



CSE:AGN | OTCQB:AGNPF | XFRA:AGW0

Q1, 2023

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Certain statements in this presentation (the “Presentation”) are forward-looking statements, which are made as of the date of this Presentation or as of the date of the effective date of information described in this presentation, as applicable. Forward-looking statements relate to future events or future performance and reflect current estimates, predictions, expectations or beliefs regarding future events and include, without limitation, statements with respect to: (i) Algernon Pharmaceuticals Inc. (“Algernon” or the “Company”) obtaining the necessary regulatory approvals; (ii) that regulatory requirements will be maintained; (iii) general business and economic conditions; (iv) the Company’s ability to successfully execute its plans and intentions; (v) the availability of financing on reasonable terms; (vi) the Company’s ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company’s competitors; (ix) the maintenance of the Company’s current good relationships with its suppliers, service providers and other third parties; (x) financial results, future financial position and expected growth of cash flows; (xi) business strategy, including budgets, projected costs, projected capital expenditures, taxes, plans, objectives, potential synergies and industry trends; (xii) research and development; (xiii) expectations concerning the size and growth of the global medical technology market; and (xiv) the effectiveness of the Company’s products compared to its competitors’ products.

Forward-looking statements relate to future events or the future performance of Algernon and involve known and unknown risks, uncertainties and other factors that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. Generally, forward-looking information can be identified by the use of forward-looking terminology such as “plans”, “expects”, or “does not expect”, “is expected”, “budget”, “scheduled”, “estimates”, “projects”, “targets”, “forecasts”, “intends”, “anticipates”, or “does not anticipate”, or “believes” or variations (including negative and grammatical variations) of such words and phrases or state that certain actions, events or results “likely”, “may”, “could”, “would”, “might”, or “will be taken”, “occur”, or “be achieved”. Forward-looking information is based on the opinions and estimates of management at the date the information is made, and is based on a number of assumptions and is subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of the Company to be materially different from those expressed or implied by such forward looking information, including without limitation: (i) the availability and continuation of financing; (ii) the effectiveness of the Company’s technology and the Company’s ability to bring its technology to commercial production; (iii) any statements regarding the Company’s intention to seek additional indications for its products; (iv) continued growth of the global medical technology market; (v) the Company’s limited operating history, difficulty in forecasting sales and limited market for the securities; and (vi) a continued minimal regulatory/legal burden concerning the development, production, sale and use of the Company’s technology. While the Company believes the expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company’s control. These and other important factors may cause actual results, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. Except as required by law, the Company assumes no obligation and does not intend to update these forward-looking statements or to conform these statements to actual results or to changes in the Company’s expectations.

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## DISCLAIMER (cont.)

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## ALGERNON MODEL

# Algernon is a Clinical Stage Drug Development Company

Global Disease Indications – Unmet Needs

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# Algernon is Advancing 3 Drugs

