PharmaIN

PHIN-214: First-in-class subcutaneous vasopressor therapy for patients with advanced cirrhosis

June 2026

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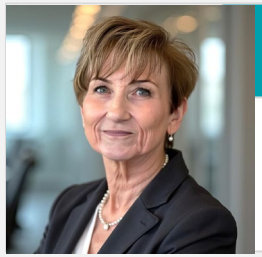

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PHIN-214: Subcutaneous vasopressor therapy for patients with advanced cirrhosis

Developing first-in-class self-administered subcutaneous therapy for patients with advanced cirrhosis

Decompensated cirrhosis

No effective long-term therapies exist for the treatment of decompensated cirrhosis, a high-morbidity, high-mortality condition

~0.5M+ patients affected each year in the U.S.[1,2]

PHIN-214

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

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

~$2.2B U.S. Peak Sales in decompensated cirrhosis population[3]

Milestones

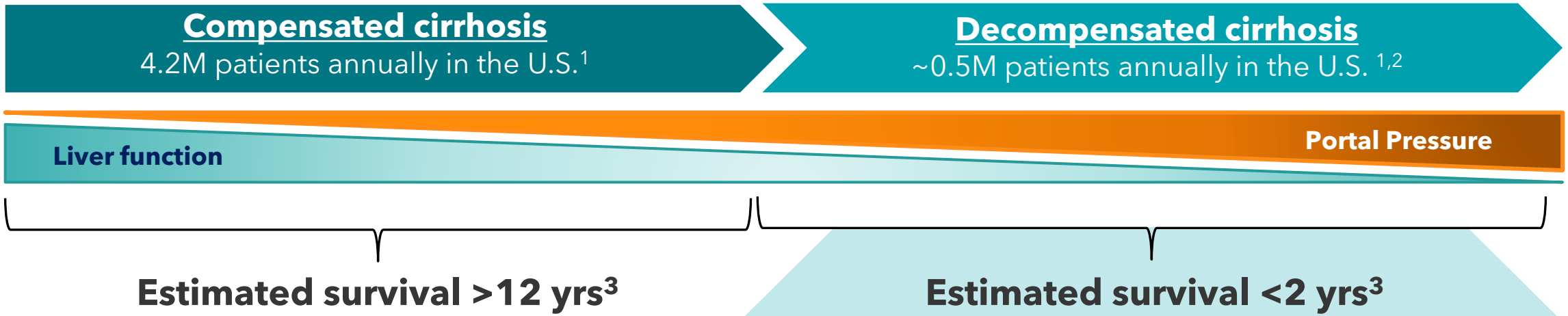
Phase 1 Single ascending dose in advanced cirrhosis: **complete**

Phase 1 Multiple ascending dose: enrolling

Complete phase 1 (Q4 2026); Initiate registrational study (YEQ4 2027 est.)

1. *GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterol Hepatol (2020) Mar; 5(3);*
2. *Ladner, D. P, et al., PLoS ONE (2024) 19(2): e0298887.*
3. *Based on addressable population with inclusion/exclusion criteria, patients with clinically significant hemodynamic dysfunction, 25% peak penetration, a conservative analog-based WAC and standard market access and compliance adjustments.*

Significant unmet need: Transplant as the only curative treatment option in decompensated cirrhosis



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

1. GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterol Hepatol (2020) Mar; 5(3);
2. Ladner, D. P, et al., PLoS ONE (2024) 19(2): e0298887
3. Kaplan, D. E., et al., Hepatology (2023) 10; pp1097

Supportive care does not adequately address multi-organ complications of decompensation

- ~12% of cirrhosis patients decompensate each year [1]
- Median survival is ~2 years after decompensation [2]
- No effective pharmacological options to treat progression of decompensated cirrhosis
- Liver transplant is currently the only curative option
- Cirrhosis and chronic liver disease are the 9th leading cause of death in the U.S.[3], accounting for ~52,000 [3] deaths annually, and is associated with significant morbidity and expense

Compensated cirrhosis
4.2M annually in the U.S. [1]

Decompensated cirrhosis
~0.5M annually in the U.S. [1]

