



Corporate Presentation

November 2023

Forward looking statements

This presentation contains “forward-looking statements” within the meaning of the federal securities laws regarding the current plans, expectations and strategies of Gyre Therapeutics, Inc. and its subsidiaries (“Gyre”), which statements are subject to substantial risks and uncertainties and are based on management’s estimates and assumptions. All statements, other than statements of historical facts included in this presentation, are forward-looking statements, including statements concerning Gyre’s plans, objectives, goals, strategies, future events, or intentions relating to Gyre’s products and markets, the safety, efficacy and clinical benefits of Gyre’s product candidates, the anticipated timing and design of any planned and ongoing preclinical studies and clinical trials, Gyre’s research and development efforts, plans and objectives of management for future operations and future results of anticipated product development efforts, potential addressable market size and our liquidity and capital resources and business trends. In some cases, you can identify forward-looking statements by terms such as “believe,” “can,” “could,” “design,” “estimate,” “expect,” “forecast,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “objective,” “should,” “strategy,” “will,” “would,” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause Gyre’s actual results to differ materially from the forward-looking statements expressed or implied in this presentation, in addition to those risks and uncertainties, such as the uncertainties inherent in the clinical drug development process, the regulatory approval process, the timing of any regulatory filings, the potential for substantial delays, the risk that earlier study results may not be predictive of future study results, manufacturing risks, and competition from other therapies or products, described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Definitive Proxy Statement filed with the U.S. Securities and Exchange Commission (“SEC”) on July 20, 2023 and elsewhere in such filing and in Gyre’s other periodic reports and subsequent disclosure documents filed with the SEC.

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Forward looking statements (continued)

Gyre obtained the data used throughout this presentation from its own internal estimates and research, as well as from research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information and Gyre's own internal research and experience, and are based on assumptions made by management based on such data and its knowledge, which it believes to be reasonable. In addition, while Gyre believes the data included in this presentation is reliable and based on reasonable assumptions, Gyre has not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors.

This presentation concerns a discussion of investigational drugs that are under preclinical and/or clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representations are made as to their safety or effectiveness for the purposes for which they are being investigated.

Gyre: Investment Highlights



An Anti-Fibrotic With Pleiotropic Mechanism of Action

1. Hydronidone is expected to ameliorate liver fibrosis by inhibiting activation of HSCs via Smad7-mediated degradation of TGFβR
2. Phase 2 Proof of Concept: Hydronidone was **well-tolerated**, and patients treated showed **statistically significant improvement** of Hepatitis B liver fibrosis
3. Opportunity for expansion into additional fibrosis indications based on shared pleiotropic anti-fibrotic mechanism of action

Path to Clinic in the United States

Initiation of Phase 2a U.S. trial in liver fibrosis associated with MASH planned in 2024

Market Opportunity

Worldwide Liver Fibrosis Market (2022):
~\$15 Billion¹

Financial Backing by Parent Company & Controlling Interest in Profitable Pharma Company Funds Operations

Operations funded through 65% ownership of Beijing Continent



2023 Projected
Revenue: \$106M



Financial backing from
parent company

¹ Source: Coherent Market Insights: August 2022: <https://www.coherentmarketinsights.com/market-insight/liver-fibrosis-treatment-market-2320>

Experienced executive team

Charles Wu, Ph.D.
Chief Executive Officer



Songjiang Ma
President



Ruoyu Chen
Chief Financial Officer



Weiguo Ye
Chief Operating Officer



Board with biopharma expertise



[Ying Luo, Ph.D.,
Chairman of the Board](#)

President and CEO,
GNI Group
President and CEO,
Cullgen Inc.



[Gordon G. Carmichael,
Ph.D.](#)

Board Member



[Thomas Eastling](#)

Board Member and
Chief Financial Officer,
Cullgen Inc.



[Songjiang Ma](#)

Board Member and
President, Gyre
Therapeutics



[Renate Parry, Ph.D.](#)

Board Member



[Nassim Usman, Ph.D.](#)

Board Member and
Former President and
Chief Executive Officer,
Catalyst Biosciences, Inc.



[Charles Wu, Ph.D.](#)

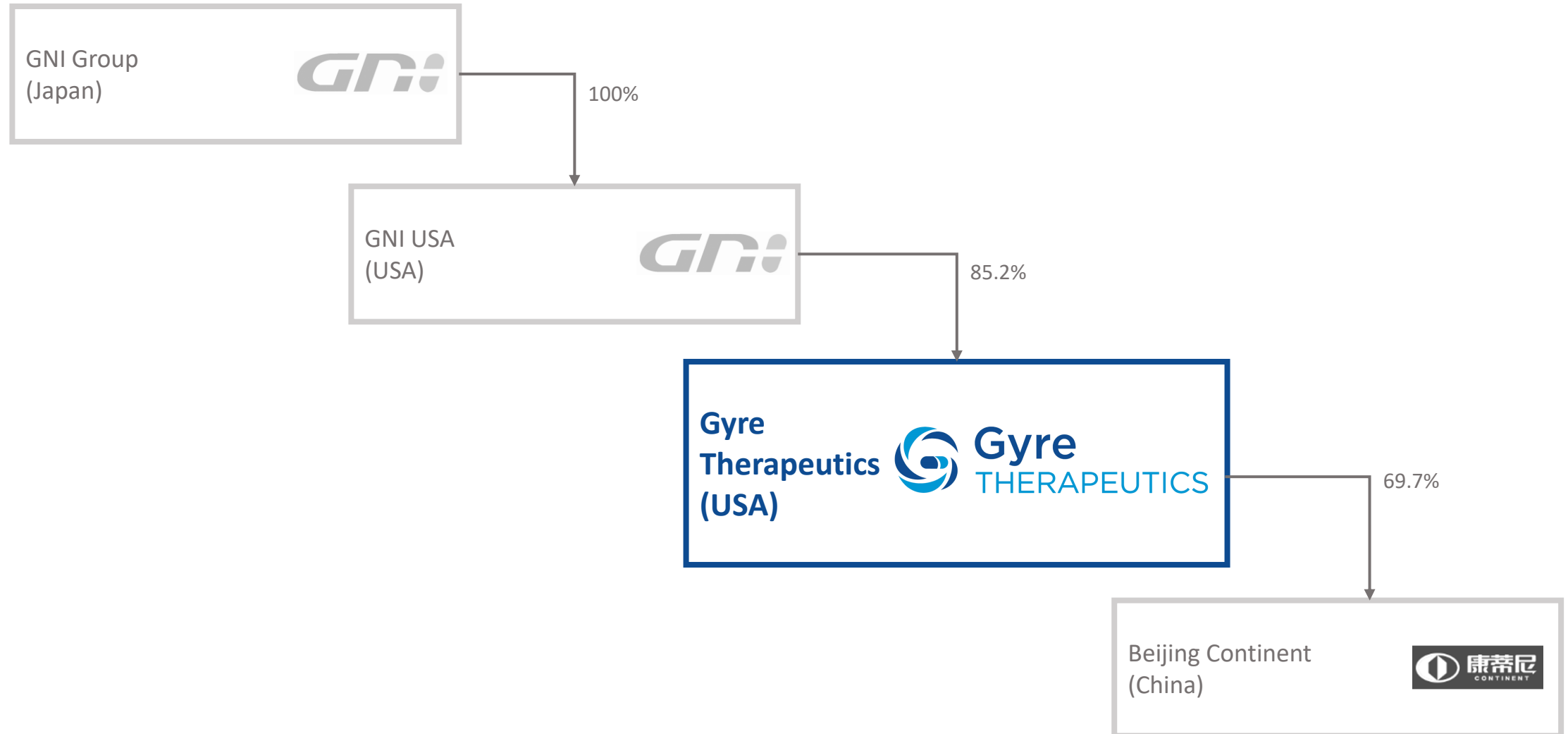
Board Member and Chief
Executive Officer, Gyre
Therapeutics






