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TopAlliance

Annual Report 2024

Shanghai Junshi Biosciences Co., Ltd (1877.HK; 688180.SH)

March 2025

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2024 Business Overview （As of 27th March 2025）

International approval for Toripalimab

- HK, US, EU, UK, Australia 、India、Jordan、Singapore etc. approval for **toripalimab (trade name: TUOYI®/LOQTORZI®)**
- The first and only drug used for NPC in HK, Europe, UK, Australia and Singapore
- Marketing applications under review by multiple health authorities
- Achieved international collaboration in more than 80 countries

Steady growth in Sales Revenue

- **TUOYI®:** 11 indications approved in Chinese mainland, 10 covered by the NRDL, 1 sNDA under review by the NMPA
- **MINDEWEI:** converted from conditional approval to regular approval by the NMPA; officially covered by the NRDL
- **JUNMAIKANG:** 8 indications approved in China, all covered by the NRDL
- **JUNSHIDA**: 1 indication approved in China, 2 sNDA under review by the NMPA

Efficiently pushed forward R&D pipelines

- **Tifcemalimab (BTLA)**: Ph3 clinical study of maintenance therapy for LS-SCLC has been conducted in more than 150 centers in 15 countries, Ph3 clinical study for cHL is enrolling patients
- **JS005 (IL-17A)**: Ph3 registrational clinical study for moderate to severe plaque psoriasis finished subjects enrollment; Ph2 clinical study for ankylosing spondylitis has completed enrollment and is in follow-up.
- **JS207(PD-1×VEGF), JS203(CD3×CD20), JS015(DKK1) , JS107(Claudin 18.2 ADC), JS105(PI3K-α)**: continuing to explore
- **JS125(HDACs), JS212(EGFR×HER3 ADC), JS213(PD-1×IL-2):** IND approved

Production Capacity Expansion

- **Suzhou Wujiang production base:** A fermentation capacity of 4,500L (9*500L), completed the Pre-License Inspection (PLI) conducted by the FDA, complete EMA GMP on-site inspection; GMP certification by NMPA/FDA/EMA; responsible for the production of the commercial batches of toripalimab in the US, India and HK
- **Shanghai Lingang production base:** A production capacity of 42,000L (21*2,000L) , NMPA GMP certification
- Strictly control the quality standards, establish and continuously improve the quality audit mechanism combining internal audit and external audit.

2024 Financial Results

	FY 2024 (RMB/MN)	FY 2023 (RMB/MN)	YoY (%)
Total Operating Income	**1,948**	**1,503**	**+29.67%**
PD-1 Domestic Sales Revenue	**1,501**	**902**	**+66%**
Total Operating Expense	**3,216**	**3,812**	**-15.64%**
Selling Expenses	**984**	**844**	**+16.60%**
R&D Expenses	**1,275**	**1,937**	**-34.18%**
Administrative Expenses	**523**	**536**	**-2.47%**
Net loss attributable to shareholders	**-1,281**	**-2,283**	**/**
Net loss attributable to the shareholders after deducting non-recurring profit and loss	**-1,290**	**-2,298**	**/**

*The audited financial data is prepared in accordance with the Chinese Accounting Standards(CAS).

Key Projects Entering the Clinical R&D Stage (As of 27 March 2025)

Phase I/II		Phase III	Approval for marketing
JS213 PD-1×IL2	**JS207** PD-1×VEGF	**Tifcemalimab** BTLA	**Toripalimab** PD-1
JS212 EGFR×HER3 ADC	**JS015** DKK1	**JS001sc** PD-1	**Adalimumab** TNF-α
JS006 TIGIT	**JS107** Claudin18.2 ADC	**JS005** IL-17A	**Deuremidevir Hydrobromide Tablets** RdRp
JS007 CTLA-4	**JS203** CD3×CD20		**Ongericimab** PCSK9
JS009 CD112R	**JS105** PI3K-α		
JS112 Aurora A	**JS110** XPO1		
JS214 VEGF×TGF-β	**JS111** EGFR exon 20		
JS010 CGRP	**JS125** HDACs		
UBP1213sc BLyS	**JT002** small nucleic acid immunomodulator		
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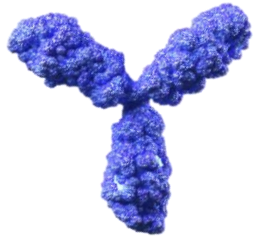
- Oncology
- Metabolism
- Immunology
- Neurologic
- Infectious disease

