



CSE:AGN | OTCQB:AGNPF | XFRA:AGW0

Q3, 2023

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## ALGERNON MODEL

# Algernon is a Clinical Stage Drug Development Company

**Global Disease Indications – Unmet Needs**

# Algernon Pharma is Advancing 2 Drugs

**NP-120 (Ifenprodil): Refractory Chronic Cough**  
**Repurposed**

**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.**

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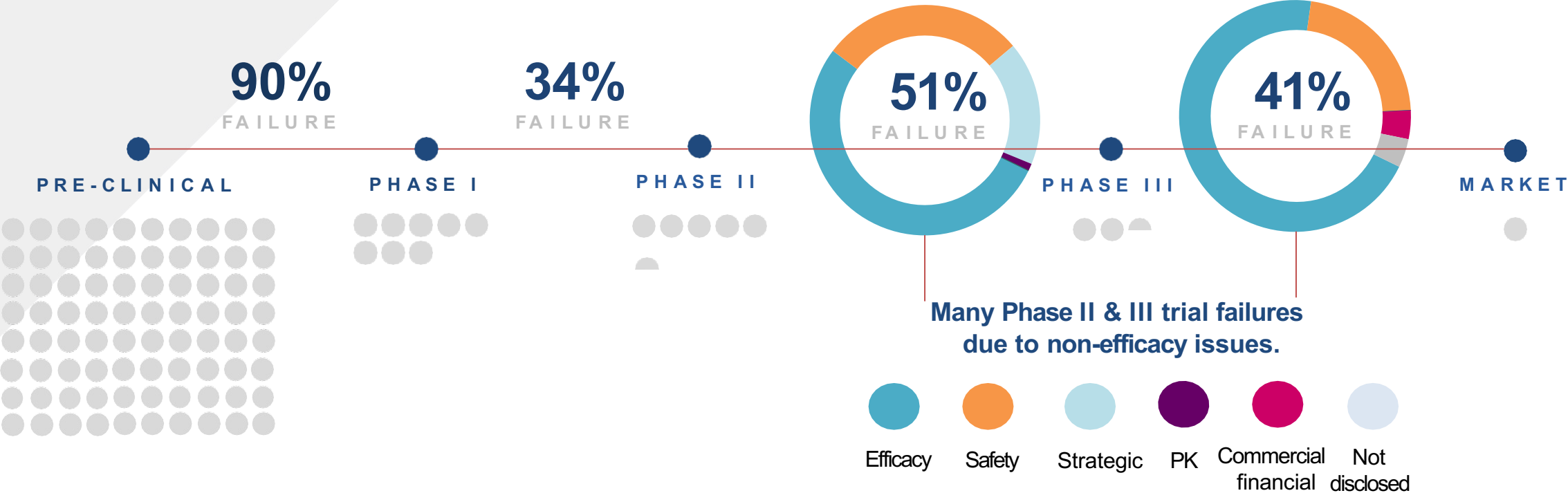
# ALGERNON MODEL

## **New Intellectual Property:**

- Method of Use
- Dosing
- Formulation
- New Composition of Matter: Novel Salt Forms

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# New Chemical Entity (NCE) Development Pathway And Failure Rates



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

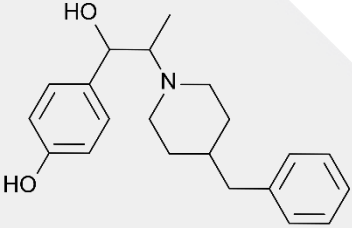


# DRUG REPURPOSING: CASE STUDIES



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&gt; Drug was Withdrawn from the Market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>