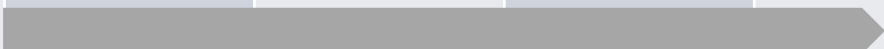

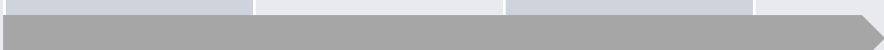
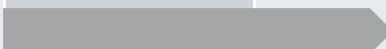
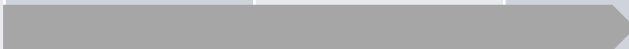

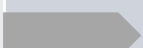
[Han Ying, Ph.D.](#)

Board Member

Corporate structure



Innovative pipeline as a leader in anti-fibrotic therapies

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Location
Hydronidone (F351)	Liver Fibrosis associated with MASH						United States
	Chronic Hepatitis B Liver Fibrosis						China ¹
Etuary® (Pirfenidone)	Idiopathic Pulmonary Fibrosis (IPF)						
	Dermatomyositis Interstitial Lung Disease (DM-ILD)						
	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						
	Pneumoconiosis						
	Diabetic Kidney Disease (DKD)						
F573	ALF/ACLF						
F528	Chronic Obstructive Pulmonary Disease (COPD)						
F230	Pulmonary Arterial Hypertension (PAH)						



Hydronidone (F351)

Lead Candidate: Hydronidone (F351)



New chemical entity for oral use



Pleiotropic anti-fibrotic TGF- β -targeting mechanism of action



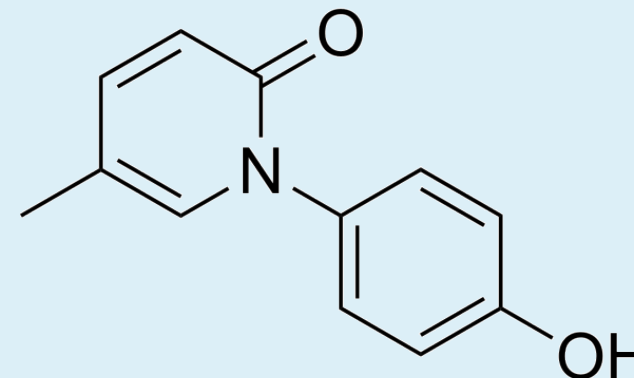
Patents granted/filed in major markets



Positive Phase 2 trial in China in 2022 with breakthrough therapy status for chronic HBV-associated liver fibrosis



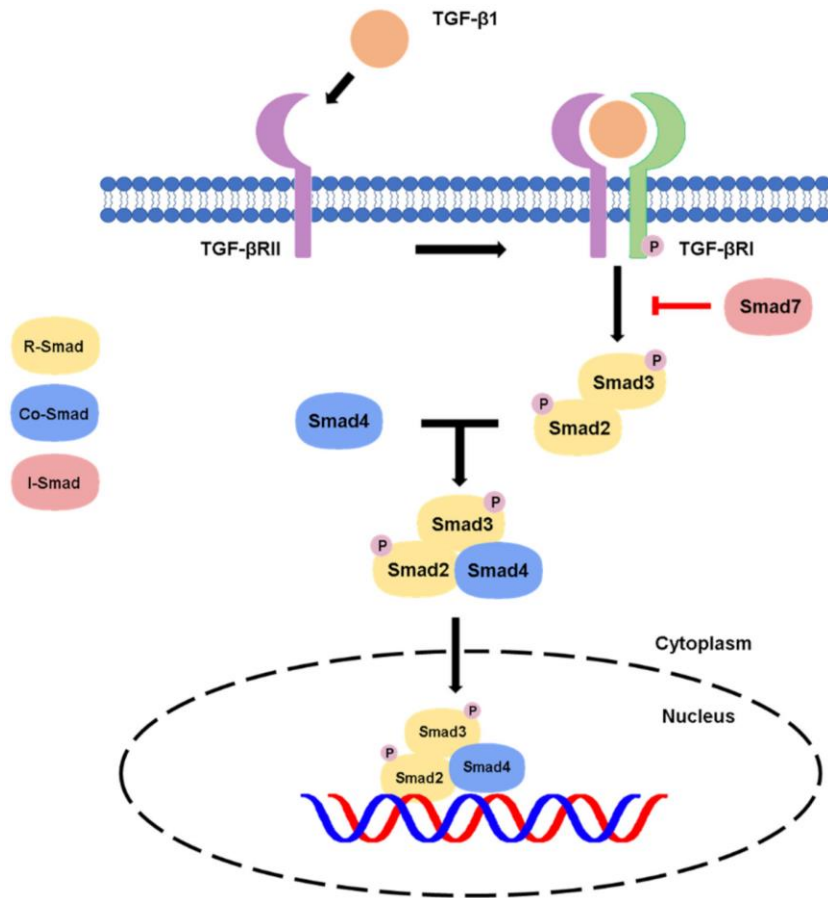
Confirmatory Phase 3 is ongoing in China