Broad Technology Platforms

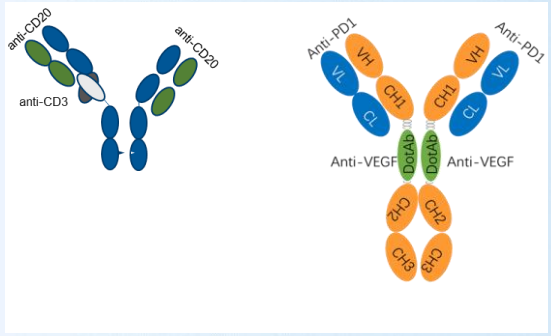
50+ Drug Candidates

mAbs



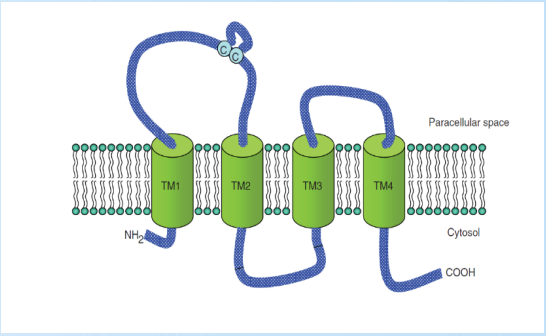
Oncology: Toripalimab (PD-1), Tifcemalimab (BTLA) …; **Immunology:** Adalimumab (TNF-α), JS005 (IL-17A)…; **Metabolism:** Ongericimab (PCSK9); **Infectious disease:** Etesevimab (S protein)

BsAbs



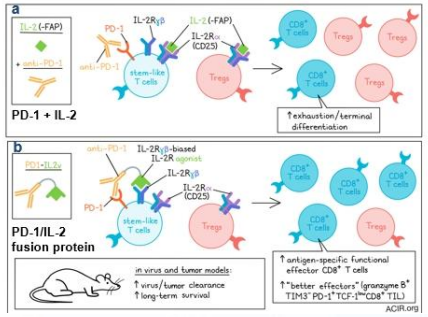
Oncology: JS203(CD20xCD3), JS207(PD-1xVEGF)…

ADCs



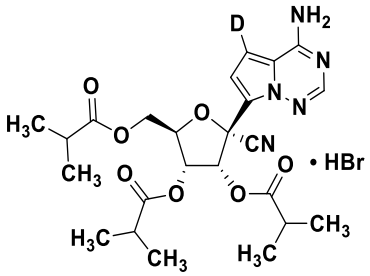
Oncology: JS107 (Claudin18.2 ADC)…

Fusion Proteins



Oncology: JS213 (PD-1×IL-2)

Small Molecules

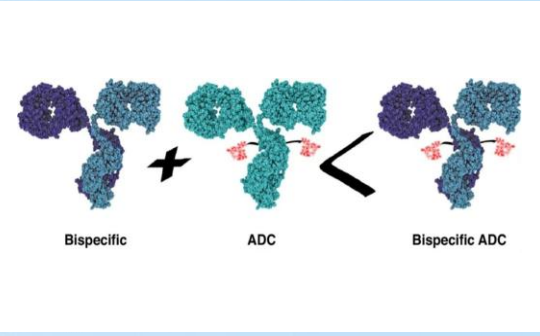


Oncology: JS105(PI3K-α), JS110(XPO1), JS111 (EGFR exon 20)…; **Infectious disease:** Deuremidevir Hydrobromide Tablets (RdRp)

Nucleic Acid Drugs

Metabolism: JS401(ANGPTL3 siRNA), JT002（IAMA-001 Nasal Spray)

BsADC



Oncology : JS212（EGFR×HER3 BsADC）

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Immuno-Oncology Backbone: Toripalimab

Our mission is to provide patients with treatment options that work better and cost less.

FDA Approval for Marketing of Toripalimab

On October 27, 2023, the FDA approval of LOQTORZI® (toripalimab-tpzi) for the treatment for R/M NPC.

On January 2, 2024, Coherus announced the commercial launch of toripalimab in the US.

