GNI Group Ltd.

Fibrosis Drug Market in China

Securities Code: 2160

We Bring New
Hope to Life.

Director, Representative Executive Officer, President, and CEO

Ying Luo Ph.D.

- As a Chinese-American, he pioneered the new profitable business model that leverages the unique strengths of the pharmaceutical industry in the PRC, the U.S., and Japan in developing new therapeutic products for unmet medical needs.

- He obtained a Ph.D. in Molecular Biology/Biomedical Sciences from the University of Connecticut Health Center in 1991. He has co-authored over 35 research studies and publications and is an inventor on over 16 patents during his 30+ years of biotech career.

Company Overview

Head Office
3rd Floor, Nihonbashi Honcho YS Building,
2-2-2, Nihonbashi-Honcho
Chuo-ku, Tokyo 103-0023

Main Business
Global pharmaceutical R&D,
manufacturing and distribution,
and biomaterials business

Incorporation
November 2001

Director, Representative Executive Officer, President, and CEO
Ying Luo Ph.D.

Paid Capital
13,218 million yen (as of Jun 30, 2024)

Number of Employees (group-wide)
960 (as of Jun 30, 2024)

Listing
TSE Growth Market
Listed in August 2007
Securities code: 2160

Operating Countries
Japan, USA, the People's Republic of China, and Australia

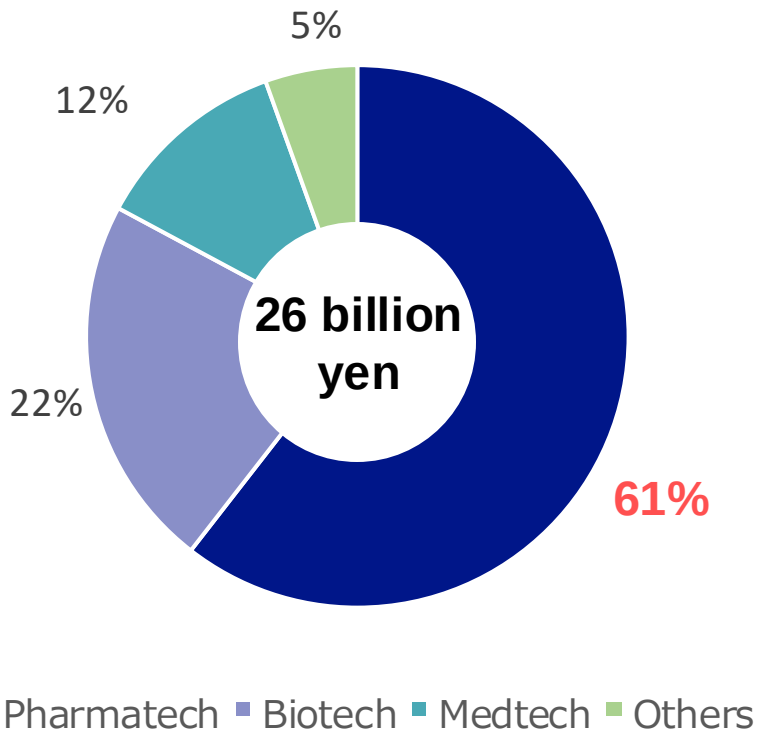
Business model	Pharmatech	Biotech	Medtech (Biomaterials)
Name	**Gyre Therapeutics,Inc.** **Gyre Pharmaceuticals**	**Cullgen Inc.**	**Berkeley Advanced Biomedicals LLC (BAB)** **Berkeley Biologics LLC (BB)**
Topics	• Listed on NASDAQ • Development of anti-fibrotic and anti-inflammation drugs • Manufacturing and commercialization (ETUARY® and others)	• Drug discovery platform (TPD) in cancers and others • Research Collaboration (Astellas Pharma) • Received investment from AstraZeneca	• M&A executed last year
FY2023 Revenue/ Operating profit	BC: 15.7 billion yen 3.99 billion yen	5.8 billion yen 2.69 billion yen	2.74 billion yen 1.33 billion yen
Q2 FY2024 Revenue	7.38 billion yen (Q2 FY2023) ↓ 7.84 billion yen	0 yen*(Q2 FY2023) ↓ *Received 4.72 billion yen as an upfront payment from Astellas Pharma 750 million yen *Next milestone (additional)	1.23 billion yen (Q2 FY2023) ↓ 2.53 billion yen
FY2024 Forecasts	• F351 clinical trial results • Commercialization of other orphan drugs acquired in 2024	• NASDAQ listing • Approx. 2 billion yen in profit in 2023 • Aiming for the next milestone • Prepare for listing in 2024	• New CEO from J&J joined • Expecting to nearly double sales this fiscal year • Prepare for future listing

