Shanghai Haiju Biotechnology Co., Ltd.

- Novel Platinum-Based Drug Targeting Tumor Microenvironment (HJ-550 FIC)
- Novel MET Amplification-Targeting Small-Molecule Kinase Inhibitor (HJ-462 BIC)

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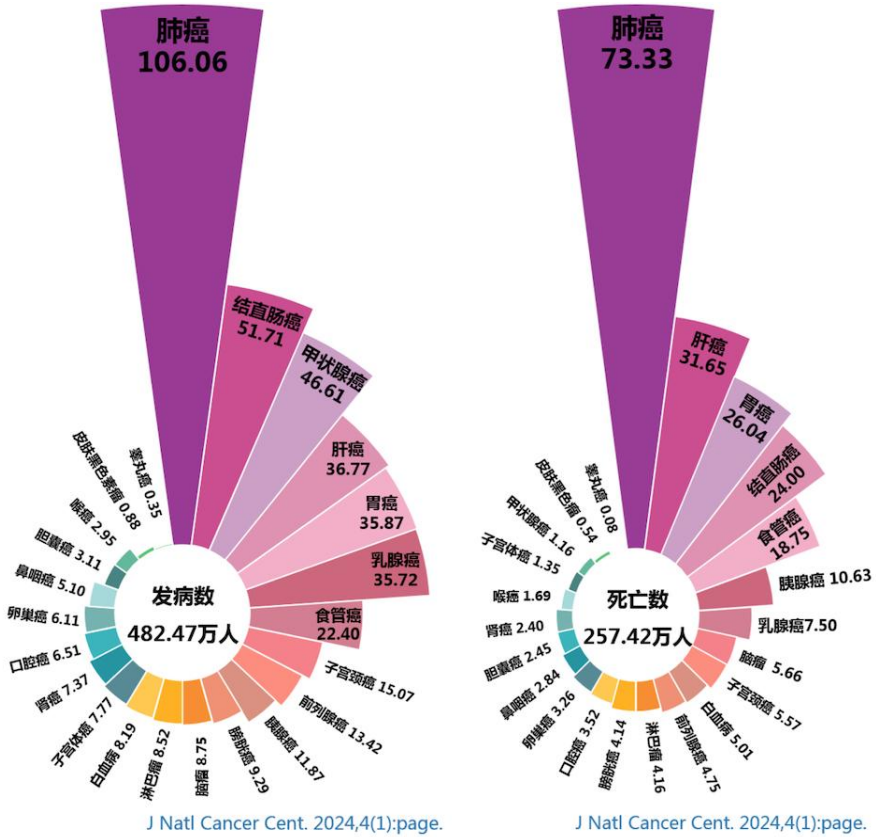
01 Market Analysis

Market overview of China's anti-tumor industry

HaiJu BIOTECH

01

The situation is critical, with substantial clinical challenges. The current five-year cancer survival rate in China is 43.7% (compared to 69% in the United States).



J Natl Cancer Cent. 2024,4(1):page.

J Natl Cancer Cent. 2024,4(1):page.

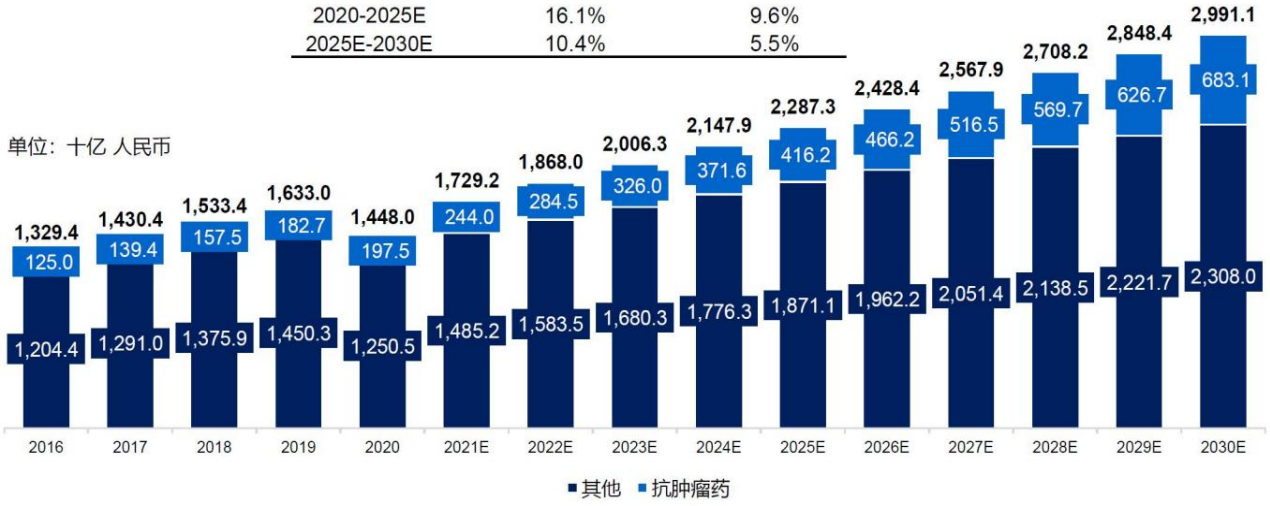
FROST & SULLIVAN

02

The anti-tumor drug market boasts a substantial market size, with China's domestic market projected to reach nearly 960 billion US dollars by 2030.

中国医药市场规模及预测，按抗肿瘤药物拆分，2016-2030E

年复合增长率	抗肿瘤药	总市场
2016-2020	12.1%	2.2%
2020-2025E	16.1%	9.6%
2025E-2030E	10.4%	5.5%



Novel anti-tumor drugs will be the most significant investment opportunity over the next decade or two!

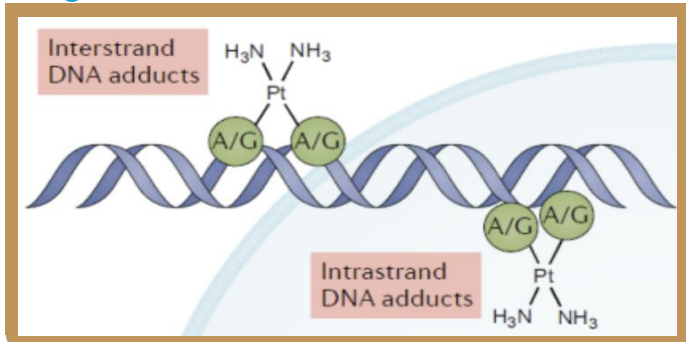
02

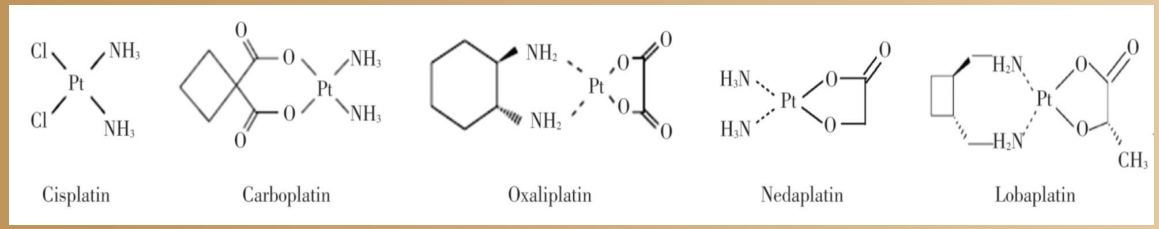
HJ-550

Novel Platinum-Based Drug

Targeting Tumor Microenvironment (FIC)

