#### **Submission Data File**

General Information			
Form Type*	8-K		
Subject-Company File Number			
Subject-Company CIK			
Subject-Company Name			
Subject-Company IRS Number			
Contact Name	Federal Filings		
Contact Phone	512-450-5011		
Filer File Number			
Filer CIK*	0001326205 (IGC Pharma, Inc.)		
Filer CCC*	******		
Confirming Copy	No		
Notify via Website only	No		
Return Copy	No		
Group Name			
Items*	8.01 Other Events		
	9.01 Financial Statements and Exhibits		
SROS*	NYSE		
Depositor CIK			
Depositor 33 File Number			
Fiscal Year			
Item Submission Type			
Period*	06-17-2025		
ABS Asset Class Type			
ABS Sub Asset Class Type			
Sponsor CIK			
Emerging Growth Company	No		
Elected not to use extended transition period	No		
(End General Information)			

Document Information			
File Count*	56		
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Document Type 2*	EX-99.1		
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E-mail 1 production@federalfilings.com			
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Federal Filings LLC	IGC Pharma, Inc.	06/14/2025 03:25 PM

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 17, 2025



#### IGC PHARMA, INC.

(Exact name of registrant as specified in charter)

Maryland	Maryland 001-32830	
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
	10024 Falls Road, Potomac, Maryland 20859 (Address of principal executive offices) (Zip Code)	
	(Registrant's telephone number, including area code)	
(Fo	rmer Name or Former Address, if Changed since Last Report	)
Check the appropriate box below if the Form 8-K filing is General Instruction A.2. below):	intended to simultaneously satisfy the filing obligation of t	he registrant under any of the following provisions (see
☐ Written communications pursuant to Rule 425 under the	e Securities Act (17 CFR 230.425)	
☐ Soliciting material pursuant to Rule 14a-12 under the E	exchange Act (17 CFR 240.14a-12)	
☐ Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))	
☐ Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))	
Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$.0001 par value	IGC	NYSE American
Indicate by check mark whether the registrant is an emergin	ng growth company as defined in Rule 405 of the Securities A	ct of 1934 (§240.12b-2 of this chapter)
Emerging growth company $\square$ .		
If an emerging growth company, indicate by check mark i accounting standards provided pursuant to Section 13(a) of	f the registrant has elected not to use the extended transition the Exchange Act. $\Box$	period for complying with any new or revised financial

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#### **Item 8.01 Other Events**

On June 17, 2025, IGC Pharma, Inc. ("IGC" or the "Company") made available on its website an updated corporate presentation titled *Clinical Study Update*, dated June 17, 2025. The Company expects to use this presentation at upcoming conferences, business events, and in meetings with analysts, investors, and other stakeholders. A copy of the presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits

#### (d) Exhibits

Exhibit No.	Description
99.1	Clinical Study Presentation dated June 17, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

The exhibits listed in the following Exhibit Index are filed as part of this current report.

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#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IGC PHARMA, INC.

Dated: June 17, 2025 /s/ Claudia Grimaldi By:

Name: Claudia Grimaldi
Title: Principal Financial Officer and Vice President

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Exhibit 99.1





**IGC**PHARMA

NYSE AMERICAN: IGC

**Date:** 

June 16, 2025

-Service to humanity-

NYSE American: IGC

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Safe Harbor ( SIGC PHARMA

The information presented in these slides includes forward-looking statements regarding the business prospects of IGC Pharma, Inc. ("IGC" or the "Company"). These forward-looking statements are based on management's current expectations as of the date of this presentation and are subject to a number of risks and uncertainties, many of which are beyond our control. Forward-looking statements can often be identified by words such as "believes," "expects," "anticipates," "plans," "will," "goal," "may," "intends," "assumes," or similar expressions. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected or implied. These risks and uncertainties include, but are not limited to: clinical trial outcomes, patient recruitment timelines, clinical site performance, management's ability to recruit sites, patients, and monitor clinical trials, regulatory approvals, competition, funding availability, intellectual property protection.

The forward-looking statements are based on assumptions that the Company has made in light of its industry experience and its perceptions of historical trends, current conditions, expected future developments, and other factors believed to be appropriate under the circumstances. However, these assumptions are inherently subject to uncertainty and changes. IGC's actual results may differ materially from those anticipated in these forward-looking statements due to various factors. The forward-looking statements are not guarantees of future performance. Important factors that could cause actual results to differ materially from recent results or those projected in forward-looking statements are included in the Company's filings with the Securities and Exchange Commission (the "SEC"), including its most recent Annual Report on Form 10-K and subsequent filings on Form 10-Q, which are accessible on the SEC's website (<a href="https://www.sec.gov">www.sec.gov</a>). The Company undertakes no obligation and expressly disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. Potential investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation.



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## MoA <u>Hypothesis:</u> Dual-Agent Liquid Therapy for Alzheimer's

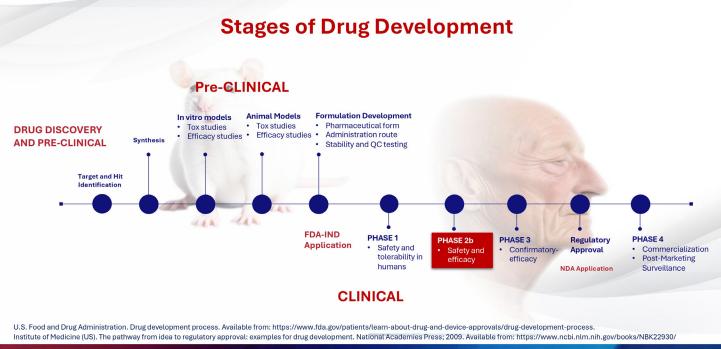
- Preclinical work done by Dr. Chuanhai Cao and his team at USF.
- IGC-AD1's technology is licensed from USF and protected by Patents.