**NP-120 (Ifenprodil): Idiopathic Pulmonary Fibrosis and Cough**

**Repurposed**

**AP-188 (DMT): Psychedelic Drug – Stroke**

**Naturally Occurring**

**NP-251 (Repirinast): – Chronic Kidney Disease**

**Repurposed**

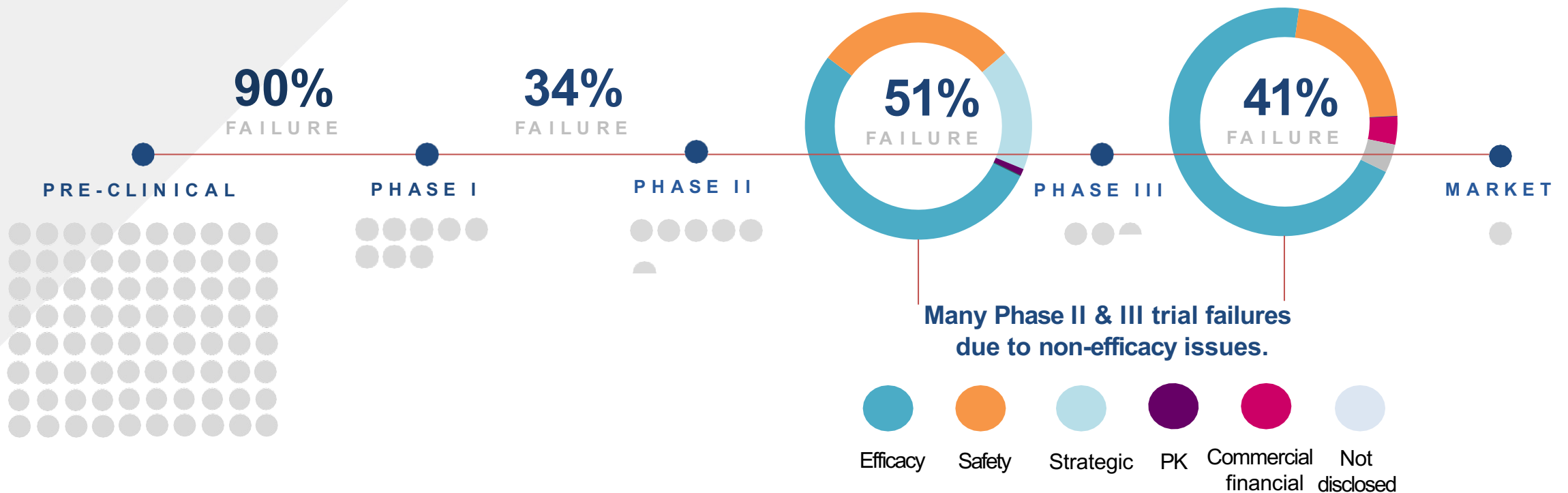
## ALGERNON MODEL

**\*Drug Repurposing** is the Process of  
Discovering New Therapeutic Uses for  
Approved Drugs

RISK REDUCTION – CAPITAL EFFICIENT – SHORTER DEVELOPMENT PATHWAY

**\* Drugs Not Approved or Marketed in U.S. or Europe.**

# NEW CHEMICAL ENTITY (NCE) DEVELOPMENT PATHWAY AND FAILURE RATES



Biostatistics (2019) 20:273-6  
Nature (2011) 477:526-8

# DRUG REPURPOSING: CASE STUDIES

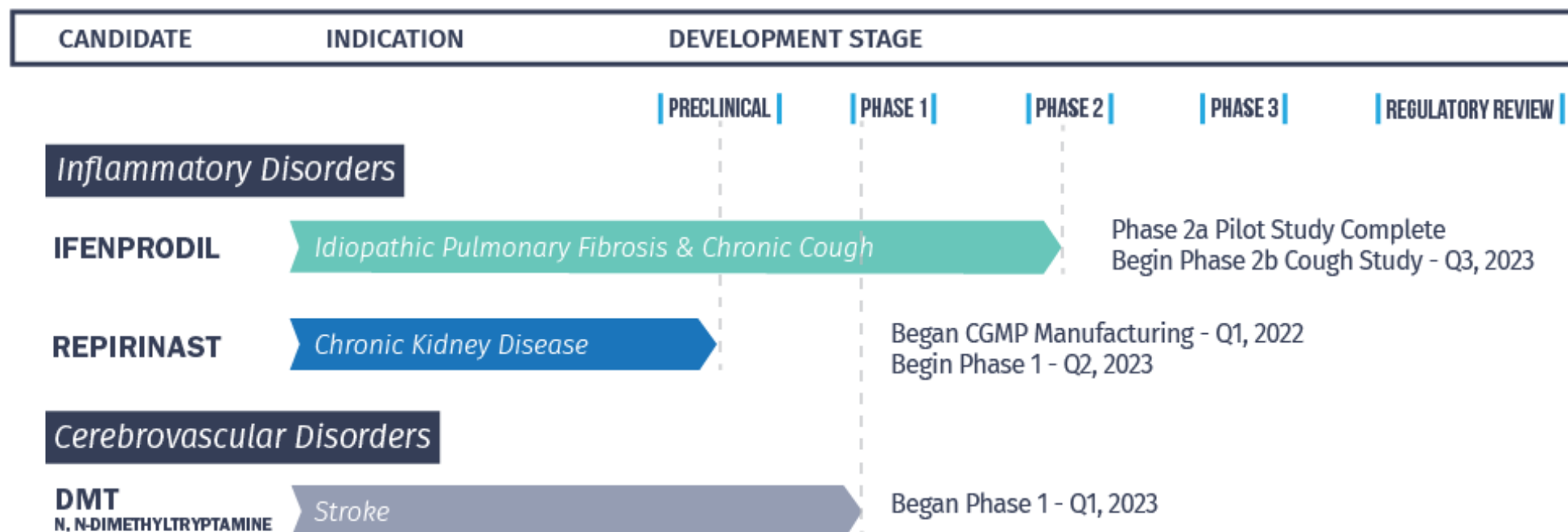


COMPANY	DRUG	OLD INDICATION	NEW INDICATION	NOTES
BIOGEN	<b>Tecfidera</b>	Psoriasis	Multiple sclerosis	<ul style="list-style-type: none"> <li>&gt; Drug Only Approved in Germany (50 yrs)</li> <li>&gt; Blockbuster (&gt;US\$1B in Sales)</li> </ul>
CELGENE	<b>Thalidomide</b>	Morning sickness	Cancer	<ul style="list-style-type: none"> <li>&gt; Drug was Withdrawn from the Market</li> <li>&gt; Blockbuster (&gt;US\$1B in Sales)</li> <li>&gt; Purchased EntreMed's Thalidomide Analogues</li> </ul>

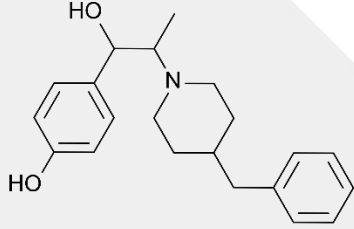


# ALGERNON PHARMACEUTICALS LEAD DRUG CANDIDATES

## CLINICAL PIPELINE\*



\* In addition to the above, the Company is considering repurposing additional drug candidates currently in the preclinical stage



# LEAD DRUG: NP-120 (IFENPRODIL)



## Prior / Existing Indications

- Peripheral Arterial Obstructive Disease (France until 2015)
- Vertigo (Japan & South Korea)

## Our Indications

Idiopathic Pulmonary Fibrosis



Phase 2



Phase 2

## Current Therapies

- Ofev (Nintedanib)
- Esbriet (Pirfenidone)
- No Regulatory Approved Treatment in the U.S.

## Sales / Market Size

- Ofev - \$2.28B<sup>(1)</sup>
- Esbriet - >\$1B<sup>(2)</sup>
- Est. Market Size \$1.4B in 2018, growing at CAGR of 6.6% to 2024<sup>(3)</sup>

(1) <https://www.thepharmaletter.com/article/boehringer-says-it-did-well-in-2020-despite-impact-of-covid-19>  
 (2) <https://www.biopharmadive.com/news/roche-promedior-acquisition-ipf-fibrosis/567447/>  
 (3) [https://www.industryarc.com/Research/Cough-Remedies-Market-Research-501866?mod=article\\_inline](https://www.industryarc.com/Research/Cough-Remedies-Market-Research-501866?mod=article_inline)

# IPF – BLEOMYCIN ANIMAL STUDY

FIBROSIS  
REDUCTION (TRICHROME)

- N=10 / Arm
- Treatment Day 7-21
- Clinically Relevant Doses

**55.3%**  
p = 0.015



IFENPRODIL  
(4 mg / kg) TID

**43.9%**  
p = NS



PIRFENIDONE  
(100 mg / kg) BID

**50.6%**  
p < 0.05



NINTEDANIB  
(60 mg / kg) QD

# MECHANISM OF ACTION – COUGH

## CLINICAL CANDIDATES



### CNS Receptors Control Urge to Cough

#### Drug Candidates Acting on CNS Receptors

- Ifenprodil (Algernon)
  - NMDAR Antagonist

### Lung Irritants That Cause Cough

- Cigarette Smoke
- Allergens
- Pollution

#### Drug Candidates Acting on Nerves in Lung/Airway Tissue

- Gefapixant (Merck)
- BLU-5937 (Bellus)
  - Both P2X3R Antagonists

# ACUTE COUGH – CITRIC ACID MODEL STUDY

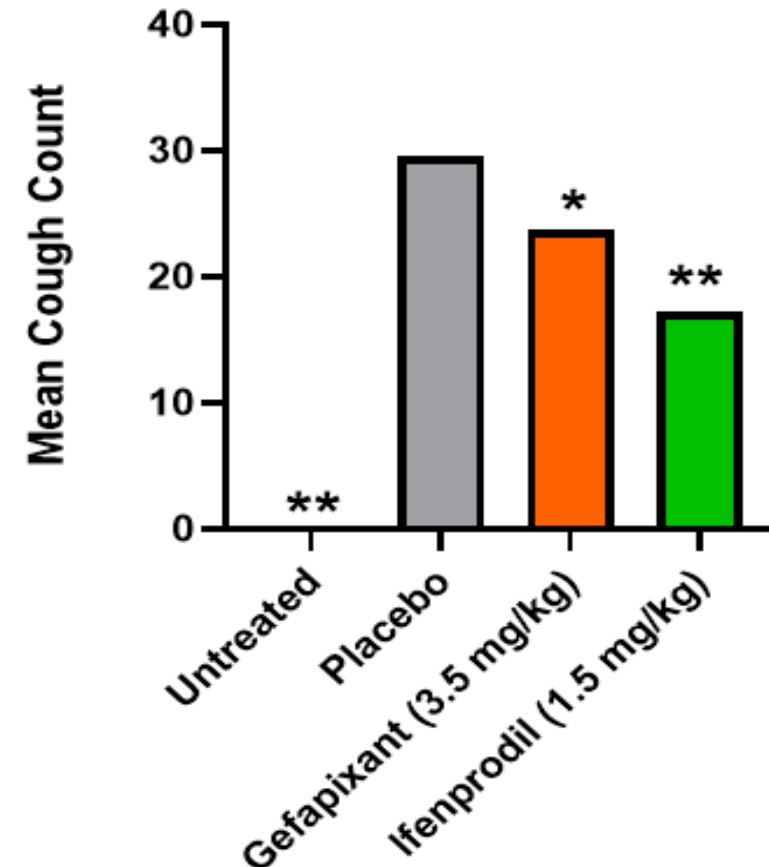
- Acute Guinea Pig Citric Acid Model
- (n=6/arm) Using Clinically Relevant Doses of Ifenprodil and Gefapixant

## Data – Cough Count

- Ifenprodil = 42% Reduction ( $p < 0.01$ )
- Gefapixant<sup>†</sup> = 20% Reduction ( $p < 0.05$ )

