



# US FDA Approval of ICOTYDE™ (Icotrokinra) For Treatment of Moderate-to- Severe Plaque Psoriasis

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Now FDA Approved: ICOTYDE™

ICOTYDE is the first and only targeted oral peptide that blocks the IL-23 receptor



ICOTYDE™  
(icotrokinra) tablets

*For the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy*

# ICOTYDE™

## US FDA approval of ICOTYDE™, formerly PN-235, for treatment of moderate-to-severe plaque psoriasis

- Johnson & Johnson partnership overview
  - 2017 to present
  - Protagonist completed pre-clinical and first Ph1 study<sup>1</sup>
  - J&J responsible for further development and commercialization
- ICOTYDE is the first and only IL-23R targeted oral peptide to
  - deliver injectable biologics-like skin clearance, and
  - a favorable safety profile, with
  - the convenience of a once-daily pill
- Approval supported by four phase 3 studies that met all primary endpoints and demonstrated a favorable safety profile in 2,500 patients

1. Fourie, AM et al. JNJ-77242113, a highly potent, selective peptide targeting the IL-23 receptor, provides robust IL-23 pathway inhibition upon oral dosing in rats and humans. *Sci Rep* 2024(14):17515. <https://doi.org/10.1038/s41598-024-67371-5>.

# Icotrokinra Clinical Development Program

Successful Studies in Psoriasis & UC; PsA studies Ongoing; Phase 3 UC and CD studies underway

## Plaque Psoriasis

**FRONTIER 1<sup>1</sup> & 2<sup>2</sup>** Ph2b, n = 255 & 227, in moderate-to-severe psoriasis

Reference(s)

Bissonnette R, et al. *N Engl J Med.* 2024;390:510-21.

Primary Endpoint Met?



**ICONIC-LEAD<sup>3</sup>** Ph3, n = 684, in moderate-to-severe psoriasis

Bissonnette R, et al. *N Engl J Med.* 2025;393:1784-95.



**ICONIC-TOTAL<sup>4</sup>** Ph3, n = 311, psoriasis in special areas of body

Gooderham M, et al. *NEJM Evid.* 2025;Epub ahead of print.



**ICONIC-ADVANCE 1<sup>5</sup>** Ph3, n = 774, Icotrokinra vs. Deucravacitinib

Gold LS, et al. *Lancet.* 2025;406:1363-74.