Clinical Pain Points of Traditional Platinum-Based Drugs & Highlights of HJ-550





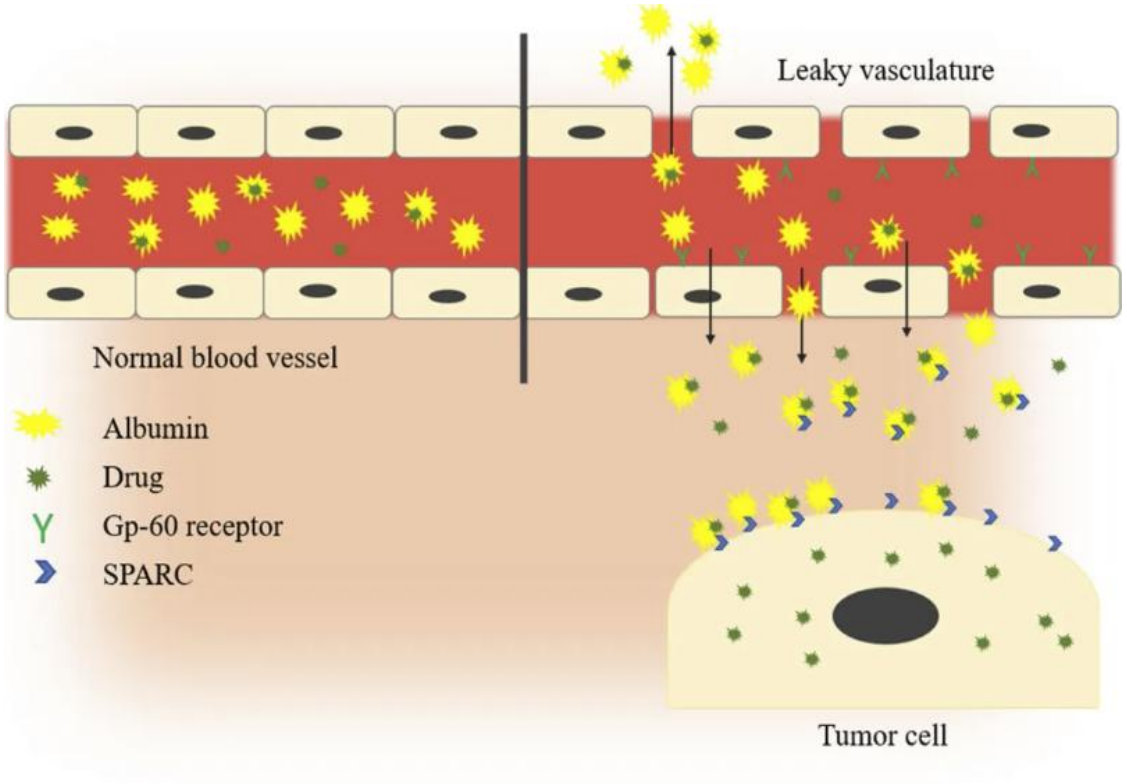
Clinical Pain Points:

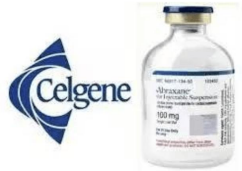
Non-targeted action;

High toxicity and severe side effects;

Prone to induce drug resistance

Traditional platinum-based drugs are cornerstone agents in first-line cancer therapy.





$2.9 Billion Acquisition Deal

Global Annual Sales of $1.0-1.2 Billion

Success Story: Implications from Albumin-Bound Paclitaxel

紫杉醇利用人源性白蛋白作为载体，给药前不需给予抗过敏预处理，输注时间只需30分钟，简化了给药方式，提高了药物耐受剂量（治疗剂量也由175mg/m2提高至260mg/m2），大大提高了药物疗效。白蛋白结合型紫杉醇 血浆峰浓度是传统紫杉醇的6.5倍：组织穿透速度是传统紫杉醇的7.5倍，组织分布能力是其3倍，对肿瘤组织靶向性更强，强效低毒，且使用更加方便、灵活。

HJ-550 Highlights

1. Monotherapy Efficacy:

Significantly superior to existing traditional platinum-based drugs.

2. Combination Therapy:

Outperforms current first-line treatment regimens.

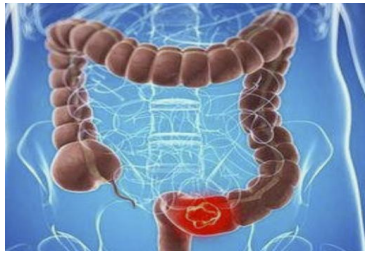
3. Resistance Reversal:

Effectively counteracts drug resistance mechanisms.

4. Long-Term Mechanism:

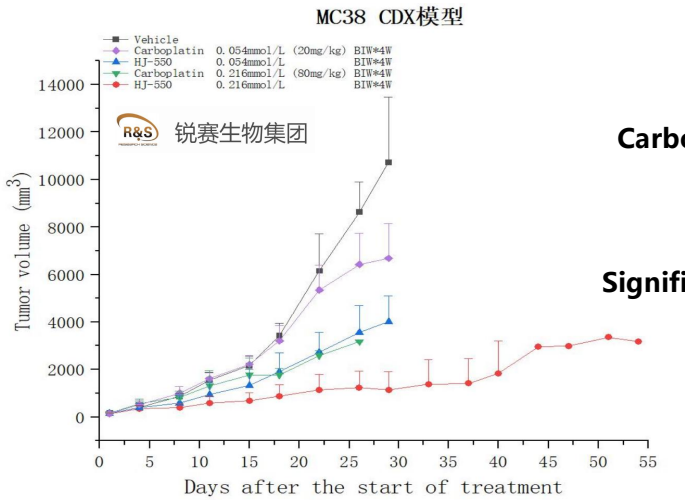
Sustained therapeutic effects with reduced recurrence risk.

Patent： PCT/CN/2020114659 （Authorized）； CN/202110485682.X



Colorectal Cancer

In 2020, China recorded 560,000 newly diagnosed cases of colorectal cancer, ranking it as the second most common newly diagnosed cancer!



Tumor Inhibition Rate:

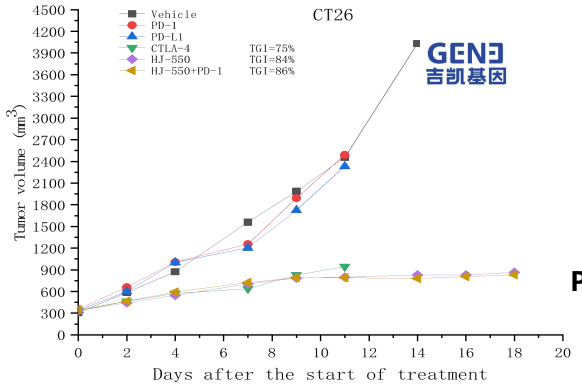
Carboplatin 58% vs. HJ-550 90%!

Safety:

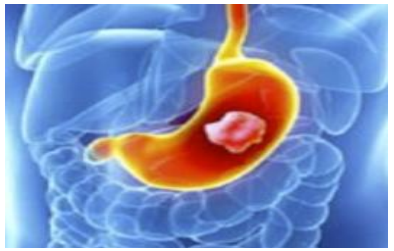
Significantly superior to carboplatin!