# Lead Drug: NP-120 (Ifenprodil)



## Prior / Existing Indications

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

## Our Indication



Phase 2

## Current Therapies

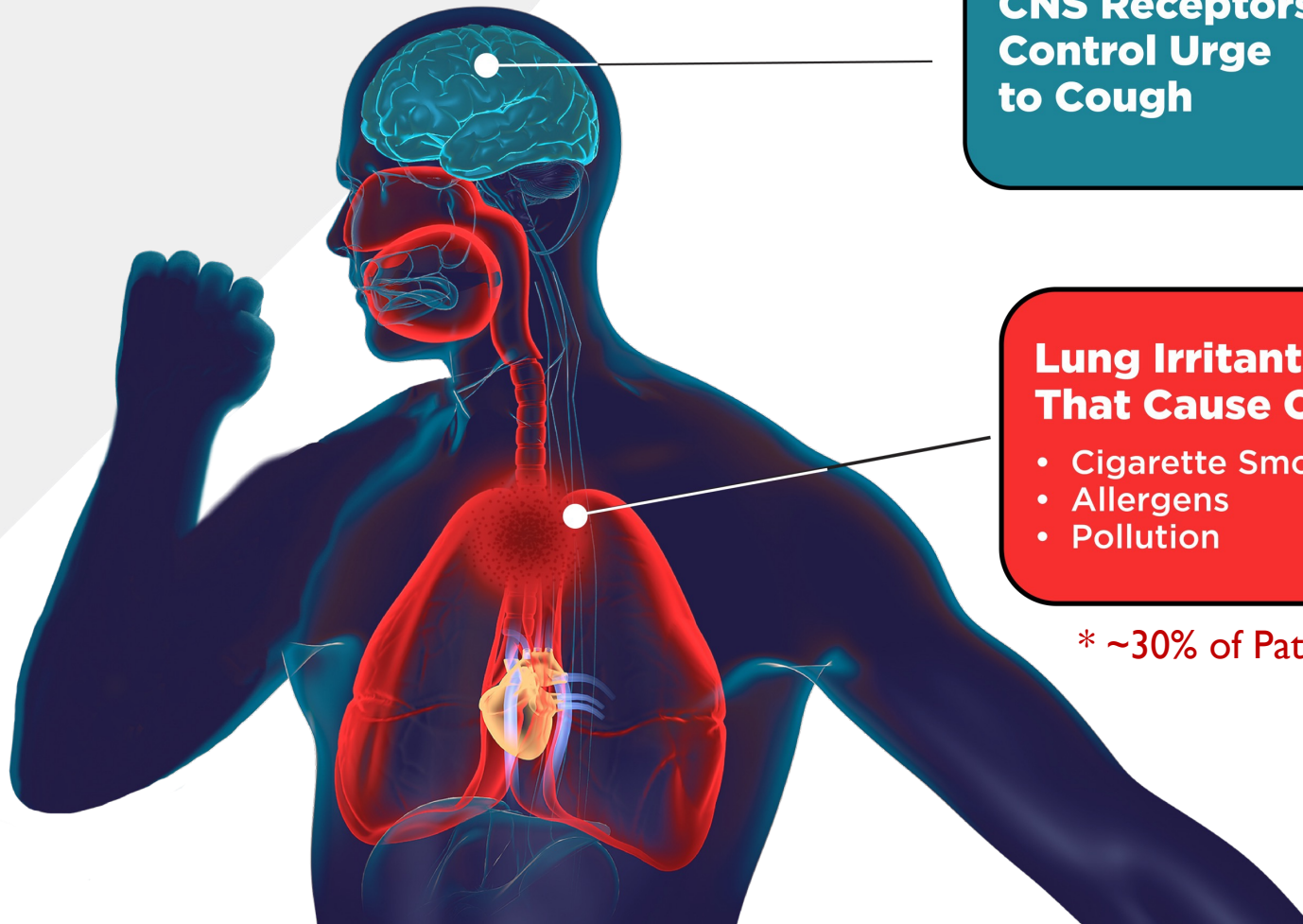
- No Regulatory Approved Treatment in the U.S.

## Sales / Market Size

- Est. Market Size \$6.15B in 2021; Projected to Grow to 11.38B by 2029 <sup>(1)</sup>

(1) <https://www.pharmiweb.com/press-release/2023-07-18/chronic-cough-market-to-witness-outstanding-growth-of-usd-1138-billion-by-2029#:~:text=Data%20Bridge%20Market%20Research%20analyses,in%20the%20mentioned%20forecast%20period.>