**ICONIC-ADVANCE 2<sup>6</sup>** Ph3, n = 731, Icotrokinra vs. Deucravacitinib



**Pustular/Erythrodermic Psoriasis<sup>7</sup>** Ph3, n = 19



**ICONIC-ASCEND<sup>8</sup>** Ph3, n = 752, Icotrokinra vs. Ustekinumab

~Mar '26

## Psoriatic Arthritis

**ICONIC-PsA 1<sup>9</sup>** Ph3, n ~ 540, in biologic-naive active psoriatic arthritis

~May '26

**ICONIC-PsA 2<sup>10</sup>** Ph3, n ~ 750, in biologic exposed active psoriatic arthritis

~Feb '27

## Ulcerative Colitis

**ANTHEM-UC<sup>11</sup>** Ph2b, n = 252, in ulcerative colitis



**ICONIC-UC<sup>12</sup>** Ph3, n ~ 882, in ulcerative colitis

~Jan '28

## Crohn's Disease

**ICONIC-CD<sup>13</sup>** Ph 2/3, n ~ 1092, in Crohn's disease

~Sept '28

# Icotrokinra

## JNJ and Protagonist Collaboration Economics



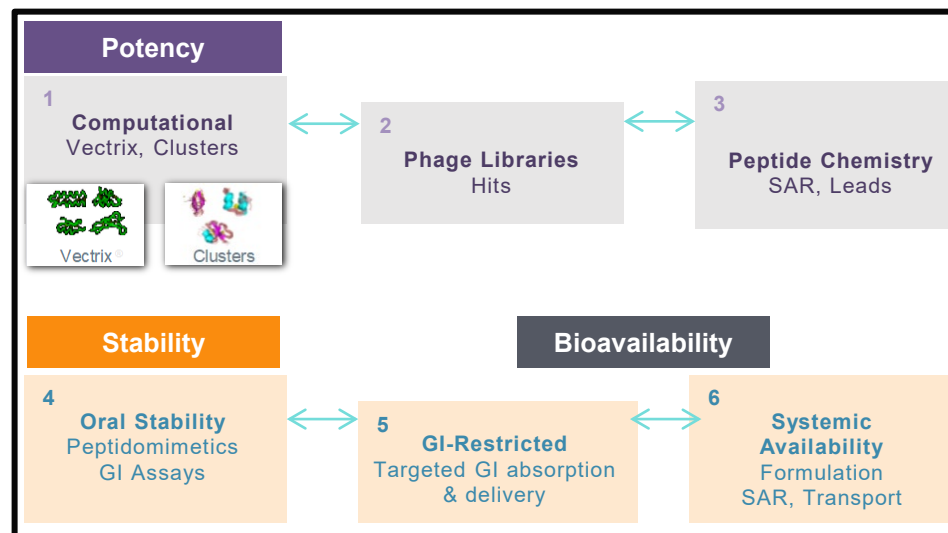
Potential Development milestones through 2028			Expected
Any indication	Receipt of marketing approval	\$50M	~2026 ✓
<b>Remaining milestones</b>			
2 <sup>nd</sup> indication	NDA filing acceptance	\$25M	~2027
	Receipt of marketing approval	\$45M	~2028
3 <sup>rd</sup> indication	NDA filing acceptance	\$35M	~2028
	Receipt of marketing approval	\$50M	~2028-29
<b>Total potential development milestones</b>		<b>\$155M</b>	

Icotrokinra Sales Milestones*	
Calendar Year Net Sales	Sales Milestone
\$1 Billion	\$70M
\$2 Billion	\$95M
\$3 Billion	\$160M
\$5 Billion	\$100M
<b>Total Potential Sales Milestones</b>	<b>\$425M</b>

Illustrative royalties in peak sales year				
Annual net sales*	\$5.0B	\$10.0B	\$15.0B	\$20.0B
Pre-tax royalty receivable*	\$0.4B	\$0.9B	\$1.4B	\$1.9B

# Protagonist's Peptide Technology Platform

## Core Competitive Advantage



**PN-458o**  
**PN-458sc**  
Dual  
GLP/GIP

**PN-8047**  
Oral Hepcidin  
Functional  
mimetic

**PN-477o**  
Oral  
Triple Agonist  
Anti-Obesity  
DC

**PN-477sc**  
Weekly sc  
Triple Agonist  
Anti-Obesity  
DC

**PN-881**  
Oral  
IL-17  
Antagonist

**Rusfertide**  
SC Weekly  
Hepcidin Mimetic  
PV, Ph3



**Icetrokinra**  
Oral IL-23r  
Antagonist

**Johnson & Johnson**  
Innovative Medicine

IND-Enabling

Phase 1

NDA: PV  
29 Dec '25

FDA approval for  
Plaque Psoriasis  
Ph 3: PsA, UC, CD

# Protagonist Therapeutics

## Two Potential Blockbuster Approvals, Multiple R&D Readouts & Strong Cash Position

### Commercial Value Drivers

- ❑ **Icotrokinra**: First-in-class oral IL-23R antagonist



- ❖ US FDA approval for plaque psoriasis: Mar '25 ✓
- ❖ MAA submitted Sep '25
- ❖ 3 additional indications