Overall Group Performance and Revenue by Segments

Overall Group Performance（2023）

Millions of yen	FY2022 Actual	FY2023 Actual	Vs. revenue	YoY
Revenue	**17,418**	**26,010**	**100.0%**	**49.3%**
Gross profit	**14,744**	**22,431**	**86.24%**	**52.1%**
Selling, general and administrative expenses	10,965	15,292	58.8%	39.5%
R&D	2,545	2,557	9.8%	0.50%
Operating profit	**1,377**	**13,108**	**50.0%**	**851.3%**
Income before income taxes	**767**	**12,612**	**48.4%**	**1,542.5%**
Net income	**△868**	**9,504**	**36.5%**	**-**
Profit attributable to owners of parent	**388**	**8,094**	**31.1%**	**1,981.7%**

Revenue by Segments（2023）



Industry Overview of Organ Fibrosis in China

The Chinese organ fibrosis market is expanding, and the Group aims to establish a leading position in fibrosis treatment drugs.

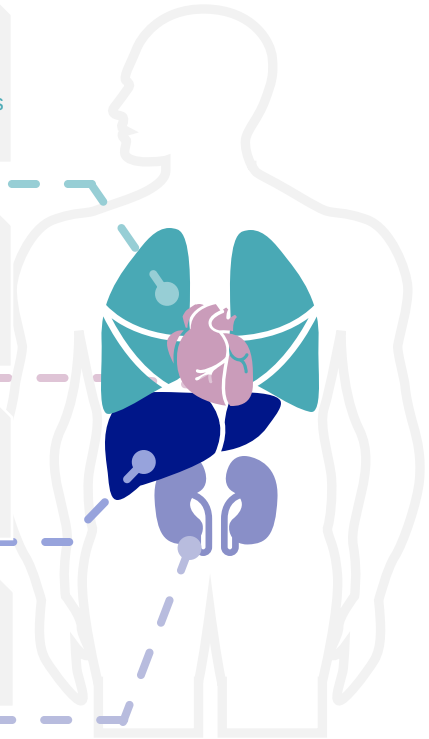
Types of Organ Fibrosis

Pulmonary fibrosis: Common causes include environmental pollution, certain medications, connective tissue diseases, infections and interstitial lung diseases

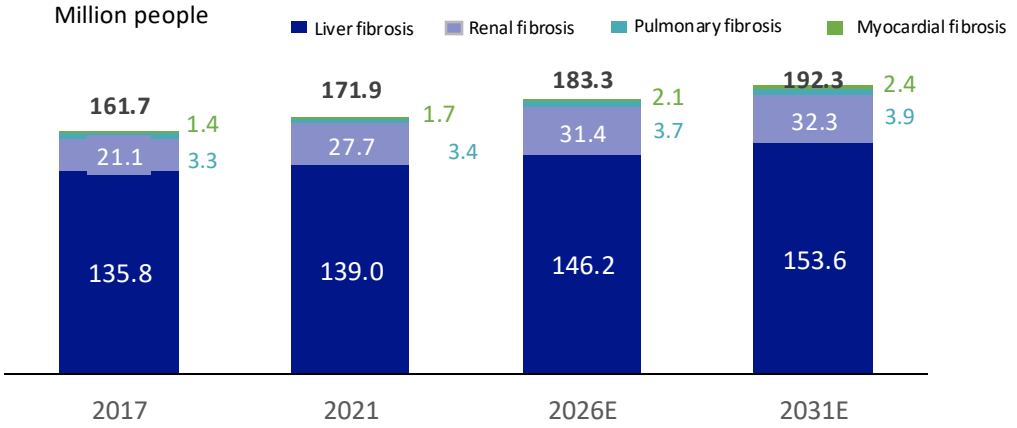
Myocardial fibrosis: Coronary heart disease, aortic stenosis and hypertension are the most frequent causes of myocardial fibrosis, which can lead to heart failure and death

