

Developing Anti-Fibrotic Therapeutics for Chronic Organ Diseases

Corporate Presentation

May 2024

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Gyre Therapeutics - Investment Highlights



1

Strong track record: developed ETUARY® (Pirfenidone) from research to commercialization. Sales are re-invested to fund Gyre's clinical development pipeline.

2

Robust Phase 2 proof-of-concept clinical dataset improves relative risk profile of F351, a derivative of ETUARY® (Pirfenidone), and positions it as a promising oral therapy for the treatment of NASH*-associated liver fibrosis.

3

Phase 3 China trial in Chronic Hepatitis B (CHB)-associated liver fibrosis expected to confirm promising safety and efficacy profiles of F351, guiding initiation of Phase 2a U.S. trial in NASH-associated liver fibrosis.

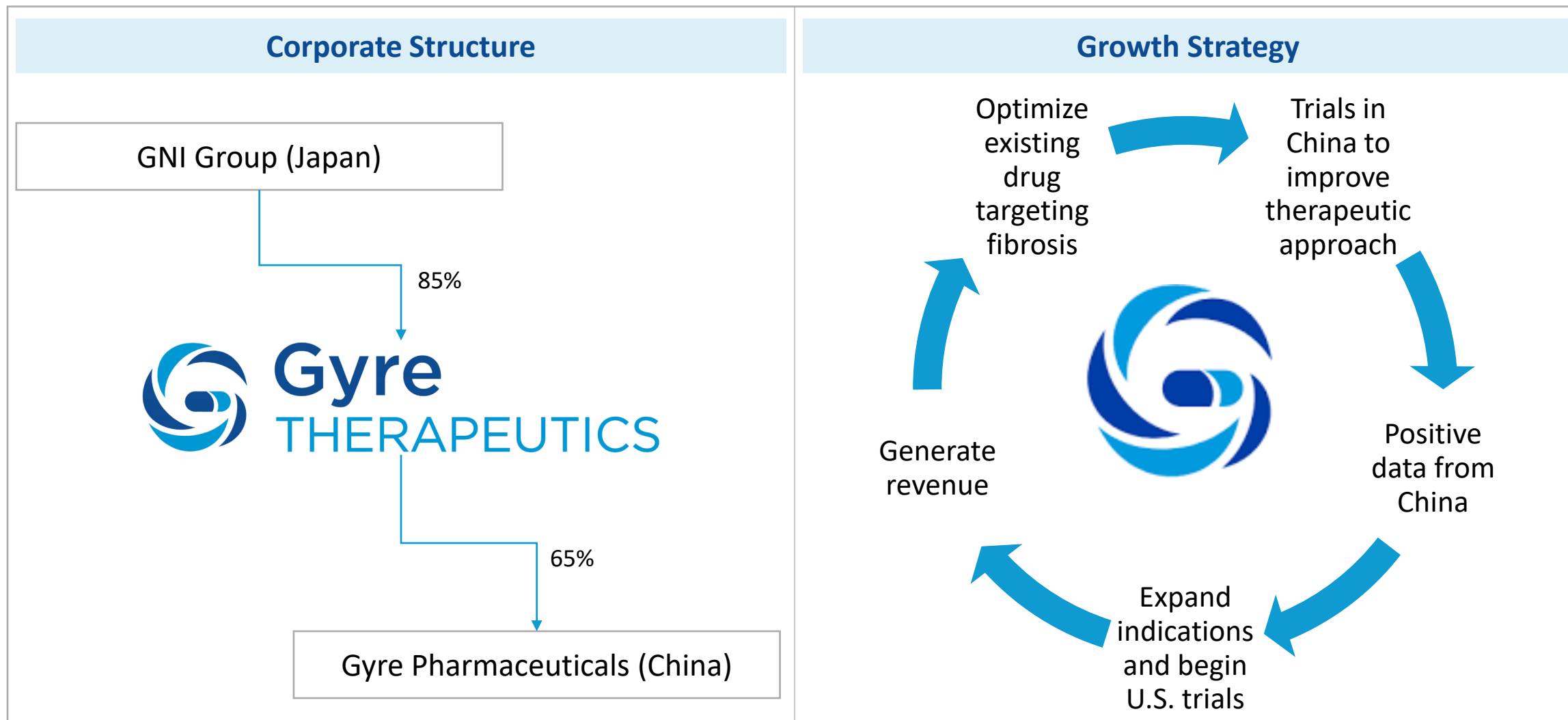
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NASH is experiencing significant tailwinds following resmetirom approval and robust data readouts, which have reduced risk in the space and increased investor interest.

