



CSE: AGN | OTCQB: BTHCF | XFRA: AGW

REVISED October 22, 2019

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DRUG DEVELOPMENT TODAY

**>90% OF DRUGS FAIL BEFORE PHASE II**

Drug development costs have ballooned to nearly \$2.5B, with an average timeline of 15 years.

**And most drugs fail to reach market.**

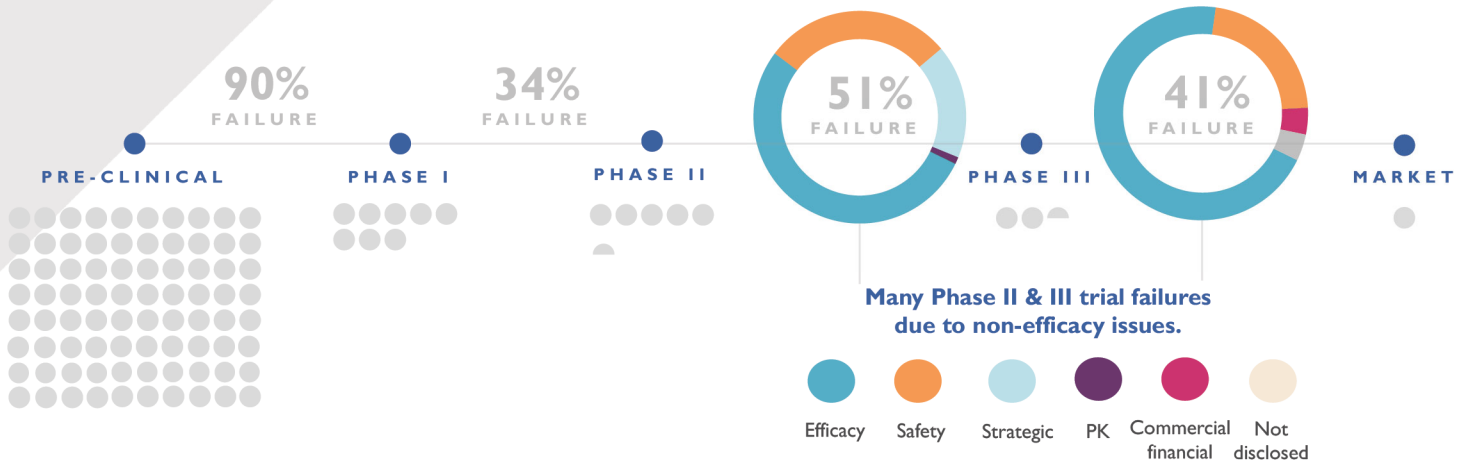
TIME ►



REPURPOSING FOREIGN DRUGS TO

# DRAMATICALLY REDUCE RISK, TIME & COST RELATED TO SAFETY

Algernon's drug development strategy repurposes SAFE, approved foreign drugs  
(1) into known animal models of disease vs. accepted controls  
(2) for **efficient, low risk entry Phase II trials.**



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

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BUSINESS MODEL

# ALGERNON'S VALUE PROPOSITION

**Identify** multiple approved drugs not available in US or Europe  
**No risk of generic competition**

**Conduct preclinical testing** on promising candidates



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PRODUCT CRITERIA

# ALGERNON'S NOVEL REPURPOSING STRATEGY

Algernon reduces corporate risk by having several chemically distinct phase II ready compounds selected using the following criteria:



**Safety**  
Using approved (not in US or Europe) drugs reduces risk of study failure



**Effectiveness**  
All Leads comparable or better activity in gold standard models. Reduced efficacy risk failure in studies



**Speed to market**  
Rapid entry phase II trials or reduced development times. **Maximize patent life**



**Pricing**  
Original drugs not approved in US or EU eliminates risk off label prescriptions (major concern with repurposing strategies)



**IP**  
Method of Use and Markush derivatives patents filed to secure lead compound and follow-on analogues.



SAFETY HISTORY

# 20+ YEARS



## REPURPOSING: CASE STUDIES



COMPANY	DRUG	OLD INDICATION	NEW INDICATION	NOTES
BIOGEN	<b>Tecfidera</b>	Psoriasis	Multiple sclerosis	<ul style="list-style-type: none"> <li>➤ Drug only approved in Germany (50 yrs)</li> <li>➤ Blockbuster (&gt;US\$1B in Sales)</li> </ul>
ASPREVA	<b>Cell Cept</b>	Organ transplant	Lupus	<ul style="list-style-type: none"> <li>➤ Orphan strategy – <b>sold \$1B</b></li> </ul>
MEDIVATION	<b>Dimebon</b>	Allergies	Alzheimer's Disease	<ul style="list-style-type: none"> <li>➤ Drug only approved in Russia</li> <li>➤ <b>\$400M deal</b> with Pfizer post Phase II</li> </ul>
CELGENE	<b>Thalidomide</b>	Morning sickness	Cancer	<ul style="list-style-type: none"> <li>➤ Drug was withdrawn from the market</li> <li>➤ Blockbuster (&gt;US\$1B in Sales)</li> <li>➤ Purchased EntreMed's Thalidomide analogues</li> </ul>