Liver fibrosis: Liver fibrosis is a main pathological change in the progression from chronic liver disease to cirrhosis

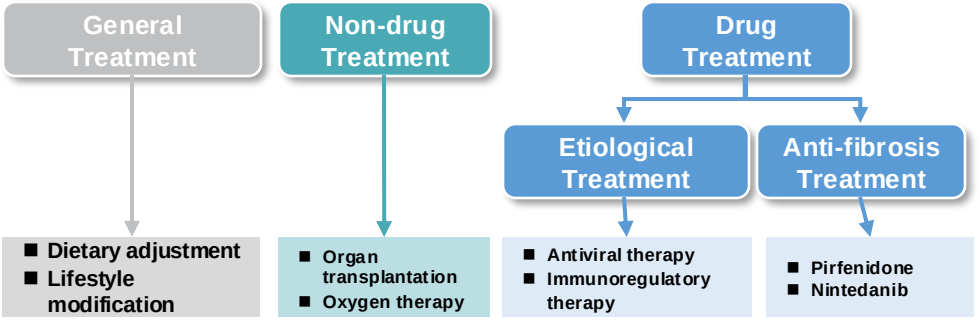
Renal fibrosis: Renal fibrosis is the most common tissual and pathological change of chronic kidney disease



Prevalence of Organ Fibrosis Diseases in China



Treatment Paradigm for Organ Fibrosis



Source: Frost& Sullivan

Volume-based Purchasing System in China

Volume-based Purchasing System

- A bidding system where hospitals commit to specific purchase quantities
- Notable for high purchase volumes and low prices, leading to intense price competition
- Only one orphan drug (generic medicine) has been included in this system in the past

Reason ETUARY is Not Included in the System

- Limited manufacturers: Only two companies have approved pirfenidone oral formulations, which does not meet the "sufficient competition" requirement for inclusion in the volume-based purchasing system

→Currently, only GYRE Pharmaceuticals (BC) and one other company sell pirfenidone in China, keeping it out of the system and resulting in stable drug pricing

Price Reduction Rate in Volume-Based Purchasing

Frequency of implementation	Bidding period	Bid products	Awarded items	Bidding companies	Winning companies	Discount rate (%)
1st round	2018.12	25	25	77	45	59
2nd round	2020.01	33	32	122	77	53
3rd round	2020.08	56	55	189	125	53
7th round	2022.07	61	60	295	217	48
8th round	2023.03	40	39	251	174	56
9th round	2023.11	42	41	262	205	58
Total / Average		380	374	1,560	1,120	54

ETUARY® [Chinese: 艾思瑞® , (Generic name: Pirfenidone)]