Complications of Decompensation

CLINICAL MANIFESTATIONS OF DECOMPENSATED CIRRHOSIS	Ascites / Fluid Overload	Variceal Bleeding	HRS-AKI	Hepatic Encephalopathy	Hypotension
CURRENT TREATMENT OPTIONS	• Diuretics • Albumin • Paracentesis • TIPS	• Non-selective β-blockers (NSBBs) • Endoscopic Band Ligation • Vasopressors • TIPS	• Vasopressors (e.g., terlipressin, norepinephrine, midodrine) • Albumin	• Lactulose • Rifaximin	• Albumin • Vasopressors

Recurrent Hospitalization | Liver Transplant | Death

Note(s): HE = Hepatic Encepelopathy, GE = Gastroesophageal, TIPS = Transhepatic Intrajugular Portosystemic Shunt, NSBB = Non-Selective Beta-Blocker.

1. GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterol Hepatol (2020) Mar; 5(3)
2. Tapper, E.B., et al., JAMA (2023)329; pp 1589-1602
3. Centers for Disease Control and Prevention: https://www.cdc.gov/nchs/fastats/liver-disease.htm

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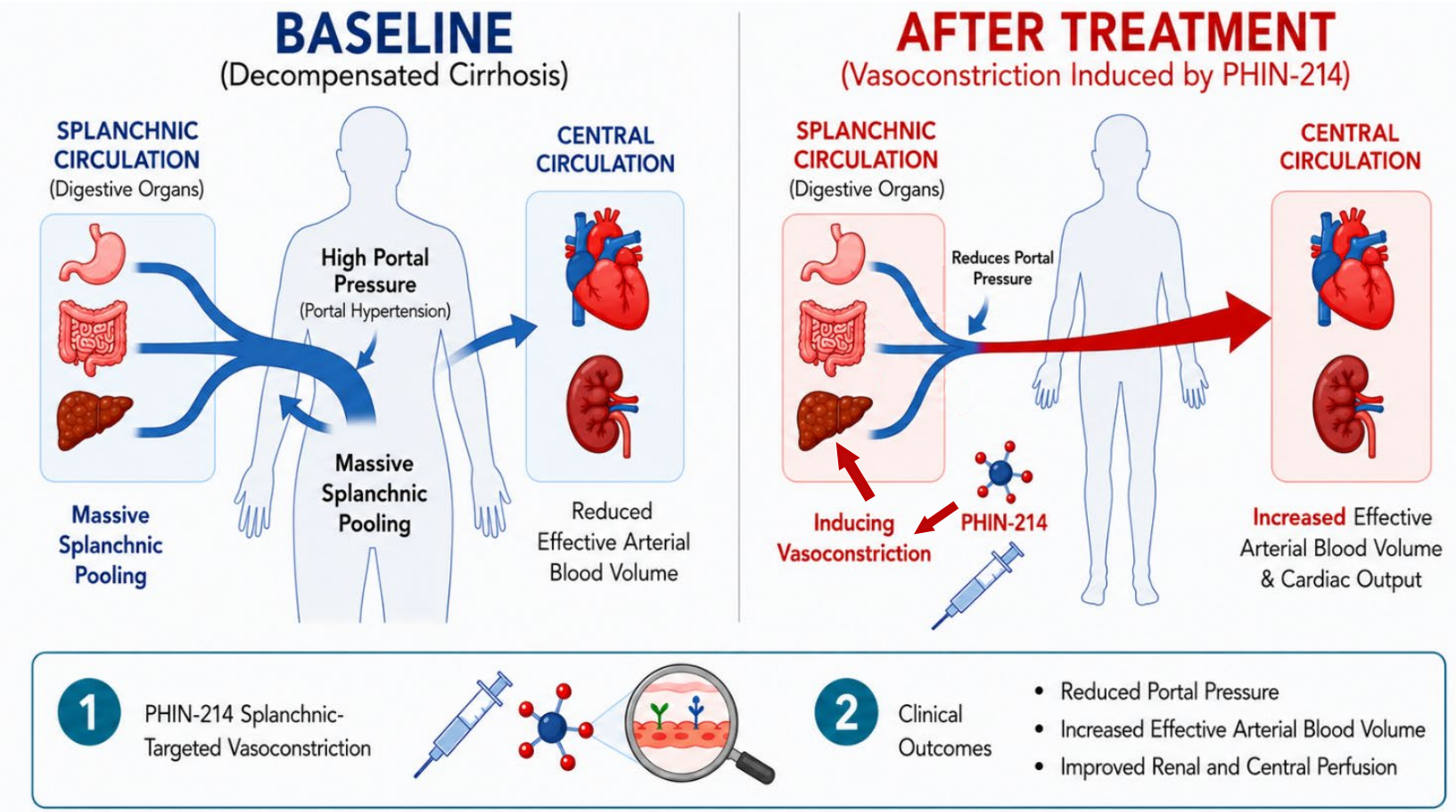
PHIN-214 MOA: Partial V1a agonism causes splanchnic vasoconstriction and relieves portal hypertension