- The FDA approves LOQTORZI® in **All Lines** of treatment for recurrent or metastatic nasopharyngeal carcinoma:
  - In combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced nasopharyngeal carcinoma,
  - As a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

- ***1st*** *innovative biological drug independently developed and manufactured in China approved for marketing by the FDA*
- ***1st and only*** *drug approved in US for the treatment of NPC*
- Only preferred regimen recommended for the comprehensive treatment of recurrent or metastatic NPC in the ***NCCN guidelines***

EU Approval for Marketing of Toripalimab

- In September 2024, toripalimab （EU trade name：LOQTORZI®）was approved by European Commission (EU) for two indications:

  In combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic **NPC**;

  in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic **ESCC**.

- The approval is applicable to all 27 member states of the European Union, Iceland, Norway and Liechtenstein

- Following China and the United States, the global marketing layout of Toripalimab has officially expanded to Europe.

- **EU 1st and only drug approved for NPC**

- **EU the only drug for first-line treatment of advanced or metastatic ESCC regardless of PD-L1 status**

Pivotal registrational clinical trial layout of Toripalimab

Exclusive or domestic leading indications of the Company

Approved countries or regions

Postoperative Adjuvant/Perioperative

- **GC Postoperative Adjuvant**
  Chemo Combo vs Chemo
- **HCC Postoperative Adjuvant**
  Mono vs Placebo
- NRDL **NSCLC Perioperative**
  Chemo Combo vs Chemo
- **ESCC Perioperative**
  Chemo Combo vs Chemo

Consolidation

- **SCLC Consolidation treatment after Chemoradiotherapy**
  Placebo vs Mono vs BTLA Combo

First Line

- NRDL **NSCLC EGFR(-)**
  Chemo Combo vs Chemo
- **NSCLC EGFR(+)**
  Chemo Combo vs Chemo
- NRDL **TNBC**
  Combo with Albumin-bound paclitaxel vs Albumin-bound paclitaxel
- NRDL **SCLC**
  Chemo Combo vs Chemo
- NRDL **RCC**
  Combo with axitinib vs sunitinib
- **ICC**
  Combo with lenvatinib & chemo vs Chemo

≥ Second Line

- **UC**
  Combo with disitamab vedotin vs Chemo
- NDA Accepted **Melanoma**
  Mono vs dacarbazine
- NRDL **NPC**
  Chemo Combo vs Chemo
- NRDL **ESCC**
  Chemo Combo vs Chemo
- Approval **HCC**
  Combo with bevacizumab vs sorafenib
- **HCC**
  Combo with lenvatinib vs lenvatinib

≥ Second Line

- **anti-PD-(L)1 monoclonal antibody refractory cHL**
  chemo vs BTLA Combo
- NRDL **Melanoma**
  Mono single arm
- NRDL **NPC**
  Mono single arm
- NRDL **UC**
  Mono single arm

Clinical Data of Toripalimab for the Treatment of Melanoma

Data* of Toripalimab Pivotal Trial

17.3% ORR, 57.5% DCR
Median OS reached 20.0 months

Registration trial in 128 patients with metastatic melanoma, 3mg/Kg, Q2W

Best Overall Response	n=127
Objective Response Rate, ORR %	**17.3%**
(95% CI)	(11.2, 25.0)
Disease Control Rate, DCR %	**57.5%**
(95% CI)	(48.4. 66.2)
Complete Response rate, CR % (n)	0.78% (1)
Partial Response rate, PR % (n)	16.5% (21)
Stable Disease rate, SD % (n)	40.2% (51)

Duration of Response, DoR	N=127
Median (months) (95%CI)	15.6 (3.7, 64.5+)
DoR range (months)	3.7 to 14.79+
% with duration ≥6 months	90.15%
% with duration ≥12 months	83.71%

Progression Free Survival, PFS	N=127
Median (months) (95% CI)	3.5 (2.2, 5.3)
PFS rate at 6 months %	36.2%
PFS rate at 12 months %	29.9%

Overall Survival, OS	N=127
Median (months) (95% CI)	22.0 (15.3, 32.5)
OS rate at 12 months %	31.7%
OS rate at 60 months %	28.5%

*Data from Toripalimab Prescription Information, 2021 ASCO #e21522, and The Oncologist

- On December 17, 2018, toripalimab obtained approval from the NMPA for the second-line treatment of unresectable or metastatic melanoma.
- Toripalimab was included in the Guidelines of CSCO for the Diagnosis and Treatment of Melanoma.
- In December 2020, toripalimab was included in Category B of the National Drug List for Basic Medical Insurance (NRDL).
- In January 2025, The indication for toripalimab as the treatment for unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.