Hydronidone (F351)

Structural derivative of marketed antifibrotic drug Pirfenidone

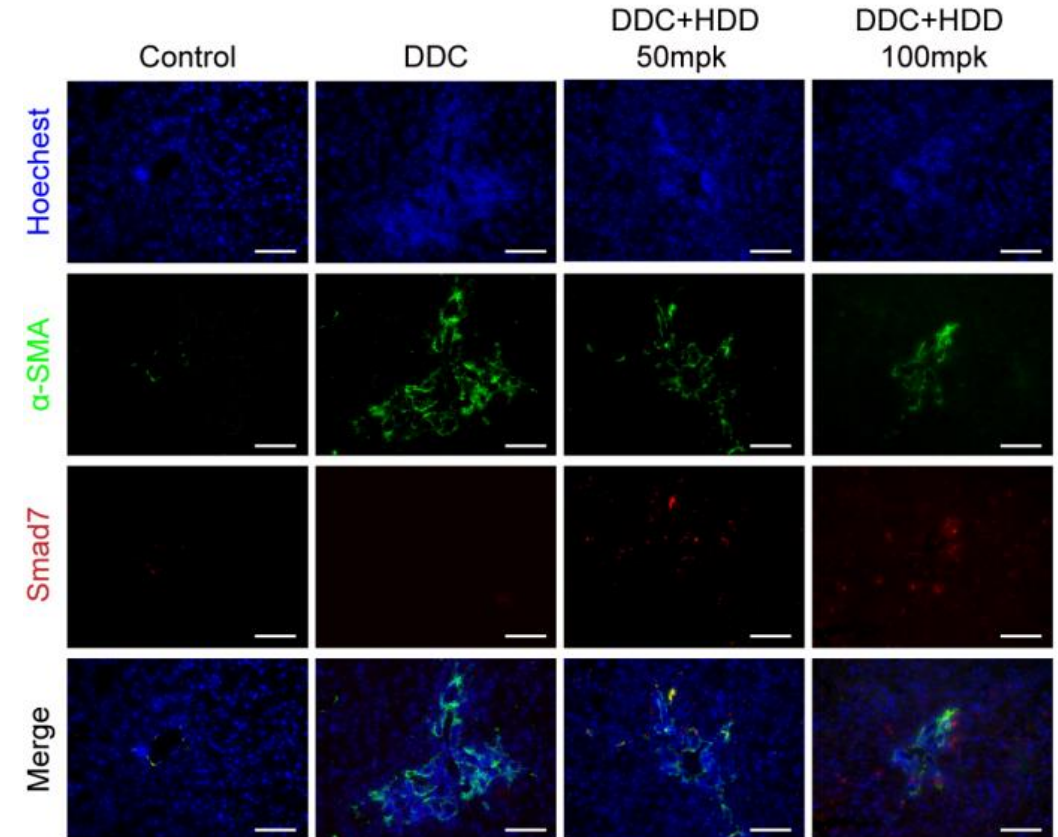
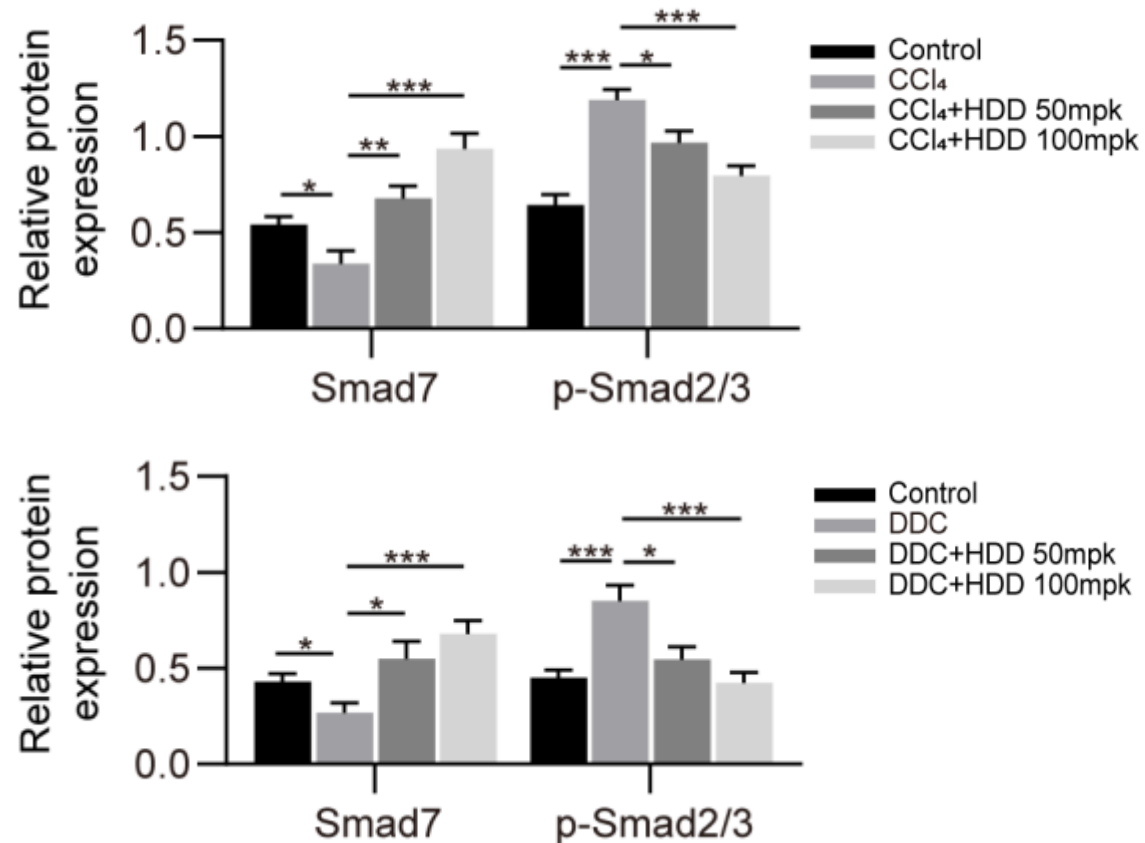
TGF β plays an important role in liver fibrosis by activating HSCs



