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PHIN-214: Evolutionary subcutaneous vasopressor therapy for patients with advanced cirrhosis

2025

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Leadership team

Elijah Bolotin, PhD
President & Chief Executive Officer

novo nordisk® · élan · NYU Langone MEDICAL CENTER

Joint ventures with Endorex

Andy Stubbs, PhD
Chief Development Officer

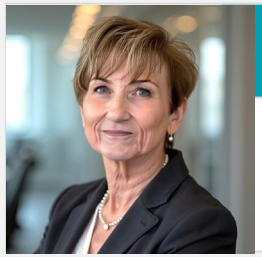
sanofi · Kiadis pharma · Dendreon · IOVANCE BIOTHERAPEUTICS · Abbott

Lorraine Tracey, PhD
VP, Clinical Development

sanofi · Kiadis pharma · IPSEN · teva

Craig Philips
Chairman of the Board & Advisor

KINETA® · Bristol Myers Squibb · BAYER · Schering-Plough · cti BIOPHARMA



Jenny Martin, RN
VP, Clinical Operations

sanofi · Kiadis pharma · JUNO THERAPEUTICS · Coherus BIOSCIENCES · BAYER

Gerardo Castillo, PhD
VP, IP and Grants | Distinguished Scientist

ProteoTech · UNIVERSITY of WASHINGTON

Shawn Iadonato, PhD
Advisor

KINETA® · illumigen · UNIVERSITY of WASHINGTON

Mike Shetzline, MD, PhD
Board member

Ironwood · Takeda · FERRING PHARMACEUTICALS · NOVARTIS

PHIN-214: evolutionary subcutaneous vasopressor therapy for patients with advanced cirrhosis

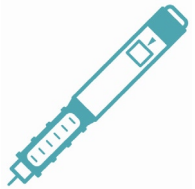
Developing best-in-class subcutaneous therapy for patients with advanced cirrhosis

Actively seeking a 2025 strategic partnership

Decompensated cirrhosis

No effective therapies for long-term treatment of decompensated cirrhosis

~500K patients in the US



PHIN-214

The only subcutaneous vasopressor therapy currently in development (phase 1)

Robust evidence of clinical activity after a single dose with benign safety profile

Projected global peak sales: $4B at 10% market penetration

Milestones

Phase 1 Single ascending dose in advanced cirrhosis: **complete**

Phase 1 Multiple ascending dose: enrolling

Complete phase 1 (Q1 2026); Initiate phase 2/3 (Q4 2026)

Decompensated cirrhosis presents enormous unmet medical need and $4B global market opportunity

Compensated cirrhosis
4.2M annually in the US [1]

Decompensated cirrhosis
~500K annually in the US [1]

Estimated survival >12 yrs[2]

Estimated survival <2 yrs[2]
Complications of increased portal hypertension: Ascites, Varices, Encephalopathy, Hepatorenal Syndrome, Acute Kidney Injury etc.

- Portal hypertension drives decompensation
  - **Rapidly progressing disease with immense morbidity & mortality**
  - Abysmal quality of life
  - High healthcare resource utilization
- Competitive landscape is wide-open
  - Current treatments are largely palliative - liver transplant is the only curative option
- Potential for LCM/market expansion into compensated cirrhosis

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Sources: 1. GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterol Hepatol (2020) Mar; 5(3); 2. Kaplan, D. E., et al., Hepatology (2023) 10; pp1097

PHIN-214 MOA: partial V1a agonism causes splanchnic vasoconstriction and relieves portal hypertension

Cirrhosis increases resistance to portal blood flow due to scarring & vascular remodeling, resulting in **portal hypertension.**

This diverts blood to the **splanchnic circulation** around abdominal organs, causing complications including ascites, esophageal varices, & hepatorenal syndrome.