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#### **Stages of Drug Development**





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#### Main Brain Alterations in Alzheimer's Disease

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#### Hallmarks of Alzheimer's and possible IGC-AD1 Mechanisms of Action (MoA)

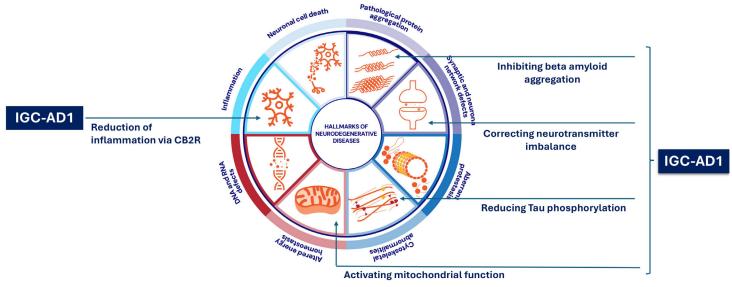


Chart: Wilson DM, Cookson MR, Van Den Bosch L, Zetterberg H, Holtzman DM, Dewachter I. Cell. 2023;186(4):693-714. doi:10.1016/j.cell.2022.12.032

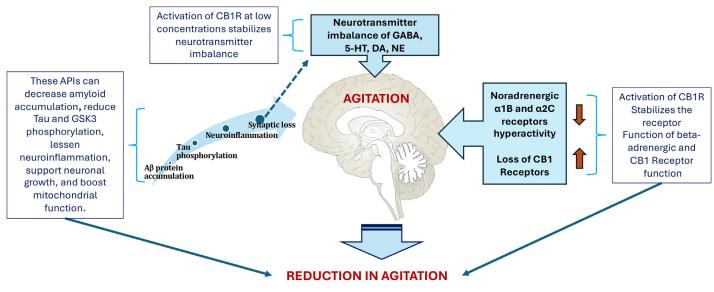
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#### Possible IGC-AD1 MoAs for Reducing Agitation in Alzheimer's

#### **(€IGC**PHARMA

#### Hallmarks of AD and possible IGC-AD1 MoA



Rao JS, Tangarife MA, Rodríguez-Soacha DA, Arbelaez MJ, Venegas MM, Delgado-Murillo L, et al. J Dement Alzheimer's Dis. 2025;2:15. doi:10.3390/jdad2020015.

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# IGC-AD1 Has Undergone Rigorous Preclinical and Regulatory Review and Is Approved for Clinical Investigation



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#### **IGC-AD1** meets all Mandatory Regulatory Requirements

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Tested and Verified for Quality, Stability, and Consistency in Compliance with FDA Regulatory Standards

TEST CATEGORY	Test	Purpose	Regulatory
Microbial Enumeration	Total Aerobic Microbial Count (TAMC) - Total Yeast and Mold Count (TYMC)	Detect overall microbial burden	USP 60, USP 61,
Specified Microorganisms	Escherichia coli - Salmonella spp.	Ensure absence of objectionable pathogens	USP62
Preservative Efficacy	Antimicrobial Effectiveness Testing	Validate preservative system (if present)	USP51
Chemical Quality	<ul> <li>Assay of API</li> <li>Impurities (related substances)</li> <li>pH</li> <li>Appearance</li> </ul>	Ensure identity, strength, quality, purity	21 CFR Part 211 Subpart I
Stability Testing	- Microbial and chemical stability over time	Establish shelf-life	21 CFR 211.166 ICH Q1A (R2)
Container Closure	- Suitability (e.g., for light protection, leachables, microbial ingress, etc.)	Ensure protection from contamination and degradation	21 CFR 211.94
Heavy Metals	Arsenic, lead, cadmium, Mercury	Detect the toxicity of the heavy metals and should be accepted levels(0.4 PPM)	21 CFR Part 211 Subpart II
Residual solvents	Beneze, butane, ethanol, hepatanes, hexanes, toluene, xylenes, Propane	Detect the toxicity of the residual toxicity, and levels should be below 2 ppm	USP <467
Mycotoxins	B1, B2, G1, G2, Orchatoxin A	Detect the toxicity should not present	21 CFR Part 211 Subpart I
Pestcides	More than 25 pesticides	To detect pesticide-induced toxicity should be less than 2-5 ppm	21 CFR Part 211
Terpenes	More than 22	Prevent additional Interctions	21 CFR Part 211
Bottles & caps -Fda compliance	No leeching	To avoid contamination	21 CFR Part 211

The specification was developed by IGC Pharma in compliance with the applicable guidelines and pharmacopeias referenced in the regulatory column.

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#### **Specification Summary and Quality Characteristics of IGC-AD1**



#### **IGC-AD1 Basic Quality Profile**

Specification			
Test	Technique/ Method	Acceptance criteria	
Appearance	Visual	Highly viscous solution, yellow to orange	
рН	pH meter USP <2> and <791>	3.0 - 9.0	
Specific Gravity	Gravimetric (Pycnometer) USP <841>	1.1 Acceptance range: 0.9 - 1.3	
Potency			
Delta-9-THC HPLC-DAD		2.5 mg/mL  Acceptance range: 2.25-2.75 mg/mL	
Melatonin		1.5 mg/mL Acceptance range:1.35-1.65 mg/mL	

Specification Specification			
lest lest	Technique/ Method	Acceptance criteria	
Microbial			
Aerobic total plate count	Plate count	≤ 100 CFU/g	
Yeast and molds		≤ 10 CFU/g	
Escherichia coli	USP <61> and <62>	Absent	
Elemental Impurities			
Arsenic		≤ 5.0 ppm	
Cadmium	Ion-coupled plasma Mass	≤ 1.7 ppm	
Lead	Spectrophotometer (ICPMS)	≤ 1.7 ppm	
Mercury	1100 1004	≤ 10 ppm	
Cobalt	USP <231>	≤ 17 ppm	
Vanadium	USP <232>	≤ 33 ppm	
Nickel		≤ 67 ppm	
Residual Solvents			
Class I			
Class II	Gas Chromatography	Lower than required by USP <467>	
Class III (excluding ethanol)	USP <467>	≤ 5000 ppm	