- Smad7 is a negative regulator of TGF β signaling
- Smad7 knockdown can promote HSC activation and liver fibrosis
- Smad7 overexpression can prevent liver fibrosis
- Hydronidone is believed to effectively target this pathway

Inhibiting HSC activation is believed to be one of the most effective therapeutic strategy to fight liver fibrosis

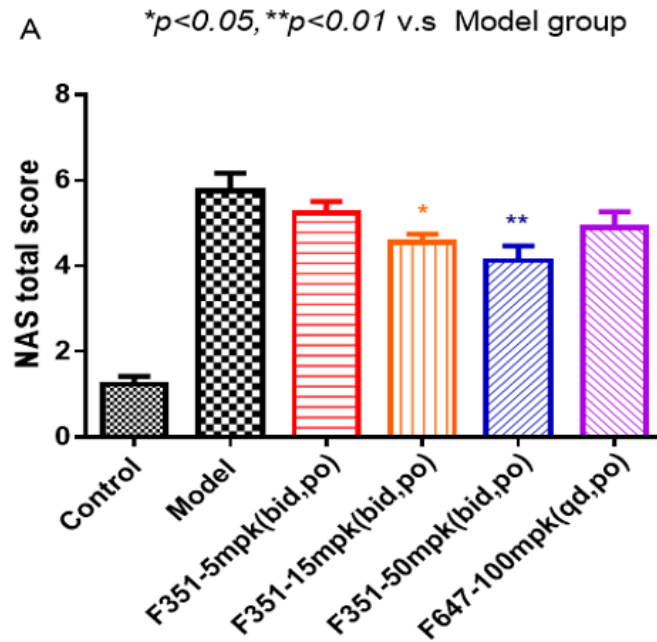
Hydronidone upregulated the expression of Smad7 and inhibited phosphorylation of Smad2/3 in vivo



Smad7 is a known negative regulator of liver fibrosis, suggesting clinical potential in a recognized cascade

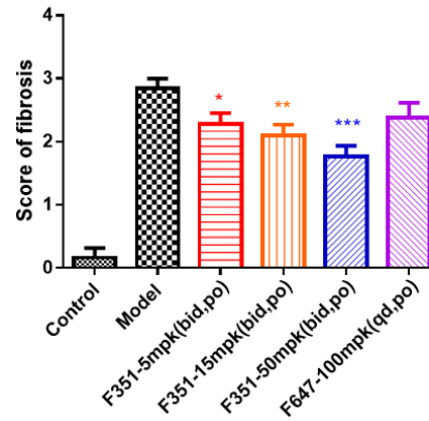
Hydronidone exhibited protective effect on CCL4+WD induced MASH model