CLINICAL PROGRAMS - OVERVIEW

# SMALL MOLECULE CLINICAL CANDIDATES

- > **First-in-class** oral small molecule drugs (Markush structure patents filed on pharmacore)
- > Strong in vivo studies with activity **better than current standard of care**
- > Strong safety profiles **with no serious adverse events reported**

		DISCOVERY	PHASE I	PHASE II	PHASE III	MARKET
<b>NP-135</b>	for NASH for CKD	● ●	● ●			<b>Current candidates</b>
<b>NP-178</b>	For CKD for IBD	● ●	● ●			
<b>NP-160</b>	for NASH for CKD	● ●	● ●			<b>Future candidates</b>
<b>NP-120</b>	for IBD for IPF	● ●	●			
<b>NP-251</b>	for CKD for IPF	● ●	●			

CLINICAL PROGRAM OVERVIEW

# DRUG SAFETY & HISTORY

Lead	Trials	Adverse Events	Notes
NP-135	~850 patients	<ul style="list-style-type: none"> <li>Rare nausea and vomiting</li> <li>Headache, irritability, insomnia (avoid evening dosing)</li> <li>No SAEs noted</li> </ul>	<ul style="list-style-type: none"> <li>Available in Russia</li> <li>Available in Ukraine as a supplement</li> <li>Performance enhancing drug</li> </ul>
NP-178	>11,000 patients	<ul style="list-style-type: none"> <li>No SAEs noted</li> <li>Symptomatic relief of GI pain noted</li> </ul>	<ul style="list-style-type: none"> <li>Available in Ukraine and Russia</li> <li>Neurological drug</li> <li>Top 10 drug in Russia based on sales</li> </ul>
NP-120	>4000 patients	<ul style="list-style-type: none"> <li>No SAEs noted</li> <li>Doses 5x expected dose safe for more than 3 months</li> </ul>	<ul style="list-style-type: none"> <li>Available in Japan</li> <li>Neurological drug</li> </ul>
NP-160	>950 patients	<ul style="list-style-type: none"> <li>Drowsiness</li> <li>No SEAs noted</li> </ul>	<ul style="list-style-type: none"> <li>Withdrawn for sales reasons in 2018</li> <li>Originally a neurological drug in Russia</li> </ul>
NP-251	Not disclosed	<ul style="list-style-type: none"> <li>Little reported in literature</li> <li>No SAEs noted or expected</li> </ul>	<ul style="list-style-type: none"> <li>Withdrawn for sales reasons in 2014</li> <li>Originally an Anti-allergy drug in Japan</li> </ul>

# INFLAMMATORY BOWEL DISEASE

Ulcerative Colitis & Crohn's Disease

## COMPETITIVE ADVANTAGE

- **Clinical:** first-in-class oral small molecule therapies
- Less toxicity vs other oral drugs (ex. steroids, immunomodulators)
- Less expensive and easier to administer vs biological drugs

**US\$14.8B**  
**GLOBAL MARKET**  
**By 2025**

## STATUS

- **2 Candidates:**
  - | active candidate (NP-178)
  - | future candidate (NP-120)
- **Safety:** No serious adverse events
- **Efficacy:** Comparable to standard of care

PRE-CLINICAL PROGRAMS - OVERVIEW

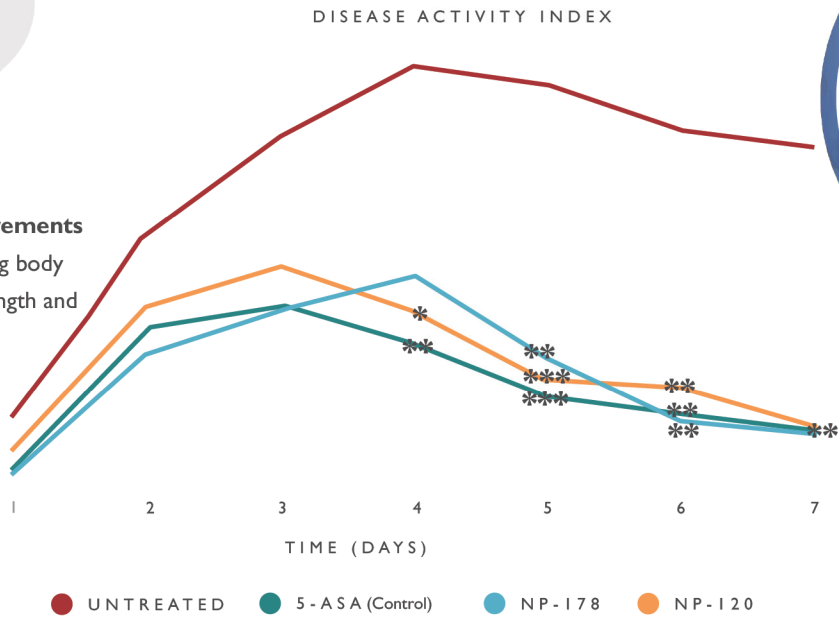
# IBD - ULCERATIVE COLITIS

## OXAZOLONE MODEL

- N=15 / arm
- Treatment Day 0-7
- Post Bonferroni corrected
- Once a day (QID) treatment
- Clinically relevant doses