<sup>†</sup>Unlike Gefapixant, Ifenprodil Has No Effect on Taste

\* $p < 0.05$ , \*\* $P < 0.01$  compared to placebo

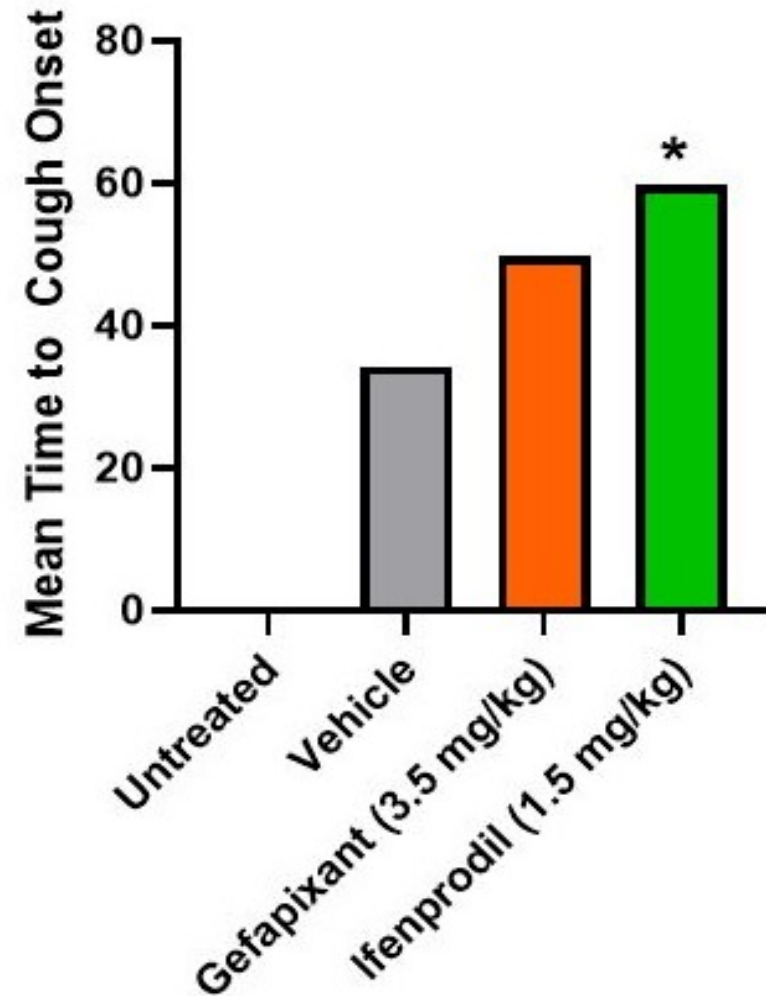


# ACUTE COUGH – CITRIC ACID MODEL STUDY

## Data – Onset of First Cough (Seconds)

- Ifenprodil = 75% Delay ( $p < 0.05$ )
- Gefapixant = 45% Delay ( $p = \text{NS}$ )

\* $p < 0.05$  compared to placebo



# IPF & COUGH EXPERTS



Dr. Martin Kolb MD, PhD



Dr. Jacky Smith, MB, ChB, FRCP, PhD



Dr. Peter Dicpinigaitis, MD, FCCP





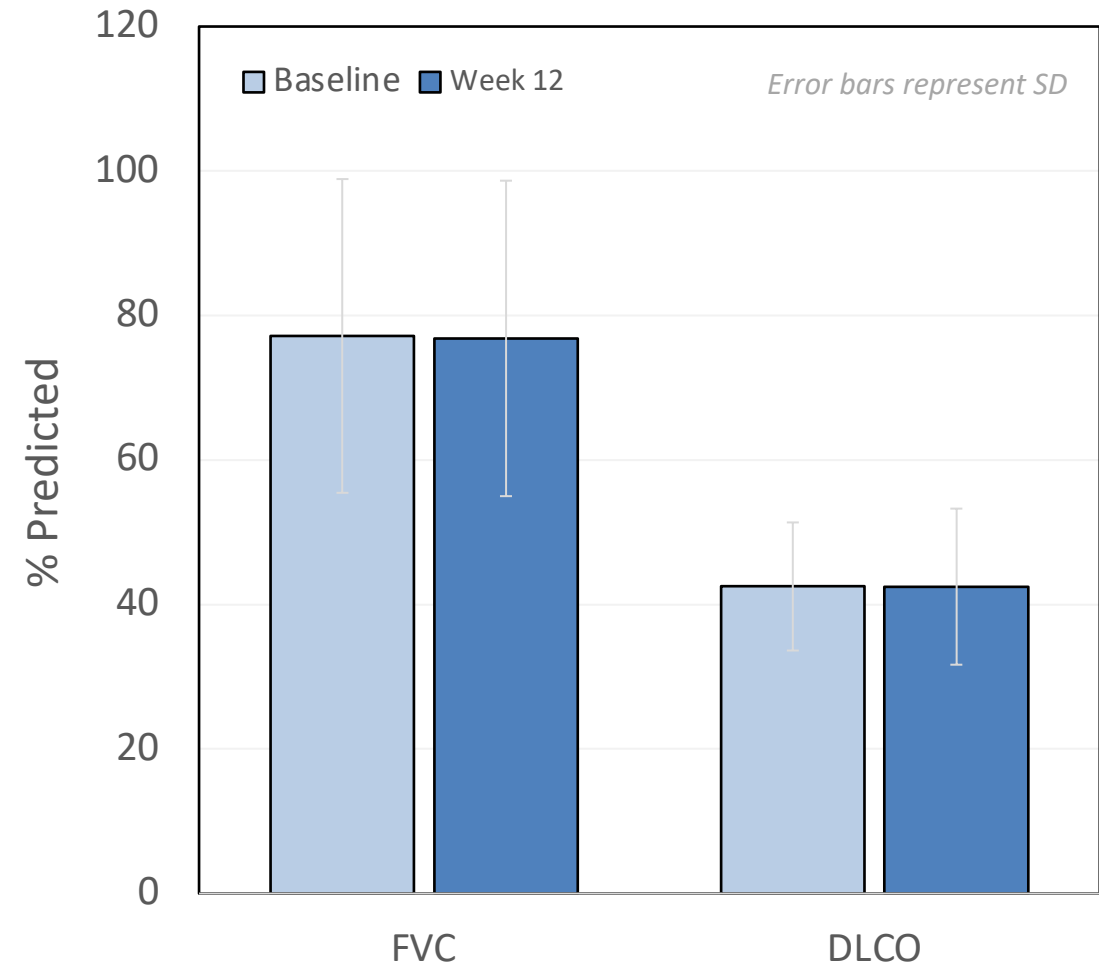
# AGN-120-1: PHASE 2a CLINICAL TRIAL IN IPF & CHRONIC COUGH

- 20 Patient Open-Label IPF Patients With Cough
- 12 Weeks of Treatment, 20 mg Ifenprodil 3 x per day
- Endpoints:
  - ✓ Primary for Cough: Reduction in 24-hour and Waking Cough Counts vs. Baseline, Measured by Ambulatory Cough Monitor
  - ✓ Primary for Lung Function: No Reduction in Forced Vital Capacity (FVC) vs. Baseline
  - ✓ Secondaries: DLCO, Patient-Reported Outcomes of Cough Severity and Quality of Life, Biomarkers of Fibrosis, and Safety
- 7 Clinical Sites (5 located in Australia and 2 located in New Zealand)
- Full data released September 1, 2022



# IPF – LUNG FUNCTION DATA

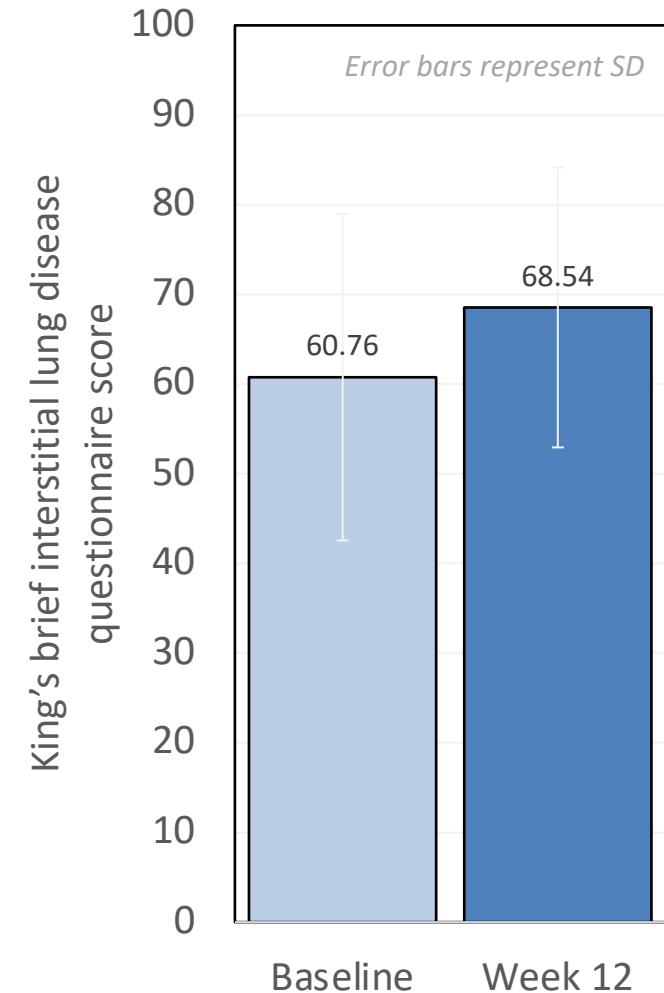
- 13/20 Patients (65%) in the Intent-to-Treat Set Experienced no Worsening of FVC (Co-primary Endpoint,  $p=0.0225$ ). This Was Superior to a Hypothesized Placebo Effect of 40% (Taken From Clinical Trials of Pirfenidone<sup>1</sup> and Expert Opinion).
- Mean 12-Week FVC Change Was -1.7% ( $p=N.S.$  Compared to Baseline). Effect Size is Consistent With 3-Month FVC Changes in Studies of Pirfenidone and Nintedanib.<sup>2</sup>
- $DL_{CO}$  was unchanged from baseline over 12 weeks, consistent with a preservation of lung function.