Sample ID	Test Item	Pt（mg/kg）	Radio（Tissue/Plasma）
Plasma	Platinum Content	1.7	1
Liver	Platinum Content	31.3	18.4
Kidney	Platinum Content	83.5	49.1
Tumor	Platinum Content	23.8	14

Major Metabolic Organs of Albumin In Vivo

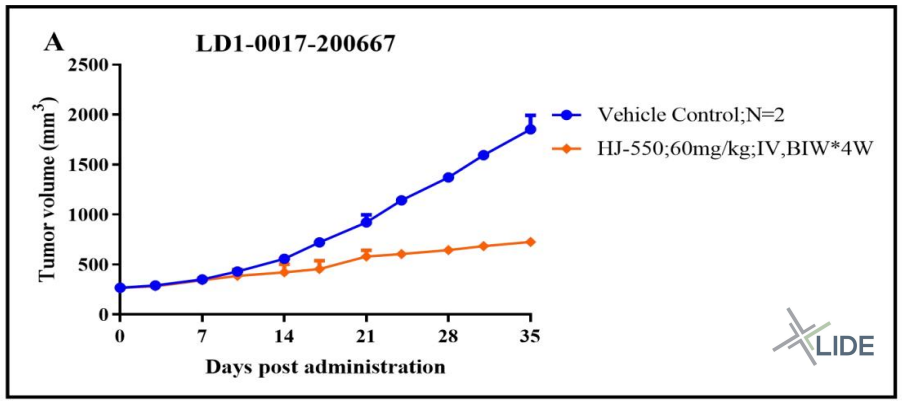


HJ-550 demonstrates significantly superior efficacy compared to CTLA-4, PD-1, and PD-L1 monoclonal antibodies



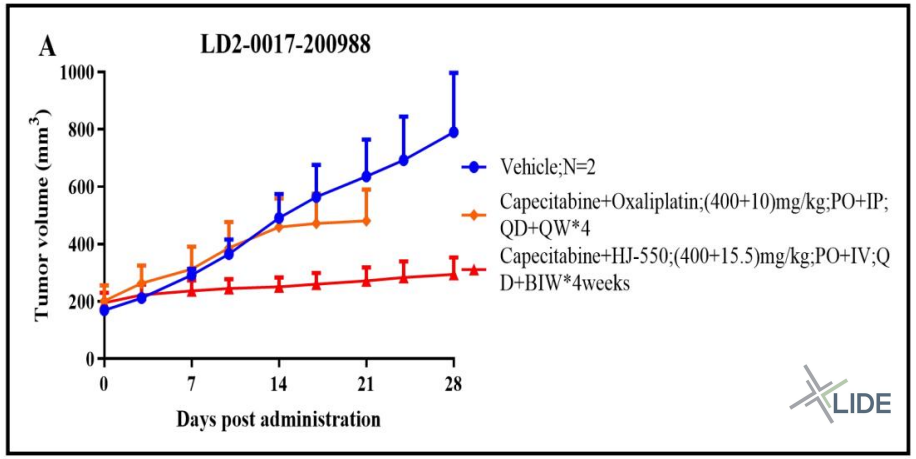
Gastric Cancer

In 2020, China reported 480,000 new cases of gastric cancer, ranking third among newly diagnosed cancers.



HJ-550 monotherapy achieves a tumor inhibition rate of 71%.

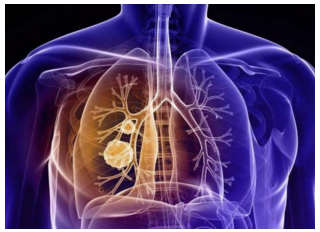
Gastric Cancer-PDX-Shanghai LIDE- LD1-0017-200667



Combination therapy of HJ-550 with capecitabine demonstrates an 84% tumor inhibition rate.

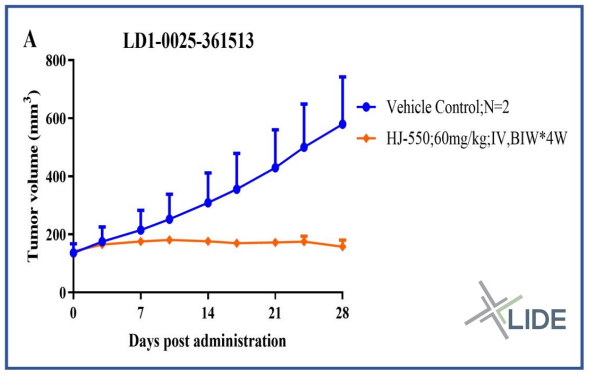
Both safety and efficacy are significantly superior to oxaliplatin (TGI = 40%).

Gastric Cancer-PDX-Shanghai LIDE- LD2-0017-200988



Lung Cancer

In 2020, China recorded 820,000 newly diagnosed cases of lung cancer, ranking first among all newly diagnosed cancers



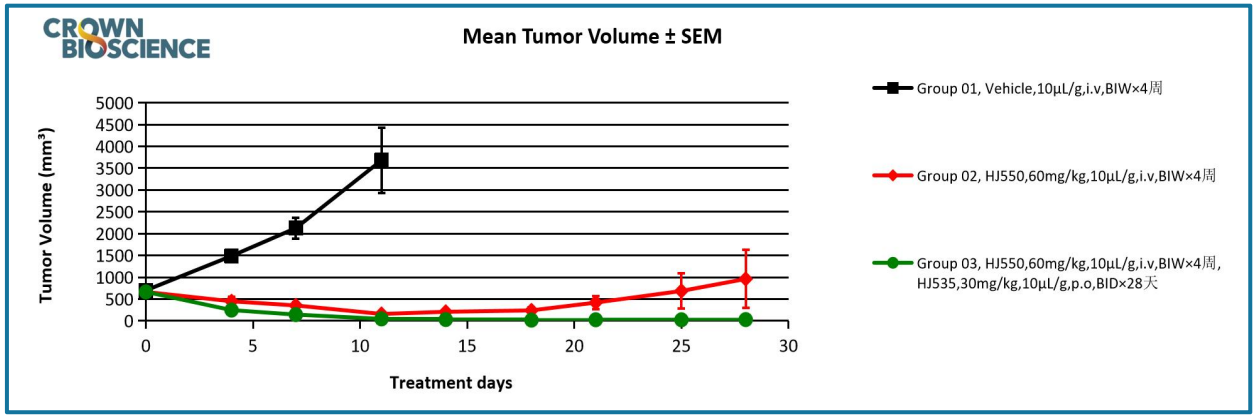
Small cell lung cancer PDX model

(Shanghai LIDE, **T4N2M0**)

showed 96.38% tumor inhibition rate

after 28-day treatment with HJ-550.

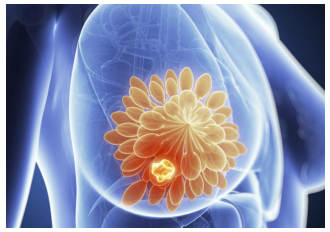
Control groups: Etoposide + Cisplatin; Irinotecan + Cisplatin; Topotecan + Nedaplatin; Nivolumab (PD-1 inhibitor) [disease progression].



CrownBio **NSCLC PDX Model (LU1901)** with EGFR Amplification and MET Amplification

Following 28-day combination therapy with HJ-550 and HJ-462, **near-complete tumor regression** was achieved! (See green line for tumor volume)

Highlights: Notably, treatment was initiated with a large baseline tumor volume (mean 662 mm³), yet exceptional efficacy was observed.