#### Tested and Verified for Quality, Stability, and Consistency in Compliance with FDA Regulatory Standards

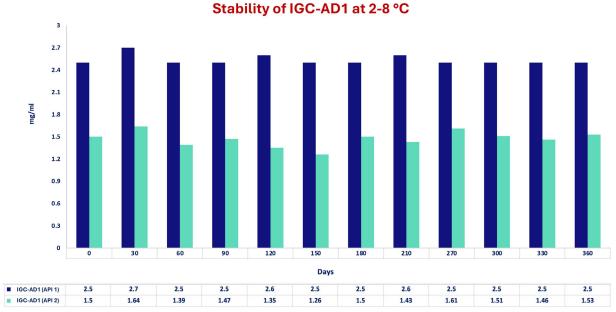
Company-owned data

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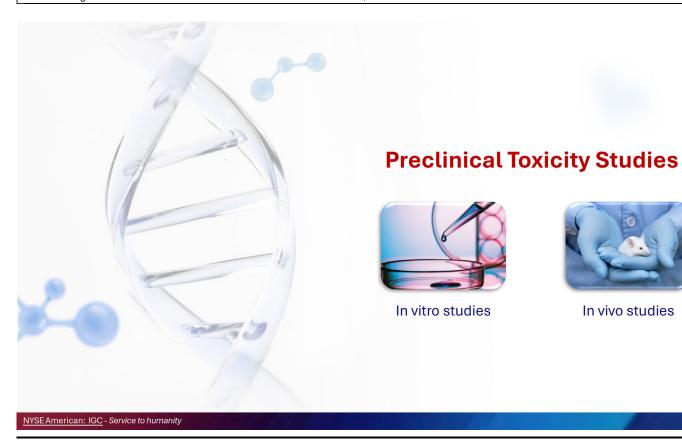
#### **IGC-AD1 APIs Exhibit 12-Month Stability Under Controlled Conditions**





Company-owned data

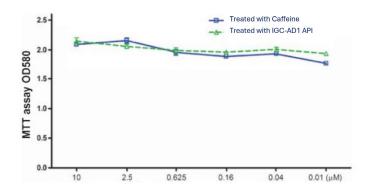
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#### In Vitro Studies Show IGC-AD1 API is Non-Toxic to AD Cells





#### **Cytotoxicity Evaluation by MTT Assay**

- IGC-AD1 API treatment exhibited no cytotoxicity at the tested concentrations
- No significant difference in toxicity was observed compared to the control at various concentrations, indicating a favorable safety profile of the compound.

#### N2a/AβPPswe Alzheimer's cell lines

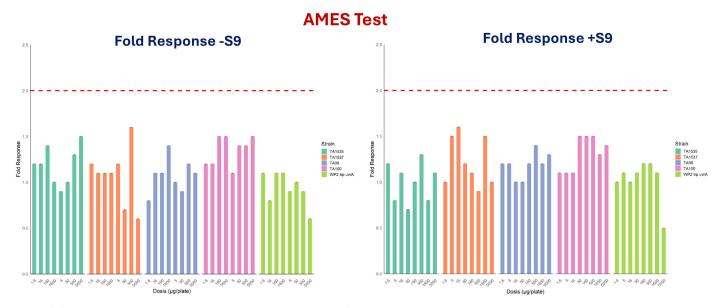
Cao C, Li Y, Liu H, Bai G, Mayl J, Lin X, Sutherland K, Nabar N, Cai J. J Alzheimers Dis. 2014;42(3):973-84. doi: 10.3233/JAD-140093

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#### **Mutagenic Assays Confirm Safety of IGC-AD1 API**





← IGC-AD1 API is Not Mutagenic in Regulatory-Compliant Testing

Delgado-Murillo L, Galindo LD, Rodríguez-Soacha D, Gutiérrez E, Rao J, et al. Presented at: The Annual Genetic Toxicology Association Meeting; 2025; Newark, DE. Poster No: 20.

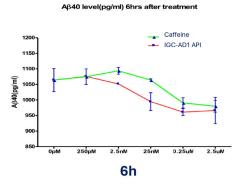
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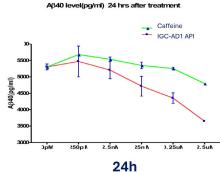


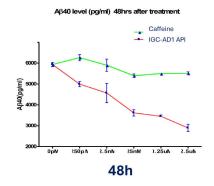
#### API Exhibits Time-and Dose-Dependent Reduction of Aβ40 production

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## Quantification of Aβ40 by ELISA in N2a/APPswe cell models







- While Aβ42 is more fibrillogenic, Aβ40 is highly abundant, influences plaque architecture, and contributes to vascular amyloid pathology. Reducing Aβ40 may lower total amyloid load, improve vascular health, and shift the Aβ42:Aβ40 ratio, making it a valuable therapeutic target alongside Aβ42.
- $\checkmark$  Hypothesis: These inherent anti- Aβ40 properties may contribute to delaying or halting Alzheimer's progression by inhibiting Aβ40 peptide production.

Cao C, Li Y, Liu H, Bai G, Mayl J, Lin X, Sutherland K, Nabar N, Cai J. J Alzheimers Dis. 2014;42(3):973-84. doi: 10.3233/JAD-140093

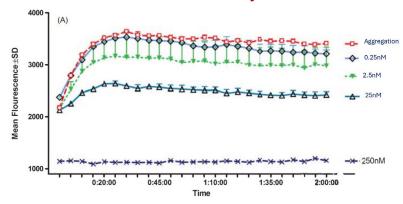
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#### API inhibit Aβ40 peptide aggregation



## API Preserves Aβ40 Monomers and Inhibits Aggregation as Assessed by ThT Assay



<u>Hypothesis</u>: These findings support a potential direct interaction between the API and Aβ peptide, enabling the API to bind and inhibit Aβ aggregation, which may contribute to lowering amyloid burden in Alzheimer's disease.