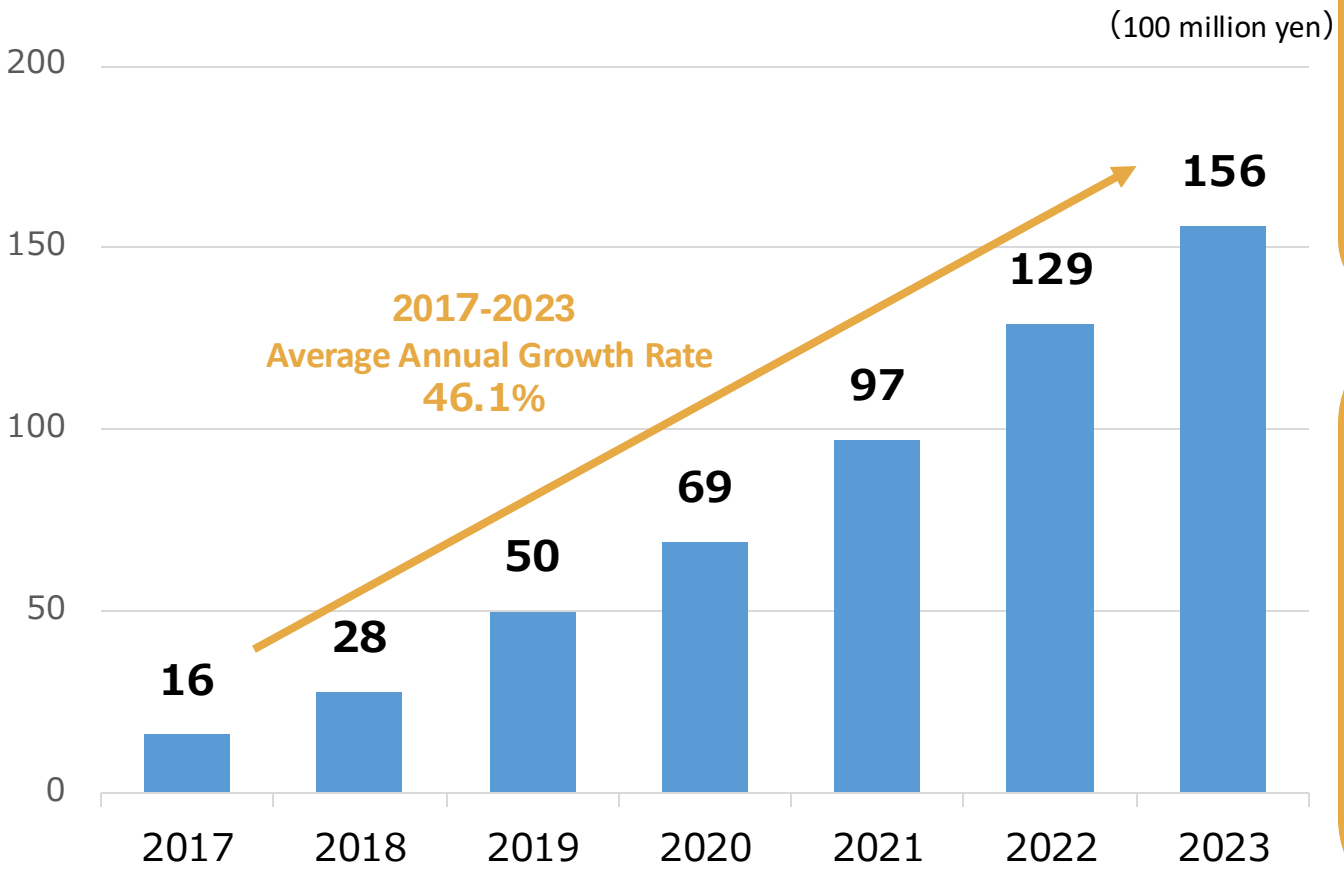
Generic Name	**Pirfenidon**
Indications	**Idiopathic Pulmonary Fibrosis(IPF)**

Beijing Continent Pharmaceutical Co., Ltd.（BC）

- ✓ **Orphan drug（medicines for rare diseases）**
- ✓ **Subsidiary GYRE Pharmaceuticals (BC) responsible for development, manufacturing, and sales**
- ✓ **Entered the Chinese pulmonary fibrosis treatment market early in 2014, achieving a market leader position**
- ✓ Proven anti-fibrotic, anti-inflammatory, and antioxidant properties
- ✓ Significant potential through expanding indications to pulmonary fibrosis beyond IPF
- ✓ Only two drugs, Pirfenidone (ETUARY) and Nintedanib, are approved worldwide for pulmonary fibrosis treatment

ETUARY Sales Trends

- Sales began in 2014
- Sales increased after insurance coverage started in 2017, with an average annual growth rate of about 46%
- **Growth rate is expected to slow, but sales are projected to continue rising until 2031**



Reason for 3-Year Delay in Insurance Coverage

The NRDL (National Reimbursement Drug List) was not updated annually and had not been revised from 2009 to 2017.
It was updated in 2019 and has since been updated annually.