5

Financial backing from China-based subsidiary Gyre Pharmaceuticals and majority shareholder GNI Group.

Leveraging Profitable Business to Fund Pipeline



Innovative Pipeline

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Location
F351 (Hydronidone)	NASH-Associated Liver Fibrosis	<div></div>			<div></div> <i>Plan to initiate Phase 2a trial in 2025</i>		United States
	CHB-Associated Liver Fibrosis	<div></div>				<div></div> <i>Phase 3 results expected by early 2025</i>	China ¹
ETUARY® (Pirfenidone)	Idiopathic Pulmonary Fibrosis (IPF)	<div></div>					
	Dermatomyositis Interstitial Lung Disease (DM-ILD)	<div></div>					
	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	<div></div>					
	Pneumoconiosis	<div></div>					
	Diabetic Kidney Disease (DKD)	<div></div>					
F573	ALF/ACLF	<div></div>					
F528	Chronic Obstructive Pulmonary Disease (COPD)	<div></div>					
F230	Pulmonary Arterial Hypertension (PAH)	<div></div>					

Gyre Pharmaceuticals Successfully Transitioned ETUARY® (Pirfenidone) from Research to Commercialization

ETUARY® (Pirfenidone) Overview



- ✓ Effective oral treatment for IPF
- ✓ Early entry into fibrosis therapy market in China since 2014
- ✓ Demonstrates **anti-fibrotic, anti-inflammatory, and anti-oxidation** properties
- ✓ Significant market potentials through **indication expansion** in interstitial lung diseases, DKD, and pneumoconiosis
- ✓ **Multiple Phase 3 trials** ongoing in China

