Gyre THERAPEUTICS

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.

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

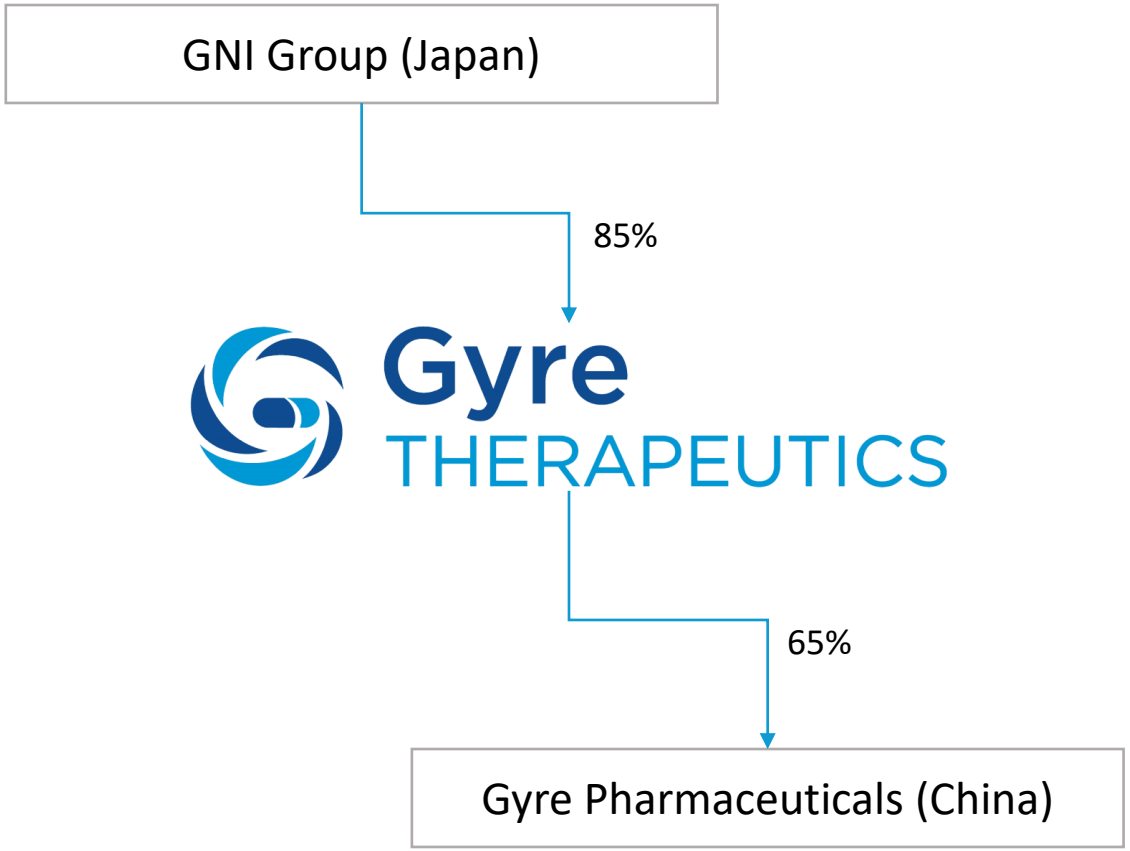
5. Financial backing from China-based subsidiary Gyre Pharmaceuticals and majority shareholder GNI Group.