IPF Drug Treatment Coverage in China is less than 10%

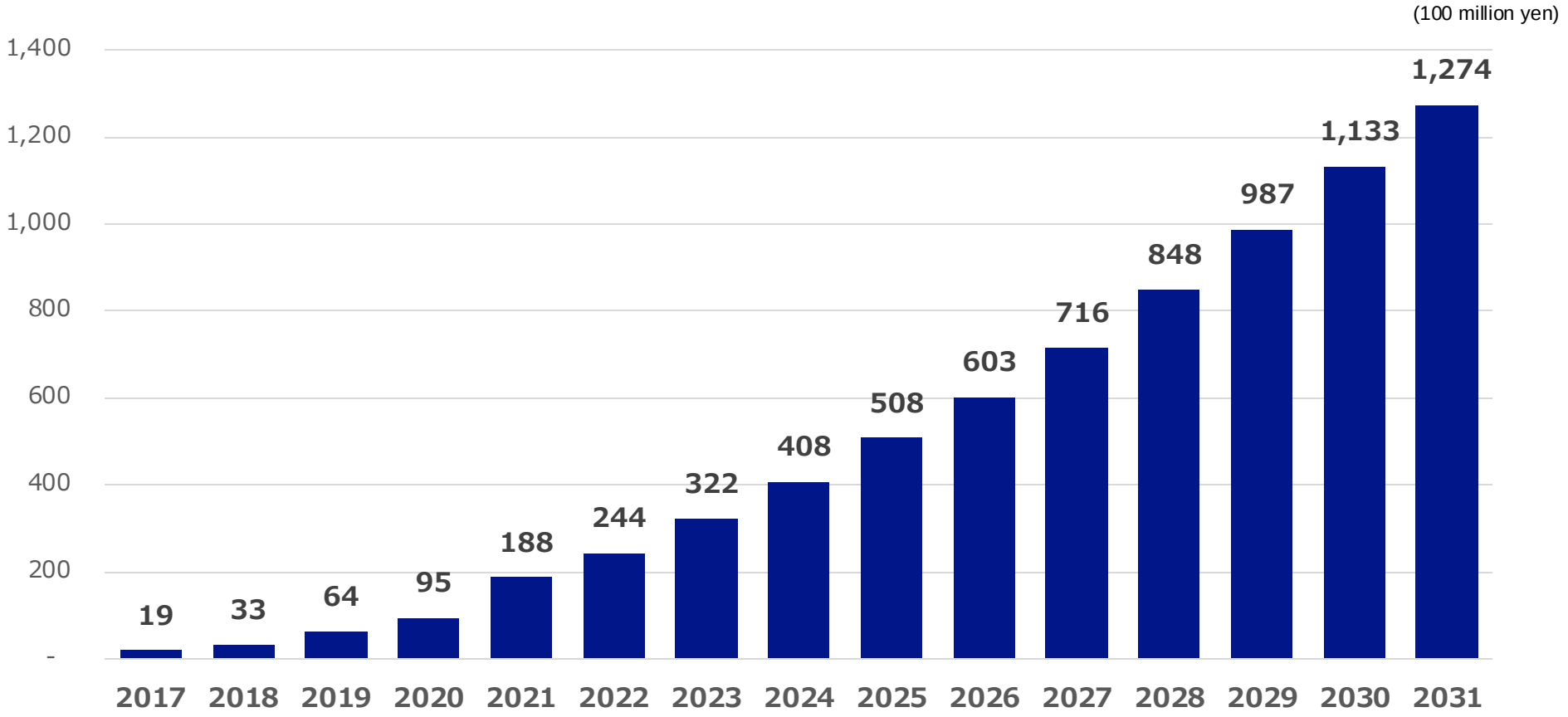
ETUARY price: Approximately 2 million JPY/year × 8,000 patients (2023)

There are about 100,000 IPF patients in China, but many remain undiagnosed:
1. Traditional medicine and differency in practices
2. Difficulty in diagnosis

IPF is a relatively rare lung disease, and the severity and importance of drug treatment are not well recognized. **→Enhancing awareness through MR marketing activities is crucial for increasing coverage**