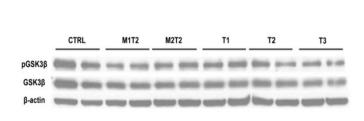
Cao C, Li Y, Liu H, Bai G, Mayl J, Lin X, Sutherland K, Nabar N, Cai J. J Alzheimers Dis. 2014;42(3):973-84. doi: 10.3233/JAD-140093

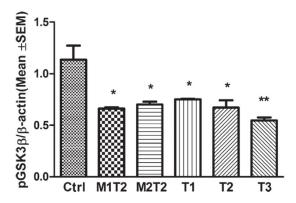
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#### API Induces Dose-Dependent Decrease in GSK-3β and pGSK-3β

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#### Effect of IGC-AD1 API on GSK-3β and pGSK-3β by Western Blot





**Hypothesis:** The API may exert neuroprotective effects by modulating GSK-3β and pGSK-3β activity, potentially reducing neuronal apoptosis through downregulation of this key kinase involved in Alzheimer's-related tau phosphorylation and cell death pathways.

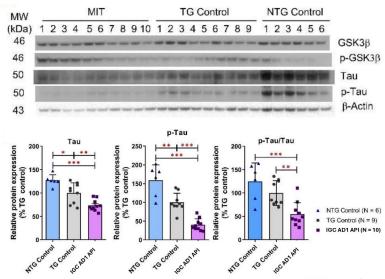
Cao C, Li Y, Liu H, Bai G, Mayl J, Lin X, Sutherland K, Nabar N, Cai J. J Alzheimers Dis. 2014;42(3):973-84. doi: 10.3233/JAD-140093

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#### API Regulates Tau and pTau Expression and Crosses the BBB

#### **(€IGC**PHARMA

### Tau, pTau, and GSK3β Expression in APP/PS1 Mouse Brain Tissue



- In vivo studies comparing transgenic (TG) and non-transgenic (NTG) controls showed that treatment with IGC-AD1 API led to reductions in total Tau, phosphorylated Tau (pTau), and the pTau/total Tau ratio in the brains of TG mice. These results demonstrate that the API crosses the blood-brain barrier (BBB) and engages with central targets.
- Mypothesis: API may offer diseasemodifying potential in AD by reducing pathological pTau and modulating Taurelated neurodegenerative processes.

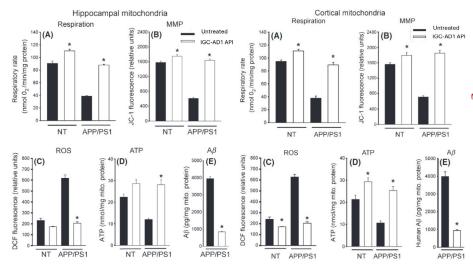
Fihurka O, Wang Y, Hong Y, Lin X, Shen N, Yang H, et al. Biomolecules. 2023;13(2):232. doi:10.3390/biom13020232

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#### **API Enhances and Restores Mitochondrial Function in Relevant Brain Regions**

**(***<b>¢* **IGC**PHARMA

## Mitochondrial Respiratory Activity in IGC-AD1 API-Treated APP/PS1 Mouse Model



- Treatment with IGC-AD1 API led to improved and restored mitochondrial function in the hippocampus and cortex, two regions affected in AD
- Hypothesis: By improving mitochondrial performance, IGC-AD1 may enhance neuronal energy metabolism and reduce oxidative stress, potentially contributing to neuroprotection and slowing disease progression in Alzheimer's patients.

Dragicevic N, Copes N, O'Neal-Moffitt G, Jin J, Buzzeo R, Mamcarz M, et al. J Pineal Res. 2011;51(1):75-86. doi:10.1111/j.1600-079X.2011.00864.x.

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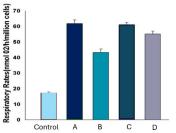
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#### **APIs Restores Mitochondrial Function in AD Cell Model**

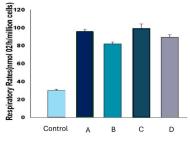
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#### State II(Basal) APP Cells Respiration rates



A: 10  $\mu$ M API 1 + 2.5 nM API 2 B: 2.5 nM API 2 C: 10  $\mu$ M API 1 D: 1  $\mu$ M API 1 + 2.5 nM API 2

#### State V(FCCP) APP Cells Respiration rates



A: 10 μM API 1 + 2.5 nM API 2 B: 2.5 nM API 2 C: 10 μM API 1 D: 1 μM API 1 + 2.5 nM API 2

#### Study of Mitochondrial Respiratory Activity in IGC-AD1 API-Treated - APP/PS1 Mouse Model

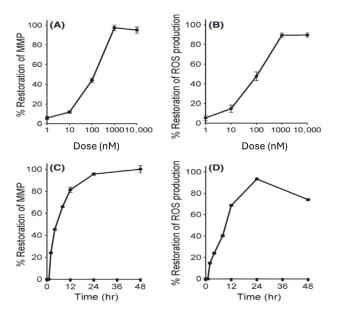
- In N2a-APPswe AD cel model, IGC-AD1 APIs treatment restored basal respiration and fully restored maximal respiratory capacity. These results indicate a significant improvement in mitochondrial function, which is commonly impaired in Alzheimer's pathology.
- Hypothesis: IGC-AD1 may promote neuronal resilience and delay neurodegeneration in Alzheimer's disease by enhancing mitochondrial respiration and energy metabolism.

Cao C, Li Y, Liu H, Bai G, Mayl J, Lin X, Sutherland K, Nabar N, Cai J. J Alzheimers Dis. 2014;42(3):973-84. doi: 10.3233/JAD-140093

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#### **API Restores Mitochondrial Function in AD Cell Model**

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#### Study of Mitochondrial Respiratory Activity in IGC-AD1 API-Treated N2a-APPswe cells

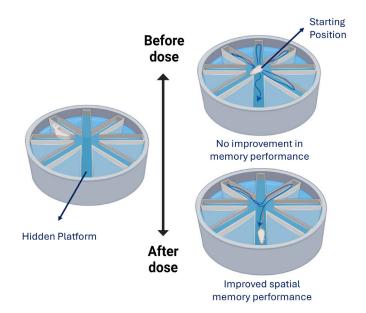
- IGC-AD1 API improves mitochondrial function in a concentration-dependent manner, achieving full restoration of Mitochondrial Membrane Potential (MMP) and ROS production at 100 nM in N2a-APPswe AD cell model.
- Approximately 24 hours of IGC-AD1 API treatment were required to fully restore mitochondrial function in N2a-APPsw cells
- Hypothesis: IGC-AD1 may enhance neuronal resilience in Alzheimer's disease by stabilizing MMP and decreasing ROS production, supporting healthier energy metabolism

Dragicevic N, Copes N, O'Neal-Moffitt G, Jin J, Buzzeo R, Mamcarz M, et al. J Pineal Res. 2011;51(1):75-86. doi:10.1111/j.1600-079X.2011.00864.x.