MASH Total Score

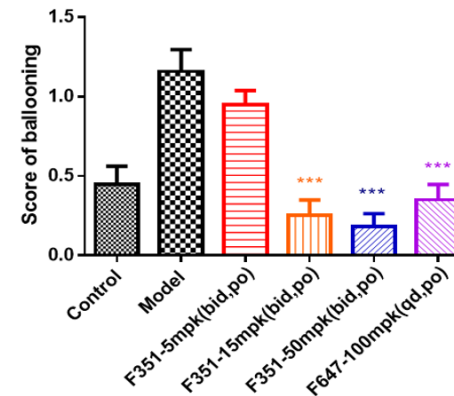


Fibrosis and Ballooning Scores

B $*p<0.05, **p<0.01, ***p<0.001$ v.s Model group



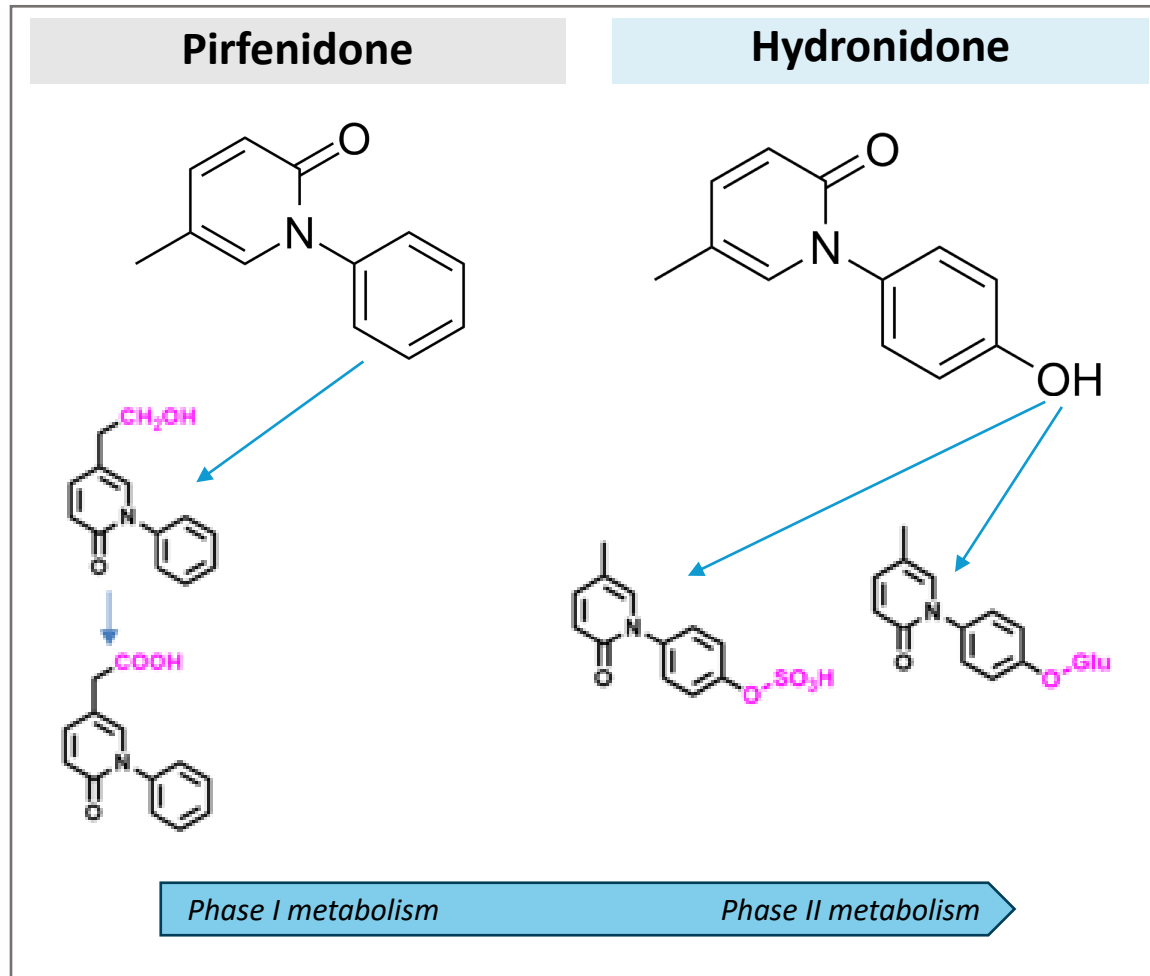
D $***p<0.001$ v.s Model group



- The MASH total score was **lowered at dosage of 15mpk and 50mpk (bid)**
- Hydronidone at 15mpk and 50mpk significantly inhibited CCL4+WD-induced **fibrosis and cell ballooning**

Anti-fibrotic effects observed in murine MASH model supports advancement of Hydronidone into clinical studies

Hydronidone's medicinal chemistry has the potential to address the metabolic liabilities of Pirfenidone



Studies indicate that Hydronidone and its major metabolites have a low potential for DDIs in terms of involvement of P-gp, CYP450, and major transporter systems.

The shift toward Phase II metabolism **may protect Hydronidone from formation of reactive metabolites and covalent protein binding, thus possibly reducing its potential for idiosyncratic liver toxicity¹**

U.S. Phase 1 study has shown that Hydronidone is well-tolerated in healthy volunteers

Study

Part I: a single ascending dose, sequential cohort study of oral capsules of Hydronidone at 30 mg and 120 mg (n=12 subjects)
Part II: a multiple ascending dose, sequential cohort study of oral capsules of Hydronidone at 30 mg thrice daily (TID) for 7 days (n=12 subjects) and 120 mg thrice daily (TID) for 7 days (n=12 subjects)

Objectives

Assess pharmacokinetics and evaluate safety and tolerability of Hydronidone

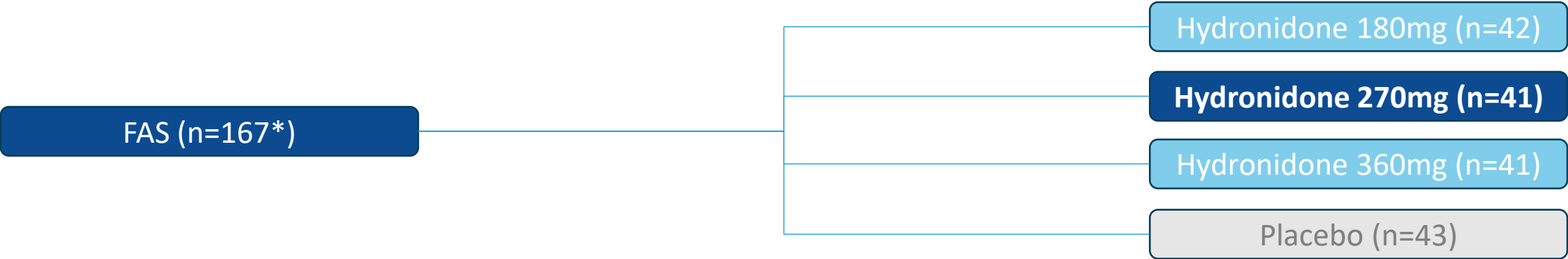
Category	Single Ascending Doses			Multiple Ascending Doses		
	Hydronidone 30 mg (N=12) n (%)	Hydronidone 120 mg (N=12) n (%)	All Subjects (N=24) n (%)	Hydronidone 30 mg TID × 7 (N=12) n (%)	Hydronidone 120 mg TID × 7 (N=12) n (%)	All Subjects (N=24) n (%)
Number of Adverse Events (AE), n	4	5	9	16	12	28
Subjects with Any AE	3 (25.0)	3 (25.0)	6 (25.0)	6 (50.0)	7 (58.3)	13 (54.2)
Number of Treatment Emergent Adverse Events (TEAE), n	4	5	9	16	12	28
Subjects with Any TEAE	3 (25.0)	3 (25.0)	6 (25.0)	6 (50.0)	7 (58.3)	13 (54.2)
Subjects with Severe TEAE	0	0	0	0	0	0
Subjects with Serious AE (SAE)	0	0	0	0	0	0
Subjects with Serious TEAE	0	0	0	0	0	0
Subjects Discontinued Due to AE	0	0	0	0	0	0
Subjects with AEs Resulting in Death	0	0	0	0	0	0

n (%) = number and percent of subjects in the specified group; N = number of subjects in the specified study population under each treatment.