The Problem: Splanchnic vasodilation causes pooling of blood in the digestive vasculature, reducing effective circulating volume and driving portal hypertension in advanced cirrhosis.



Downstream impacts

- Ascites, variceal bleeding, and hepatic encephalopathy
- Heart and kidneys receive inadequate perfusion, causing hemodynamic instability and renal failure (HRS or hepatorenal syndrome)

PHIN-214

- Selectively induces splanchnic vasoconstriction, physically narrowing the dilated vessels
- Mobilizes pooled blood back into the central circulation

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

Single Ascending Dose (Complete); n=16

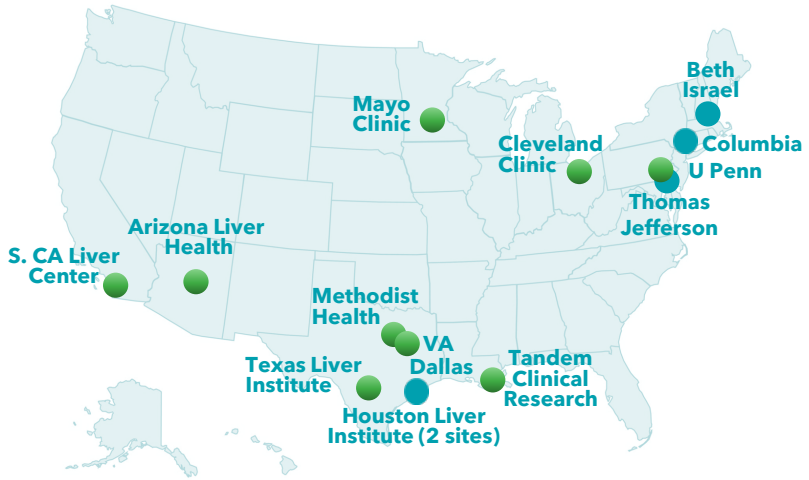
Advanced liver cirrhosis (Child-Pugh A/B)

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
- In start-up

Multiple Ascending Dose (Enrolling)

Advanced liver cirrhosis (Child-Pugh B)