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#### IGC-AD1 API Enhances Spatial Memory in APP/PS1 AD Mouse Model

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## Spatial Memory in APP/PS1 Transgenic Mice improved by 50%

- In the Radial Arm Water Maze (RAWM) test, IGC-AD1 API treatment resulted in over a 50% reduction (p < 0.001) in both latencies to escape and number of errors in APP/PS1 transgenic mice, compared to untreated controls.
- Hypothesis: These findings suggest that IGC-AD1 API may improve hippocampaldependent spatial memory by modulating underlying synaptic, mitochondrial, and neuroinflammatory pathways, offering potential cognitive benefits in Alzheimer's disease

Wang Y, Hong Y, Yan J, Brown B, Lin X, Zhang X, et al. Int J Mol Sci. 2022;23(5):2757. doi:10.3390/ijms23052757

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#### **Summary: Preclinical Data**



#### IGC-AD1: Preclinical Evidence Supporting Disease-Modifying Potential in Humans

- Decreases Aβ<sub>40</sub> production and aggregation in cell models, implicates amyloid pathway modulation. <sup>1</sup>
- Reduces pTau and total Tau in transgenic mouse models.<sup>2</sup>
- Enhances mitochondrial function and restores respiratory capacity in AD models, supports neuronal survival and synaptic health.<sup>1-3</sup>
- Improves spatial memory in APP/PS1 mice, correlating with potential cognitive benefit in human AD patients.4
- Crosses the blood-brain barrier (BBB), enabling direct central nervous system activity. 2
- Supports long-term neuroprotection through modulation of GSK-3β, a kinase involved in tau phosphorylation and apoptosis. <sup>2</sup>

These mechanistic effects provide a rationale for future clinical trials evaluating IGC-AD1 as a disease-modifying therapy with target clinical biomarker, for example, reduction in CSF pTau181 or pTau217, a validated surrogate of Alzheimer's progression

1. J. Alzheimer's disease 2014, 42, 973-984; 2. Biomolecules. 2023;13(2):232 3. J. Pineal. Res. 2011, 51, 75-86; 4. Int. J. Mol. Sci. 2022, 23, 2757;

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#### **Phase 1 Trial Results**

Phase I Randomized Placebo Controlled MAD Study to Evaluate Safety and Tolerability of IGC-AD1 in Subjects With Dementia Due to Alzheimer's Disease

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#### Phase 1 · Objectives and End Points

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#### Primary:

Safety and tolerability of IGC-AD1, in a double-blind, multiple ascending dose (MAD) study, measured by solicited and non-solicited Adverse Events (AEs) in participants with mild to severe AD.

#### Secondary:

Compare (NPS) pre and post intervention neuropsychiatric symptoms measured by the neuropsychiatric inventory (NPI-12).

#### Exploratory:

Pharmacokinetics (PK) of IGC-AD1, and the impact of polymorphisms of CYP2C9 on PK.

Trial on www.clinicaltrials.gov



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#### **Phase 1 Trial Design**



- At home-participants with caregivers
- Mild to severe Alzheimer's disease, clinical diagnosis
- Multiple Ascending Dose (MAD)
- Three dose cohorts-14 days each cohort with a washout period
- Cosing: once a day (QD), twice a day (BID), and three times a day (TID)
- Randomized, Double Blind

#### **General Design**

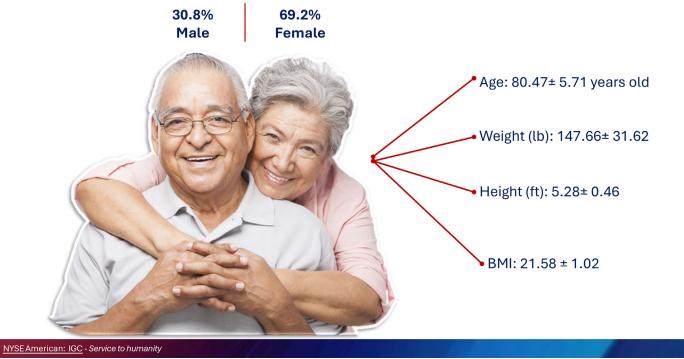


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#### **PHASE 1: Demographics**





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#### **Genotype and Phenotype for Participants**



Participant	CYP2C9 Genotype	CYP2C9 Phenotype	Sex
1001	*1/*2	Intermediate Metabolizer	Female
1002	*1/*2	Intermediate Metabolizer	Female
1003	*1/*3	Intermediate Metabolizer	Female
1004	*1/*3	Intermediate Metabolizer	Female
1005	*1/*2	Intermediate Metabolizer	Female
1006	*1/*3	Intermediate Metabolizer	Male
1007	*1/*1	Normal Metabolizer	Male
1008	*1/*1	Normal Metabolizer	Female
1009	*1/*1	Normal Metabolizer	Female
1010	*1/*1	Normal Metabolizer	Female
1011	*1/*2	Intermediate Metabolizer	Male
1012	*1/*11	Intermediate Metabolizer	Male
1013	*1/*1	Normal Metabolizer	Female
Sex	69.2% Female, 30.8% Male		
Polymorphisms	61.5%		

Rao J, Gutierrez E, Grimaldi C, Julio W, Shahnawaz SS, Mukunda R. Presented at: AAIC 2023; Amsterdam, Netherlands. Poster No: P3-648.