Toripalimab for recurrent / metastatic nasopharyngeal carcinoma

- In Sep 2020, toripalimab for the treatment of nasopharyngeal carcinoma received the FDA's **Breakthrough Therapy Designation**.
- In Feb 2021, the sNDA for toripalimab as a treatment for patients with recurrent/metastatic NPC who failed at least two lines of systemic therapy was approved by the **NMPA**. This is the **world's first** NDA of anti-PD-1 mAb for the treatment of NPC. (*Included in the NRDL*)
- Appoved in US (Oct 2023), Hong Kong SAR (Oct 2024), India (Sep 2024), Jordan (Nov 2024), Australia (Jan 2025) for all lines of treatment for recurrent/metastatic NPC.

POLARIS-02 study is a multi-center, open-label, Phase II pivotal registrational clinical. The study enrolled a total of 190 patients with recurrent or metastatic NPC after failure of prior systemic therapy, which is the world' s largest clinical study for any immune checkpoint inhibitor monotherapy for the treatment of recurrent or metastatic NPC.

In 92 patients with recurrent/metastatic NPC after failure of at least two lines of prior systemic chemotherapy, the objective response rate (ORR) was 23.9%; the median duration of response (mDOR) 14.9 months; and the median overall survival (mOS) 15.1 months.

- In Jan 2021, the results of the POLARIS-02 study were published online in the *Journal of Clinical Oncology*.

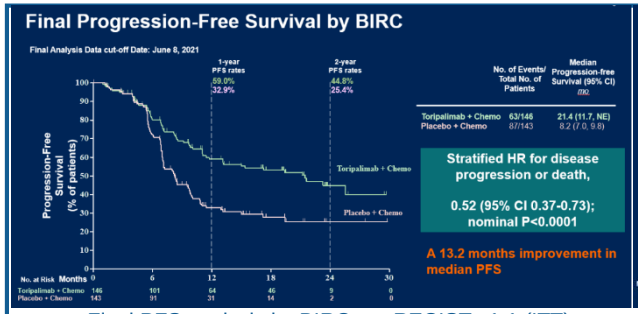
Feng-Hua Wang, etal. Efficacy, Safety, and Correlative Biomarkers of Toripalimab in Previously Treated Recurrent or Metastatic Nasopharyngeal Carcinoma: A Phase II Clinical Trial (POLARIS-02). Journal of Clinical Oncology. 2021. DOI: 10.1200/JCO.20.02712.

Toripalimab in 1L NPC

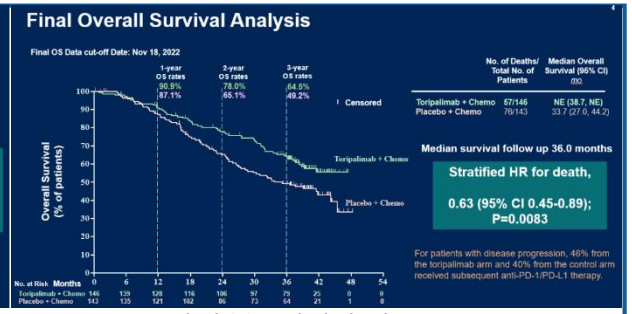
- In Aug 2021, toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma received the **FDA's Breakthrough Therapy Designation.**
- In Nov 2021, the sNDA of toripalimab in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC was approved by the NMPA. (*Included in the NRDL*)
- Appoved in US (Oct 2023), Hong Kong SAR (Oct 2024), India (Sep 2024), Jordan (Nov 2024), Australia (Jan 2025) for all lines of treatment for recurrent/metastatic NPC.
- Approved in EU (Sep 2024), UK (Nov 2024) and Singapore (Mar 2025) for the 1st-line treatment of advanced NPC.

JUPITER-02, conducted in mainland China, Taiwan and Singapore, is the largest Phase 3 clinical study to evaluate a checkpoint inhibitor plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma. The study enrolled 289 patients with advanced NPC who had received no prior chemotherapy for recurrent/metastatic disease. The addition of toripalimab to chemotherapy as first-line treatment provided superior PFS and ORR and longer DoR than chemotherapy alone.