**Statistically significant improvements** in multiple measurements including body weight, stool consistency, colon length and weight ratios and occult positivity

Up to 8% of UC patients can develop **fibrostenosis** which requires surgery and is a large unmet medical need

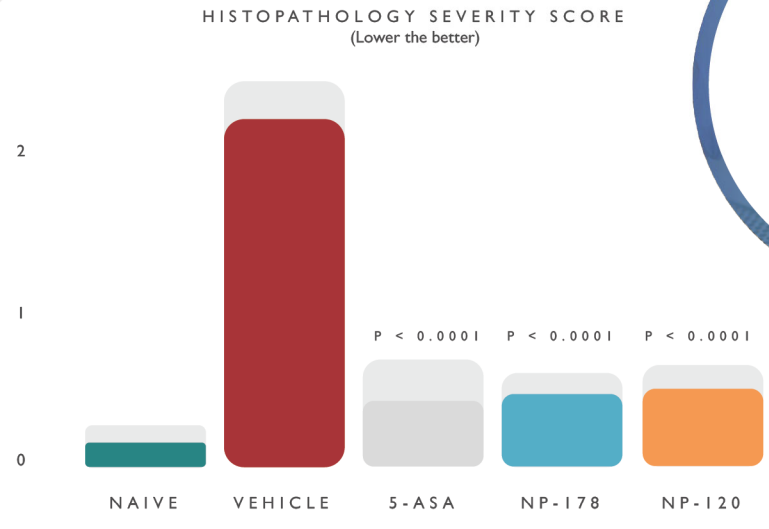


**REDUCED SEVERITY**  
OF DISEASE AS WELL AS THE STANDARD OF CARE

\* = p < 0.05  
\*\* = p < 0.01  
\*\*\* = p < 0.001

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# IBD - ULCERATIVE COLITIS



**REDUCED SEVERITY**  
OF DISEASE AS WELL AS THE STANDARD OF CARE

CLINICAL PROGRAMS - OVERVIEW

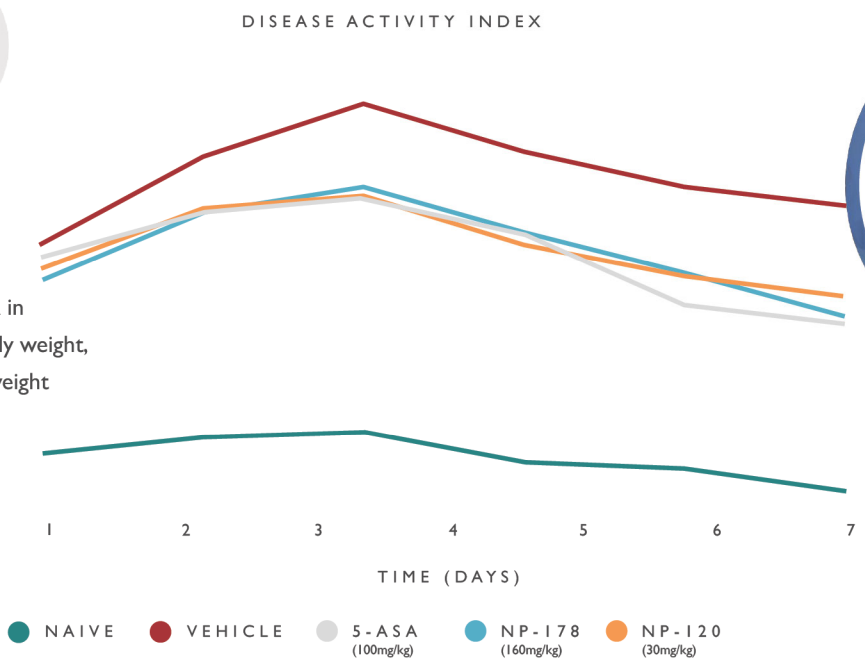
# IBD - CROHN'S

### TNBS MODEL

- N=15 / arm
- Treatment Day 0-7
- Post Bonferroni corrected
- Once a day (QID) treatment
- Clinically relevant doses

Similar improvements to 5-ASA in multiple measurements including body weight, stool consistency, colon length and weight ratios and occult positivity

Up to 50% of Crohn's patients can develop **fibrostenosis** which blocks the GI tract and requires surgery