The resulting low arterial volume **places an extra burden on the heart** & **reduces perfusion of the kidneys.**

PHIN-214

- Induces splanchnic **vasoconstriction**
- Redistributes blood back to the systemic circulation

- **Decreases portal hypertension**
- Reduces incidence of complications of decompensation
- Improves kidney function (eGFR)

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Development status: Phase 1 Single Ascending Dose complete; Multiple Ascending Dose enrolling

Single Ascending Dose

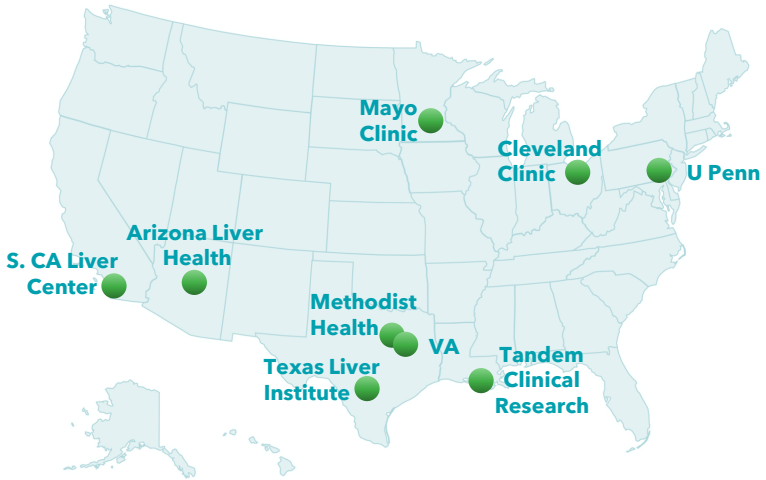
Advanced liver cirrhosis (Child-Pugh A/B)

DL-1 → DL-2 → DL-3 → DL-4 → DL-5 → DL-6 → DL-7 → DL-8

= *Cleared cohort*

DL = Dose Level

Clinical sites currently recruiting



Multiple Ascending Dose

Advanced liver cirrhosis (Child-Pugh B)

DL-4 → DL-5 → DL-6 → DL-7 → DL-8 → Escalate until MTD

Primary objectives include safety, tolerability, PK/PD assessments & evidence of clinical activity (renal function)

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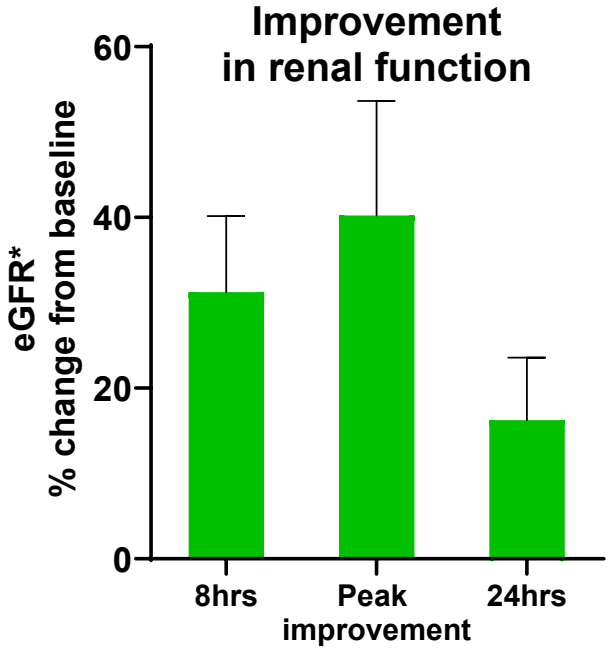
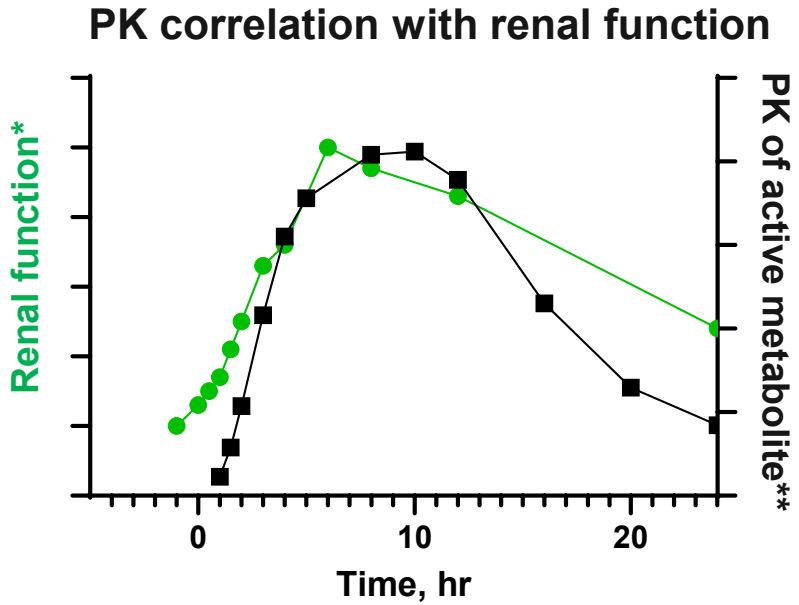
Compelling evidence of clinical benefit after a single dose