- Jun 2021, presented as LBA at ASCO 2021 plenary session
- Sep 2021, published as cover article at *Nature Medicine*, (IF: 82.9)
- Apr 2022, published final PFS analysis data at **AACR 2022**
- Jun 2023, published final OS analysis data at **ASCO 2023**
- Nov 2023, published final OS analysis date at **JAMA**
- Jun 2024, published long-term survival follow-up data at **ASCO 2024**



Final PFS analysis by BIRC per RECIST v1.1 (ITT)



Final OS analysis (ITT)

❑ **Efficacy**

- Significant improvement in PFS: mPFS 21.4 vs. 8.2 months
- mOS: NE vs. 33.7 months, HR=0.63 (95% CI: 0.45-0.89), P=0.0083); 2-year OS rates 78.0% vs 65.1%; 3-year OS rates 64.5% vs 49.2%
- The improvements of PFS in the toripalimab arm were observed across key subgroups, including all PD-L1 expression subgroups
- OS was improved in the toripalimab arm regardless of PD-L1 expression status
- ORR 78.8% vs. 67.1%; mDoR 18.0 vs. 6.0 months
- 5-year survival rate : 52%

❑ **Safety**

- No new safety signals were identified with toripalimab added to GP

ASCO 2023
Mai, HQ., Chen, QY., Chen, D. *et al.* Toripalimab or placebo plus chemotherapy as first-line treatment in advanced nasopharyngeal carcinoma: a multicenter randomized phase 3 trial. *Nat Med* **27**, 1536–1543 (2021).
Mai H, Chen Q, Chen D, et al. Toripalimab Plus Chemotherapy for Recurrent or Metastatic Nasopharyngeal Carcinoma: The JUPITER-02 Randomized Clinical Trial. *JAMA*. 2023;330(20):1961–1970.

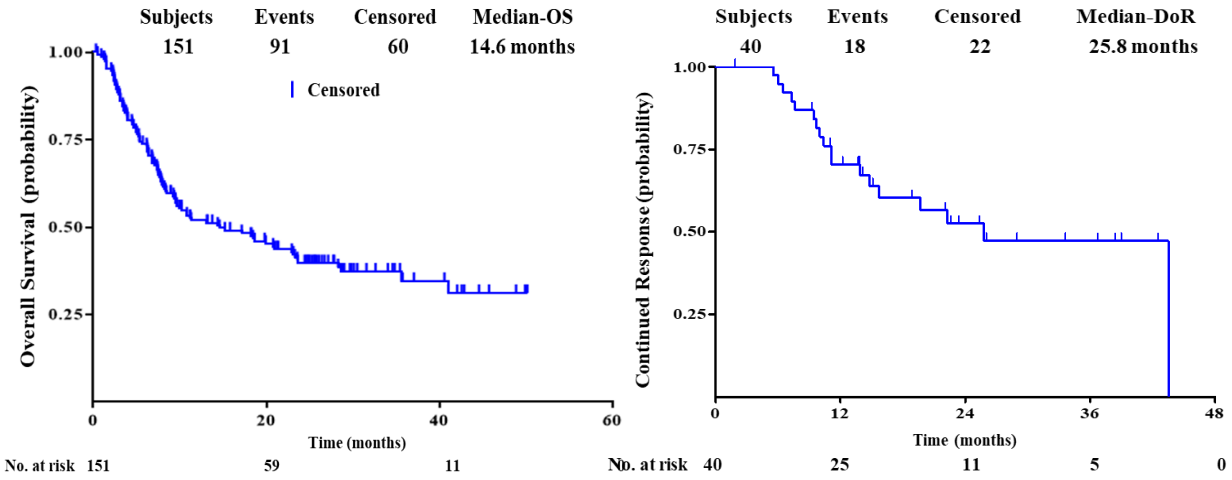
Toripalimab in UC

- **In April 2021, the sNDA of toripalimab was granted conditional approval** for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy . (*Included in the NRDL*)
- POLARIS-03 (NCT03113266) is a multi-center, open-label, phase II registration study, designed to evaluate safety and efficacy of toripalimab in advanced UC patients who have failed prior systemic treatment.