1. Nathan SD, Yang M, Morgenthien EA, et al. Eur Respir J 2020; 55: 1902151.  
2. Khan FA, Stewart I, et al. Am J Respir Crit Care Med 2022 Apr 15;205(8):936-948.

# IPF – PATIENT QUALITY OF LIFE

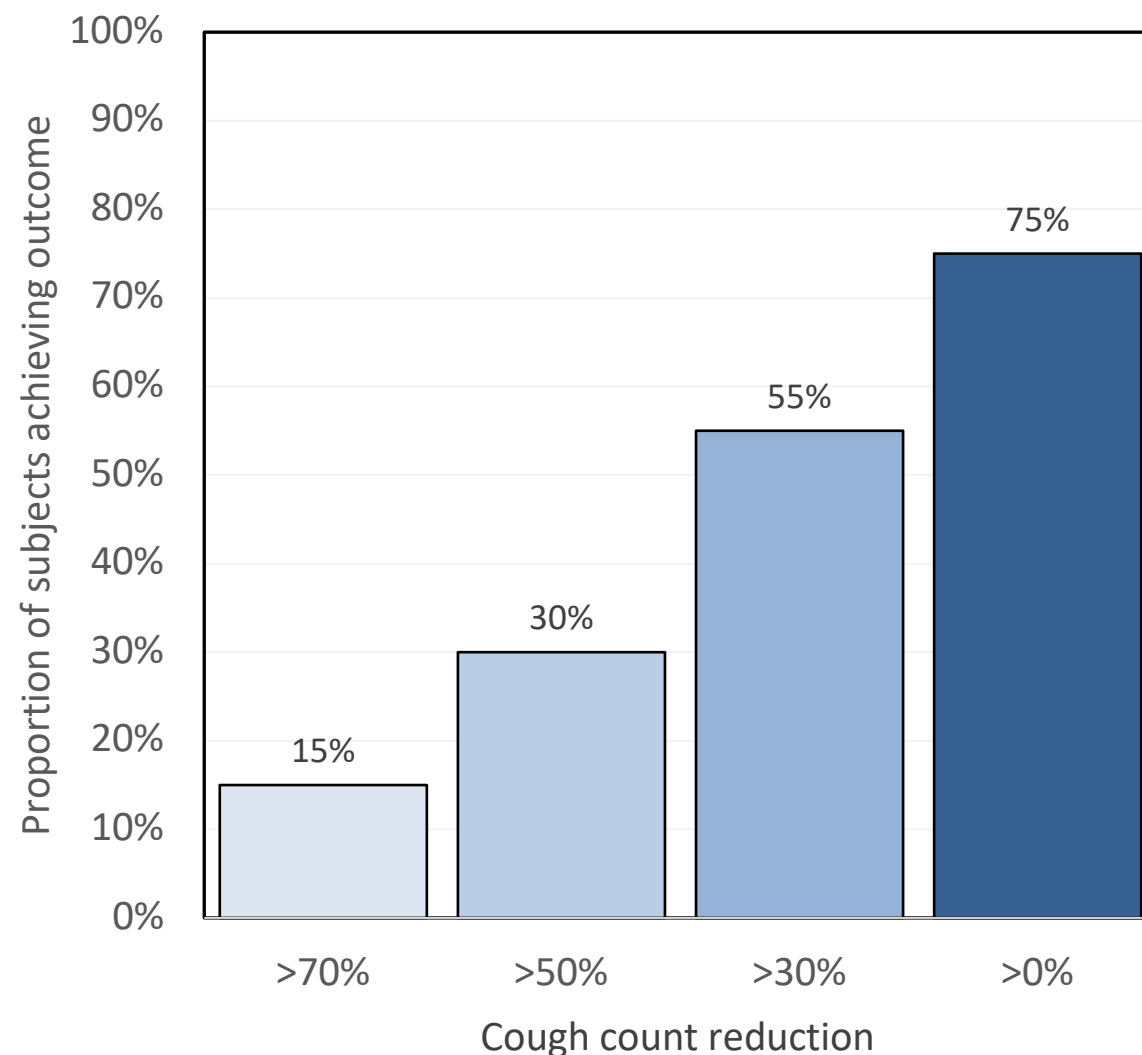
- Quality of Life was Measured using the King's Brief Interstitial Lung Disease Questionnaire.
- Patients Report Symptoms on a 7-Point Likert Scale, and Answers are Converted into a Range 0-100 (Higher Numbers are Better).
- K-BILD Scores Improved by 7.8 points ( $p = 0.12$ ). A Difference of 5 Points is Clinically Meaningful.