# Mechanism of Action – Cough Clinical Candidates



## CNS Receptors Control Urge to Cough

### Drug Candidates Acting on CNS Receptors

- Ifenprodil (Algeron)
  - NMDAR Antagonist

## Lung Irritants That Cause Cough

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

- Cigarette Smoke
- Allergens
- Pollution

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

\* ~30% of Patients with Chronic Cough will not Respond to Treatment

# Public Company Comparables For Chronic Cough



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



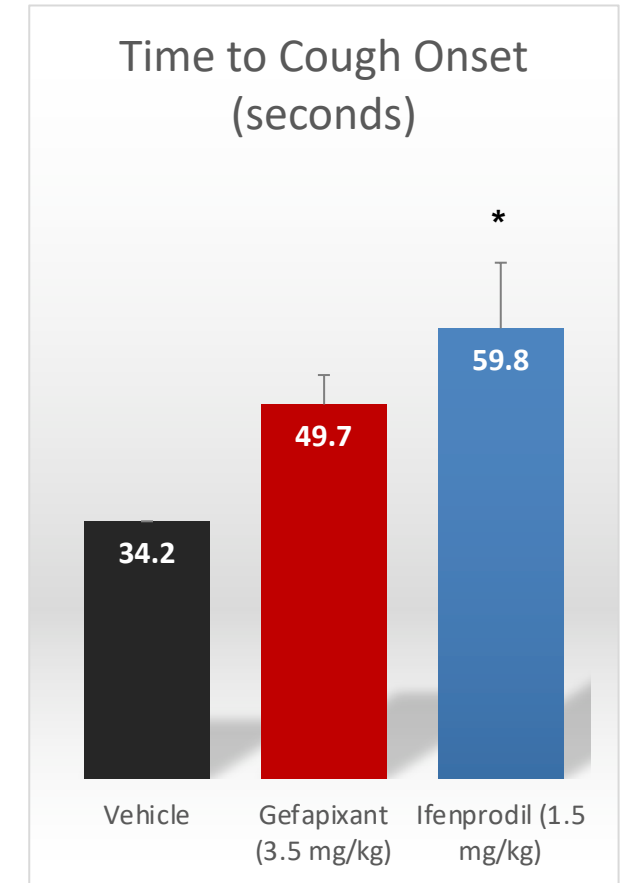
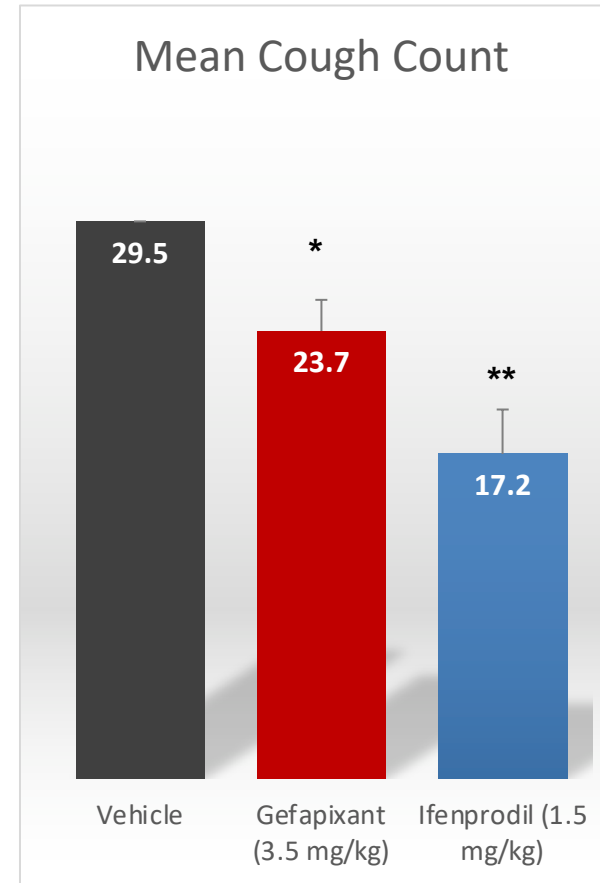
- Positive Phase 2b Results: Acquired by GSK for US \$2B (July 2023)



- Phase 2b Planned (Estimated US \$10M Clinical Trial Cost)

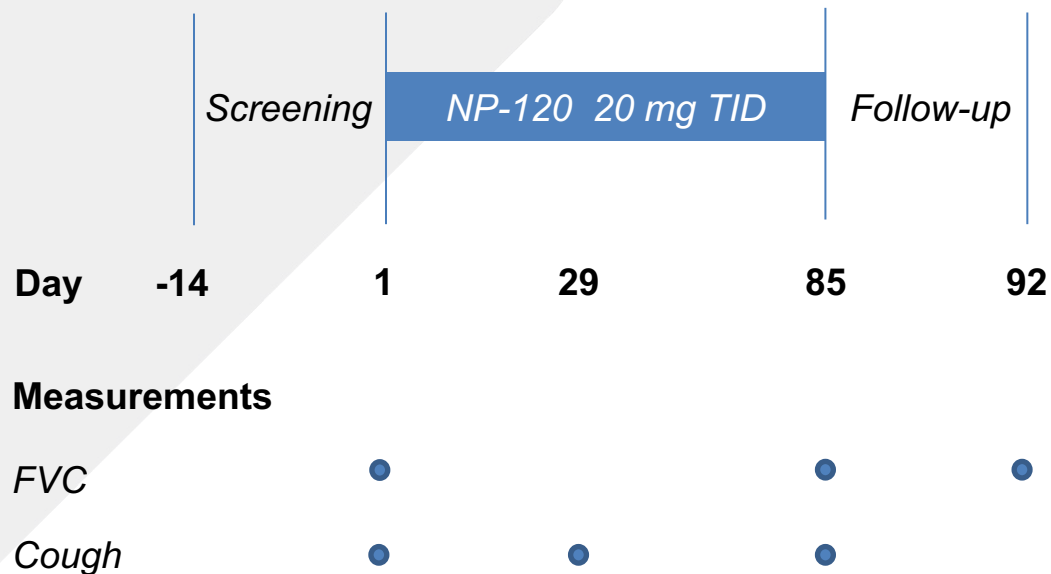
# Ifenprodil Reduces Acute Cough – Preclinical Study

- Ifenprodil was Tested in an Acute Guinea Pig Citric Acid Model Using Clinically Relevant Doses with Gefapixant as a Positive Control
- Ifenprodil *Reduced* Cough by **42%**
- Gefapixant *Reduced* Cough by 20%
- Ifenprodil *Delayed* the First Cough by **75%**
- Gefapixant *Delayed* the First Cough by 45%



