

Project

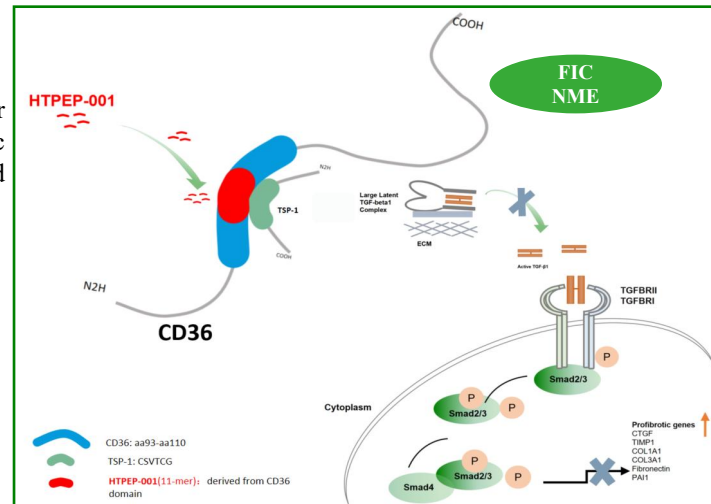
HTPEP-001: An 11-Amino Acid Derived from CD36 Domain Blocking the Activation of L-TGF-β1

Company Snapshot

The company was an IND-stage biotech company focusing on developing novel anti-fibrotic therapies, blocking the activation of L-TGF-β1 by CD36 Domain Peptidomimetics(11-mer).

Programs below are all first-in-class therapeutics from the platform:

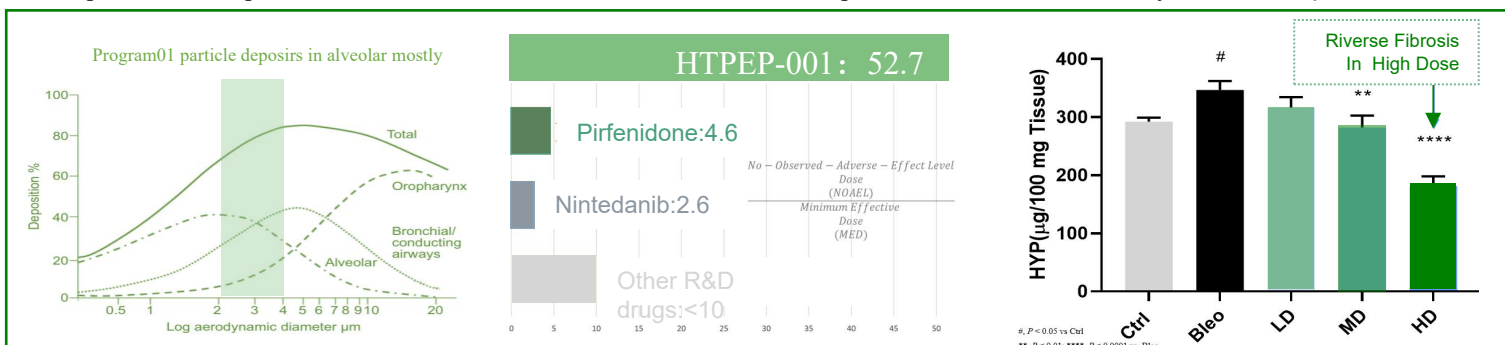
- **Program01:** HTPEP-001 for aerosol inhalation, a small molecular polypeptide for the treatment of early stage of Progressive Fibrotic Interstitial Lung Diseases (PF-ILD) patients. Current data showed potential to reverse fibrosis in lung.
- **Program02:** HTPEP-001 for injection, a small molecular polypeptide for the treatment of advanced stage PF-ILD patients. Current data showed potential a better therapy than Nintedanib (Ofev) in several indicators of preclinical endpoint.
- **Program03:** a combination therapy of HTPEP-001 together with Anti-PD-1 mAb. This therapy significantly inhibited tumor growth, and considerably much more efficacious than Anti-PD-1 mAb.



Test Result of Program01 and Program02 for Anti-fibrotic

Program01: An inhalation treatment with a 52.7-folds safety margin can reverse pulmonary fibrosis.