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#### **Phase 1 Trial Safety Results**

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## IGC- AD1 was well-tolerated at all three dose levels

#### There were no:

- Serious Adverse Events (SAEs)
- Life-threatening AEs
- Deaths reported

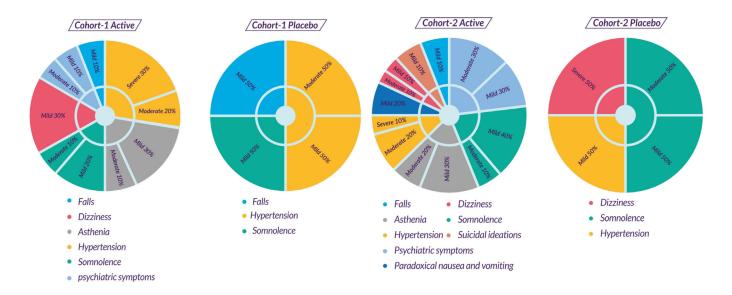


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#### Phase 1: Primary Endpoint- Safety & Tolerability





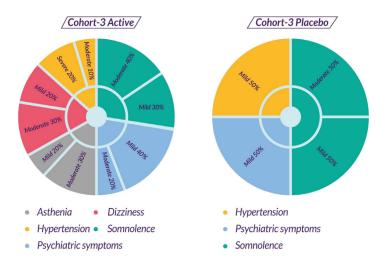
Mukunda R, Rao J, Gutierrez E, Julio W, Ghazaryan V, Pujals KY, et al. Presented at: 3rd Latinos & Alzheimer's Symposium; 2022; Bonita Springs, FL. Poster No: 35

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**Phase 1: Primary Endpoint- Safety & Tolerability** 





Two non-solicited AEs were reported: in Cohort 1, one participant reported a Grade 2 ataxic gait, and in Cohort 2, one participant reported a Grade 2 UTI. One with Grade 3 Hypertension events was unrelated to the IP.

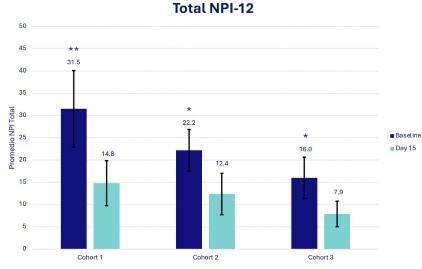
Mukunda R, Rao J, Gutierrez E, Julio W, Ghazaryan V, Pujals KY, et al. Presented at: 3rd Latinos & Alzheimer's Symposium; 2022; Bonita Springs, FL. Poster No: 35

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#### **Secondary Objective: NPS Measured by NPI-12**

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	Cohort 1	Cohort 2	Cohort 3
% Change	53.02	44.14	50.625
p value	0.005	0.024	0.021

# IGC-AD1 Demonstrated Improvement in Neuropsychiatric Symptoms in Phase 1 Trial

- Across all three dose levels, IGC-AD1 intervention led to an overall improvement in NPS as measured by the Neuropsychiatric Inventory-12 (NPI-12)
- Key Domains Showing Improvement:
  - Agitation,
  - Anxiety,
  - Depression, and
  - Caregiver Distress

Tangarife MA, Venegas M, Arbelaez MJ, Gutierrez E, Sanchez LT, Naranjo MP, et al. Presented at: AAIC 2023; Amsterdam, Netherlands. Poster No: P3-663.

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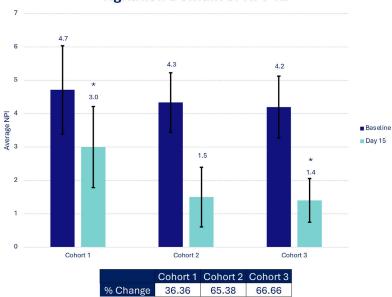
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#### **Phase 1 Agitation Scores**



#### **Agitation Domain of NPI-12**



# **IGC-AD1 Significantly Reduced Agitation** in Phase 1 Trial

- Agitation was assessed using the NPI domain score at baseline and at Day 15 (end of treatment) across three dose levels of IGC-AD1
- All three doses showed clinical and statistically significant reductions in agitation scores
- p < 0.05 for each dose group
  </p>

Demonstrates consistent, early therapeutic signal for agitation reduction

Arbelaez MJ, Venegas M, Tangarife MA, Delgado-Murillo L, Gutierrez E, Sanchez LT, et al. Presented at: AAIC 2023; Amsterdam, Netherlands. Poster No: P3-660.

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#### Phase 1 PK Data Shows PK Profile Varies by CYP2C9 Genotype



IGC-AD1 API	Mean over All	Mean over *1/*1	Mean over *1/*2	Mean over *1/*3
No. Patients	N=10	Normal (n=4)	Intermediate (n=4)	Intermediate (n=2)
T1/2 (h)	3.60	1.73	3.75	7.10
T <sub>max</sub> (h)	2.15	2.38	2.13	1.75
C <sub>max</sub> (ng/ml)	2.01	2.60	1.46	1.93
AUClast (h'ng/ml)	5.58	6.72	4.20	6.06
AUCinf (h*ng/ml)	8.92	9.04	7.24	11.22

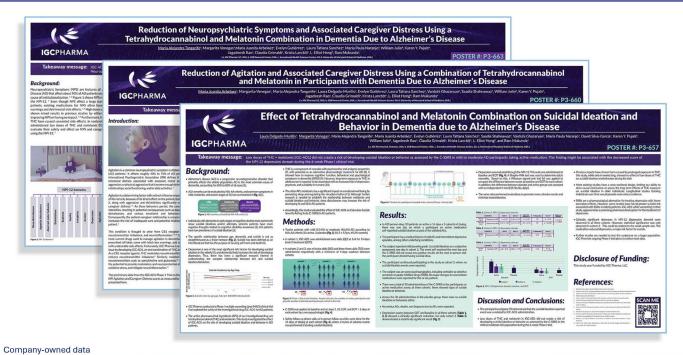
- PK data were collected across all participants and stratified based on CYP450 2C9 polymorphisms.
- As shown in the table IGC-AD1 API half-life increased significantly for intermediate metabolizers over normal metabolizers
- This genotype-dependent variation suggests the potential need for personalized dosing strategies in future trials to optimize safety and efficacy.

Rao J, Gutierrez E, Grimaldi C, Julio W, Shahnawaz SS, Mukunda R. Presented at: AAIC 2023; Amsterdam, Netherlands. Poster No: P3-648.