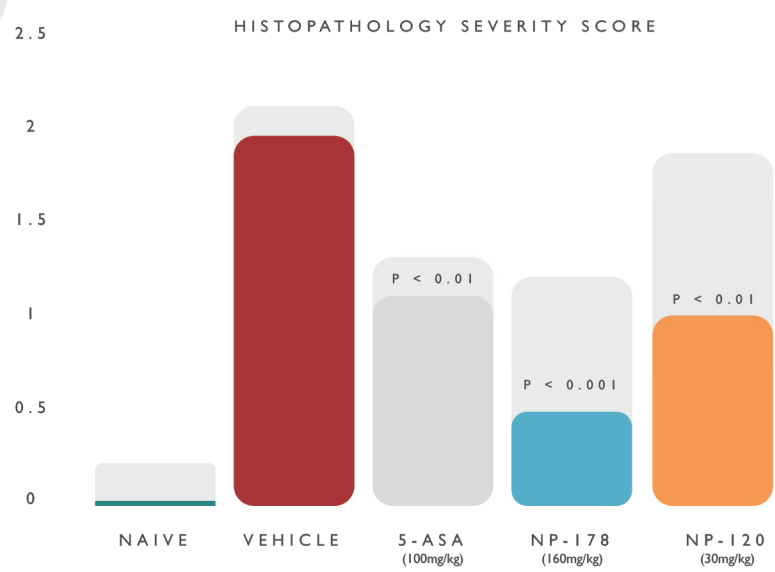


**REDUCED SEVERITY**  
OF DISEASE AS WELL AS THE STANDARD OF CARE

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CLINICAL PROGRAMS - OVERVIEW

# IBD - CROHN'S



**REDUCED SEVERITY**  
OF DISEASE AS WELL AS THE STANDARD OF CARE

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# IBD - PRODUCT POSITION

TREATMENT PROGRESSION





CLINICAL PROGRAM

# IBD TRIAL AND COMPARABLES

## NP-178

### Phase II Design Summary – Low Cost Trial to Provide Proof of Concept Data for Partnering

- 20 patients with active UC
- 15 weeks
- Open-label
- Primary Endpoint: #pts with 50% reduction in ulcer area and/or reduction of ES by 1 pt
- Secondary Endpoint: #pts with remission, % reduction in ulcer area, Geboes index change,
- Country: Australia or Ukraine
- Cost: CDN\$1.2M

### Validated Therapeutic Arena

<b>SERVIERTHERAPEUTICS</b>	
OSE Immunotherapeutics €272M Pre-clinical	
<b>JOHNSON &amp; JOHNSON</b>	
Protagonist \$940M Pre-clinical	
<b>GENENTECH</b>	
Microbiota \$534M Pre-clinical	Lodo \$1B Preclinical

# CHRONIC KIDNEY DISEASE

## COMPETITIVE ADVANTAGE

- > **Clinical:** Potential first-in-class oral small molecule therapies
- > **Market:** Favorable product positioning, high unmet medical need in late stages of disease



## STATUS

- > **4 Candidates:**  
2 active candidates (NP-135, NP-178)  
2 future candidates (NP-160, NP-251)
- > **Safety:** No serious adverse events
- > **Efficacy:** Excellent compared to the standard of care

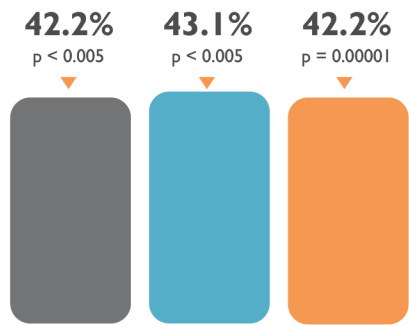
PRE-CLINICAL PROGRAMS – OVERVIEW

# CHRONIC KIDNEY DISEASE – UO MODEL STUDY I

## UNILATERAL URETER OBSTRUCTION MODEL

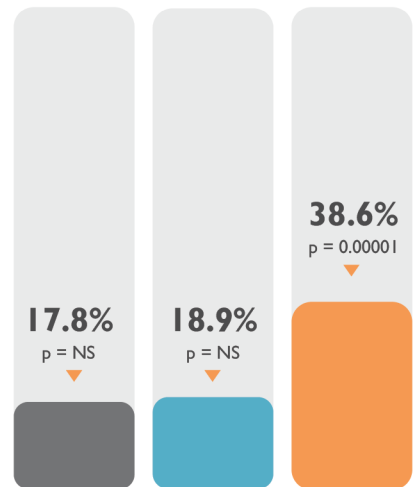
- N=8 / arm
- Treatment Day 0-14
- DMSO vehicle
- Post Bonferroni corrected
- Once a day (QID) treatment
- Clinically relevant doses
- Model of Interstitial Fibrosis
- UO is also model of FSGS
- Independent 3<sup>rd</sup> party statistical review

## FIBROSIS REDUCTION (SIRIUS RED)



TELMISARTAN (3 mg/kg)    NP-178 (160 mg/kg)    NP-135 (200 mg/kg)

## BLOOD UREA NITROGEN (BUN) REDUCTION



TELMISARTAN (3 mg/kg)    NP-178 (160 mg/kg)    NP-135 (200 mg/kg)