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

# AGN-120-I: Phase 2a Clinical Trial In IPF & Chronic Cough



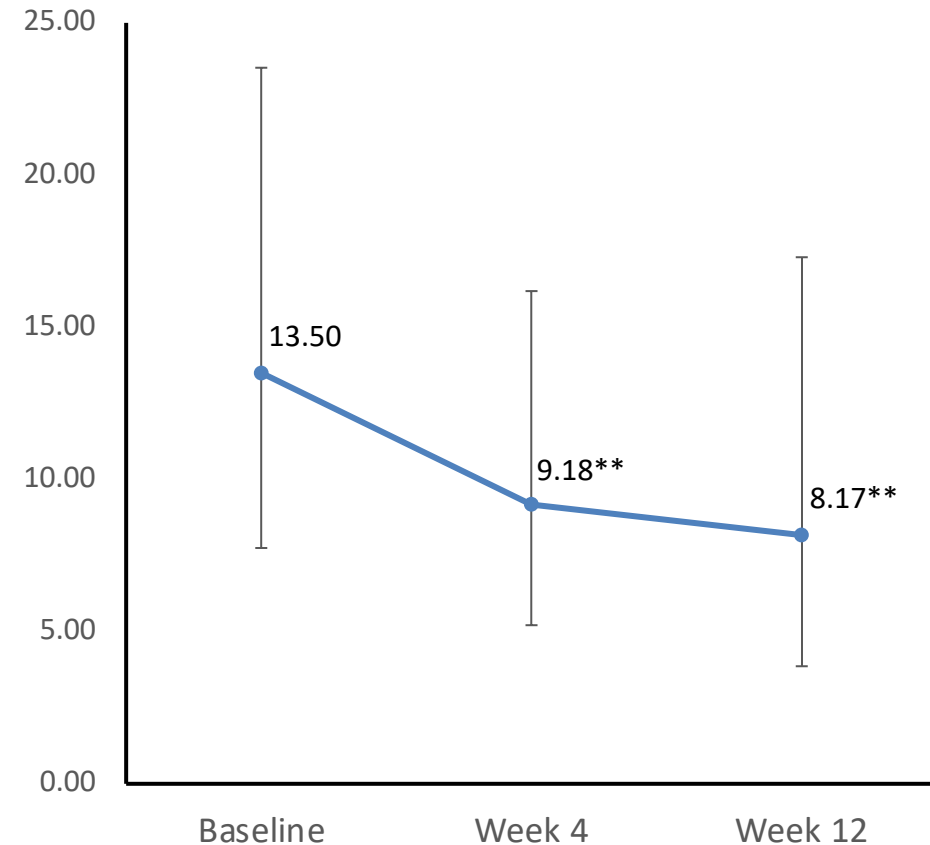
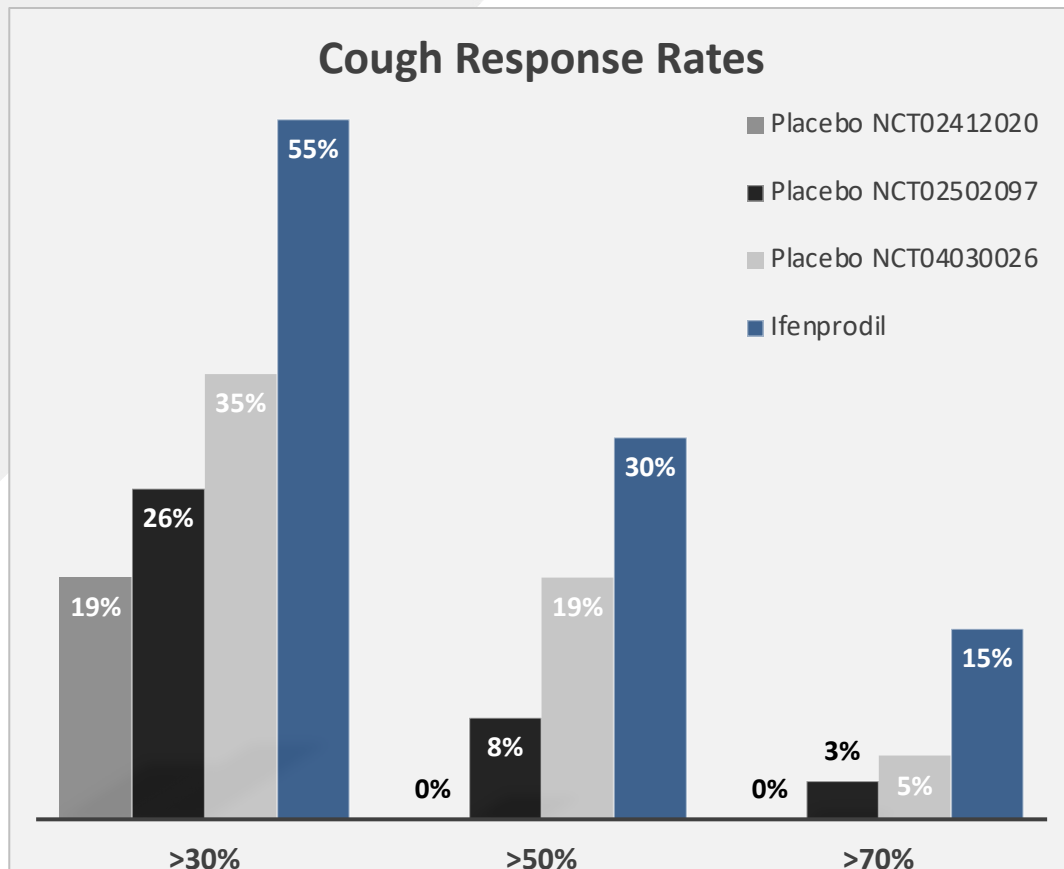
- 20 Subject Open-Label Study in **IPF patients with cough**
  - Reported September 2022
- Primary Endpoints (responder analyses):
  - ✓ Cough: 50% Reduction in 24-hour Cough Count vs. Baseline
  - ✓ Lung Function: No worsening of Forced Vital Capacity (FVC) vs. Baseline
- Secondary Endpoints:
  - ✓ DLCO
  - ✓ Patient-Reported Outcomes of Cough Severity and QOL
  - ✓ Biomarkers of Fibrosis
  - ✓ **Safety**