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#### IGC Pharma Poster Presentations at the AAIC 2023 in Netherlands

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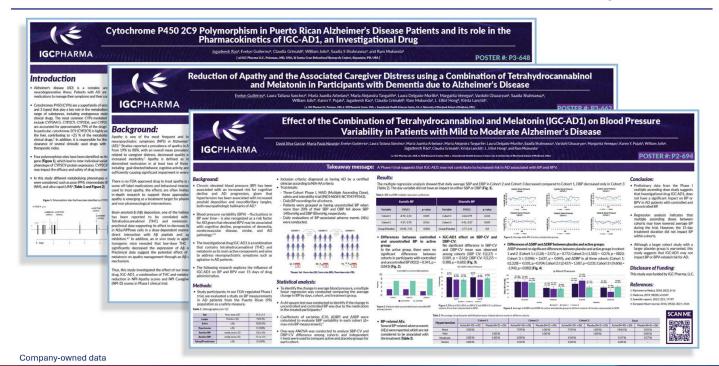


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#### IGC Pharma Poster Presentations at the AAIC 2023 in Netherlands

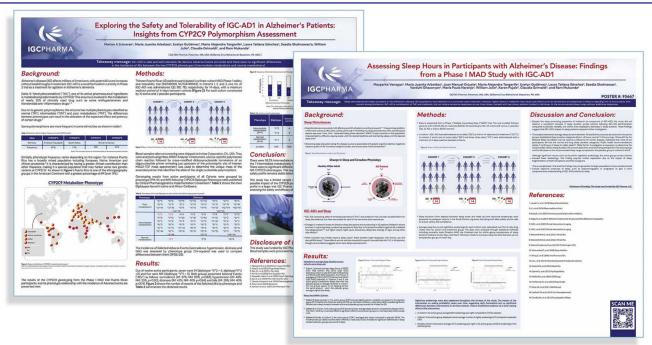
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#### IGC Pharma Poster Presentations at the AAIC 2024 in Philadelphia

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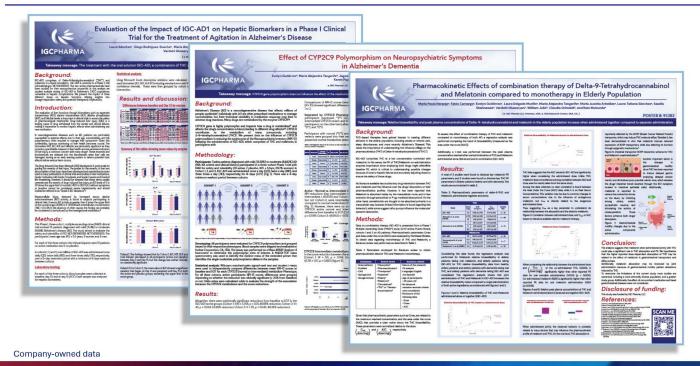


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#### IGC Pharma Poster Presentations at the AAIC 2024 in Philadelphia

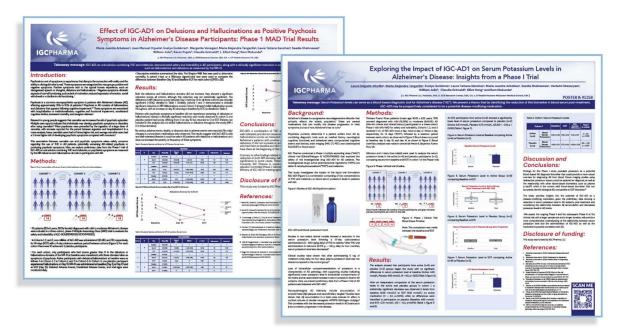
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#### **IGC-AD1 Phase 2 Strategy: Agitation in AD**

- Preclinical studies demonstrated disease modifying potential, including reduction in pTau, Aβ aggregation, and mitochondrial dysfunction.
- Phase 1 clinical data showed clinical and statistically significant improvements in results agitation symptoms in patients with AD
- Based on the strength of agitation signal and urgent unmet clinical need, IGC strategically prioritized a Phase 2 trial targeting Agitation in AD dementia.
- Disease modification remains a long-term objective

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### **Phase 2 in Progress**

Phase 2, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Trial of the Safety and Efficacy of IGC-AD1 on Agitation in Participants with Dementia due to Alzheimer's Disease.

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#### What is Agitation in Dementia Due to Alzheimer's Disease?



Agitation refers to a range of behaviors, excessive motor activity, verbal aggression, or physical aggression that is severe enough to impair personal relationships, social functioning, and/or daily activities (1).

Agitation has a significant impact on both the individuals with Alzheimer's and their caregivers.

- Agitated behavior is always socially inappropriate.
- It may be abusive or aggressive towards self or others.
- It may be appropriate behavior performed with inappropriate frequency, such as constantly asking questions.



References: (1) Cummings J et al., 2014 (2) Front Neurol, 2021, 12: 644317

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#### Agitated Behaviors - Categorization based on CMAI\* Scale

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\* CMAI: Cohen Mansfield Agitation Inventory Verbal / Vocal **Verbally Non-Aggressive Verbally Aggressive** o Complaining o Cursing and verbal aggression o Negativism o Making strange noises o Repetitive sentences or questions Verbal sexual advances Constant, unwarranted requests for attention or Screaming **Aggressive** Non-Aggressive **Physically Aggressive Physically Non-Aggressive** o Performing repetitious mannerisms o Physical sexual advances o Inappropriate robing and disrobing o Hurting self or others o Eating inappropriate substances Throwing things o Handling things inappropriately o Tearing things o Trying to get to a different place o Scratching o Grabbing Pacing Intentional falling o Pushing o General restlessness **Spitting**  Hoarding things Kicking Hiding things Biting **Physical** 

Adapted from: Cohen-Mansfield J, Billig N. J Am Geriatr Soc. 1986;34(10):711-721. doi:10.1111/j.1532-5415.1986.tb04302.x; Cohen-Mansfield J, Marx MS, Rosenthal AS. J Gerontol. 1989;44(3):M77-M84. doi:10.1093/geronj/44.3.m77