1. Patel AS et al. Thorax 2012; 67: 804-810.

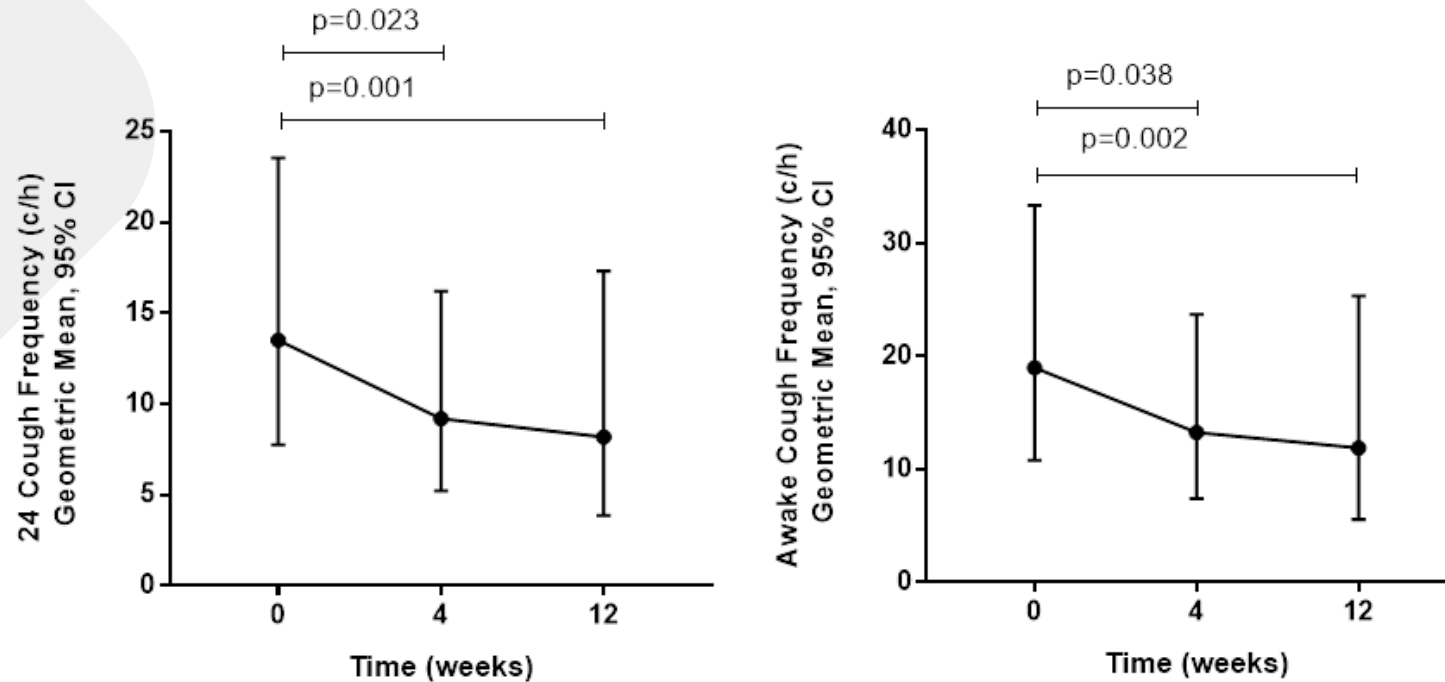
# COUGH - RESPONSE RATES

- 6/20 Patients (30%) in the Intent-to-Treat Set Experienced a >50% Reduction in Cough at 12-weeks (Co-primary Endpoint). This Was Not Significant Compared to a Hypothesized Placebo Effect of 25% (Selected Based on Data From Clinical Studies of Gefapixant).<sup>1</sup>
- The Secondary Endpoint of Relative Change in 24-Hour Cough Counts at 12 weeks was -24.9% (p=0.034).



1. Mehta A, Morice A. et al.. Chest 2019; 1564S: A1575.

# COUGH – GEOMETRIC MEAN COUGH COUNTS



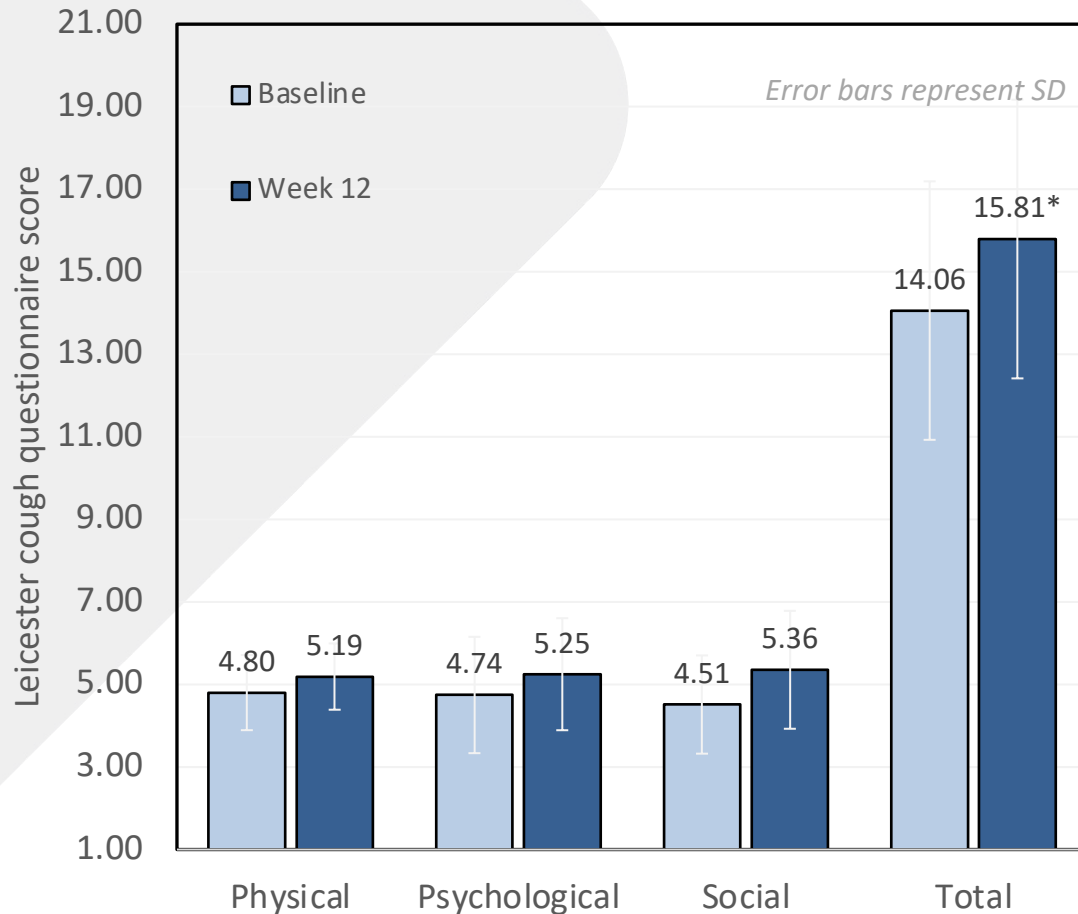
- “These data are quite compelling... To see effects of this magnitude in an IPF population, where other drugs have failed to demonstrate a benefit, is notable...”

Dr. Jacky Smith, Manchester University

- “The NMDA receptor is a fascinating target, and Ifenprodil, if successful, would be a first-in-class treatment. I am excited about the drug’s potential not only for cough in IPF, but also for the wider refractory chronic cough population.”

Dr. Peter Dicipinigaitis, Albert Einstein College of Medicine

# COUGH – QUALITY OF LIFE

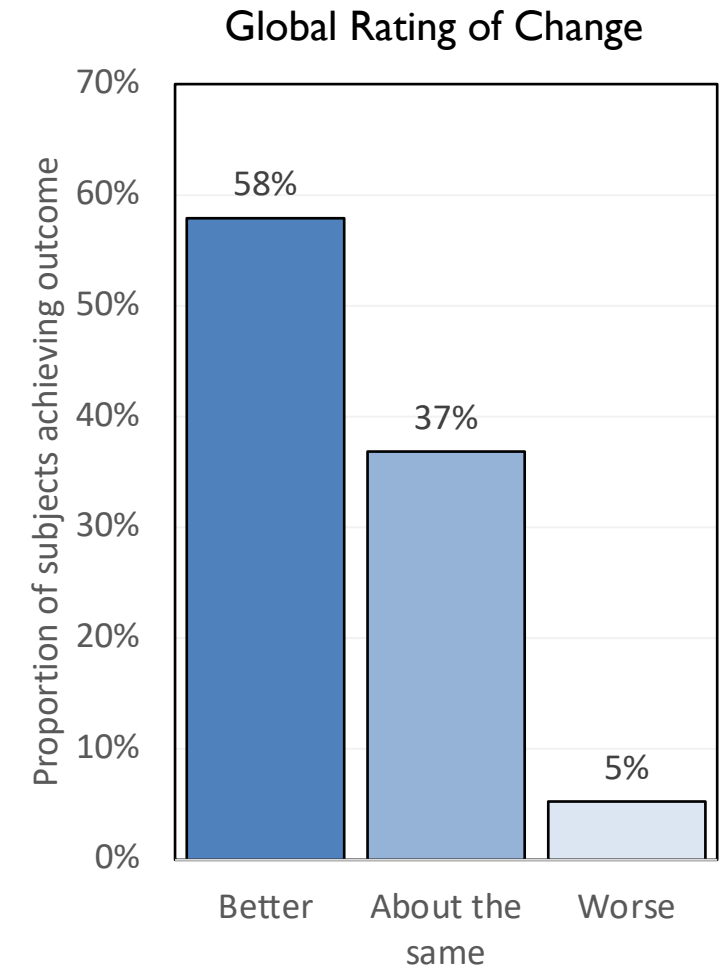
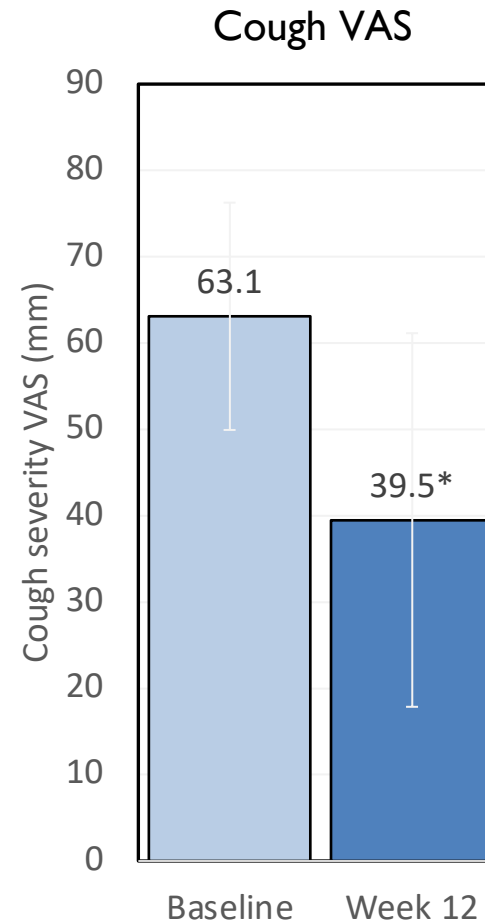