- The aerodynamic diameter of Program01 can deposit in human alveolus mostly, a promising aerosol inhalation treatment;
- Program01 has a pretty high level of safety margin about 52.7-fold, much better than approved and R&D drugs;
- High dose Program01 reverses fibrosis evaluated by the Hydroxyproline (HYP), which is the primary preclinical endpoint; Other preclinical endpoints, such as Fibrosis& Inflammation Score, Gene Expression, and Micro-CT analysis are also prominent.



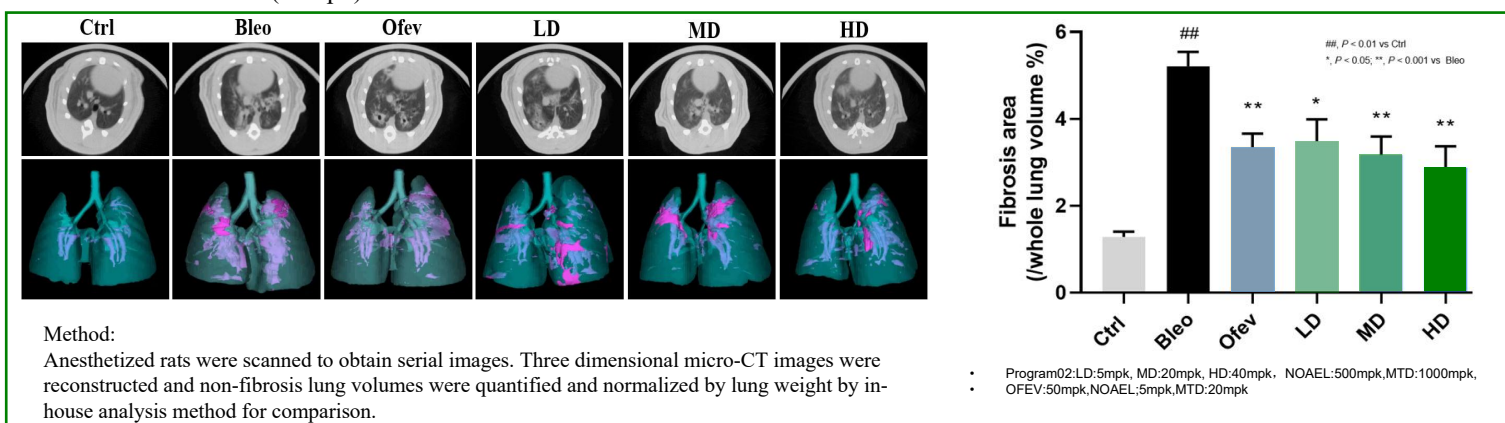
Aerodynamic Diameter and Lung Deposition (µm)

Safety Margin ratio Comparison (-fold)

Hydroxyproline (HYP): the Primary Endpoint

Program02: An intravenous treatment better than Nintedanib (Ofev) for the advanced stage patients.

- According to High-resolution Micro-CT analysis in a 21-days preclinical assessment, Program02 can reduce more fibrosis than Nintedanib (Ofev) in vivo. Especially, High dose of Program02 is far away from the NOAEL dose(500mpk), while Ofev(50mpk) exceeds its MTD(20mpk).



Method:

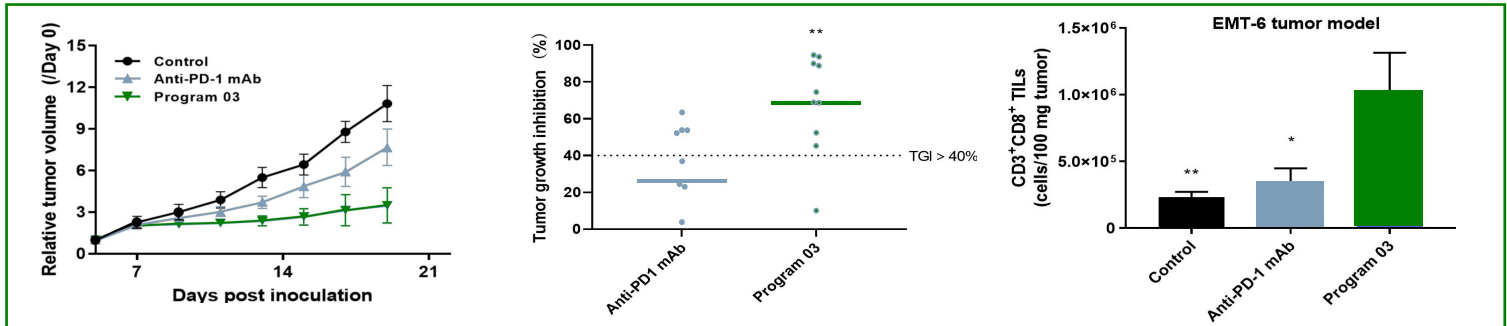
Anesthetized rats were scanned to obtain serial images. Three dimensional micro-CT images were reconstructed and non-fibrosis lung volumes were quantified and normalized by lung weight by in-house analysis method for comparison.