FY2023
Revenue

US \$112.1m

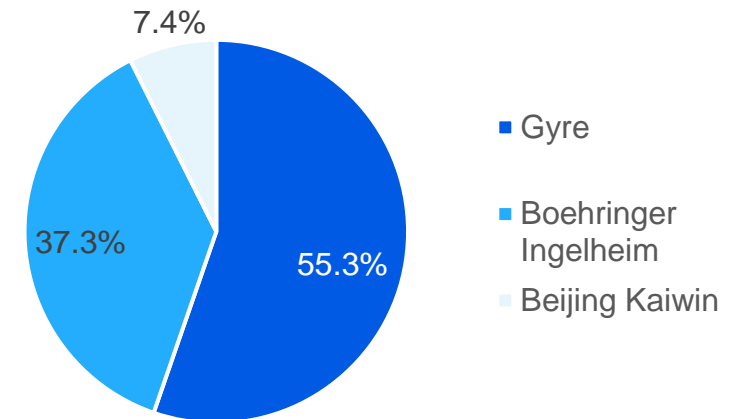
Significant Market Opportunities

China Prevalence in 2031E
Major Diseases Causing Pulmonary Fibrosis

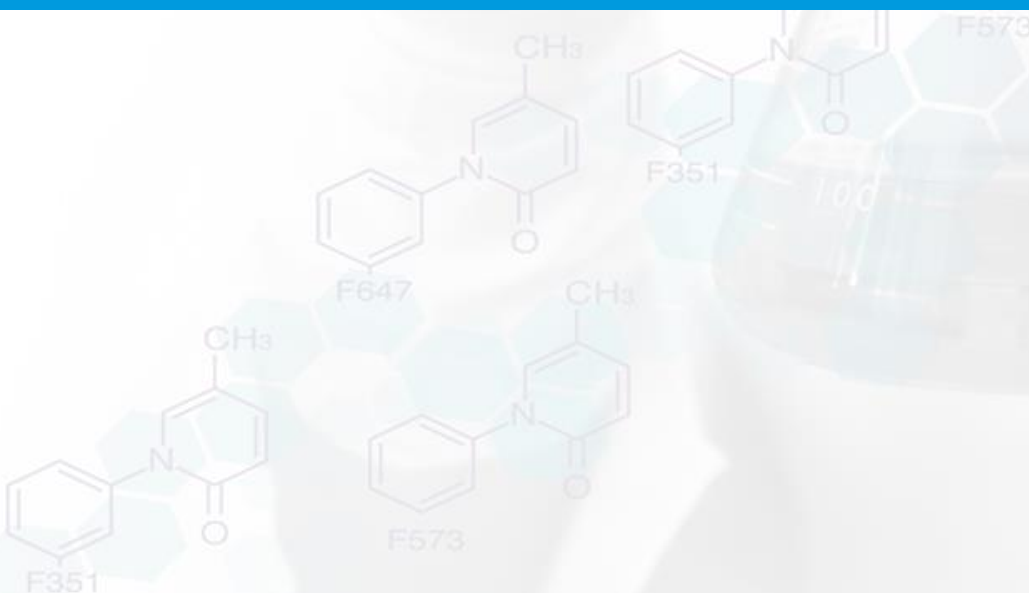


Established and Market-Dominant Commercialization

China Pulmonary Fibrosis Drug Market Share*



F351 (Hydronidone) – Lead Product Candidate Targeting Liver Fibrosis



F351 (Hydronidone)– Lead Product Candidate Targeting Liver Fibrosis Designed to Improve Upon Approved Drug Pirfenidone

Hydronidone (F351) Overview

Differentiated Product Profile

- ✓ A structural derivative of marketed antifibrotic drug Pirfenidone
- ✓ Pleiotropic anti-fibrotic TGF- β -targeting mechanism of action, expected to ameliorate liver fibrosis by inhibiting activation of hepatic stellate cells **via Smad7 mediated degradation of TGF β R**
- ✓ Possible to **reduce its potential for idiosyncratic liver toxicity** via phase II metabolism⁽¹⁾
- ✓ Obtained **breakthrough therapy designation status** for CHB-associated liver fibrosis in China

Clinical Development in the U.S.

Phase 1

- ✓ Well tolerated as single and repeated oral doses with no SAEs
- ✓ Safety profile consistent with data from clinical trials for CHB-associated liver fibrosis in China

Phase 2 (Proof-of Concept)

- ✓ Met primary endpoint of proportion of Ishak of liver fibrosis decreased by ≥ 1 point
- ✓ Well tolerated with safety profile comparable to placebo

Next Milestones

- Confirmatory China Phase 3 trial for CHB-associated liver fibrosis expected to be complete by 2H 2024
- Initiate U.S. Phase 2a trial in NASH-associated liver fibrosis

Market Opportunities

Global Liver Fibrosis Market

\$15 Billion
in 2022⁽²⁾

Global NASH Market

\$108 Billion+
in 2030⁽⁴⁾

U.S. Phase 1 Trial Has Shown That F351 Is Well-Tolerated in Healthy Volunteers, Consistent With Safety Data from Three China Trials

Trial Design

Part I: single ascending dose, sequential cohort study of oral capsules of Hydronidone at 30 mg and 120 mg (n=12 subjects)

Part II: multiple ascending dose, sequential cohort study of oral capsules of Hydronidone at 30 mg 3x daily (TID) for 7 days (n=12 subjects) and 120 mg 3x daily (TID) for 7 days (n=12 subjects)