- Quality of Life was Measured with the Leicester Cough Questionnaire.
- Patients answer Questions in Three Domains, Each Scored from 1 – 7; Domains are Summed to Produce a Score From 3 – 21 (Higher numbers are better).
- Scores Improved Over 12 weeks by 1.7 points ( $p = 0.017$ ). Scores were Improved in Each Domain.
- The MCIDs are 0.2 (physical), 0.2 (psychological), 0.8 (social) and 1.3 (total).

1. Birring SS et al. Thorax 2003; 58: 339-343.

# COUGH – QUALITY OF LIFE

- Cough VAS, a Patient-Reported Measure of Cough Severity, was Improved by 37.4% (23.6 mm,  $p = 0.001$ ). 17 mm is regarded as the MCID in acute cough.
- In the Global Rating of Change Scale, 58% of Patients Reported an Improvement After 12 Weeks; only 5% Felt Worse.



# SAFETY

- The Adverse Events Observed in this Trial were Consistent with the Clinical History of NP-120, Established in Post-Marketing Surveillance of over 8,000 Patients.
- The Majority of AEs were Mild or Moderate in Severity.
- The Most Commonly Observed Treatment Related TEAEs in the Study were GI Disorders (25.0%) and Decreased Appetite (10.0%).
- Treatment Compliance was Excellent (>90% for the study).

# NEXT STEP PHASE 2B REFRACTORY COUGH TRIAL

- Multinational, Three-arm, Randomized, Double-blind, Placebo-controlled Trial to Evaluate Ifenprodil in Approximately 180 patients with Refractory Chronic Cough
- 3 Arms: Ifenprodil Low Dose, High Dose and Placebo
- 12 Weeks Treatment
- Primary Endpoint: Reduction in 24-hour Cough Counts
- Secondary Endpoints: Patient-Reported Quality-of-Life Measures, Safety
- Design Mirrors Phase 2b Studies by Afferent Pharmaceuticals and Bellus Health in Chronic Cough
- Targeting Q3, 2023 to Initiate Cough Study; Data expected in ~18 Months



# PUBLIC COMPANY COMPARABLES FOR CHRONIC COUGH



- Announced Positive Interim Phase 2b Results; Acquired by Merck and Co. for \$1.25B



- Positive Phase 2b Results: Current Market Cap of \$1B

# REGULATORY STATUS AND INTELLECTUAL PROPERTY

## CHRONIC COUGH

- Patents Pending in Canada, US, EU, Japan and China (Int'l Priority Date: Mar 6, 2020)
- FDA Responses Received on Pre-IND Filing; Agency Agrees with Proposed Study Design

## IPF

- Granted Patent for Treatment of IPF with Ifenprodil in Canada (No. 3101853)
- Patents Pending in US, EU, Japan and China (Int'l Priority Date: Feb 14, 2020)
- Granted U.S. FDA Orphan Designation: 7 Years Data Exclusivity Upon Approval
- Plan to File pre-IND Application for Phase 2b & Breakthrough Therapy Designation

# AP-188 (N,N-DIMETHYLTRYPTAMINE) DMT

ALGERNON  
PHARMACEUTICALS

## Prior / Existing Indications

- None

## Our Indications



## Current Therapies

- Tissue Plasminogen Activator (“TPA”)
- Surgical removal of blockage (“thrombectomy”)

## Sales / Market Size

- Global Stroke Treatment Market is Expected to Reach a Value of ~ US 15B by the Year 2027<sup>(4)</sup>
- Range of 2% - 10% Globally Receive TPA<sup>(5)</sup>
- Only 15% Qualify for Thrombectomy in the U.K.<sup>(6)</sup>

(4) <https://www.transparencymarketresearch.com/pressrelease/stroke-treatment-market.htm>

(5) <https://www.ahajournals.org/doi/pdf/10.1161/STROKEAHA.111.641795>

(6) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513874/>

# DMT STROKE PROGRAM

## Preclinical Data

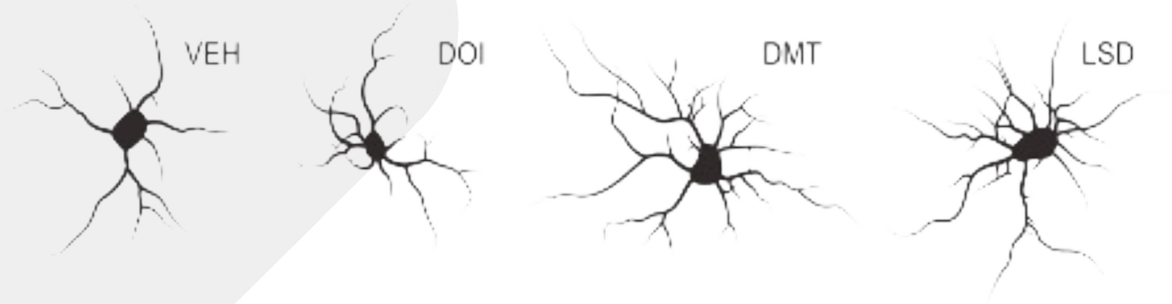
- In Vitro Research Shows DMT has Neuroplastic and Neurogenesis Effects in Cortical Neuron Assay<sup>(7)</sup>
- Research Confirms Sub-psychedelic Dose Active in Depression and Anxiety Model<sup>(8)</sup>
- DMT was Effective in an Animal Stroke Study<sup>(9)</sup>

<sup>(7)</sup> Olsen *in vitro* study: Cell Reports (2018) 23:3170-82

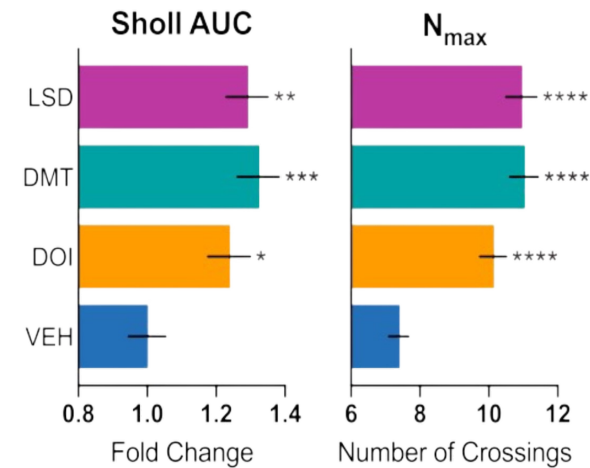
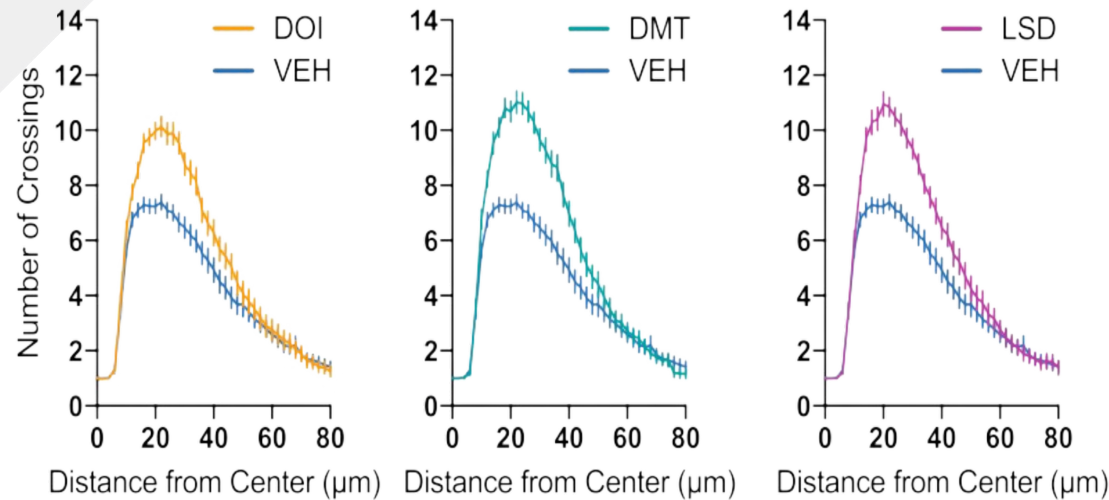
<sup>(8)</sup> Olsen *in vivo* study: ACS Chem Neurosci (2019) 10:3261-70