• Program02:LD:5mpk, MD:20mpk, HD:40mpk. NOAEL:500mpk,MTD:1000mpk,
• OFEV:50mpk,NOAEL:5mpk,MTD:20mpk

Test Result of Program03 for Anti-tumor (fibrosis-related)

Program03: A promising therapy in combination with immune checkpoint blockade for cancer.

- Program03 can turn cold tumors into hot tumors, the number of CD3+CD8+ TILs was higher in animals receiving program03 compared to Anti-PD-1 mAb, approximately **3-fold** over Anti-PD-1 mAb.
- Relative tumor volume: the program03 group is significantly smaller than in the control group, and when compared with Anti-PD-1 mAb group, program03 exhibits a trend toward greater efficacy in reducing tumor volume.
- The overall tumor growth inhibition rate was higher for program03 than Anti-PD-1mAb only (68.70% vs 26.24%).



Investment Highlights



- **The Earliest Mover with the Most Extensible Platform:** HUITAI Biomedicine is the earliest mover with the most in-depth researches on TSP-1&CD36 antagonist platform globally. Its high extensible anti-fibrotic platform has developed effective solutions to address severe fibrotic diseases, such as organ fibrosis (Lung, Liver, Kidney...) and fibrosis-related solid tumors.



- **Superior Testing Results and Extensive IP Portfolio:** HUITAI's core asset can reverse pulmonary fibrosis with a pretty high safety margin (inhalation: 52.7-fold, intravenous: 100-fold), also significantly enhance the anti-tumor efficacy of anti-PD-1. HUITAI's rich portfolios of IP rights over China, the US, Canada, Europe, Japan, Korea, Australia,.....15 countries and region in total.

Cardiovascular Diseases

- Angioplasty
- Myocardial Fibrosis
- Vascular restenosis after injury

Digestive Diseases

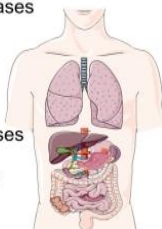
- Hepatic Fibrosis
- Cirrhosis
- Intestinal Fibrosis

Hematopoietic Diseases

- Myelofibrosis

Ophthalmic Diseases

- Proliferative retinopathy
- Glaucoma
- Cataract
- Posterior Capsule Opacification



Respiratory Diseases

- Sarcoidosis
- Pulmonary Fibrosis

Skin Injury

- Keloids
- Burn-induced Hypertrophic Scars

Systemic Disease

- Systemic Sclerosis
- Cystic Fibrosis
- Marfan Syndrome
- Rheumatoid Arthritis

Urinary System Diseases

- Renal Fibrosis

- **Huge Market Size with Unmet Demand:** Fibrotic disease can affect any organ and is responsible for up to 45% of all deaths in the industrialized world. Only two approved anti-fibrotic therapeutics, and their annual revenues exceed \$3.0 billion, despite remaining huge unmet medical need.

Therapeutic Indications of HUITAI's Platform

About HUITAI

HUITAI Biomedicine, located in Chengdu City, the Southwest of China, founded in 2017. HUITAI is a research based biotech company developing novel therapeutics for the treatment of Fibrotic Diseases by creating TGF- β 1 therapeutics based on the precise and targeted regulation of TGF- β signaling. HUITAI is developing novel therapeutics to address the most severe and difficult-to-treat fibrotic conditions of the lung, liver, kidney and other organs, and its first IND was approved by NMPA for pulmonary fibrosis in 2021. HUITAI is financed by its own founders and executives whose loved family members died because of pulmonary fibrosis, that is exactly the reason why we are persistently developing prominent anti-fibrotic treatments for patients.

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