Objectives

Assess pharmacokinetics and evaluate safety and tolerability of Hydronidone

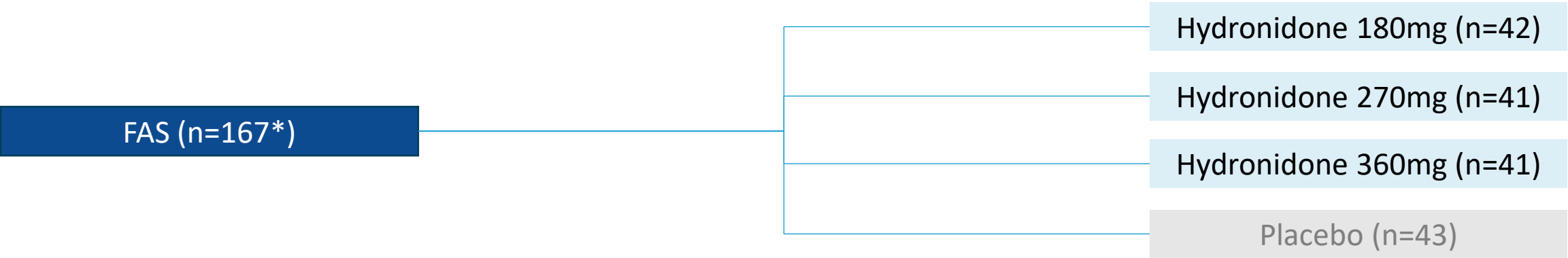
Category	Single Ascending Doses			Multiple Ascending Doses		
	Hydronidone 30 mg (N=12) n (%)	Hydronidone 120 mg (N=12) n (%)	All Subjects (N=24) n (%)	Hydronidone 30 mg TID × 7 (N=12) n (%)	Hydronidone 120 mg TID × 7 (N=12) n (%)	All Subjects (N=24) n (%)
Number of Adverse Events (AE), n	4	5	9	16	12	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 AE (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

Phase 2 Double Blind, Randomized, Placebo-controlled Trial of F351 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 Hydrnidone capsules for the treatment CHB-associated liver fibrosis
Basic Treatment	Entecavir administered continuously for 52 weeks
Primary Endpoint	Proportion of liver fibrosis Ishak scores that decreased ≥ 1 point 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

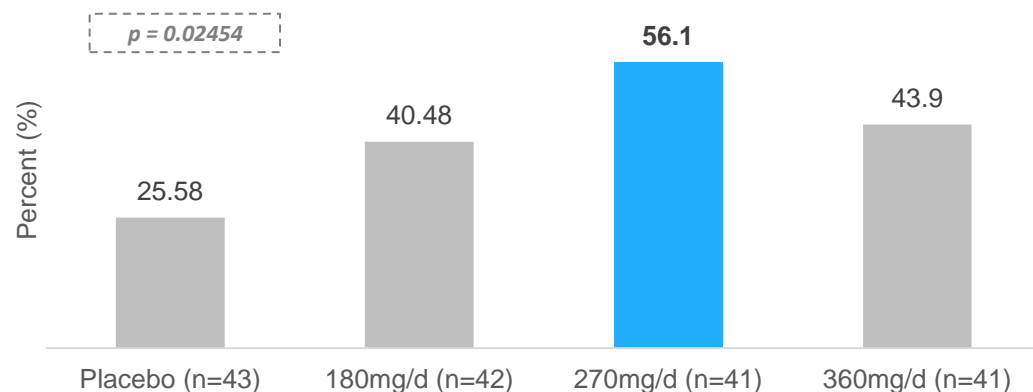


Phase 2 Proof-of-concept Trial in Chinese Patients Demonstrated F351's Anti-Fibrotic Potential in Patients with CHB-associated Liver Fibrosis