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

DL-3 → DL-2 → DL-1

Parallel enrollment of lower doses following clearance of higher dose levels

= *Cleared cohort*

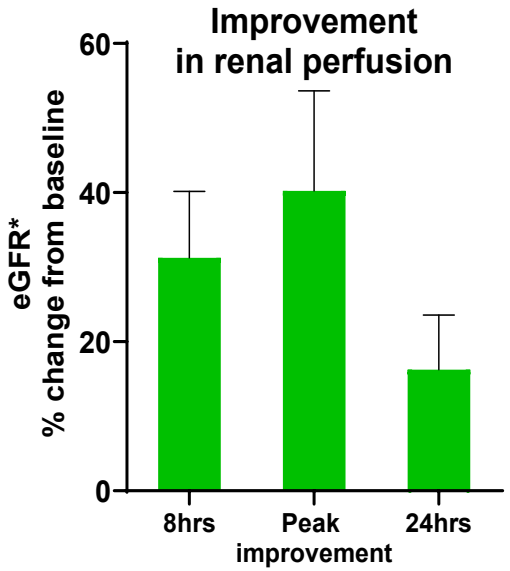
= *Enrolling*

DL = Dose Level

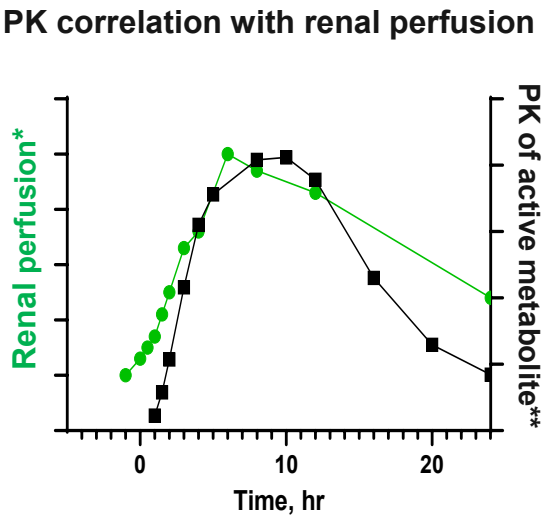
Primary objectives include safety, tolerability, PK/PD assessments, and evidence of clinical activity (renal function)

Compelling evidence of clinical benefit after a single dose

- Improved renal perfusion observed in all subjects, across all dose levels
- Clinical activity sustained up to 24h
- Improved renal perfusion correlates strongly with PK of active metabolite

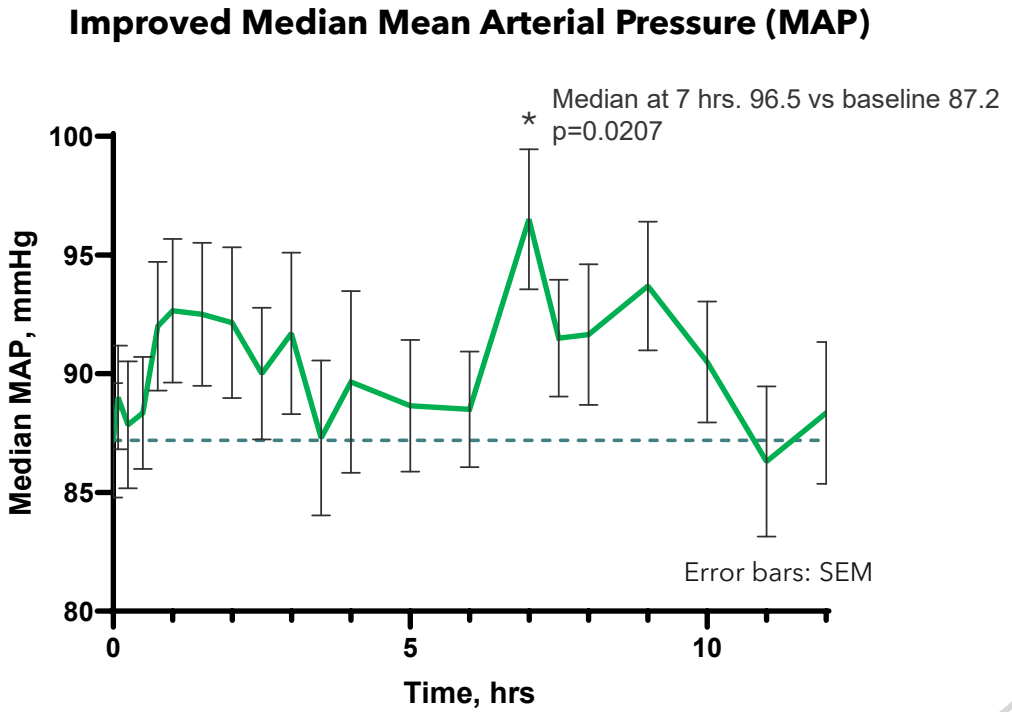


*eGFR: estimated glomerular filtration rate
Error bar: 95% CI; n=15



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

- Median Mean Arterial Pressure (MAP) increased ~3.24 mmHg over the first 12 hours following PHIN-214 administration, with a significant median MAP increase at 7 hours post treatment