# Efficacy – Cough Counts

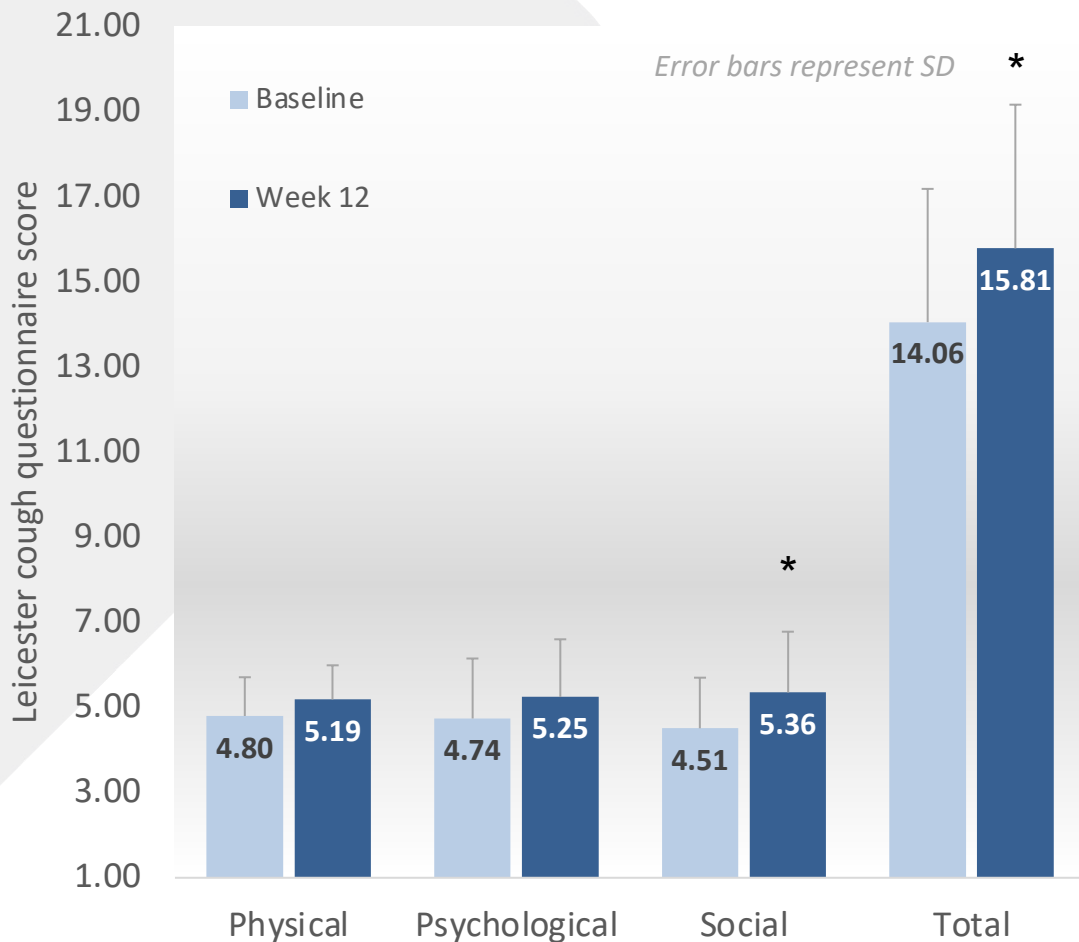
- 6/20 Patients (30%) in the Intent-to-Treat set Experienced a >50% Reduction in 24-hr Cough at 12 Weeks (Primary Cough Endpoint; Placebo Rates From Other Trials in IPF Cough Included for Comparison)

- In a Post-Hoc Analysis, Reductions in Geometric Mean Cough Count Were Observed:

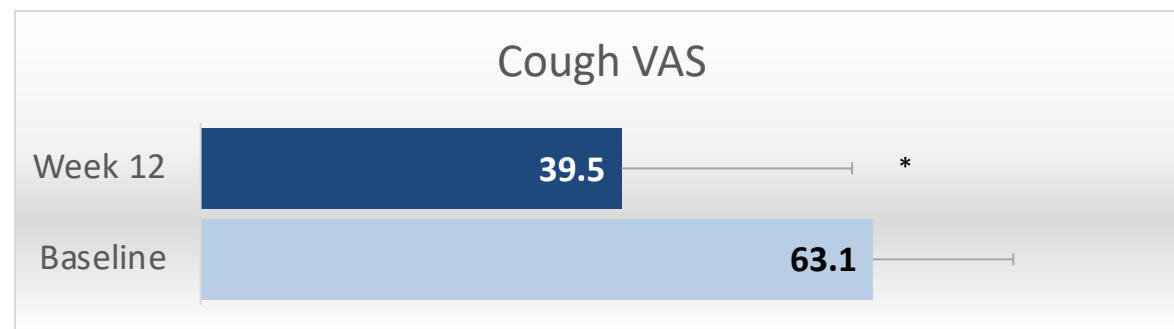
- **32%** at 4 weeks (Nominal p-value = 0.023)
- **40%** at 12 weeks (Nominal p-value = 0.001)