Triple-Negative Breast Cancer (TNBC)

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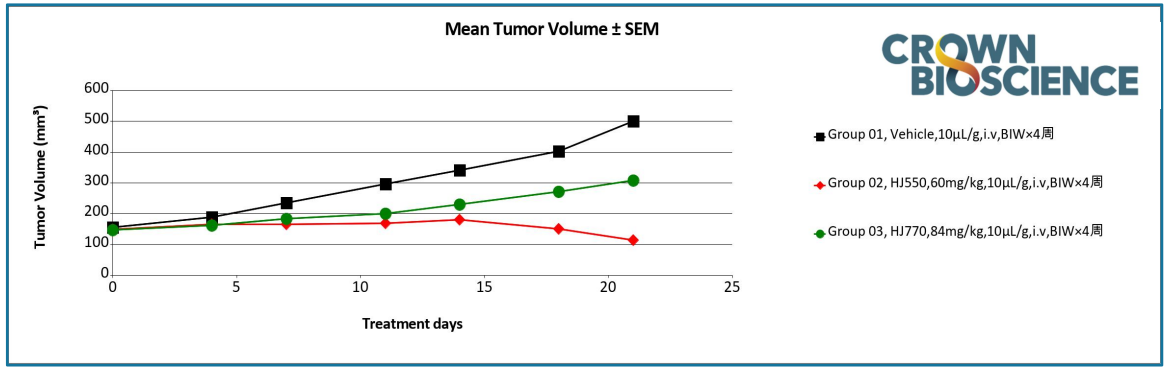
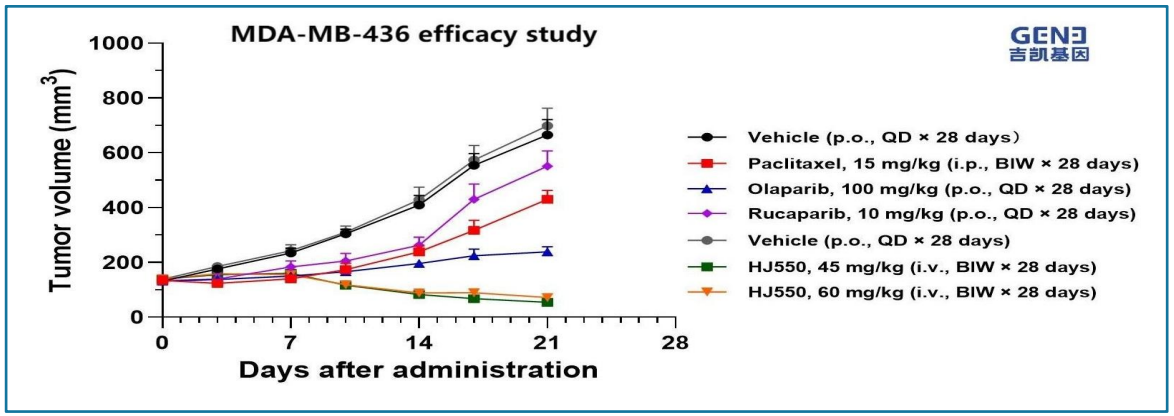
BR2014 PDX Model

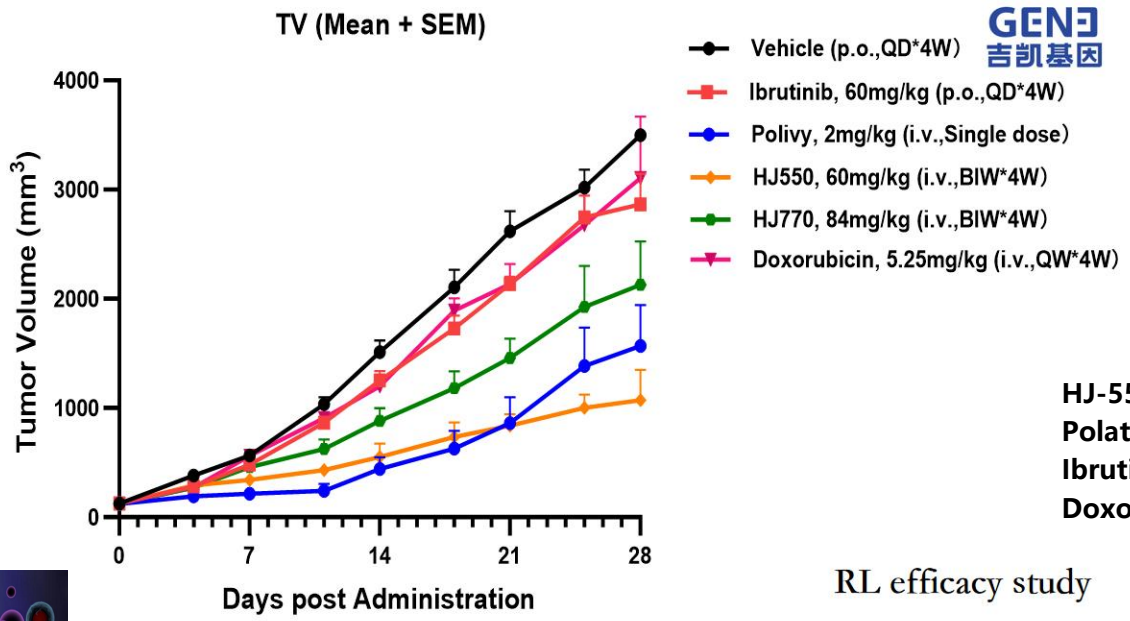


The tumor inhibition rate reached 77% after 3 weeks, demonstrating significant tumor shrinkage efficacy!



Efficacy significantly superior to Olaparib (2021 global sales: $2.35 billion)

Efficacy significantly superior to Paclitaxel (annual global sales of paclitaxel formulations exceed $5 billion; domestic sales in China reach RMB 10 billion)



RL efficacy study

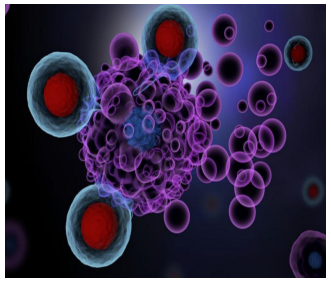
Tumor Response Rate Data and Sales Revenue of Drugs for B-Cell Non-Hodgkin's Lymphoma are as Follows:

HJ-550 79%

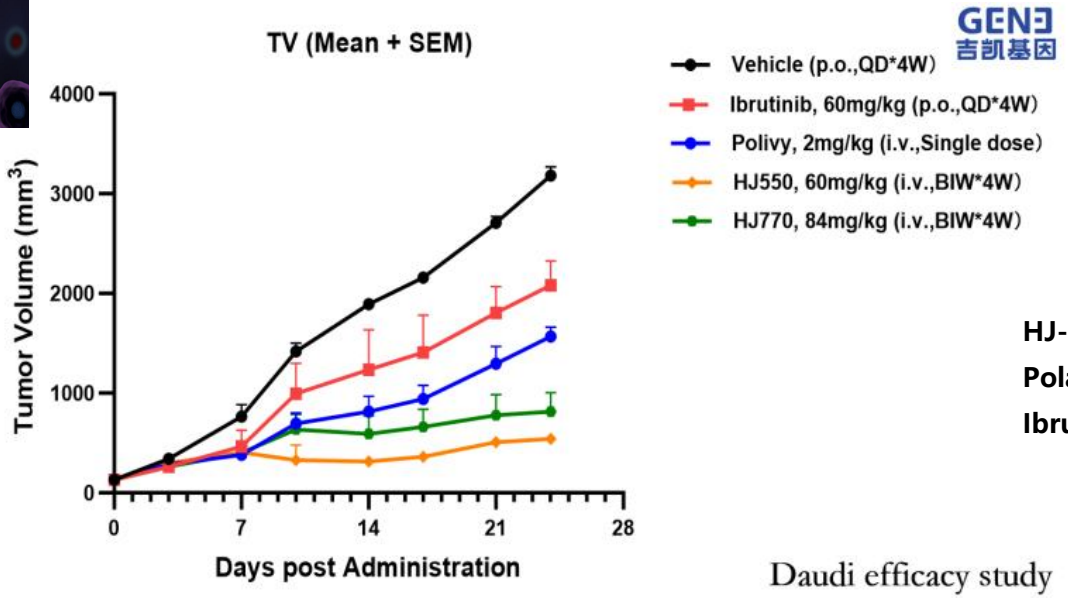
Polatuzumab Vedotin 53% (a CD79b-targeting MMAE-ADC drug,Roche, ~$574 million USD) ;

Ibrutinib 36% (Johnson & Johnson, $8.15 billion USD in 2022);

Doxorubicin 12% (currently used in hematologic cancer chemotherapy).