PRE-CLINICAL PROGRAMS – OVERVIEW

# CHRONIC KIDNEY DISEASE – UO MODEL STUDY 2

## UNILATERAL URETER OBSTRUCTION MODEL

- N=10 / arm
- Start treatment Day 0-14
- 0.5% CMC vehicle
- Post Bonferroni corrected
- \*Indicates vs negative control
- Once a day (QD) treatment
- Clinically relevant doses
- Independent 3<sup>rd</sup> party stats review

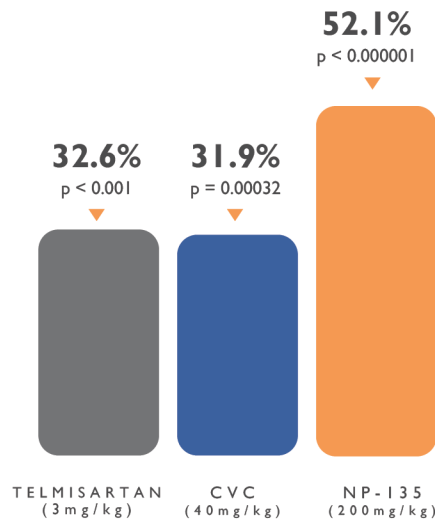
### CVC = CENICRIVIROC

CVC is similar to Chemocentryx's lead CCR2 inhibitor CCX-140 which had positive Phase II clinical trial data for CKD

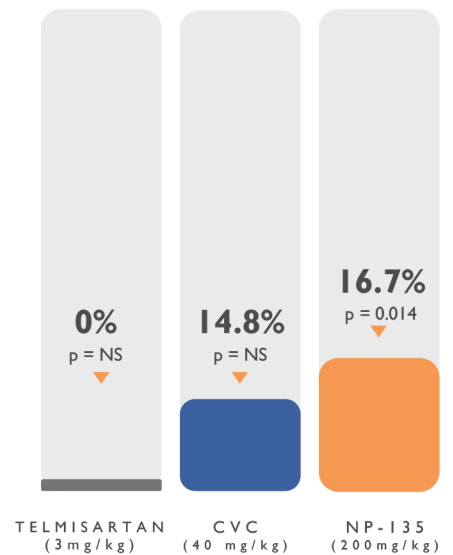
Back up candidates also reduced fibrosis

NP-160 (40 mg/kg) 57.6% (p<0.000001)  
 NP-251 (90 mg/kg) 50.6% (p<0.000001)

## FIBROSIS REDUCTION (SIRIUS RED)



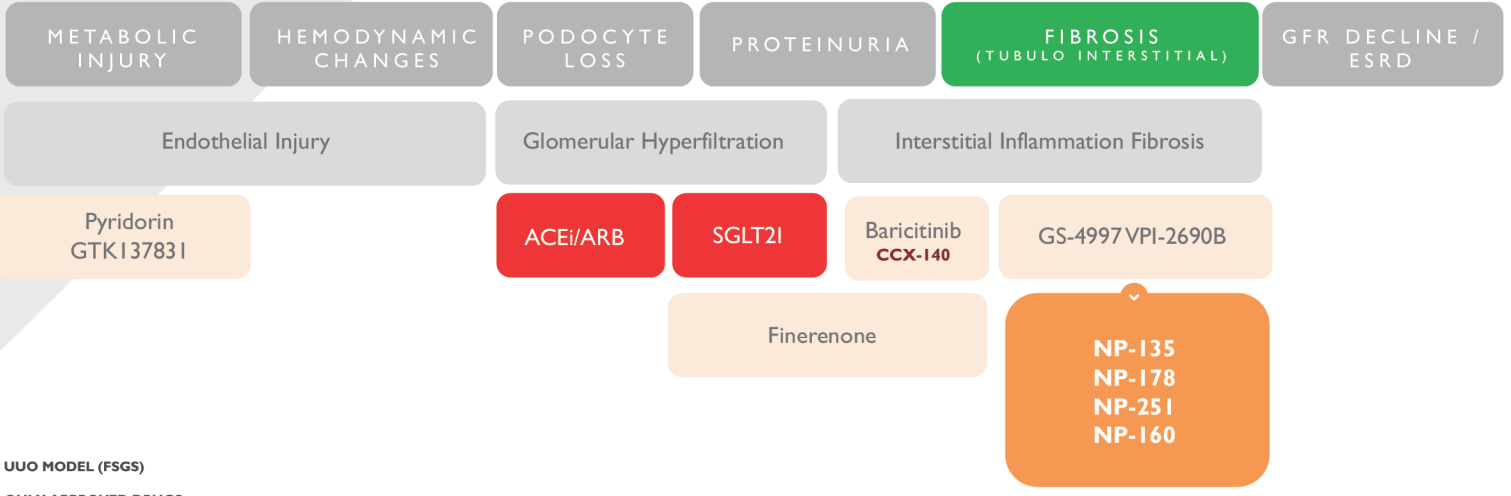
## BLOOD UREA NITROGEN (BUN) REDUCTION



CLINICAL PROGRAMS - OVERVIEW

# CKD - PRODUCT POSITION

DISEASE & TREATMENT PROGRESSION



- UO MODEL (FSGS)
- ONLY APPROVED DRUGS

Semin Nephrol. (2016) 36: 436-447

CLINICAL PROGRAM

# CKD TRIAL AND COMPARABLES

## NP-135

### Phase II Design Summary – Low Cost Trial to Provide Proof of Concept Data for Partnering

- 60 patients
- 16 weeks
- 1:1 Placebo to active
- Primary Endpoint: GFR
- Secondary Endpoint: albuminuria
- Country: Australia or Ukraine
- Cost: CDN\$1.2M