# Cough – Quality Of Life



- Quality of Life was Measured with the Leicester Cough Questionnaire (higher numbers are better).
- Scores Improved over 12 Weeks by 1.75 Points ( $p = 0.017$ ). Scores were Improved in Each Domain.
- Cough VAS, a Patient-Reported Measure of Cough Severity, was Improved by 37.4% (23.6 mm,  $p = 0.001$ ).



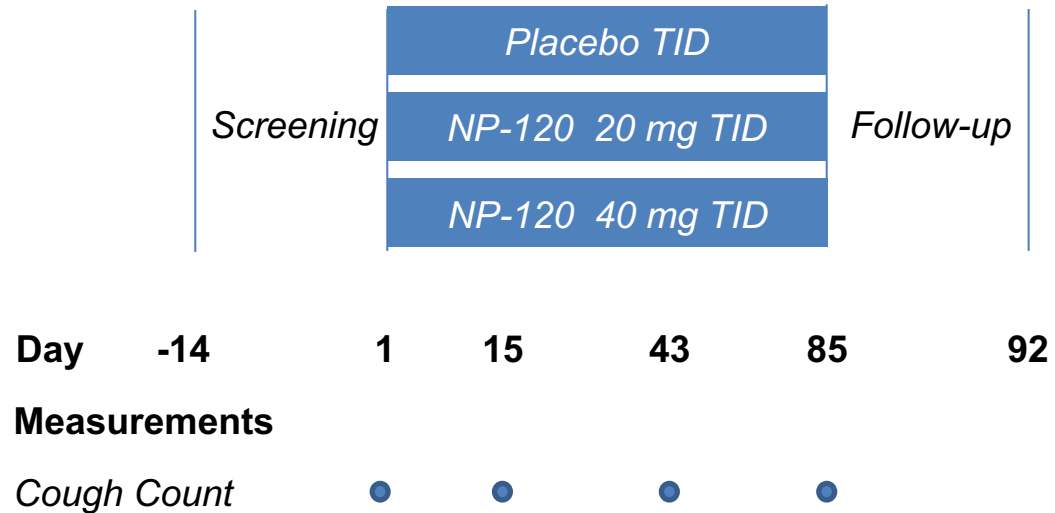
Birring SS et al. *Thorax* 2003; 58: 339-343.



# 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



- Design Mirrors Previous Phase 2b Studies in Chronic Cough (NCT02612610 and NCT04678206); FDA in Agreement with the Protocol
- Estimated Trial Size: 60 Patients per Arm (3); 24 Trial Sites; Approximate Cost US \$10M

# Chronic Cough Advisors



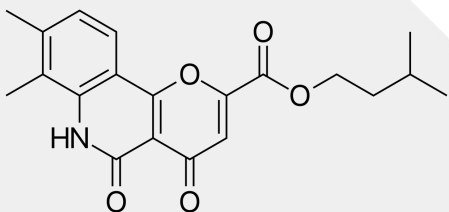
**Dr. Jacky Smith, MB, ChB, FRCP, PhD**

Jacky Smith is a Professor of Respiratory Medicine at the University of Manchester and an Honorary Consultant at Manchester University NHS Foundation Trust. She is also a Consultant to Merck, Astra Zeneca and Bellus Health.



**Dr. Peter Dicipinigaitis, MD**

Dr. Dicipinigaitis is Board-Certified in Internal Medicine, Pulmonary Diseases and Critical Care Medicine. He is a Faculty Member of the Division of Critical Care Medicine at Montefiore Medical Center and is the Founder and Director of the Montefiore Cough Center.