Lymphoma



Daudi efficacy study

Tumor Response Rate Data and Sales Revenue of Drugs for Burkitt's Lymphoma are as Follows:

HJ-550 72%

Polatuzumab Vedotin 53% (a CD79b-targeting MMAE-ADC drug,Roche, ~$574 million USD) ;

Ibrutinib 36% (Johnson & Johnson, $8.15 billion USD in 2022);

Experimental Data Summary

★Qualify for FDA Orphan Drug Designation Application

Indication	Model Type	Tumor Inhibition Rate	Reference Drug & Clinical Significance
★ Small Cell Lung Cancer (SCLC)	PDX	Monotherapy 96%	Addressing drug resistance: These regimens achieve outstanding therapeutic efficacy even when cisplatin and nedaplatin have failed.(Etoposide + Cisplatin, Irinotecan + Cisplatin, Topotecan + Nedaplatin, Nivolumab)
Non-Small Cell Lung Cancer (NSCLC)	PDX	Monotherapy 95% Combination therapy 98%	Combination administration of HJ-550 and HJ-462 **resulted in near-total tumor eradication by Day 11, with no tumor recurrence observed up to Day 28**. Despite the large average initial tumor volume (662 mm^3) at enrollment, the therapeutic efficacy remained robust.
Triple-Negative Breast Cancer (TNBC)	PDX	Monotherapy 77%	HJ-550 demonstrates superior efficacy to existing mainstream drugs in triple-negative breast cancer (TNBC), showing outstanding therapeutic outcomes. Specifically, the tumor suppression rate of **paclitaxel is only 44%**.
	CDX	Monotherapy 113%	
Colorectal Cancer	CDX	Monotherapy 90%	HJ-550 monotherapy demonstrated efficacy comparable to a 4-fold dose of carboplatin(**TGI = 58%**), with the trial group showing significantly prolonged survival and superior therapeutic effects over carboplatin and CTLA-4 monoclonal antibody.
Gastric Cancer	PDX	Monotherapy71% Combination therapy 84%	HJ-550 **monotherapy** has demonstrated strong efficacy (**TGI = 71%**), and the combination therapy (**HJ-550 + Capecitabine, TGI = 84%**) significantly surpasses the current first-line treatment regimen (**Oxaliplatin + Capecitabine, TGI = 40%**)
★B-Cell Non-Hodgkin Lymphoma	CDX	Monotherapy 79%	The tumor inhibition rate of HJ-550 is **79%**, significantly higher than the following drugs: Polatuzumab vedotin (53%), Ibrutinib (36%), and Doxorubicin (12%).
★ Burkitt's Lymphoma	CDX	Monotherapy 72%	The tumor inhibition rate of HJ-550 is **72%**, significantly higher than the following drugs: Polatuzumab vedotin (57%), Ibrutinib (19%)
★Intrahepatic Cholangiocarcinoma	CDX	Monotherapy 51%	HJ-550 monotherapy and combination therapy demonstrate significantly superior safety and efficacy compared to the current first-line treatment regimen (Cisplatin + Gemcitabine).
★Pancreatic Cancer	CDX	Monotherapy 47%	HJ-550 Monotherapy Demonstrates Superior Efficacy to Gemcitabine (TGI=26%,Current First-Line Chemotherapy for Pancreatic Cancer)

Haiju Biotechnology has constructed a robust pipeline of divalent platinum-based novel drugs and therapeutic indications, leveraging cutting-edge drug design philosophies.

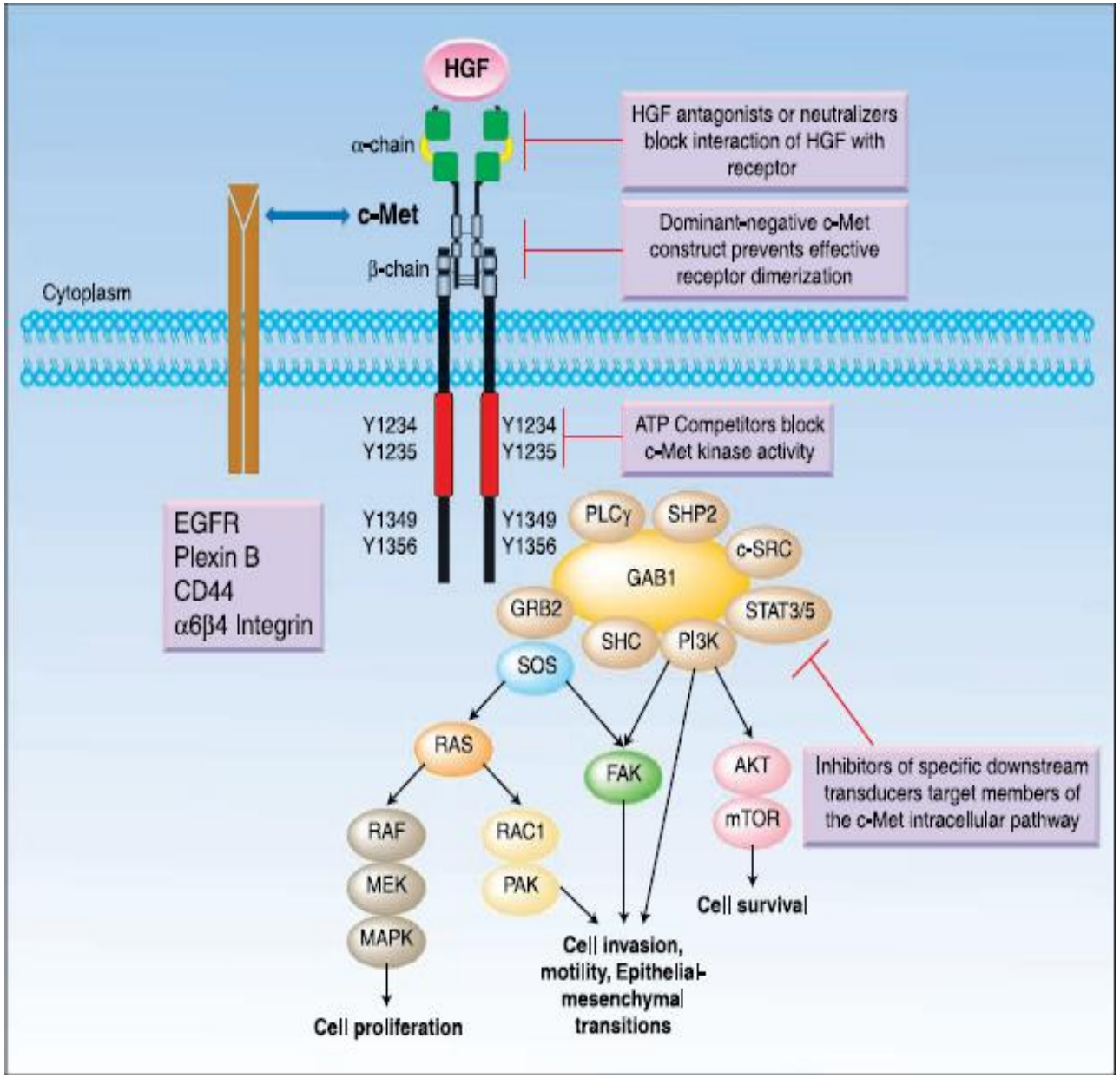
Clinical candidate compound		Indication	Pharmacological studies	CMC	IND	Phase I
Novel Platinum-Based Drug Targeting Tumor Microenvironment	HJ-550	☆ Small Cell Lung Cancer (SCLC)				
		Non-Small Cell Lung Cancer (NSCLC)				
		Triple-Negative Breast Cancer (TNBC)				
		Colorectal Cancer				
		Gastric Cancer				
		B-Cell Non-Hodgkin Lymphoma				
		☆ Burkitt's Lymphoma				
		☆Intrahepatic Cholangiocarcinoma				
		☆Melanoma				
Bivalent platinum drugs targeting integrin receptors	HJ-770	Lymphoma				
		Triple-Negative Breast Cancer (TNBC)				