Intend to file for Orphan drug status in FSGS for NP-135

- Phase III <120 patients
- Estimated \$2B market

### Validated Therapeutic Arena

<p><b>KYOWA KIRIN</b></p> <p>Reata \$272M (Asia only) Post-Phase II</p>
<p><b>VIFOR PHARMA</b></p> <p>CARA Therapeutics \$540M Post-Phase II</p>
<p><b>CHEMOCENTRYX</b></p> <p>&gt;\$200M USD market cap Post-Phase II (CCX-140)</p>

# NASH



COMPETITIVE ADVANTAGE

- **Clinical:** Potential first-in-class oral small molecule therapies
- **Market:** Favorable product positioning in competitive market: there are few anti-fibrotic focused products in development

STATUS

- **2 Candidates:**
  - | active candidate (NP-135),
  - | future candidate (NP-160)
- **Safety:** No serious adverse events
- **Efficacy:** Compounds are metabolically neutral, but anti-fibrotic

PRE-CLINICAL PROGRAMS – OVERVIEW

# NASH

## SMC MOUSE MODEL

- N=8 / arm
- Start treatment weeks 6-9
- Post Bonferroni corrected
- Once a day (QID) treatment
- Clinically relevant doses
- Very highly reproducible model

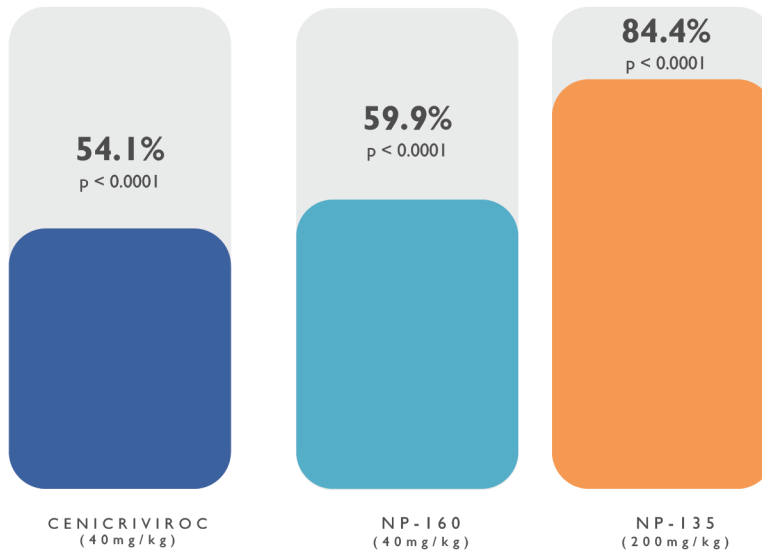
## REDUCTION IN NAS SCORES:

CVC	1.5 (p<0.01)
NP-135	1.1 (p = ns)
NP-160	1.25 (p<0.05)

No effect of compounds on metabolic markers :

- Glucose
- Lipids
- Cholesterol

## FIBROSIS REDUCTION (SIRIUS RED)

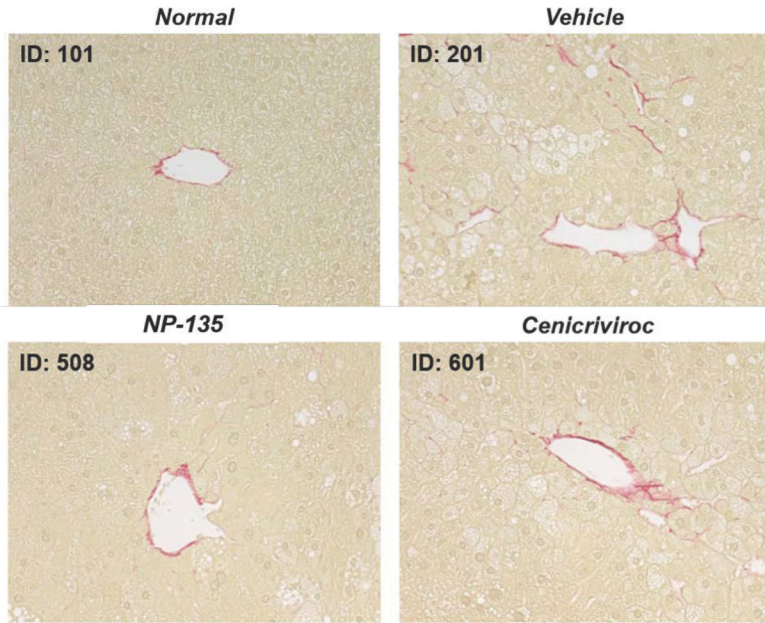


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# NASH – FIBROSIS HISTOLOGY (SIRIUS RED)