Source: Published Nov 7, 2025; AASLD abstract 2404

PHIN-214 was generally well tolerated across dose levels; emerging safety profile is consistent with V1a activity

- Only 4/15 patients experienced AEs (mostly grade 1-2) related to PHIN-214 administration

Reported AEs possibly/probably/definitely related to PHIN-214 administration

Dose Level	Subject	AE (verbatim term)	CTCAE Grade	Relationship to PHIN-214*	DLT
4	106-028	Injection Site Reaction-Blanching	1	Definite	No
5	107-032	Acid Reflux	2	Possible	No
		Abdominal pain	1	Possible	No
		Diarrhea	1	Possible	No
6	100-027	Diarrhea	2	Probable	No
8	105-037	**Increased systolic blood pressure**	**3**	**Probable**	**YES**
		Blood in stool	2	Possible	No
		Abdominal cramping	2	Probable	No
		Weight loss	1	Possible	No
		Nausea	1	Possible	No
		Headache	1	Possible	No
		Abdominal distension	1	Possible	No
		Irregular, frequent bowel movements	1	Possible	No

**Physician designated relationship to PHIN-214*

Future development

 Primary indication	▪ Prevention of disease progression in patients with decompensated cirrhosis (~0.5M patients annually in U.S.) ▪ 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 [Public FDA guidance: NASH with Compensated Cirrhosis Link] ▪ Potential for expedited development designations: extremely high unmet need, high morbidity, mortality & healthcare-resource burden ▪ Planned Breakthrough or Fast Track Designation submissions immediately following Phase 1 MAD completion
 Label expansion opportunities	▪ Prevention/delay of decompensation in compensated patients with clinically-significant portal hypertension at high risk of decompensation ▪ Treatment of patients with AKI/CKD at high risk of progression or hospitalized patients with Acute-on-Chronic Kidney Failure (ACLF)

AKI = Acute Kidney Injury
CKD = Chronic Kidney Disease

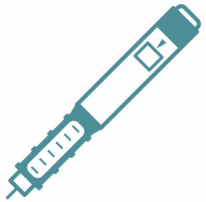
PHIN-214: Major Catalysts including anticipated initiation of registrational study in 2027

Milestones	2026		2027			
	Q3	Q4	Q1	Q2	Q3	Q4
☑ Completed phase 1 SAD study						
☑ Initiated phase 1 MAD study						
☑ Completed 90-day GLP tox study						
Interim MAD data release (under CDA)	●					
Establish MTD/OBD*	●					
Type C FDA meeting	●					
End of phase 1 Type B FDA meeting			●			
Initiate chronic GLP tox study			●	→	→	→
Initiate registrational study						●

*MTD = Maximum tolerated dose

*OBD = Optimal biological dose

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



Feature

- Subcutaneous vasopressin analog
- Patent protection up to 2041
  - US: issued
  - China, EU, Japan: published
- Established & scalable manufacturing, liquid form stable at RT
- Low cost of goods

Opportunities

- A novel therapy for long-term treatment providing:
  - Inpatient & at-home care applications
  - Addresses immense unmet need, improves morbidity & mortality
- Potential U.S. peak sales in decompensated cirrhosis: ~$2.2B[3]

Clinical

- Target indication with ~0.5M+ patients in the U.S.[1,2]:
  - Prevention of disease progression in patients with decompensated cirrhosis
- Potential for label expansion

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1. *GBD 2017 Cirrhosis Collaborators, Lancet Gastroenterol Hepatol (2020) Mar; 5(3);*
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Accelerating clinical momentum for PHIN-214

- Current data support continued development of PHIN-214 as a self-administered, SC therapy for complications of portal hypertension in decompensated cirrhosis
- Emerging MAD data remain consistent with SAD, supporting a favorable tolerability profile and clear indications of clinical activity
- Enrollment accelerated with site expansion and additional subjects queued
- MAD data will be presented at the AASLD annual Liver Meeting 2026 (Nov 5–9, Denver)
- Engagement with regulators planned for Q4 2026
- Complete phase 1 MAD (Q4 2026); Initiate registrational study (YE 2027)

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