# NP-251 (REPIRINAST)



## Prior / Existing Indications

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

## Our Indication



## 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>(1)</sup>

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

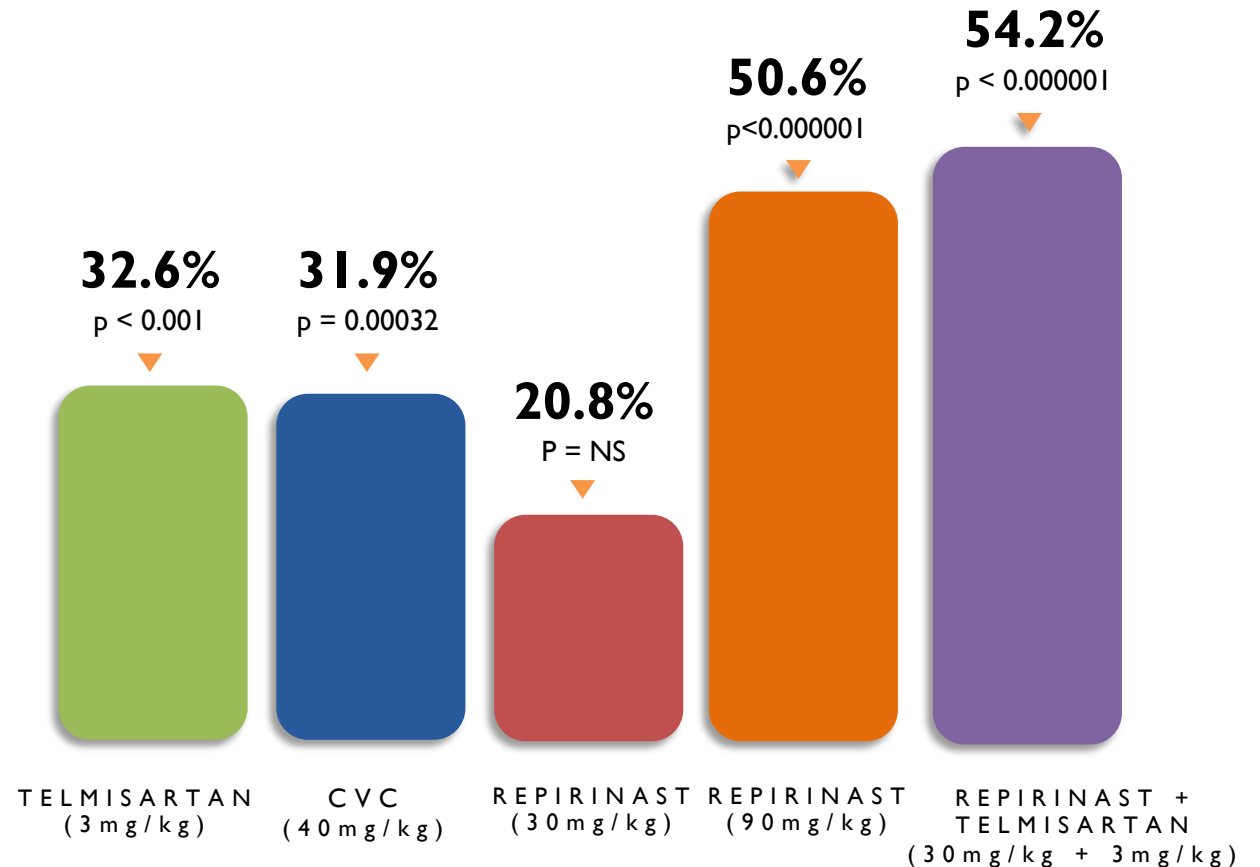
# CHRONIC KIDNEY DISEASE – UO MODEL STUDY

## 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

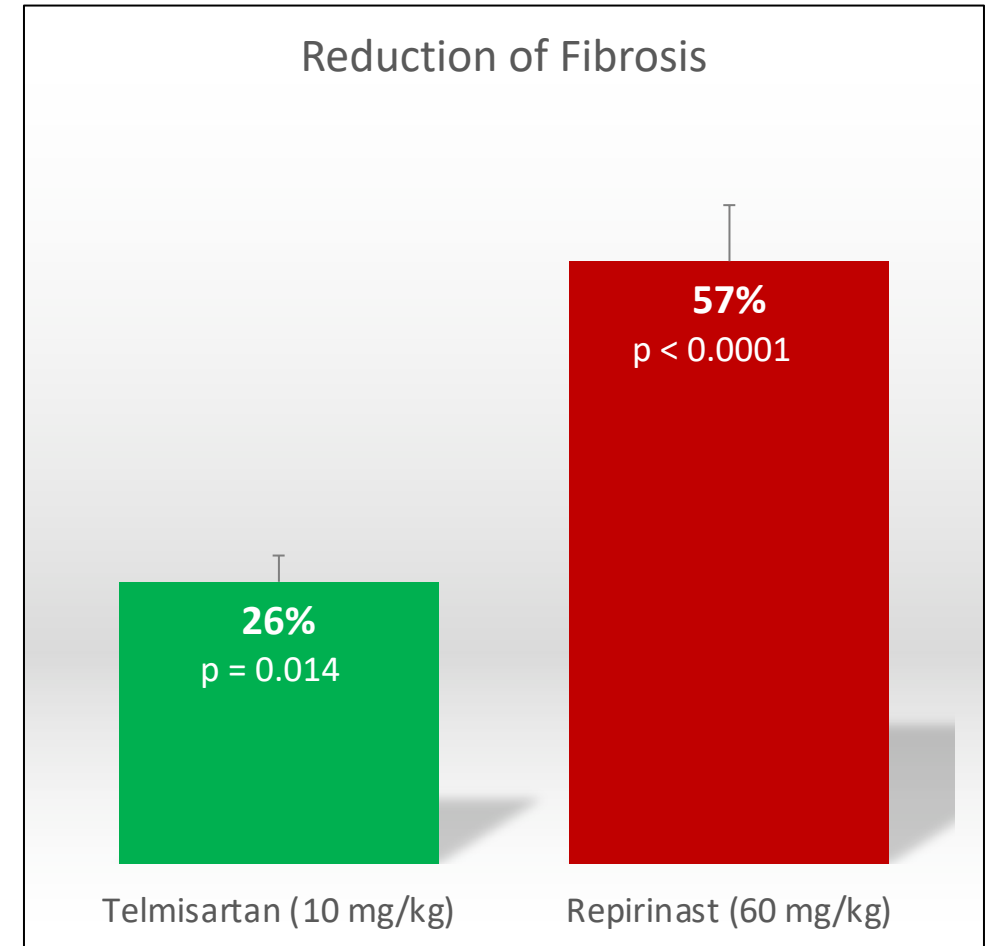
- In Addition, the Mass of the Fibrotic Kidney was Lower Than the Negative Control in the Combined Treatment Group (p<0.001)