Hydronidone was well tolerated as single and repeated oral doses with no SAEs
Performs consistently with safety data observed in China clinical trials

Phase 2 double blind, randomized, placebo-controlled study of Hydronidone in Chinese patients with chronic Hepatitis B-associated liver fibrosis

Design	Randomized, double-blind, placebo-controlled, multicenter, entecavir-based, dose-exploration Phase 2 trial of Hydronidone capsules for the treatment of liver fibrosis associated with CHB
Basic Treatment	Entecavir administered continuously for 52 weeks
Primary Endpoint	Proportion of liver fibrosis Ishak scores that decreased ≥ 1 after treatment compared to pre-treatment
Secondary Endpoints	<ul style="list-style-type: none">• Conversion rate and decrease of HBV DNA after treatment• Proportion of decrease in liver transient elastography values after treatment compared to pre-treatment• Proportion of liver tissue inflammation grading decreased \geq grade 1 after treatment compared to pre-treatment without worsening fibrosis• Improvement of liver function ALT index

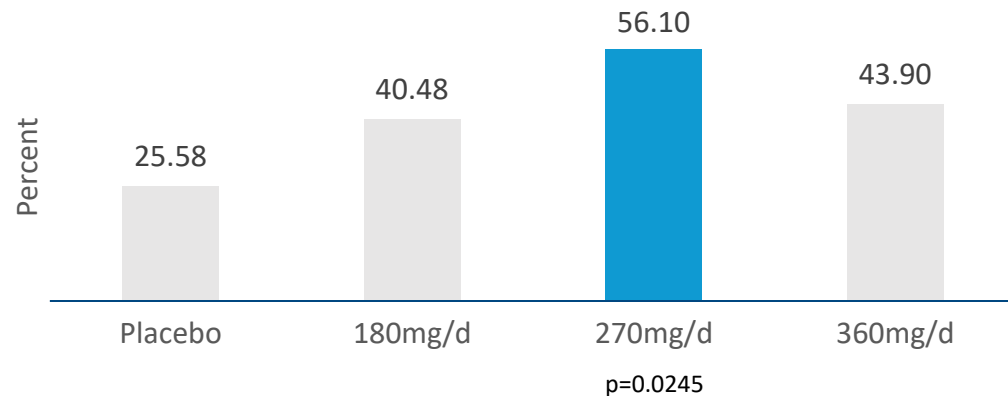


Proof of concept demonstrated for Hydronidone as anti-fibrotic treatment in patients with chronic hepatitis B-associated liver fibrosis

Safety and Efficacy Data

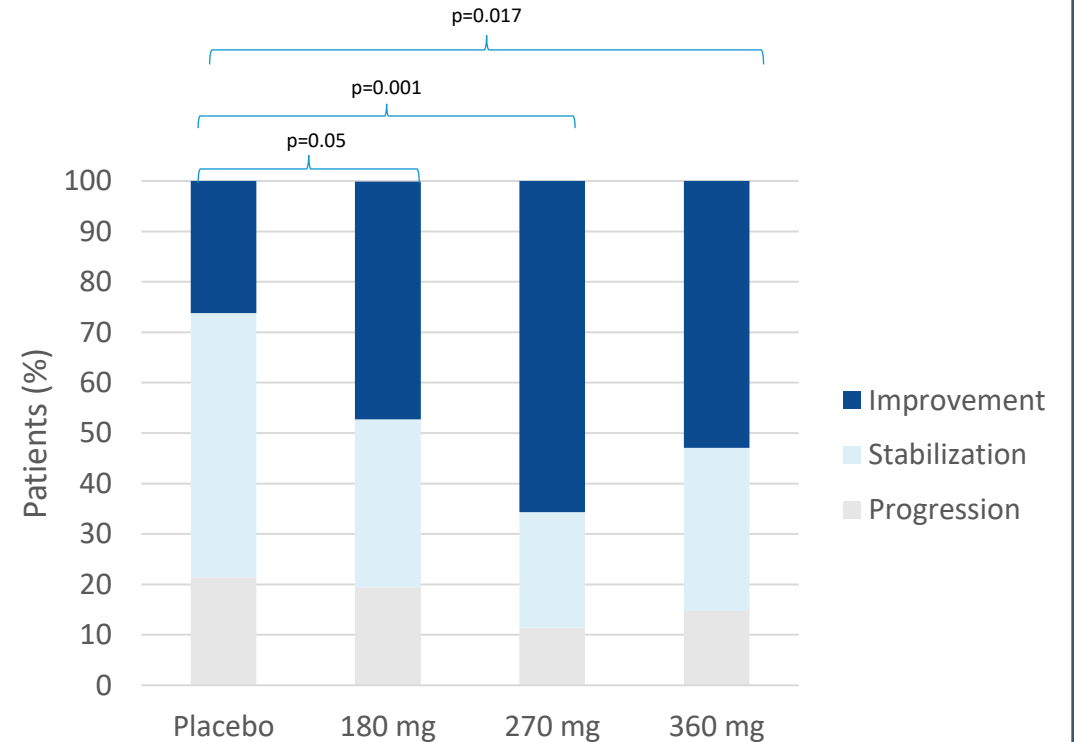
Achieved Primary Endpoint:

The proportion of Ishak of liver fibrosis decreased by ≥ 1 point (fibrosis regression) from baseline after 52 weeks treatment.



There was **no statistical difference** in the occurrence of AEs, adverse reactions and SAEs between the four groups during the study. A total of 7 patients (4.17%) experienced 7 serious adverse events (SAEs) throughout the study, 2 (4.6%) in the placebo group, and 5 SAEs in the Hydronidone groups.