Market size of ETUARY: IPF drug market in China

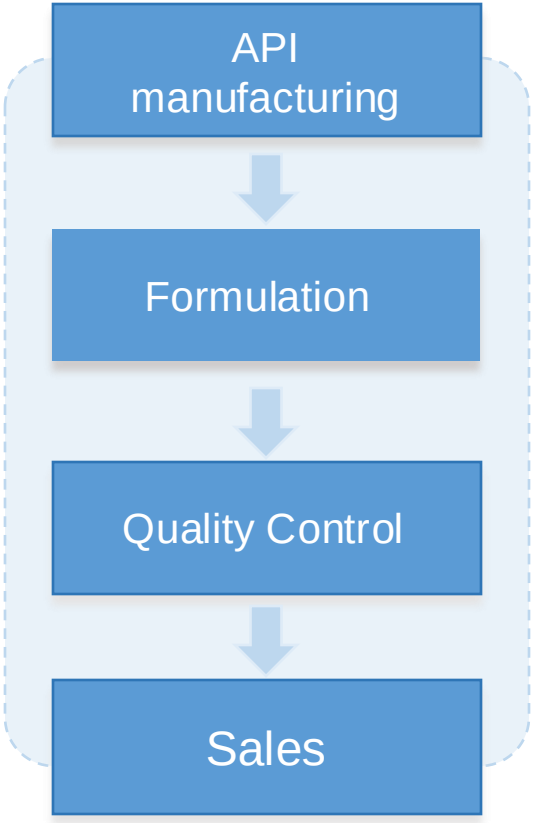
- Market size was approximately 32.2 billion yen in 2023, projected to reach around 130 billion yen by 2031.
- Increasing incidence of pulmonary fibrosis due to an aging population.
- **IPF is a chronic disease with a poor prognosis, as the average survival after diagnosis is only 2 to 3 years and it is irreversible → Continuous use of the medication enables patients to survive**



Source: Frost & Sullivan (converted to JPY by GNI)

Highly profitable vertical integration model

- Developed a unique model by integrating all stages from API production to sales within the group
- **The average gross profit margin over the past five years: 94.7%**
- Strong sales force and network with approximately 400 MRs, a key strength of the group



Owns API (active pharmaceutical ingredient) manufacturing facility in Hebei Province (site area: 8,682 ㎡)
Very few companies in Japan manufacture APIs in-house*

Owns manufacturing facility in Beijing (total construction area: 9,994 ㎡)
Produces 700 million ETUARY capsules annually, with an annual production value of 1.2 billion RMB (approximately 24 billion yen)

377 MRs cover markets in 30 provinces, autonomous regions, and municipalities in China.
Rapid expansion of the sales network reached 2,613 hospitals and pharmacies in China by 2023.

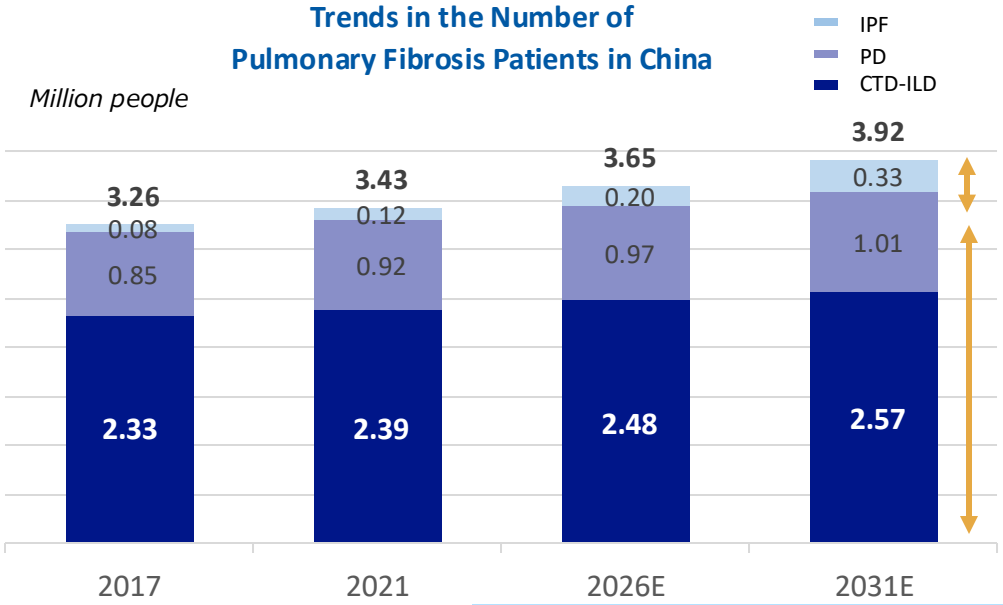
*Source: 抗生物質原料も脱中国　政府が明治ホールディングス系や塩野義製薬系支援、安定供給へ国産化 - 日本経済新聞 (nikkei.com)