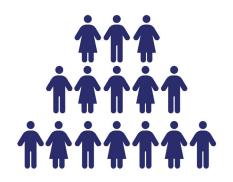
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#### **IGC-AD1 CALMA Phase 2 Trial: Ongoing**





The study targets completion by 146 participants

#### Multicenter, Double Blind, Randomized, Placebo-Controlled Trial

#### **Objectives:**

- Primary: evaluate the safety and efficacy of IGC-AD1 on agitation in AD at week 6 using the CMAI
- Secondary: Agitation at week 2 using the CMAI
- Exploratory: AD Blood biomarkers (p-tau217/Aβ42 ratio, p-tau217, NFL...) CGI, MMSC, ZBI, and other scales

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

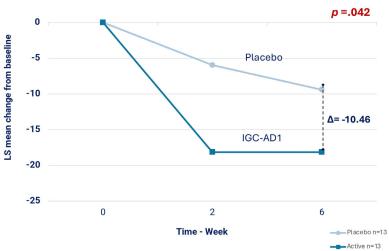
- Diagnosis of probable AD using the NIA-AA criteria
- Clinically significant agitation using a score ≥4 in NPI agitation domain

#### CALMA Phase 2 Interim Results: Primary Objective - Week 6

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#### **CMAI Total Score**

Clinical and statistically significant improvement in agitation at week-6 based on the CMAI



LS mean difference (95%CI)	p value	Cohen d
-10.46 (-20.53, -0.4)	0.042	0.79

	Active	Placebo
Baseline mean	68.58	72.27

Company-owned data

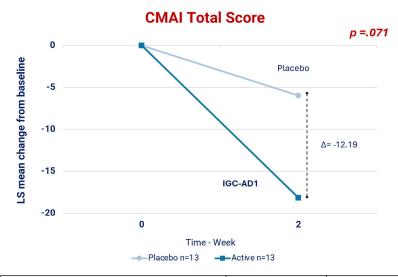
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#### CALMA Phase 2 Interim Results: Secondary Objective- Week 2

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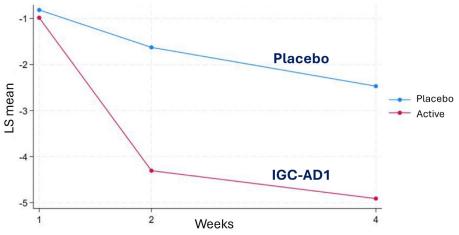
LS mean difference (95%CI)	p value	Cohen d
-12.19 (-25.52, 1.14)	0.071	0.79

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#### **CALMA Phase 2 Interim Results: Exploratory Objective: Sleep Disturbance**

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- Week 2: Reduced 71% (p=0.012)
- Week 6: Reduced 78% (p=0.02)

NPI-12 Sleep Subdomain Least Squared Mean change from baseline comparing placebo and active groups

Company-owned data

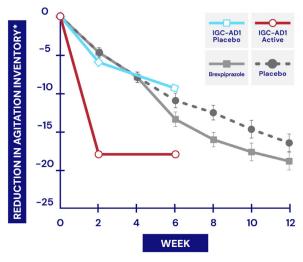
## IGC-AD1 Improves Sleep Disturbance in AD Patients

- Treatment led to clinically and statistically significant improvements in sleep disturbance at both week 2 and week 6- NPI-12 sleep & nighttime behavior disorder subscale
- These findings suggest that IGC-AD1 may help improve sleep quality, providing early and sustained benefits for patients and caregivers

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#### CALMA Phase 2 Interim Results: IGC-AD1 Compared to Brexpiprazole Data





\*  $\Delta$  ADJUSTED MEAN OF COHEN MANSFIELD AGITATION INVENTORY (CMAI)

- Compared to published results of Brexpiprazole, IGC-AD1 appears to be faster acting than Brexpiprazole.
- IGC-AD1 demonstrates a large effect size (Cohen's d = 0.79) and is more strongly distinguished from placebo at week 2 and 6 compared to Brexpiprazole
- Brexpiprazole has limited effect at week 2
- Brexpiprazole starts to show effect at week 6
- Brex Cohen's d = 0.4, (p=.001) at week 12

Grossberg GT, Kohegyi E, Mergel V, et al. Am J Geriatr Psychiatry. 2020;28(4):383-400. doi:10.1016/j.jagp.2019.09.009

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<sup>\*</sup> 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<0.01, bp<0.001; Mixed Model of Repeated Measures. SE: Standard Error; CMAI: Cohen-Mansfield Agitation Inventory.

\* This is a not a direct comparison

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#### CALMA Phase 2 Interim Results Adverse Events: IGC-AD1 vs. Brexpiprazole

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### **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

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

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#### **Protected Intellectual Property**



Target	Description	Patent Applications	US Patents Granted	Foreign Patents Granted	
(IGC-AD1)	Composition & Method for treating CNS Disorders.	1	2		
(IGC-AD1)	Composition & Method for treating CNS Disorders.	12		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	5			
(IGC-M3)	Naphthalene Monoimide Derivatives with ability to impact AB plaque buildup and neurofibrillary tangle formation	4			In-house patents / applications
Cancer (Naphthalene Dimdes)	Naphthalene diimide Derivatives with ability to self-assemble molecular interactions for biological and nonbiological systems		1	1	Patents / applications acquired through exclus
(IGC-LMP)	Composition, Synthesis & Medical use of Hybrid Molecule	1			license agreements
Epilepsy	Composition & Method for treating Seizures in humans & Cats/Dogs.		2		
Eating Disorders	Natural formulation with Cyproheptadine for treating Cachexia & Eating Disorders.		1		
<ul> <li>Stuttering &amp; Tourette</li> <li>Syndrome</li> </ul>	Formulation for Treating Stuttering & Symptoms of Tourette Syndrome.	1			
• Pain	Formulation containing Cobalamin and method for pain management.	1	2	2	

We have 31 patent applications in process, which are distributed among the US, Canada, Europe, Colombia, India, Brazil, Japan and Hong Kong and 12 granted Patents in US, Canada, Europe and Mexico.

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