The indications marked in red have the qualifications to apply for FDA orphan drug status and NMPA rare disease designation;

03

Project Introduction HJ-462

Novel MET Amplification-Targeting Small-Molecule Kinase Inhibitor (BIC)



In multiple cancers, c-Met exhibits abnormal activity and is associated with gene mutations, amplification, and recombination events. For example, c-Met overexpression has been observed in pancreatic cancer, gastric cancer, colorectal cancer, breast cancer, prostate cancer, lung cancer, renal cancer, brain tumors, ovarian cancer, liver cancer, esophageal cancer, and other malignancies1. Elevated c-Met expression is closely linked to tumor drug resistance, poor prognosis, and cancer metastasis.

The development of small-molecule c-Met kinase inhibitors holds dual significance:

They can serve as standalone therapeutic agents;

They can be used in combination with EGFR-targeting monoclonal antibodies, offering immense market potential!

Design Challenges and Clinical Pain Points

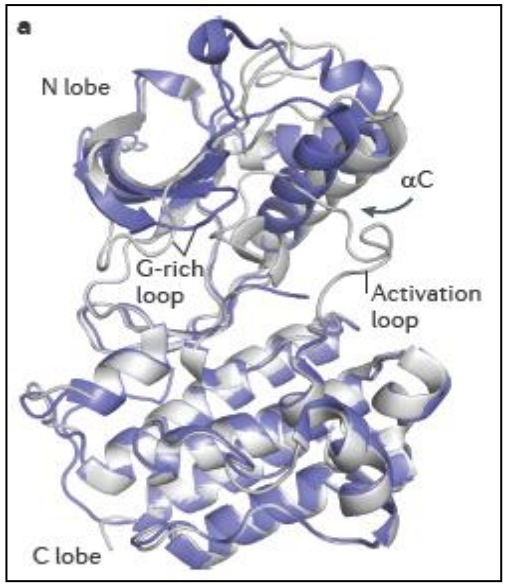
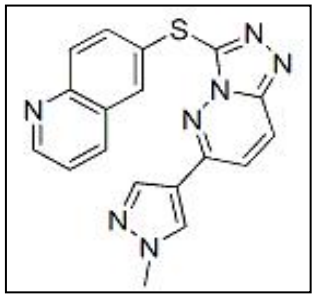
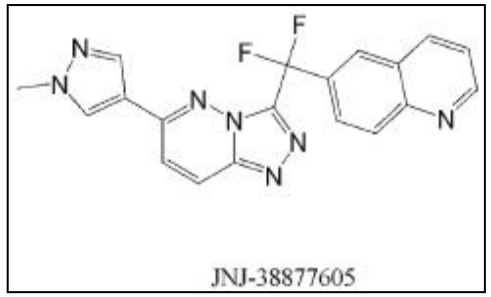


Figure: Structures of the MET kinase



SGX Pharmaceuticals



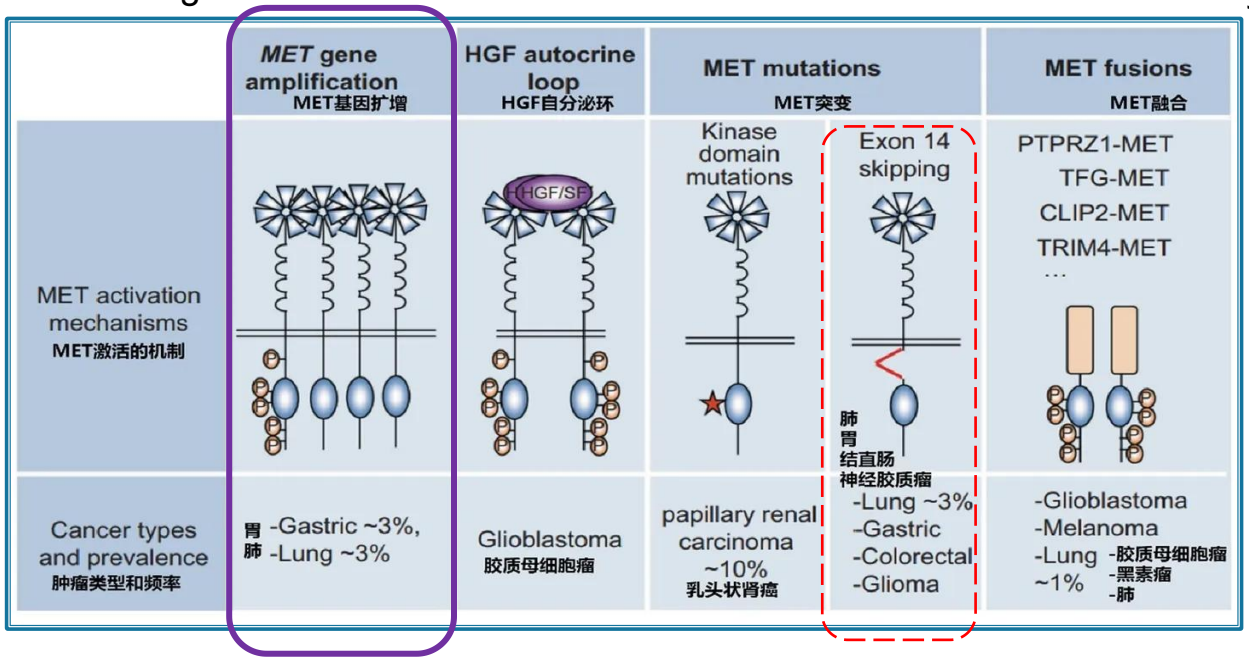
Johnson & Johnson

- Phase 1 clinical trials were discontinued after renal toxicity was observed in patients.

- This study has been terminated.
  (Early termination due to increase in serum creatinine levels and minimal PD activity.)

Design Challenges

The quinoline ring is the core pharmacodynamic group that binds kinases, but its poor metabolic properties greatly affect the drug properties of the molecule!



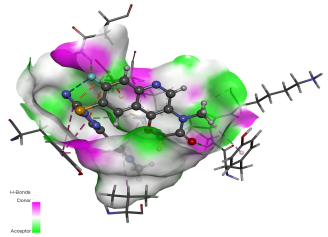
Clinical Pain Points

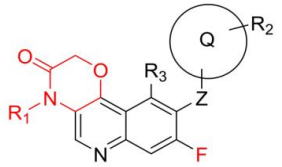
Approved indications are limited to: unresectable, advanced, or recurrent non-small cell lung cancer (NSCLC) caused by MET exon 14 skipping mutations.

Clinical demands for MET gene amplification in gastric cancer (~3%), lung cancer (~3%), and hepatocellular carcinoma (1-5%) remain unmet!