Strategy for Expanding Market Share in Pulmonary Fibrosis Treatment

- Approximately 3.4 million pulmonary fibrosis patients in China (2021)
- Conducting clinical trials targeting other types of pulmonary fibrosis to expand ETUARY's indications
- **Acquired sales rights for Nintedanib in May 2024**
- Only two drugs, Pirfenidone (ETUARY) and Nintedanib, are globally approved for pulmonary fibrosis treatment

CAGR	CTD-ILD	Pneumoconiosis	IPF
2017 – 2021	0.7%	2.0%	9.6%
2021 – 2026E	0.7%	1.2%	10.6%
2026E – 2031E	0.8%	0.8%	10.9%

Generic Name	Nintedanib
Indications	Idiopathic Pulmonary Fibrosis(IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD) and progressive fibrotic interstitial lung disease (PF-ILD)



- **IPF: Approved**
- **Pneumoconiosis ("PD"): Phase 3 clinical trial ongoing**
- **Connective Tissue Diseases Associated Interstitial Lung Disease: Phase 3 clinical trial ongoing**

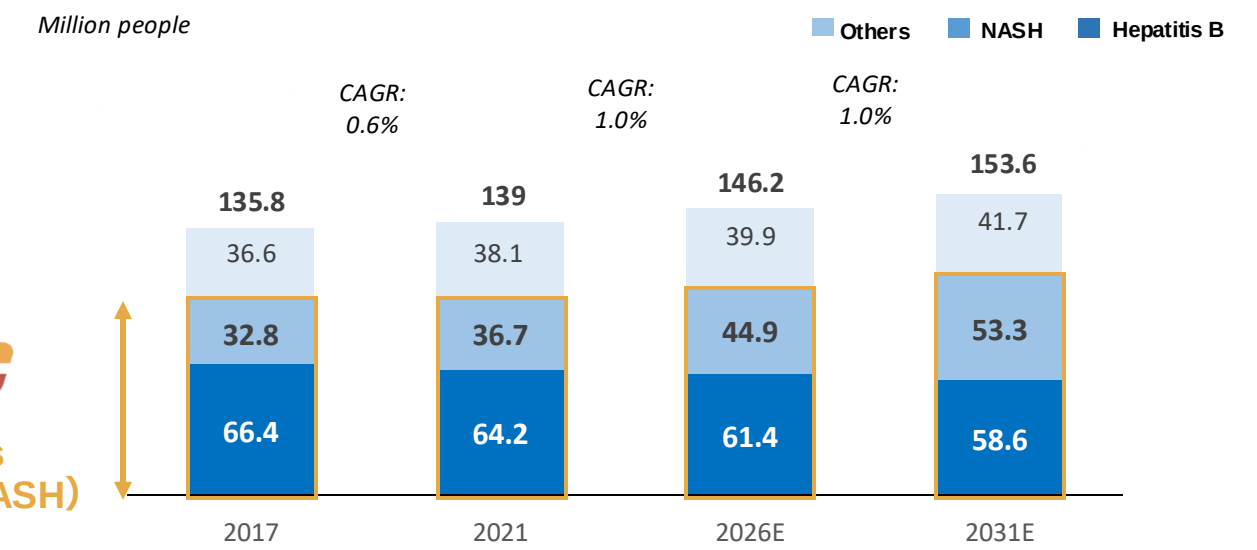
Source: Frost&Sullivan

Potential of F351 for Liver Fibrosis Treatment

The number of liver fibrosis patients in China is expected to exceed 150 million by 2030