Distribution of Fibrosis Disease Following Treatment



Hydronidone was **well-tolerated**, and patients treated showed statistically significant improvement of liver fibrosis, with the best efficacy results at **270 mg orally – received breakthrough status in China**

Ongoing Hydronidone Phase 3 trial in China for chronic hepatitis B-associated liver fibrosis

Study Details:

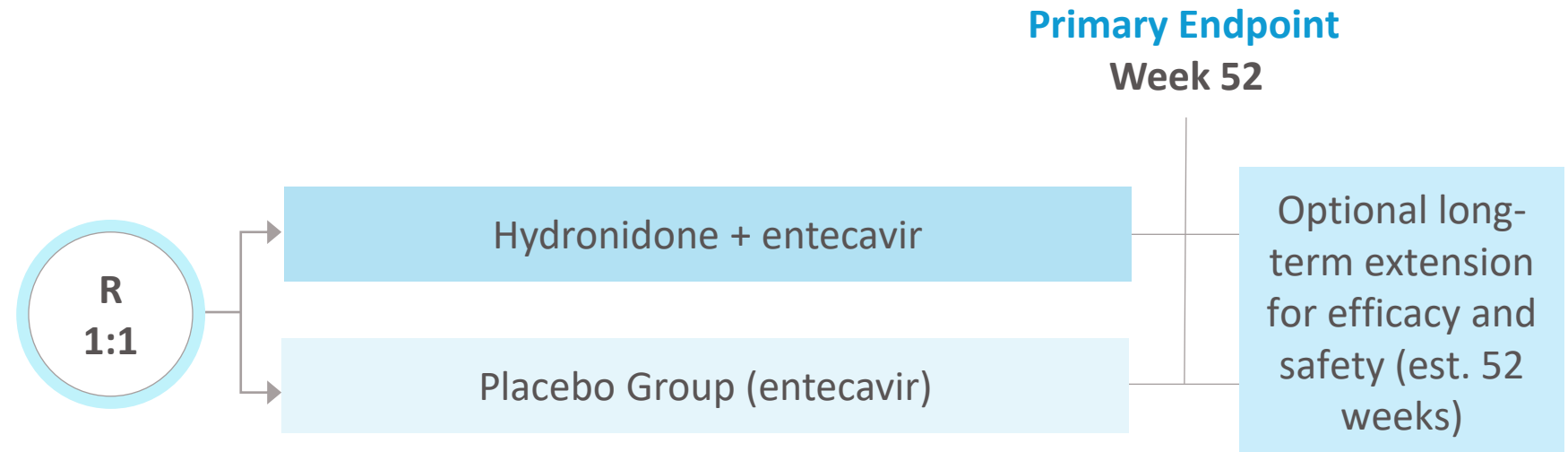
Randomized, double-blind, placebo-controlled, entecavir basic treatment, multicenter clinical study

Primary Objective:

Confirm the efficacy and safety of Hydronidone in the treatment of chronic hepatitis B liver fibrosis

Primary Endpoint:

Pathological score of Ishak stage at 52 weeks



Patient enrollment completed (248 patients) in Q4 2023; data anticipated in 2024



Competitive Advantage and Company Strategy

Competitive landscape in MASH-associated liver fibrosis

Current Late-Stage Landscape



Drug	Hydronidone	Resmetirom	Efruxifermin	VK2809	Pegozafermin
Stage	Phase 2	Phase 3	Phase 2b	Phase 2b	Phase 2
MOA	TGF- β /Smad	THR- β agonist	FGF21 analog	THR- β agonist	FGF21 analog

Gyre's Competitive Advantage



Positive Phase 2 proof-of-concept data



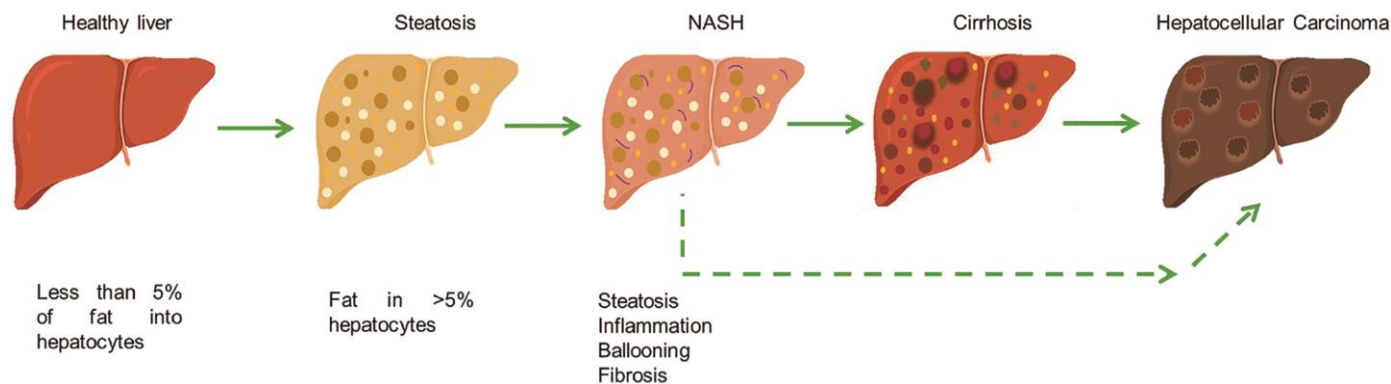
Substantially de-risked clinical program



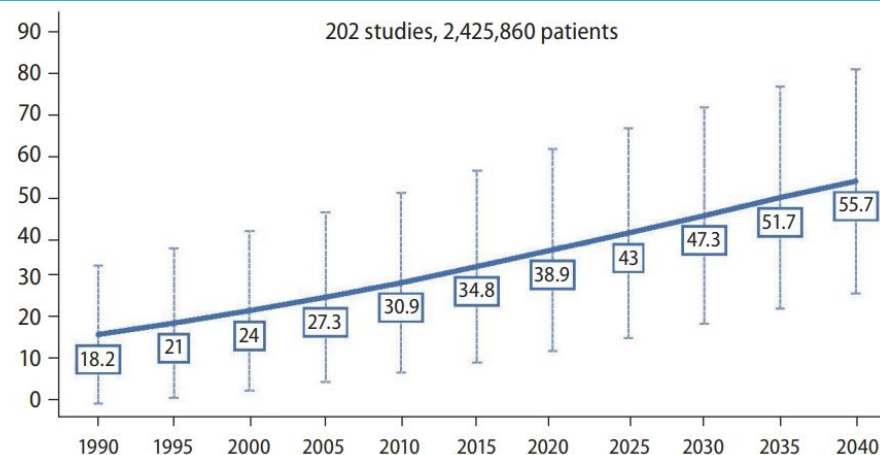
Differentiated mechanism targeting fibrosis