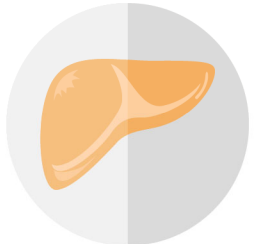
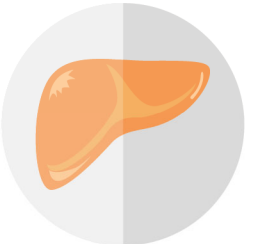
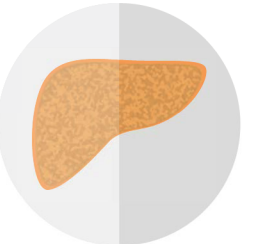
Both NP-135 and CVC were also anti-fibrotic in the CKD UUO model



Original magnifications, x200.

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# NASH – PRODUCT POSITION

HEALTHY LIVER	FATTY LIVER	LIVER FIBROSIS	CIRRHOSIS
			
<ul style="list-style-type: none"><li>&gt; HbA1c &lt; 6.4%</li><li>&gt; Pre-diabetes</li><li>&gt; TE &lt; 7 kPa</li><li>&gt; CAP &gt; 250 db/m</li><li>&gt; Rx = lifestyle Δ</li></ul>	<ul style="list-style-type: none"><li>&gt; 6.5% &lt; HbA1c &lt; 9%</li><li>&gt; Controlled T2D</li><li>&gt; 7 &lt; TE &lt; 9.9 kPa</li><li>&gt; CAP &gt; 250 db/m</li><li>&gt; Rx = Metabolic</li></ul>	<ul style="list-style-type: none"><li>&gt; HbA1c &gt; 9%</li><li>&gt; Uncontrolled T2D</li><li>&gt; 10 &lt; TE &lt; 14.9 kPa</li><li>&gt; CAP &gt; 250 db/m</li><li>&gt; Rx = Anti-fibrotic</li><li>&gt; <b>NP-135, NP-160</b></li></ul>	<ul style="list-style-type: none"><li>&gt; T2D Complications</li><li>&gt; CKD, CAD</li><li>&gt; TE &gt; 15 kPa</li><li>&gt; HCC screening</li><li>&gt; Rx = Combination Therapy</li><li>&gt; <b>NP-135, NP-160</b></li></ul>

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CLINICAL PROGRAM

# NASH TRIAL AND COMPARABLES

## NP-135

### Phase II Design Summary – Low Cost Trial to Provide Proof of Concept Data for Partnering

- 50 patients
- 6 months of treatment
- 1:1 Placebo to Active
- Primary Endpoint: Enhanced Liver Fibrosis (ELF) Panel
- Secondary Endpoint: Fibroscan for fibrosis and steatosis, proC3
- Country: Australia (difficult), NZ, HK or Ukraine
- Cost ~ CDN\$1.5M (includes cGMP synthesis)

### Validated Therapeutic Arena

<b>ALLERGAN</b>		
Tobira \$1.7B Post-Phase II		
<b>NOVARTIS</b>		
Conatus \$700M Post-Phase IIa		
<b>GILEAD</b>		
Nimbus \$1B In Phase I	Phenex \$470M Post Phase I	Yuan\$750M Pre-clinical

# IPF - RESEARCH STAGE



### COMPETITIVE ADVANTAGE

- **Clinical:** First-in-class oral small molecule therapies
- **Market:** Orphan with two approved therapies: Ofev (Nintedanib) and Esbriet (Pirfenidone)

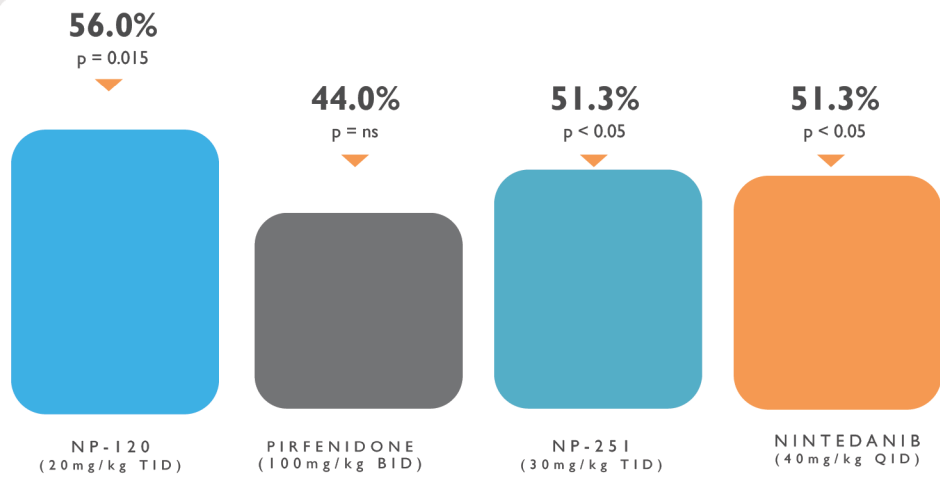
### STATUS

- **2 Candidates in animal testing:**  
NP-120  
NP-251
- **Safety:** No serious adverse events
- **Efficacy:** experiments suggest activity greater than Pirfenidone and Nintedanib