Efficacy Profile

Achieved Significant Liver Fibrosis Improvement

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

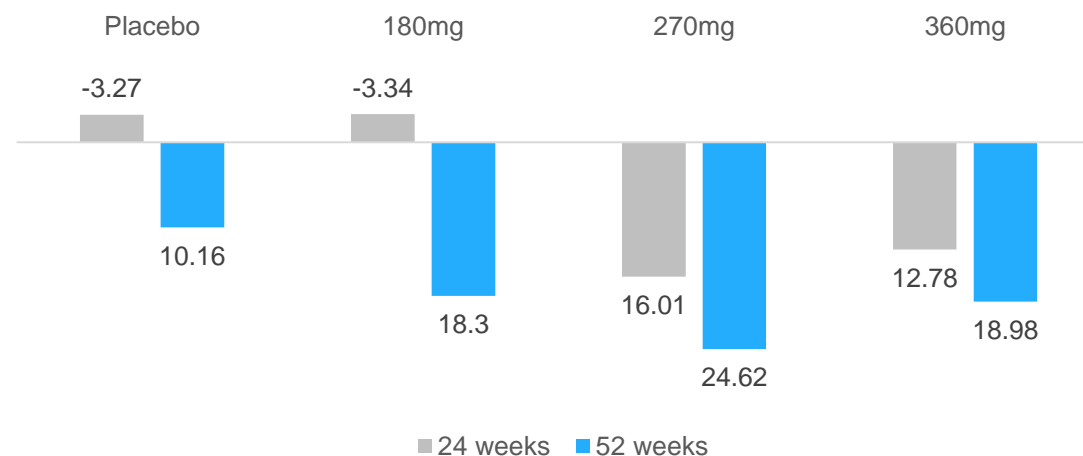


Safety Profile

- There was **no statistical difference** in the occurrence of AEs and SAEs between the four groups
- A total of 7 patients (4.2%) experienced 7 SAEs
 - 2 SAEs (4.6%) in the placebo group
 - 5 SAEs (4.0%) in F351 groups

Liver Stiffness Measurement

Ephemeral changes in the rate of decline of LSM (kPa) in liver transient elastography

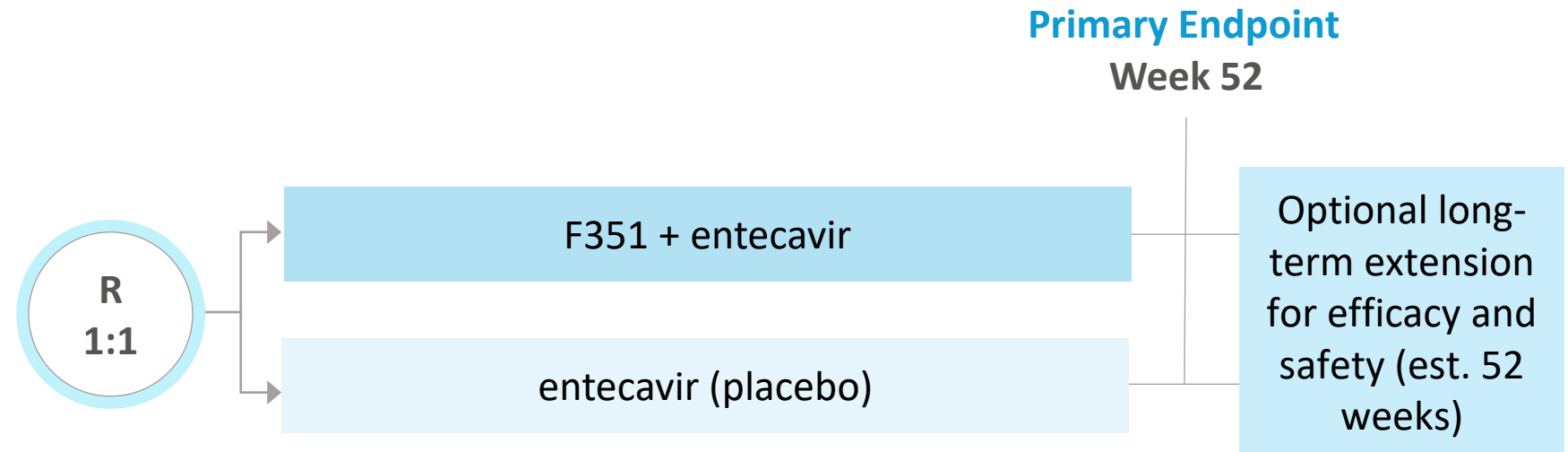


F351 was **well-tolerated**, and patients treated achieved significant improvement of liver fibrosis, with the best efficacy results at **270mg orally – received breakthrough therapy status in China**

Phase 3 Trial in China Ongoing for CHB-Associated Liver Fibrosis

Trial Details: Randomized, double-blind, placebo-controlled, multicenter clinical trial with 248 patients.