<sup>(9)</sup> Rat stroke study (Nardai): Experimental Neurology (2020) 327:113245

# DMT PROMOTES NEURITOGENESIS AND SYNAPTIC GROWTH



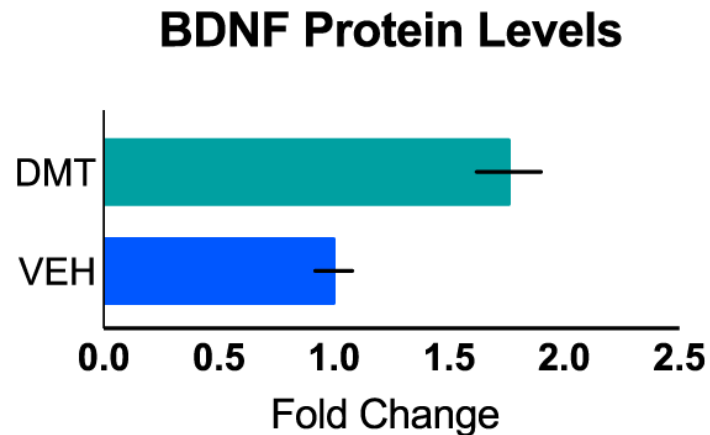
- Psychedelics Increased Dendritic Arbour Complexity After 72 Hr Treatment *In Vitro*<sup>(10)</sup>



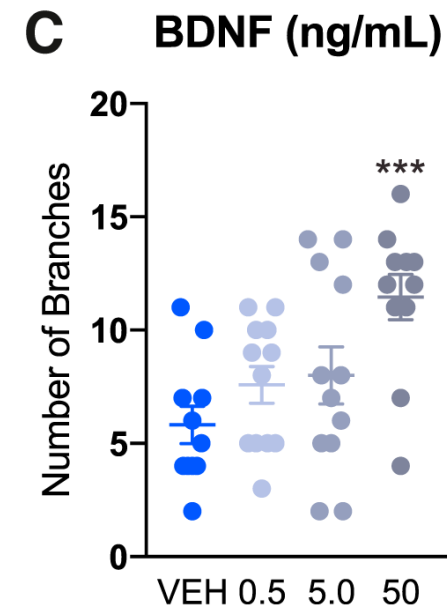
<sup>(10)</sup> Olsen *in vitro* study: Cell Reports (2018) 23:3170-82

# DMT STIMULATES NEURITOGENESIS THROUGH BDNF

- When Cortical Neurons Were Treated With DMT for 24 HR a 2X Increase in BDNF Protein was Observed.

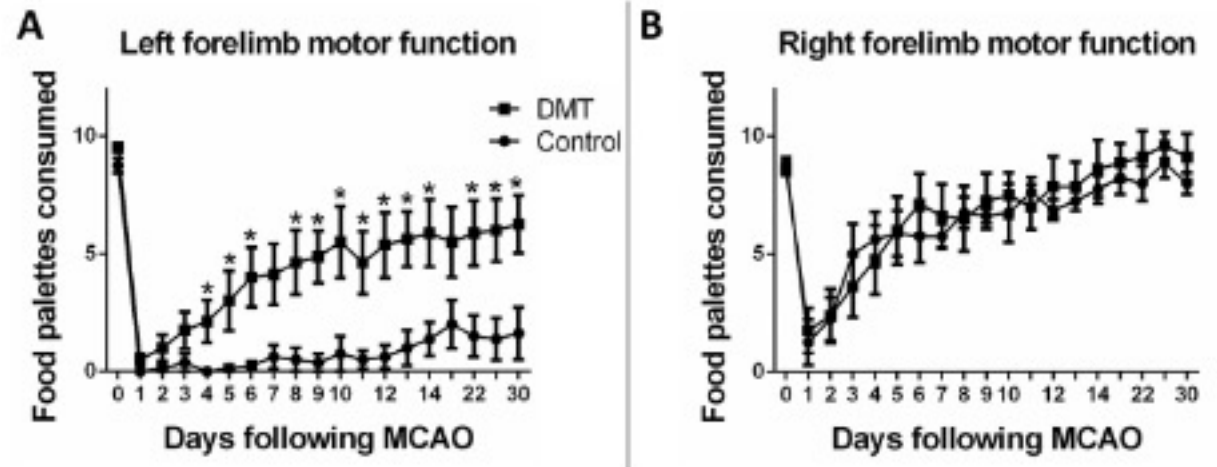
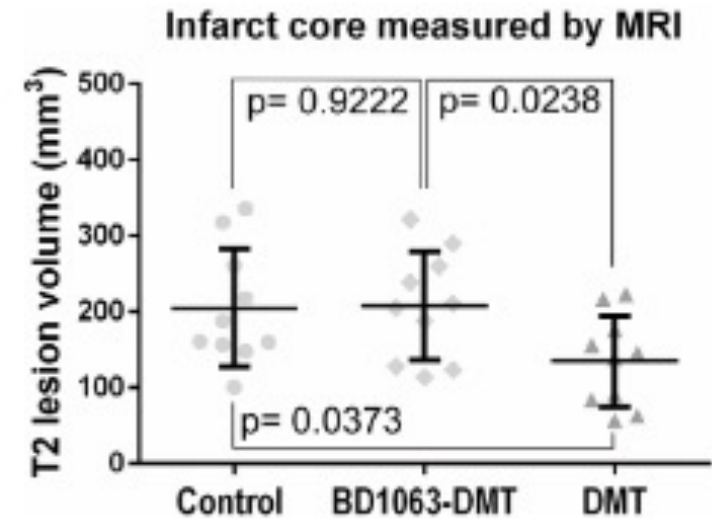


- Application of BDNF to Cortical Neurons Showed a Dose-Dependent Response on Neuritogenesis.



# DMT STROKE PRECLINICAL IN VIVO

- Transient (60 Min) MCAO was Applied to Male Wistar Rats.
  - DMT was Infused Immediately Before Removal of the Filament and Continued for 24 Hr.
- Individual T2 Lesion Volumes 24 Hr After MCAO Were Significantly Lower in DMT Treat Animals Compared to Controls and Animals Treated with a Sigma-1 Receptor Antagonists (BD1063).
- The Effect of DMT on Motor Function Recovery Utilizing the Serial 'Staircase Testing'.
- The Left Forelimb Showed Significant Motor Function Improvement.
- DMT Also Increased Expression of Brain Derived Neurotrophic Factor (BDNF) and Had a Systemic Anti-Inflammatory Effect



# DMT STROKE PROGRAM

- ✓ IP Filed for New Salt Forms of DMT, Dosing, Formulation, Method of Use and Combination Therapy for Stroke Rehabilitation.
- ✓ Algernon has Received Approval to Conduct a Phase I Clinical Study of Intravenous Formulation of DMT for the Treatment of Stroke in the Netherlands.
- ✓ Phase I Study has Begun Screening; Enrollment to Begin by End-of-Year



# DMT STROKE PROGRAM PHASE I STUDY

- Up to 60 Healthy Volunteers - Psychedelic Experienced and Psychedelic Naïve Patients.
- Identify Safety, Tolerability, and Pharmacokinetics of DMT - Intravenous Bolus Followed by Prolonged Infusion for Durations Which Have Never Been Studied Clinically.
- Study Pharmacodynamic Measures Associated With Neuroplasticity, Including Both Measurements of Biochemical Markers and Electroencephalographic Readings.