- ❑ **Rusfertide**: First-in-class hepcidin hormone mimetic



- ❖ NDA submitted for PV: Dec '25
- ❖ Priority review granted: Mar '26

### Multiple Clinical Programs I&I, Obesity and Hematology

#### I & I

- ❑ **PN-881**: Oral IL-17 antagonist
  - ❖ Ph1 in progress<sup>1</sup>

#### Heme

- ❑ **PN-8047**: Oral hepcidin functional mimetic
  - ❖ IND enabling studies

#### Obesity

- ❑ **PN-477sc & PN-477o**: Triple-G, weekly sc and daily oral
  - ❖ Ph1 initiation in 2H
- ❑ **PN-458sc & PN-458o**: Dual GLP-1R/GIPR agonist
  - ❖ IND-enabling studies

### Next Wave of Active Discovery Programs

#### Lead optimization/Pre-clinical:








- ❑ **IL-4R $\alpha$**  oral antagonist
- ❑ **Amylin** oral mono/poly-agonists
- ❑ Other programs

### Strong Cash Position

- ❑ Fund internal, fully-owned programs to clinical PoC
- ❑ Capital return to shareholders – consider share buybacks

# Protagonist Therapeutics

## Expected Clinical Trial Initiations, Data Readouts, and Development Candidate Nominations

	1H 2026	2H 2026	2027
 <p>Icotrokinra</p>	<ul style="list-style-type: none"> <li>❖ Psoriasis NDA &amp; MAA</li> <li>❖ Ph3 PsA 1 &amp; 2; UC &amp; CD ongoing</li> </ul>	<ul style="list-style-type: none"> <li>★ <b>ICOTYDE approved for Plaque Psoriasis</b></li> <li>❖ Ph3 ICONIC-ASCEND and PsA 1 Primary Completion</li> </ul>	<ul style="list-style-type: none"> <li>❖ Commercial</li> <li>❖ Ph3 ICONIC-PsA 2 Primary Completion</li> </ul>
 <p>Rusfertide</p>	<ul style="list-style-type: none"> <li>❖ NDA submitted</li> </ul>	<ul style="list-style-type: none"> <li>❖ NDA accepted; priority review granted</li> <li>❖ Opt-in/Opt-out decision</li> </ul>	<ul style="list-style-type: none"> <li>★ <b>US approval/launch for PV</b></li> <li>❖ Commercial</li> </ul>
 <p>PN-881*</p>	<ul style="list-style-type: none"> <li>Oral IL-17 antagonist</li> <li>❖ Ph1 ongoing</li> </ul>	<ul style="list-style-type: none"> <li>❖ Ph1 ongoing</li> </ul>	<ul style="list-style-type: none"> <li>❖ Ph1 completion</li> <li>❖ Ph2 PsO Initiation</li> <li>❖ Ph2 PsO Interim Analysis</li> </ul>
 <p>PN-477sc* PN-477o*</p>	<ul style="list-style-type: none"> <li>Anti-obesity DCs</li> <li>❖ IND-enabling studies</li> </ul>	<ul style="list-style-type: none"> <li>❖ PN-477sc Ph1 initiation</li> </ul>	<ul style="list-style-type: none"> <li>❖ PN-477sc Ph1 clinical PoC</li> <li>❖ PN-477o Ph1 initiation</li> <li>❖ Ph1 Topline</li> </ul>
 <p>PN-8047*</p>	<ul style="list-style-type: none"> <li>❖ Oral Hepcidin DC</li> </ul>		<ul style="list-style-type: none"> <li>❖ Ph1 initiation</li> <li>❖ Ph1 Topline</li> </ul>
 <p>PN-458sc* PN-458o*</p>	<ul style="list-style-type: none"> <li>Dual GLP/GIP DCs</li> <li>❖ PN-458sc</li> <li>❖ PN-458o</li> </ul>		<ul style="list-style-type: none"> <li>❖ Ph1 initiation</li> </ul>
 <p>Discovery*</p>	<ul style="list-style-type: none"> <li>❖ AmylinR-based mono &amp; poly-agonists</li> <li>❖ Oral IL-4R<math>\alpha</math> antagonist</li> </ul>		

\*Fully owned by Protagonist Therapeutics, Inc.  
DC, Development candidate; ready for IND-enabling studies.

**Thank you**