PRE-CLINICAL PROGRAMS – OVERVIEW

# IPF – BLEOMYCIN MODEL STUDY 2

## FIBROSIS REDUCTION



NP-120  
(20 mg/kg TID)

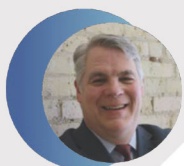
PIRFENIDONE  
(100 mg/kg BID)

NP-251  
(30 mg/kg TID)

NINTEDANIB  
(40 mg/kg QID)

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## EXPERIENCED MANAGEMENT TEAM



**Christopher J. Moreau**

CHIEF EXECUTIVE OFFICER

- President, CEO & director of a TSX:V listed company in the life sciences sector for over nine years
- Experienced with startups, licensing, acquisitions, and integration
- Over 25 years of SNR Management experience in private/publicly traded company environments



**Mark Williams PhD MBA**

CHIEF SCIENCE OFFICER

- Repositioned 3 drugs from preclinical studies directly to positive Phase II data
- Invented DMI99 (recombinant protein) in Phase II trials for Stroke & Kidney Disease
- Secured analyst coverage and KOLS for Diamedica (DMA.V)
- Assisted in raising valuation of DMA.V > \$125M on 5 FTE

## MEDICAL & SCIENTIFIC ADVISORY



**Dr. Arun Sanyal**

Dr. Arun Sanyal, MD, is a leading global expert and clinician in the area of chronic liver disease.



**Dr. Walter Reinisch**

Dr. Walter Reinisch, MD, is a leading global scientific expert and clinician in the area of IBD.

CORPORATE OVERVIEW

# FINANCIALS

## CAPITAL STRUCTURE

Trading symbols: (CSE:AGN) (CNSX:BTH)  
(FRANKFURT:AGW) (OTCQB:BTHCF)

Shares O/S: 47.3M

Warrants: 22.1M

Fully Diluted: 69.4M

Recent Share Price: \$0.22

90 Day High: \$0.33

Market Cap: \$10.4M

\$1M Cash Feb 28, 2019

### Insiders

Kulwant Malhi – 23%

Management – 12.7%

## CAPITAL REQUIREMENTS

### Minimum Raise:

Working Capital	\$ 320,000
IBD or IPF Trial	\$ 1,200,000
Financing Costs	\$ 480,000
<b>Total</b>	<b>\$ 2,000,000</b>

### Maximum Raise:

Working Capital	\$ 320,000
IBD or IPF Trial	\$ 1,200,000
Additional Phase II Planning	\$ 400,000
Research & Development	\$ 146,000
Financing Costs	\$ 534,000
<b>Total</b>	<b>\$ 2,600,000</b>

SUMMARY

# EXECUTIVE SUMMARY

Algernon Pharmaceuticals is a clinical stage pharmaceutical company focused on the areas of non-alcoholic steatohepatitis (NASH), chronic kidney disease (CKD) and inflammatory bowel disease (IBD).

5 PHASE IIA CANDIDATES	EXPERIENCED TEAM	INTELLECTUAL PROPERTY
<ul style="list-style-type: none"><li>➤ First-in-class candidates</li><li>➤ Better than current standard of care</li><li>➤ Orphan drug route</li><li>➤ Strong <i>in vivo</i> studies</li><li>➤ Oral small molecules with optimal dosing</li><li>➤ Confirming MOA</li><li>➤ Repurposing strategy bypasses safety and manufacturing hurdles</li></ul>	<ul style="list-style-type: none"><li>➤ Executive team with diverse and deep experience in drug development and financing</li></ul>	<ul style="list-style-type: none"><li>➤ Provisional Method of Use Patents filed for all lead compounds</li><li>➤ New Class of Compounds Broad NCE Markush Patents</li><li>➤ Composition of Matter Patents on lead compounds have expired.</li></ul>



DEVELOPMENT PLANS

# MILESTONES & TIMELINES

(Based on Maximum Raise)

2019

Q4

- Begin cGMP synthesis of NP-135
- Initiate additional pre-clinical research

2020

Q1

- Ethics Approval for IBD or IPF trial
- Complete pre-clinical research and
- Publish research papers
- Begin IBD or IPF trial

Q2

- Complete cGMP synthesis of NP-135
- Submit for ethics in Australia/New Zealand/Ukraine for the NASH NP-135 study and/or CKD Study

2021

Q4

- Expect data from either IBD or IPF study