# DMT STROKE PROGRAM EXPERTS



Dr. David Nutt DM, FRCP, FRCPYCH, FSB, FMEDSCI



Dr. Rick Strassman MD  
Author of the book *DMT: The Spirit Molecule* (2001)



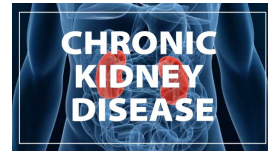
# NP-25I (REPIRINAST)



## Prior / Existing Indications

- Sold for 25 years in Japan under Romet™ for Asthma
- Pediatric formulation approved in 1990

## Our Indications



## Current Therapies

- Focus on managing symptoms and complications that include high blood pressure, swelling and anemia

## Sales / Market Size

- CKD market opportunity expected to reach \$15.8B by 2024<sup>(11)</sup>

(11) <https://www.transparencymarketresearch.com/chronic-kidney-disease.html>

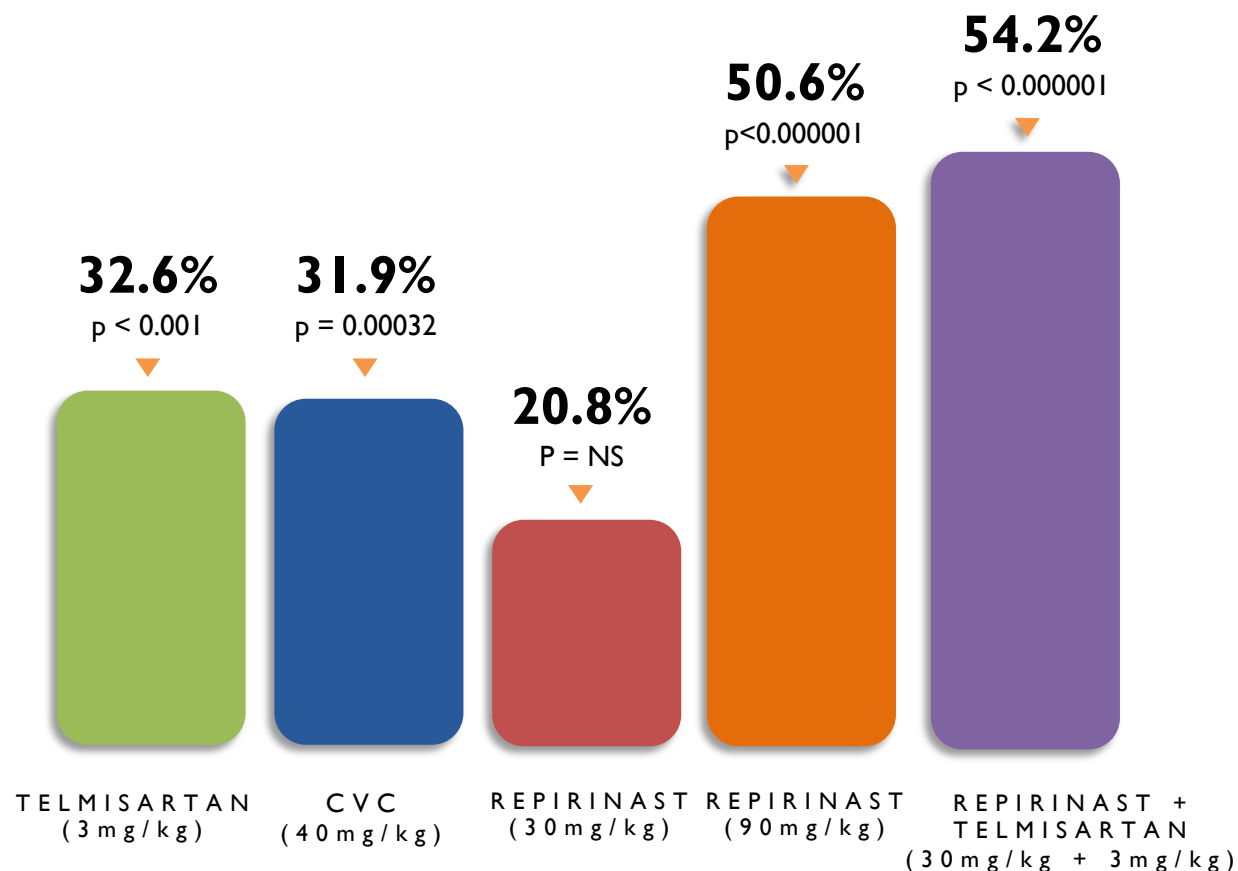
# CHRONIC KIDNEY DISEASE – UUO MODEL STUDY 2

## UNILATERAL URETER OBSTRUCTION MODEL

- N=10 / Arm
- Start Treatment Day 0-14
- Post Bonferroni Corrected
- Reduction in Fibrosis vs Negative Control
- Once a Day (QD) Treatment
- Clinically Relevant Doses
- Independent 3<sup>rd</sup> Party Stats Review
- CVC = Cenicriviroc

- In Addition, the Mass of the Fibrotic Kidney was Lower Than the Negative Control in the Combined Treatment Group ( $p < 0.001$ )

## FIBROSIS REDUCTION (SIRIUS RED)



# UPCOMING MILESTONES & POTENTIAL CATALYSTS

Q1 2023

Q2 2023

Q3 2023

Q4 2023

CHRONIC COUGH

US FDA IND Filing

Begin Phase 2b Study

IPF

US FDA IND filing / Fast  
Track Application

DMT / STROKE

Began Phase 1 Study

Phase 1 DMT Data

Begin Phase 2

CKD

Complete Manufacture

Begin Phase 1 Study

# CLINICAL TRIAL EXPERIENCED MANAGEMENT TEAM



**Christopher J. Moreau**

CHIEF EXECUTIVE OFFICER

- President, CEO & director of a TSX:V listed R&D company in the life sciences sector for over nine years
- Experienced with startups, licensing, mergers & acquisitions, and integration
- Over 30 years of Senior Management experience in private/publicly traded company environments



**Dr. Christopher Bryan, PhD**

VP RESEARCH AND OPERATIONS

- Graduated from the University of Toronto, with a PhD in organic chemistry
- Has synthesized hundreds of novel small molecules as potential therapeutic agents
- Management experience in R&D, manufacturing, sales, clinical trial, IP and regulatory affairs
- Has extensive experience in scientific writing, data analysis and literature review.



**James Kinley, CPA, CA**

CHIEF FINANCIAL OFFICER

- Mr. Kinley is a Certified Professional Accountant ("CPA, CA") with over 15 years of experience in building, leading, and advising corporations through their daily operations
- Is well versed on complex restructurings, mergers, acquisitions, and capital markets transactions.
- Is accomplished in structuring and negotiating favorable terms with commercial and investment banks.

## Board of Directors

Harry Bloomfield, QC  
Christopher J. Moreau

Dr. Mark Williams  
Dr. Raj Attariwala

Ambassador (Rtd) Howard Gutman

# BALANCE SHEET & CAPITALIZATION

Estimated Cash (as of March 9<sup>th</sup>, 2022)

\$0.3M CDN

Debt (as of March 9<sup>th</sup>, 2022)

-

Capitalization	Common Stock Equivalents
Common Stock	9,653,656
Warrants (VWAEP \$2.05)	2,769,768
Options (VWAEP \$1.01)	931,000
RSU's	780,004
Total Fully Diluted	14,134,428

**Recent Share Price: \$0.63**



CSE:AGN | OTCQB:AGNPF | XFRA:AGW0