Haiju Biotech's Innovative Design

(Patents have been applied for and granted in both China and the United States.)

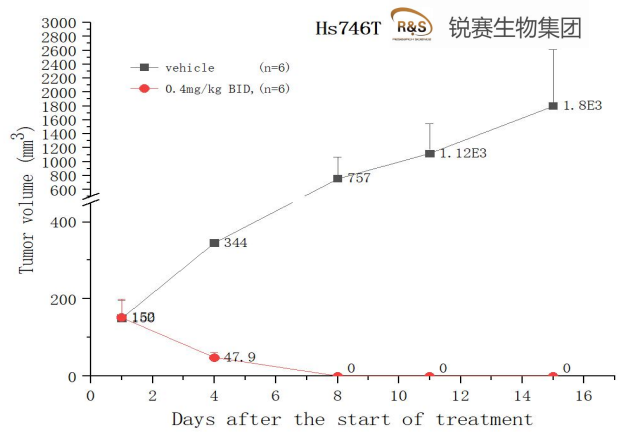


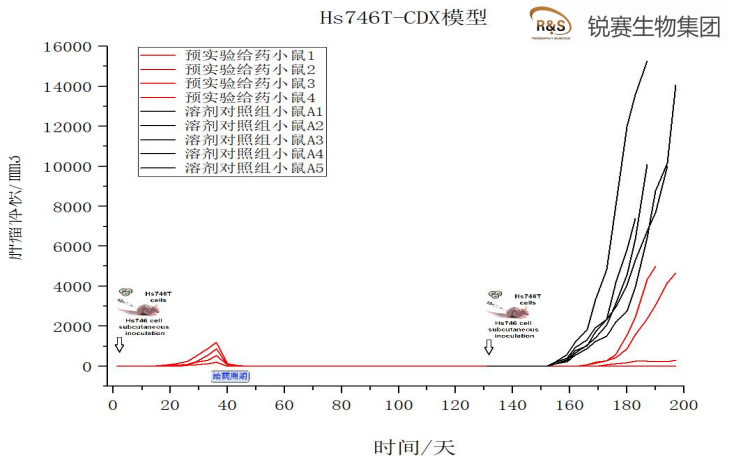


中美专利授权

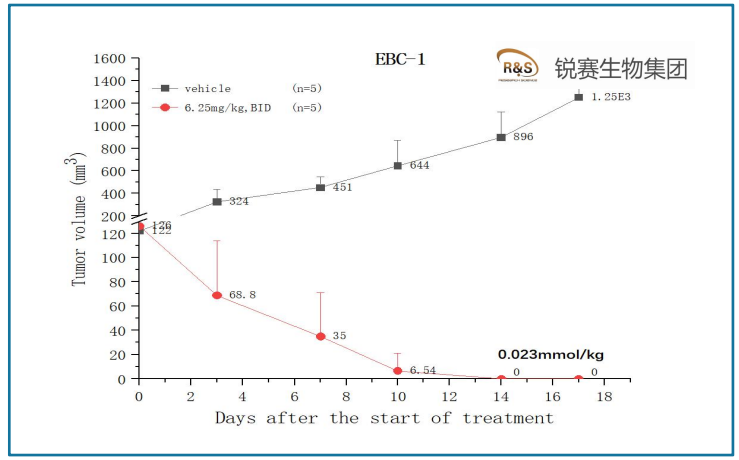
Comprehensive kinase, cellular, and in vitro/in vivo studies (particularly highlighting metabolic advantages) have confirmed the candidate compound's exceptional efficacy and outstanding safety profile, positioning it as a strong contender for best-in-class status in this therapeutic category!

The Molecule Fully Occupies the Active Pocket of the MET Kinase Protein.

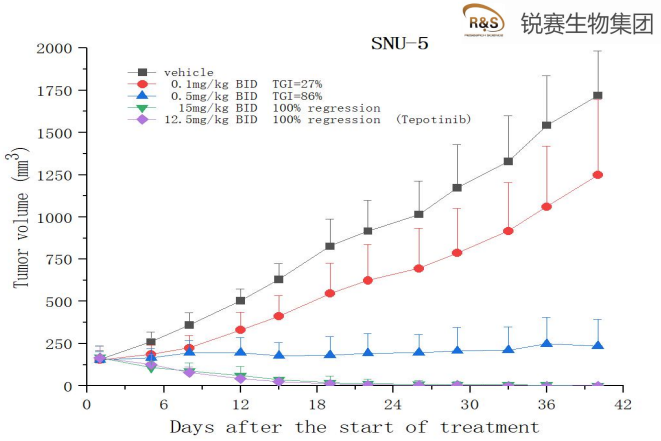




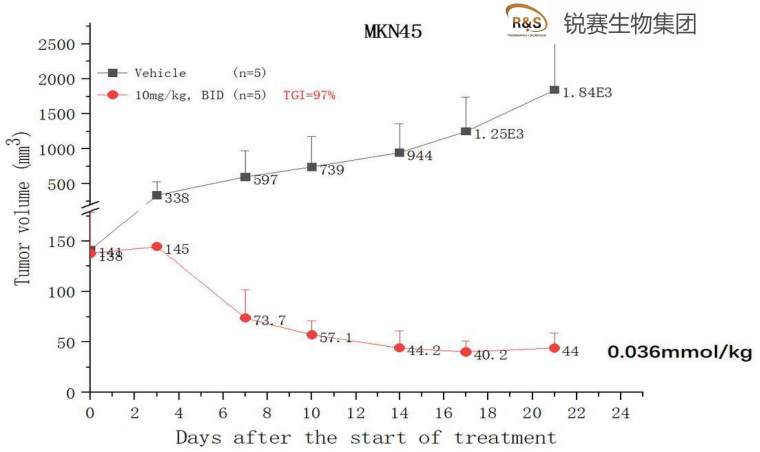
Gastric Cancer Model (New Indication): 100% Tumor Regression Observed!



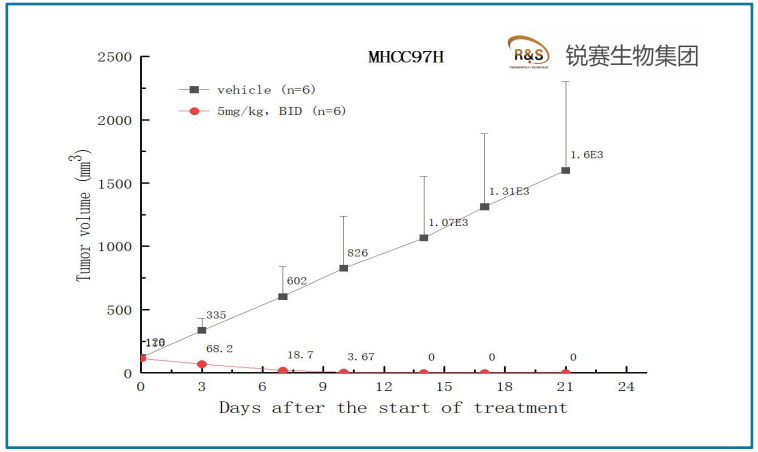
Non-small Cell Lung Cancer Model (New Indication): 100% Tumor Regression Observed!



Gastric Cancer Model (New Indication): 100% Tumor Regression Observed!



Gastric Cancer Model (New Indication): 97% Tumor Inhibition Rate



Hepatocellular Carcinoma Model (New Indication): 100% Tumor Regression Observed!