Efficacy and Safety

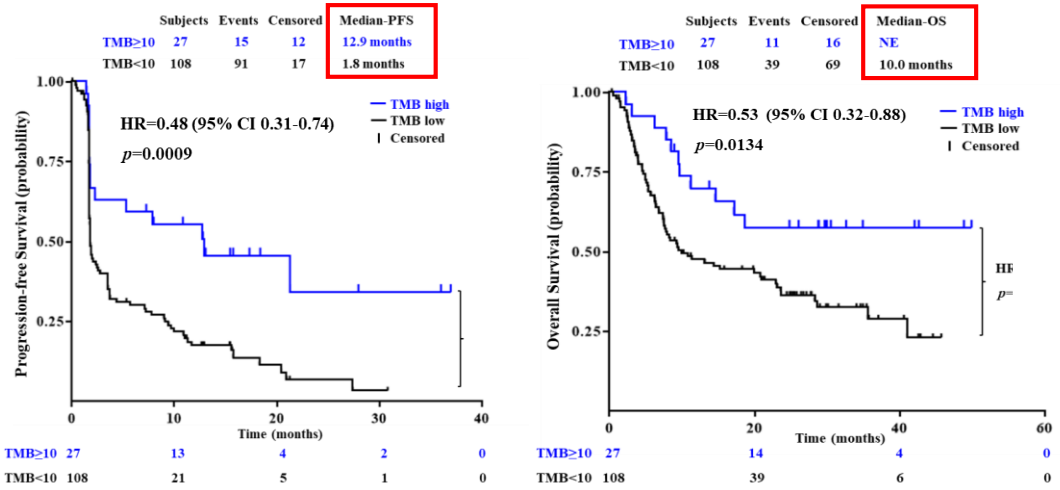
As of 8 Sep. 2021, among the ITT population (n=151):

- **The ORR was 26.5%** (incl. 3 CR, 37 PR and 28 SD); **DCR** was 45.0%; **mDoR** was 25.8 months
- **mPFS was 2.3 months**; **mOS was 14.6 months**
  - Among PD-L1+ population (n=48), the ORR was 41.7%; mDoR was not reached
- **No new safety signal** was observed in this 2-year follow-up.



Biomarkers Analysis Results

- **According to the WES analysis**, mutations in SMARCA4/ PBRM1 or tumor suppressor RB1 or FGFR2/FGFR3 mutations or gene fusions, and NECTIN4 genomic alternations were favorable for patients to response to toripalimab.



Toripalimab in 1L ESCC

- In November 2021, the FDA granted **Orphan Drug Designation** for toripalimab for the treatment of esophageal cancer.
- In May 2022, the NMPA approved the sNDA for toripalimab in combination with paclitaxel and cisplatin in the first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma (ESCC). (*Included in the NRDL*)
- The European Commission (Sep 2024) and MHRA (Nov 2024) approved toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC

JUPITER-06: A randomized, double-blind, Phase 3 clinical trial comparing the efficacy and safety of toripalimab versus placebo in combination with TP as a first-line treatment for patients with advanced or metastatic ESCC.

Toripalimab + TP chemotherapy showed superior PFS and OS over chemotherapy alone with a manageable safety profile.

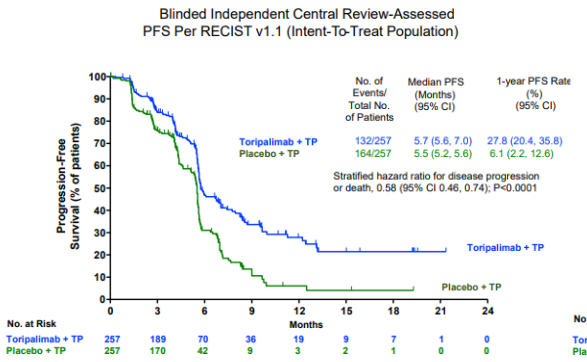
- **A statistically significant improvement in PFS** (mPFS 5.7 vs. 5.5 months) , reduced the risk of progression or deaths by 42% (HR=0.58，95% CI：0.46-0.74，P < 0.0001)

  PD-L1 expression subgroups:
  - CPS ≥ 1: 5.7 vs. 5.5 months （HR=0.58，95% CI：0.44-0.75）
  - CPS < 1: 5.7 vs. 5.6 months （HR=0.66，95% CI：0.37-1.19）

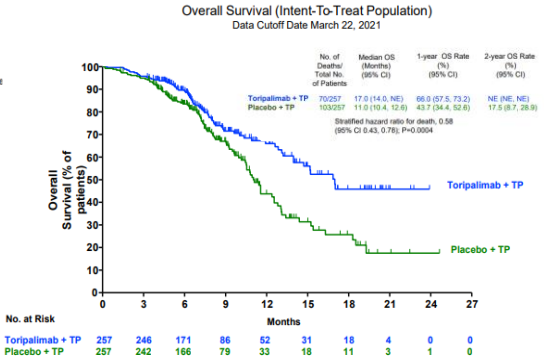
- **A significant improvement in OS** (mOS 17.0 vs. 11.0 months), reduced the risk of deaths by 42% (HR=0.58，95% CI：0.43-0.78 , P=0.0004)

- **An outperformed ORR** (69.3% vs 52.1%), increased by 17.2%.