Gyre THERAPEUTICS

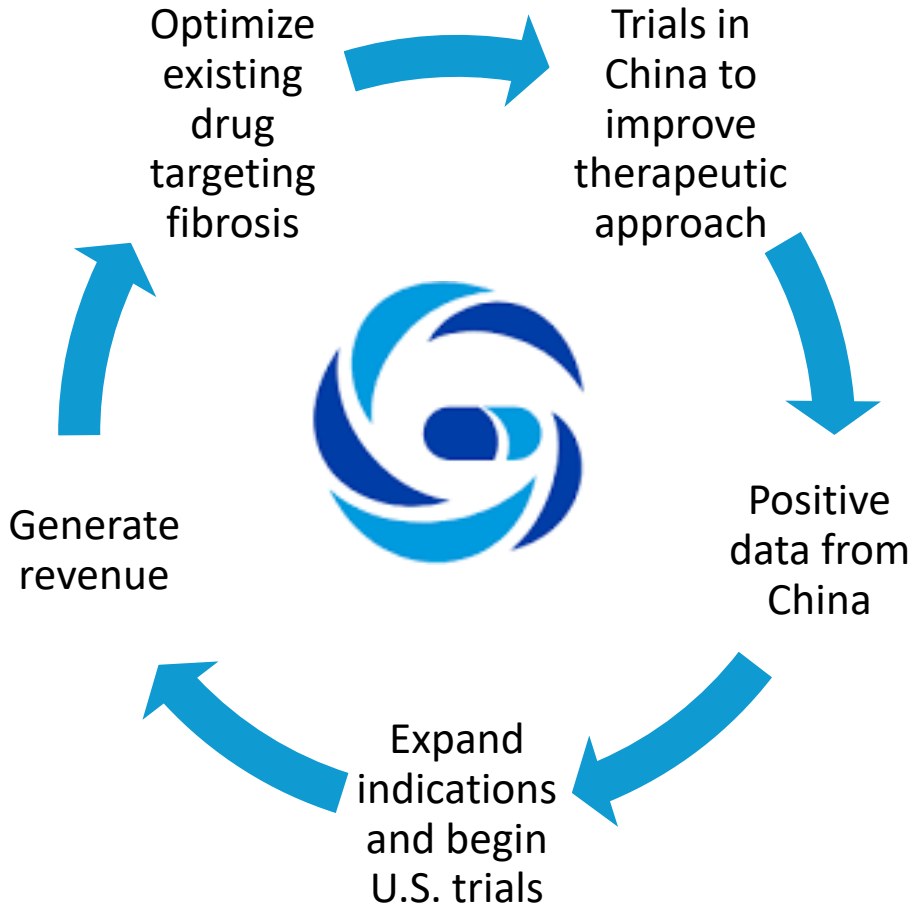
*NASH: nonalcoholic steatohepatitis

Leveraging Profitable Business to Fund Pipeline

Corporate Structure



Growth Strategy



*Simplified structure diagram for illustrative purposes

Innovative Pipeline

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed	Location
F351 (Hydronidone)	NASH-Associated Liver Fibrosis			★ *Plan to initiate Phase 2a trial in 2025*			United States
	CHB-Associated Liver Fibrosis				★ *Phase 3 results expected by early 2025*		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)						

1. Product/product candidate of Gyre Pharmaceuticals

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

ETUARY® (Pirfenidone) Overview

FY2023 Revenue

US $112.1m

- ✓ **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

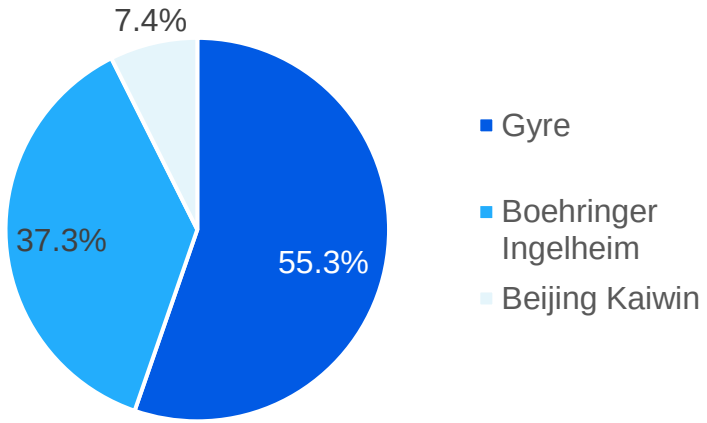
Significant Market Opportunities

China Prevalence in 2031E
Major Diseases Causing Pulmonary Fibrosis

332,000	1,014,000	2,574,000
IPF	Pneumoconiosis	CTD-ILD
Approved	*Ongoing Phase 3 Trials*	

Established and Market-Dominant Commercialization

China Pulmonary Fibrosis Drug Market Share*



*Frost and Sullivan, June 2023

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 TGFβR**
- ✓ 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 trails 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)

(1) Zhou S et al., J Med Chem 2020. (2) Source: Coherent Market Insights. (4) Vantage Market Research.