Primary Endpoint:
Proportion of treated liver tissue with Ishak staging pathology score of liver fibrosis decreased by ≥ 1 point compared to pre-treatment



Patient enrollment completed (248 patients) in Q4 2023; data expected in early 2025

Gyre's Business Plan and Upcoming Milestones for F351

China		United States	
Date	Milestone	Date	Milestone
Complete	Positive Phase 2 results for F351	Complete	Phase 1 trial of F351
Early 2025	Phase 3 topline results	Complete	Gyre publicly listed on Nasdaq
2025	Submit NMPA application for F351 for CHB-associated liver fibrosis	2025	Initiate Phase 2a in NASH-associated liver fibrosis
2025	Initiate Phase 3 trial in NASH-associated liver fibrosis		
Gyre plans to advance additional pipeline compounds including pirfenidone , F573 , F528 , and F230 in a variety of fibrotic and inflammatory diseases			

Gyre's Competitive Advantages



Positive **Phase 2 proof-of-concept** data for F351



Robust **clinical program** with upcoming Phase 3 data in chronic CHB-associated liver fibrosis



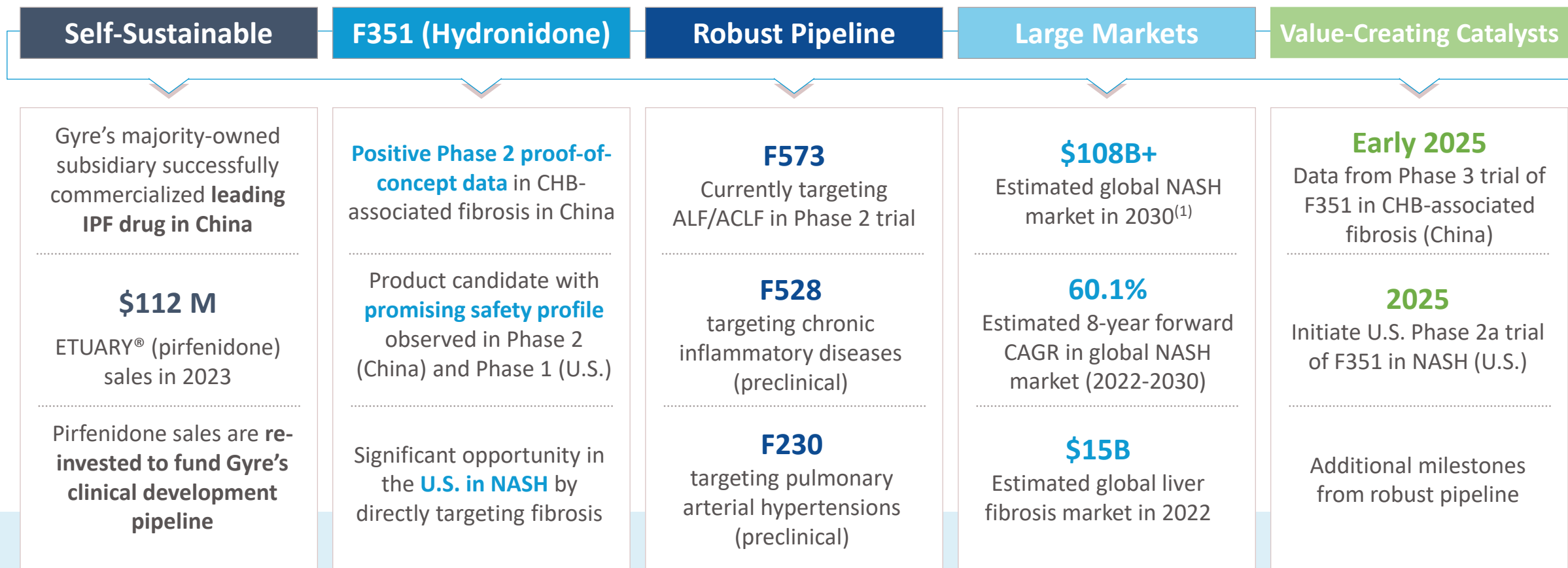
Unique mechanism capable of **directly targeting** fibrosis



Gyre is funded by **profitable** ETUARY® commercial program

**Gyre is uniquely
positioned to succeed in
NASH**

Gyre Investment Highlights



Gyre is a self-sustainable biotech company aiming to enhance the safety & efficacy of approved drugs, targeting large fibrotic markets with unmet need

Thank you

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