## FIBROSIS REDUCTION (SIRIUS RED)



# REPIRINAST REDUCES FIBROSIS IN A MURINE MODEL OF NASH

- Repirinast Was Evaluated in a Mouse STAM Model of NASH Using Telmisartan as a Positive Control
- Fibrosis was Measured Histopathologically Using Sirius Red Staining.
  - Repirinast Reduced Fibrosis by **57%**
  - Telmisartan Reduced Fibrosis by 26%
- Repirinast also Reduced the NAFLD Score (Composite Measure of Steatosis, Inflammation & Hepatocellular Ballooning) by **31%** (Not Shown)
- Risk of CKD is Higher in Patients with NASH (OR: 2.12)<sup>1</sup>

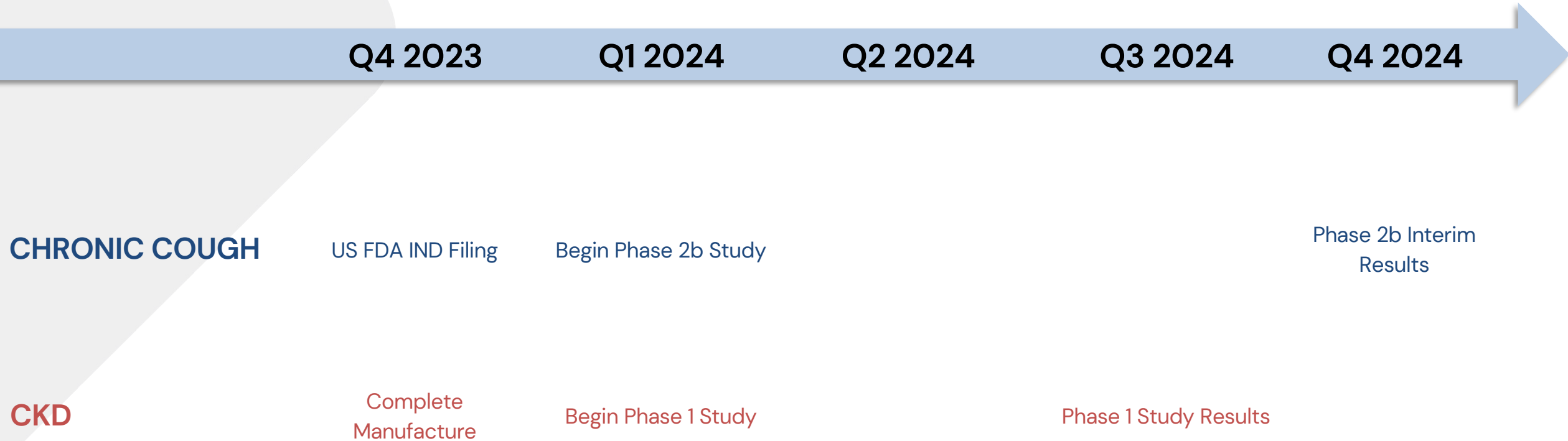


1. Musso G *PLoS Med.* 11:e1001680, 2014.

# CKD Program Next Steps

- Since the Drug was Discontinued in Japan, Algernon is Manufacturing its own Supply
- Phase 1a/1b Planned in Australia (no Further Preclinical Data Required)
  - Phase 1a: Healthy Volunteer Cohort (Safety and PK)
  - Phase 1b: CKD Patients (Safety and PK)
- Algernon has Filed Method of use Patents for Repirinast for CKD and NASH Giving Protection Through 2038
  - Notice of Allowance for NASH Received From the USPTO
- IND to be Filed Once Phase 1 data are Available

# UPCOMING MILESTONES & POTENTIAL CATALYSTS





# 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, KC      Dr. Mark Williams  
Christopher J. Moreau      Dr. Raj Attariwala  
Ambassador (Rtd) Howard Gutman

## Chronic Cough Advisors

Dr. Jacky Smith      Dr. Peter Dicipinigaits

# Algernon Summary

- ✓ 2 Clinical Stage Assets (Billion Dollar Markets)
  - Ifenprodil: Chronic Cough Phase 2b-Ready
  - Repirinast: CKD Phase I-Ready
- ✓ Comprehensive Intellectual Property Suite
- ✓ Capital-Efficient Business Model
- ✓ Experienced Senior Management Team
  - Public Company/ Capital Markets
  - FDA (Global) Clinical Trials
- ✓ Previous Conditional Approval for Nasdaq/SEC

**ALGERNON**   
PHARMACEUTICALS <sup>TM</sup>

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