- Improved renal function observed in all subjects, across all dose levels.
- Clinical activity sustained up to 24h.



*eGFR: estimated glomerular filtration rate
Error bar: 95% CI; n=15

- Improved renal function correlates strongly with PK of active metabolite.



* Kidney function by estimated glomerular filtration rate (eGFR)
** PHIN-156 (active metabolite of PHIN-214) concentration
Representative data set

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PHIN-214: single dose well tolerated – safety profile consistent with on-target V1a engagement

- 4/15 patients experienced AEs (mostly grade 1/2) related to PHIN-214 administration:
  - Injection site blanching
  - Abdominal pain/cramping
  - Diarrhea
  - Hematochezia
  - Hypertension
- AE profile is consistent with on-target MOA (V1a receptor engagement)

Future development

 Primary indication (phase 2/3)	▪ Prevention of disease progression in patients with decompensated cirrhosis (500K patients in US) ▪ Study Design: Randomized, double-blind, placebo-controlled study evaluating PHIN-214 plus SoC vs SoC alone ▪ Primary Endpoint: Time from randomization to disease progression (further decompensation) or death [composite endpoint]
 Regulatory outlook	▪ Primary endpoint follows FDA guidance to industry in patients with compensated cirrhosis ▪ Potential for breakthrough designation: Extremely high unmet need, high morbidity, mortality & healthcare-resource utilization
 Label expansion opportunities	▪ Treatment of patients hospitalized with ACLF or HRS/AKI ▪ Prevention/delay of decompensation in compensated patients with clinically-significant portal hypertension at high risk of decompensation

PHIN-214: Upcoming development milestones

Anticipated Milestones	2025				2026			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Completed phase 1 single dose	☑							
Initiate phase 1 multiple dose		☑						
Complete phase 1 study					●			
Type A FDA meeting						●		
Initiate phase 2/3 clinical study								●

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PHIN-214: Partnership opportunity to translate compelling clinical activity into blockbuster potential

Actively seeking a 2025 strategic partnership

Feature

- Subcutaneous vasopressin analog
- Patent protection up to 2041
- Established & scalable manufacturing, liquid form stable at RT
- Low cost of goods

Opportunities

- A novel therapy for long-term treatment providing:
  - Inpatient & outpatient care applications
  - Addresses immense unmet need, improves morbidity & mortality
- $4B global peak sales at 10% market penetration

Clinical

- Target indication with ~500k patients in US: Prevention of disease progression in patients with decompensated cirrhosis
- Potential for label expansion

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For additional information:

Andy Stubbs, Chief Development Officer
AStubbs@pharmain.com

Lorraine Tracey, VP, Clinical Development
ltracey@pharmain.com

Akiko Nishimoto-Ashfield (西本晶子), Associate Director, BD
aashfield@pharmain.com

To discuss business opportunities:
bd@pharmain.com

https://pharmain.com/