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

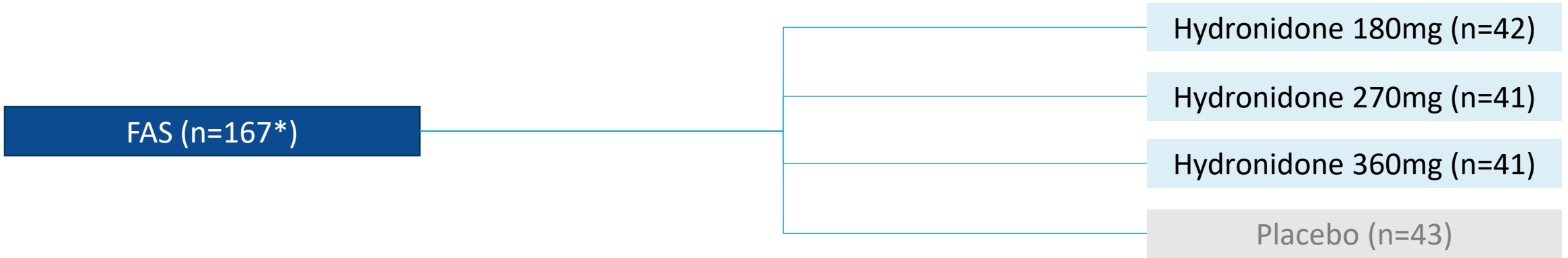
	Single Ascending Doses			Multiple Ascending Doses		
Category	**Hydronidone 30 mg (N=12) n (%)**	**Hydronidone 120 mg (N=12) n (%)**	**All Subjects (N=24) n (%)**	**Hydronidone 30 mg TID × 7 (N=12) n (%)**	**Hydronidone 120 mg TID × 7 (N=12) n (%)**	**All Subjects (N=24) n (%)**
Number of Adverse Events (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 Hydronidone 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	• 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 ≥ grade 1 after treatment compared to pre-treatment without worsening fibrosis • Improvement of liver function ALT index



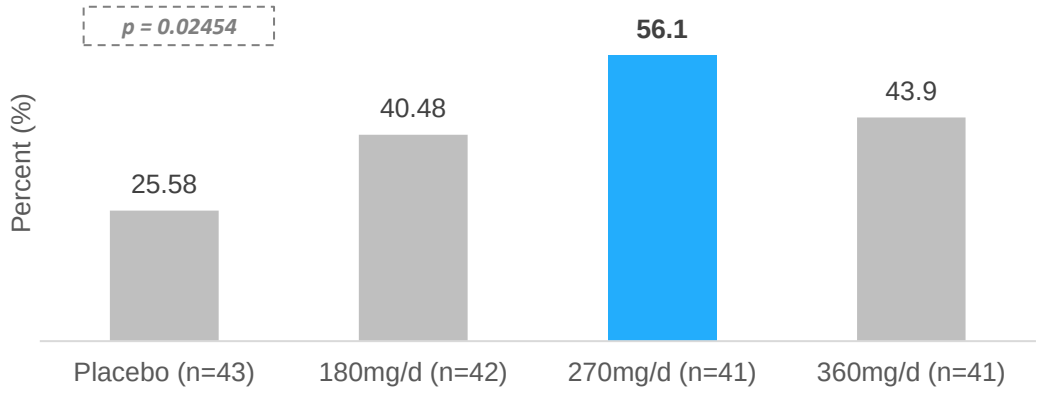
*Target enrollment was 168 participants. One patient was excluded from the 270 mg cohort after three days of treatment as they did not meet the inclusion criteria.

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

Efficacy Profile

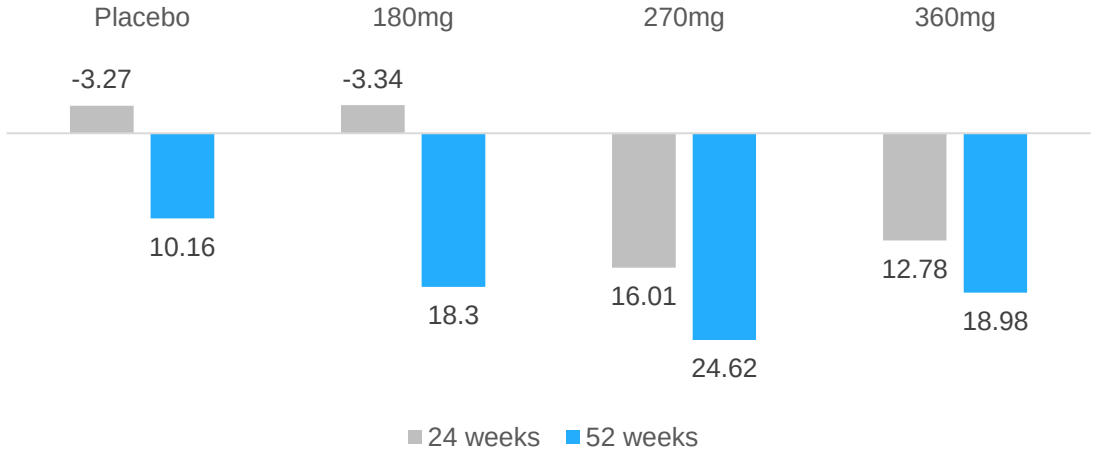
Achieved Significant Liver Fibrosis Improvement