- Currently conducting a Phase 3 clinical trial targeting liver fibrosis caused by hepatitis B (results expected in October)
- No approved liver fibrosis treatments exist in China
- Designated as a "breakthrough therapy" by the NMPA
- Planned clinical trials targeting liver fibrosis caused by NASH in 2025 (Phase 3 in China, Phase 2a in the U.S.)

Trends in the Number of Liver Fibrosis Patients in China



Target areas (Hepatitis B・NASH)

Source: Frost& Sullivan

Development Pipeline of Gyre Therapeutics & Gyre Pharmaceuticals

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			USA
	CHB-Associated Liver Fibrosis				Completed enrollment of patients in October 2023		
ETUARY® (Pirfenidone)	Idiopathic Pulmonary Fibrosis (IPF)						PRC
	Dermatomyositis Interstitial Lung Disease (DM-ILD)						
	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						
	Pneumoconiosis						
	Diabetic Kidney Disease (DKD)						
F573	ALF/ACLF				Initiated Phase 2 trial in March 2023		
F528	Chronic Obstructive Pulmonary Disease (COPD)						
F230	Pulmonary Arterial Hypertension (PAH)		Received IND approval in May 2024				

F351 Phase 2 trial top-line data overview (1/3)

Efficacy results

Efficacy Analyses	Placebo	F351: 60mg/dose 3 doses/day	F351: 90mg/dose 3 doses/day	F351: 120mg/dose 3 doses/day
Ishak score down by 1+ As of 52nd week (FAS)	11 (11/43, 25.58%)	17 (17/42,40.48%)	23 (23/41,56.10%)	18 (18/41,43.90%)
Ishak score down by 1+ As of 52nd week (PPS)	11 (11/42,26.19%)	17 (17/36,47.22%)	23 (23/35,65.71%)	18 (18/34,52.94%)
p value	FAS: 0.0245, PPS: 0.0058			
Ratio Difference (Placebo - F351)% & 95% CI		FAS: -14.89 (-33.32,4.99) PPS: -21.03 (-40.20,0.26)	FAS: -30.52 (-48.12,-9.50) PPS: -39.52 (-56.83,-17.26)	FAS: -18.32 (-36.76,1.96) PPS: -26.75 (-45.78,-4.75)

Source: GNI Group disclosure dated on October 23, 2020

F351 Phase 2 trial top-line data overview (2/3)

Efficacy results: additional analyses for patients with Ishak score = 6 (cirrhosis stage)

Efficacy analyses	Placebo	F351 (all groups)
Ishak score decreased by ≥ 1 point after 52 weeks treatment (FAS)	1 (1/4, 25%)	12 (12/15,80%)
Ishak score decreased by ≥ 1 point after 52 weeks treatment (PPS)	1 (1/4, 25%)	12 (12/14,85.71%)
p value	FAS: 0.0407, PPS: 0.0201	
Ratio Difference (Placebo - F351)% & 95% CI		FAS:
		-55.00 (-79.20,-3.49)
		PPS:
		-60.71 (-83.59,-8.97)

Source: GNI Group disclosure dated on October 23, 2020

F351 Phase 2 trial top-line data overview (3/3)

Safety and tolerability results

- ✓ **Adverse Events severity: mild to moderate**
- ✓ **Serious Adverse Events incident rate: same among the groups**
  - ➢ **Placebo: 4.65%**
  - ➢ **F351: 60mg/dose, 3 doses/day group: 2.38%**
  - ➢ **F351: 90mg/dose, 3 doses/day group: 2.38%**
  - ➢ **F351: 120mg /dose, 3 doses/day group: 7.32%**
- ✓ **No fatalities in the trial**

Source: GNI Group disclosure dated on October 23, 2020

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