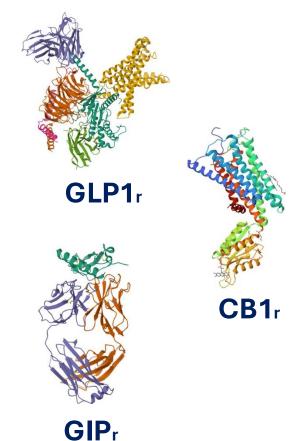
IGC is building a Foundation Model for Alzheimer's that can help predict early markers and disease progression using data from around the world

The model will be deployed on the web for doctors to use as a tool to help diagnose early Alzheimer's



# Strategic Expansion into Metabolic Disorders

#### Leveraging AI-driven insights, IGC Pharma is expanding its portfolio to include GLP-1 agonists



- Expansion into GLP-1 therapies allows IGC to tap into the **multi-billion-dollar global market** for weight management and type-2 diabetes treatments, while maintaining a strong foothold in Alzheimer's care
- Research indicates potential synergies between neuroprotection and metabolic regulation via GLP-1 mechanisms, providing a unique, dual-therapy approach with IGC's proprietary molecules
- Diversifying the pipeline with GLP-1 candidates complements ongoing AD trials, enabling IGC to capitalize on emerging markets and create substantial long-term value for shareholders

#### **Scientific Advisors**

#### **Chemistry and Pharmaceutical Sciences**



Prof. Joseph
Fortunak,
PhD
Professor
Chemistry and
Pharmaceutical
Sciences



Prof. Chuanhai
Cao,
PhD
Professor of
Pharmaceutical
Sciences



Prof. T.
Govindaraju,
PhD, FRSC.
Professor Bioorganic
Chemistry



#### **Psychiatry and Al**



Prof. Elliot Hong, MD Professor Psychiatrist



Prof. James
Saunders,
PhD
Ret.
Professor,
Molecular
Biology



Prof. Jeffrey
Cummings,
MD, ScD, Chair of the
ACTC
Neuropsychiatric
Symptoms
Committee



Prof. Pablo Arbelaez, PhD Professor Biomedical Engineering













#### **Science Team**

Internal CRO to conduct and manage clinical trials



Partnered with manufacturers and top universities for Al and animal studies



**Dr. Juan Orjuela, MD**Neuropsychiatrist



**Dr. Juanita Arbeláez, MD, MPH**Medical Director



**Evelyn Gutiérrez, Eng. MPH**CRO Manager



Diego Rodriguez, Ph.D. Senior Chemist



**Paola Ruiz, MS**Al Manager



Margarita Venegas, MS Clinical Psychologist



Maria Tangarife, MS
Neuroscientist



**Andres Sanchez, Ph.D.**Corporate Affairs Manager

# **Executive Management & Board**

#### **Executive management**



Ram Mukunda, CEO, Director



Claudia Grimaldi VP & Director



Richard Prins
Chairman

#### **Board**



Ex. Congressman
James Moran
Director



Terry Lierman
Director

#### **Board Advisors**



**Governor** Terry McAuliffe



Amb. (Rtd)
Howard Gutman

# Join Us in The Fight to Conquer Alzheimer's



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# Thank you



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