MASH: global market with no approved therapy

Metabolic Dysfunction Associated Fatty Liver Disease (MAFLD) Spectrum



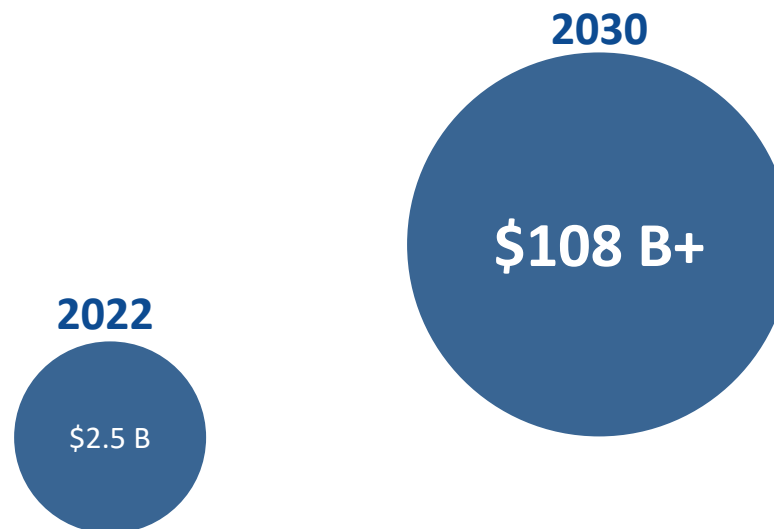
Alarming Growth in MASH seen through Forecasted Prevalence Rate



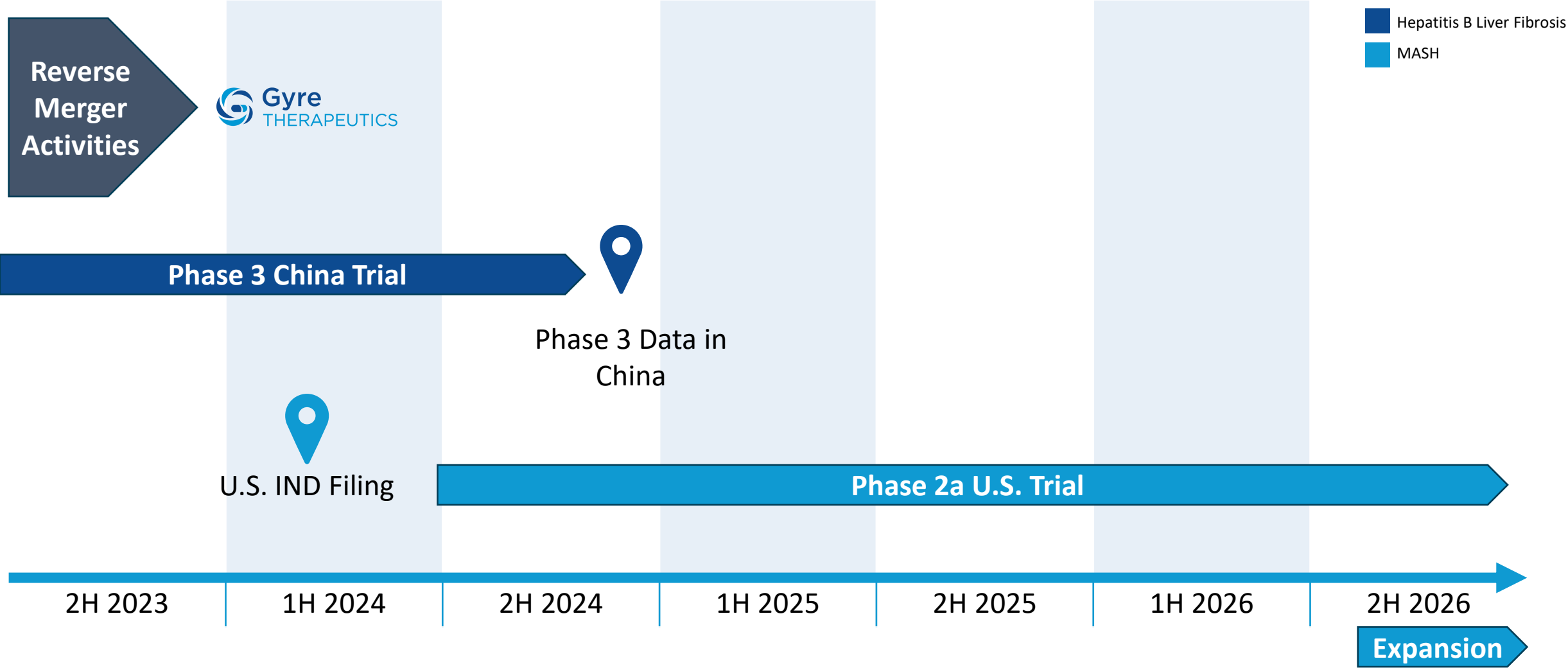
Common Risk Factors

- ☒ Obesity
- ☒ Type 2 Diabetes
- ☒ Metabolic Syndrome
- ☒ High BP
- ☒ High Blood Sugar

Rapidly Growing Market



Upcoming milestones*



Gyre: Investment Highlights



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Path to Clinic in the United States

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Market Opportunity

Worldwide Liver Fibrosis Market (2022):
~\$15 Billion¹

Financial Profile

NASDAQ listed under “**GYRE**” following reverse merger in October 2023

85.3 million shares of common stock outstanding on an as converted basis²



Beijing Continent 2023 Revenue Forecast: \$106M

¹Source: Coherent Market Insights: August 2022: <https://www.coherentmarketinsights.com/market-insight/liver-fibrosis-treatment-market-2320>

²As of November 10, 2023, Gyre had approximately 85,350,954 shares of common stock outstanding on an as converted basis – which included 76,583,625 common shares and 8,767,334 preferred shares