The aforementioned biological experiments and tests were validated and completed by the following collaborative partners

HaiJu BIOTECH

中国科学院上海药物研究所
Shanghai Institute of Materia Medica.
Chinese Academy of Sciences

JIUZHOU Pharmaceutical

南京康川济生药科技有限公司
NAN JING KANG CHUAN JI PHARMATECH CO.,LTD

Medicilon 美迪西生物医药

药明康德 WuXi AppTec

Sundia

ChemPartner
Dedicated to LifeScience

上海应用技术大学
SHANGHAI INSTITUTE OF TECHNOLOGY

南模生物
SHANGHAI MODEL ORGANISMS

innoModels

中科普瑞昇 PRECEDO

CROWN BIOSCIENCE

LIDE

R&S RESEARCH SCIENCE 锐赛生物集团

GENE 吉凯基因

VIVA

★ PDX models demonstrate over 90% correlation with clinical trials

04 Team introduction

Team introduction

Wang Haiyang CEO

With 15 years of experience in novel drug R&D, focusing on oncology and cardiovascular/cerebrovascular diseases, leading three Class 1.1 new drug projects into advanced clinical stages

01
Bachelor's degree of Applied Chemistry,
Huazhong University of Science and Technology,
Master degree of Medicinal Chemistry,
Shanghai Institute of Pharmaceuticals,
Supervisor: Researcher Shen Jingkang

02
Central Research Institute of Shanghai Pharmaceutical Group
SPH3127 Renin Inhibitor (International collaborative project, co-developed with Mitsubishi Tanabe Pharma Corporation of Japan; Project Manager, China side)
A new-generation non-peptide small-molecule renin inhibitor; completed global multi-center clinical trials; entered the New Drug Application (NDA) submission phase in 2025

03
Hansoh Pharmaceutical Group Co., Ltd.
The HS-10241 project, selected for the 2016 National Major New Drug Discovery and Development Program,
has now entered Phase III clinical trials.

04
Shanghai Affinity Biopharmaceutical Co., Ltd.
Legubicin (Class 1.1 Innovative Drug)
The World's First Legumain-Activated Drug Targeting Tumor Microenvironment
Now in Phase III Clinical Trials

05
Shanghai Haiju Biotechnology Co., Ltd.
- Novel Platinum-Based Drug Targeting Tumor Microenvironment (HJ-550 FIC)
- Novel MET Amplification-Targeting Small-Molecule Kinase Inhibitor (HJ-462 BIC)

Team introduction

CHEN Liu Deputy General Manager of Operations

Master Degree | Shanghai Jiao Tong University | Business Administration

Formerly served at Wanda Group, Baozun Group

Over 10 years of experience in corporate operations management

Dr. Zhenmin Xu Vice President of R&D

Former Pharmaceutical Chemistry Project Director at Fosun Pharma Group; Senior Project Manager at Central Research Institute of Shanghai Pharmaceuticals Holding Co., Ltd.

Participated in the sub-project of the National Major Science and Technology Project "Major New Drug Innovation"

Involved in the "Innovation Action Plan" Industry-Academia-Research-Medical Collaboration Project in the biopharmaceutical field by Shanghai Municipal Science and Technology Commission

Dr. Qiangsheng Guo Director of Haiju University-Enterprise Joint Laboratory

Deputy Director of Analytical Testing Center, Shanghai Institute of Technology

Presided over and participated in over 10 research projects including those funded by the National Natural Science Foundation of China, Shanghai Higher Education Connotation Construction Plan, Shanghai Alliance Program, and enterprise-sponsored initiatives.

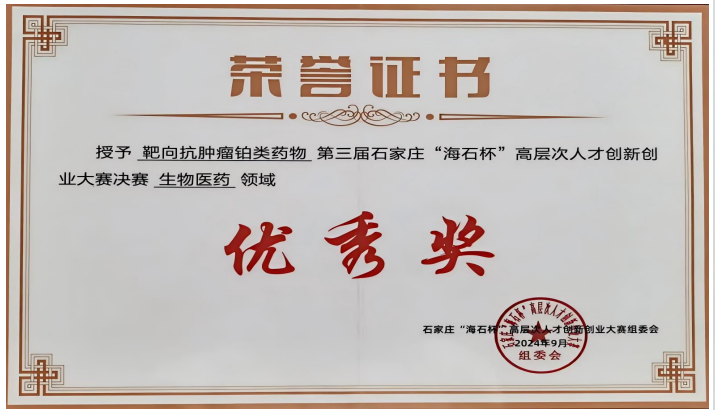
Project Honors

★Sep 2024: The company was awarded the Excellence Award in Biotechnology at the 2024 Shijiazhuang "Hai Shi Cup" Final

★Nov 2024: The company received the "Rising Star of the Year" title in Shanghai Biomedical Industry .

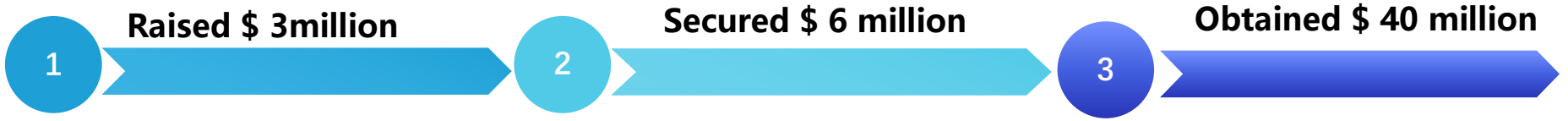
★Dec 2024: The company was listed among the "Top 50 Biotech Innovation Enterprises in the Greater Bay Area—Promising Enterprise"

★Mar 2025: The company won the Third Prize at the 4th Jianghai Talents Innovation and Entrepreneurship Competition.



05 Financing Plan

Financing Plan



Founding Team with 100% Equity Ownership

BEST IN CLASS

Milestone 1-1	Milestone 2-1	Milestone 3-1
HJ-462 will submit a clinical trial application for Class 1.1 new drug within 12 months.	HJ-462 will complete Phase I clinical trials within 18-24 months.	HJ-462 will complete Phase II clinical trials and submit a conditional marketing authorization application within 18-24 months.

Benchmark

Hutchison Whampoa's Savolitinib ($140 million deal value & net sales royalties);

FIRST IN CLASS

Milestone 1-2	Milestone 2-2	Milestone 3-2
HJ-550 will submit 2 clinical trial applications for Class 1.1 new drug within 12-18 months.	HJ-550 will complete Phase I clinical trials within 18-24 months.	HJ-550 will complete Phase II clinical trials and submit a conditional marketing authorization application within 18-24 months.

Disruptive platinum-based novel drug!

Reshaping the landscape of first-line tumor treatment

The company's explosive growth will be realized incrementally with the initiation of high-certainty clinical trials in the future.

Investment Returns

After HJ-550 is approved for marketing,

the Chinese market sales are expected to reach 4.2 billion US Dollars and the global market can reach 16.8 billion US Dollars.

(The calculation basis is as follows:

There are 4.8 million new cancer patients in China in 2022,

and the average five-year cancer survival rate in China is 40.5%;

more than 60% of first-line cancer treatment options contain platinum drugs;)

After HJ-462 is approved for marketing,

the Chinese market sales are expected to reach 224 million US Dollars, and the global market can reach 532 million US Dollars.

(The calculation basis is as follows:

The number of gastric cancer patients in China is no less than 2.2 million;

patients with gastric cancer Met mutation and Met amplification are 3%;

considering Met amplified liver cancer and lung cancer patients,

especially EGFR late-stage lung cancer patients, nearly 30% will occur Met amplification.

The actual sales amount will be much higher than the above data)

Thank you for your attention!

Haiju Biotechnology's vision is to become the pioneer of novel anti-tumor drugs!