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



Liver Stiffness Measurement

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



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

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**

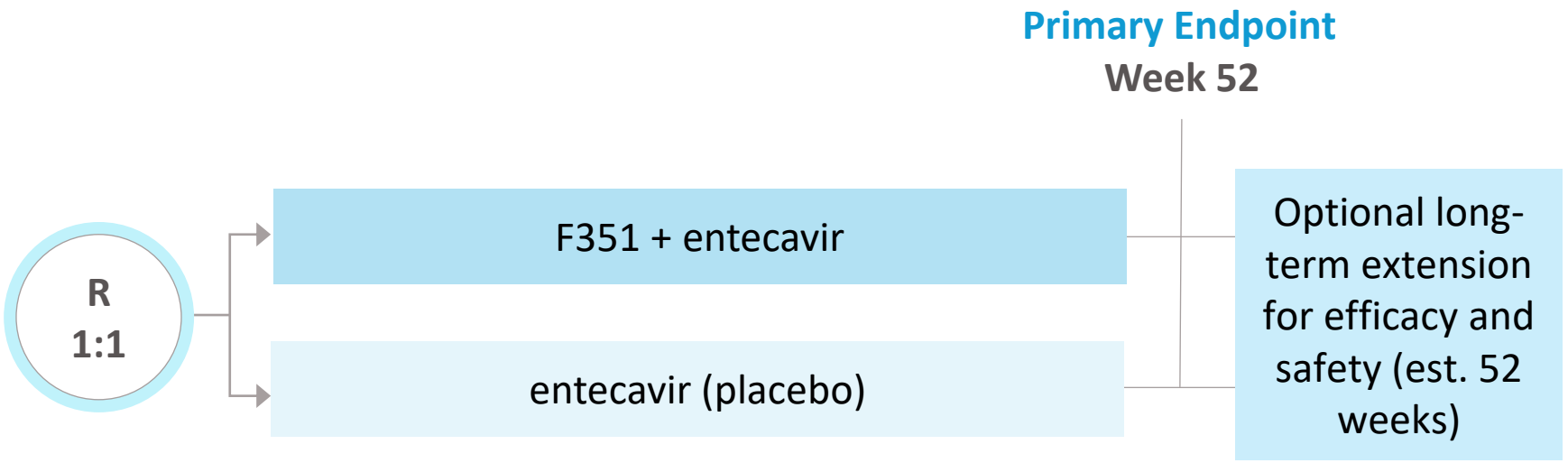
1. Hydronidone for the Treatment of Liver Fibrosis Related to Chronic Hepatitis B: A Phase 2 Randomized Controlled Trial, Clinical Gastroenterology and Hepatology (2022)

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

Self-Sustainable

Gyre's majority-owned subsidiary successfully commercialized **leading IPF drug in China**

$112 M

ETUARY® (pirfenidone) sales in 2023

Pirfenidone sales are **re-invested to fund Gyre's clinical development pipeline**

F531 (Hydronidone)

Positive Phase 2 proof-of-concept data in CHB-associated fibrosis in China

Product candidate with **promising safety profile** observed in Phase 2 (China) and Phase 1 (U.S.)

Significant opportunity in the **U.S. in NASH** by directly targeting fibrosis

Robust Pipeline

F573

Currently targeting ALF/ACLF in Phase 2 trial

F528

targeting chronic inflammatory diseases (preclinical)

F230

targeting pulmonary arterial hypertensions (preclinical)

Large Markets

$108B+

Estimated global NASH market in 2030[1]

60.1%

Estimated 8-year forward CAGR in global NASH market (2022-2030)

$15B

Estimated global liver fibrosis market in 2022

Value-Creating Catalysts

Early 2025

Data from Phase 3 trial of F351 in CHB-associated fibrosis (China)

2025

Initiate U.S. Phase 2a trial of F351 in NASH (U.S.)

Additional milestones from robust pipeline

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

(1) Vantage Market Research.

Thank you

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