- Sep 2021, made its debut at the **ESMO 2021**
- Mar 2022, published in **Cancer Cell** (IF: 50.3)
- Dec 2022, posthoc analysis of JUPITER-06 and meta-analysis published in **Journal of Clinical Oncology** (IF:45.3)
- Apr 2023, translational study published in **Cancer Cell** (IF: 50.3)
- Apr 2023, selected in "China 2022 Important Medical Progress"



PFS analysis by BICR per RECIST v1.1 (ITT)



OS analysis (ITT)

Wang, Z. X., Cui, C., Yao, J., Zhang, Y., Li, M., Feng, J., ... & Wang, F. (2022). Toripalimab plus chemotherapy in treatment-naïve, advanced esophageal squamous cell carcinoma (JUPITER-06): A multi-center phase 3 trial. Cancer Cell.

Toripalimab in 1L NSCLC

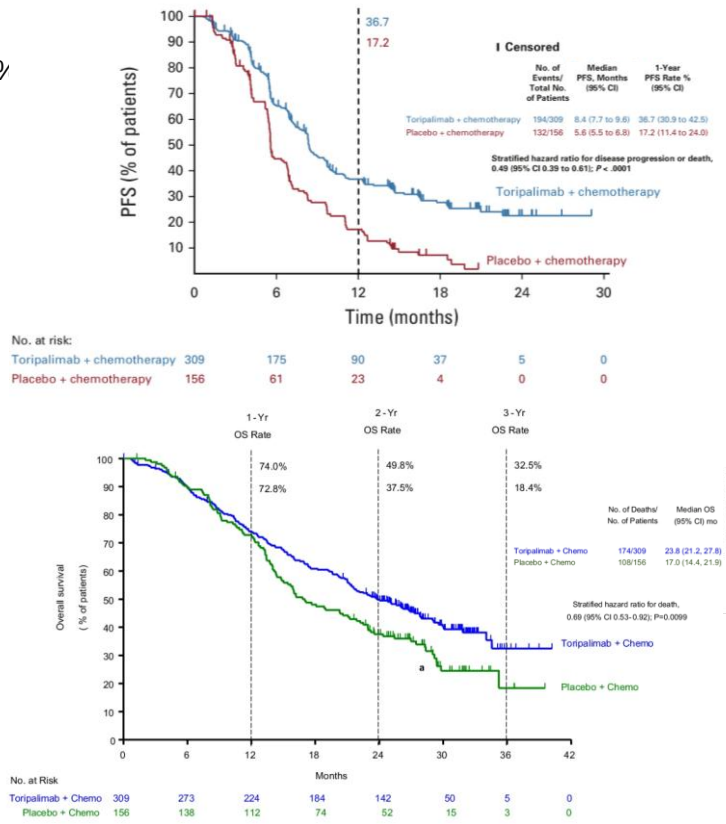
- In September 2022, **the NMPA** approved the sNDA for toripalimab in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-SQ NSCLC. (*Included in the NRDL*)
- **The CHOICE-01** study (NCT03856411) is a randomized, double-blind, placebo-controlled, multicenter, phase 3 trial. The study enrolled a total of 465 NSCLC patients in 63 centers in China, among which 245 non-SQ NSCLC patients were randomly allocated in the ratio of 2:1 to receive toripalimab/placebo in combination with pemetrexed and cisplatin/carboplatin. After disease progression, eligible control subjects could receive crossover treatment with toripalimab monotherapy.

Significant improvement in PFS

- mPFS: **8.4 vs. 5.6 months,** HR=0.49 (95% CI: 0.39, 0.61), P <0.0001
- 1-year PFS rate was more than doubled over the control arm
- PFS benefits were observed regardless of PD-L1 expression
- Non-SQ subgroups: mPFS **9.7 vs. 5.5 months,** HR=0.48 (95% CI: 0.35, 0.66), P <0.0001

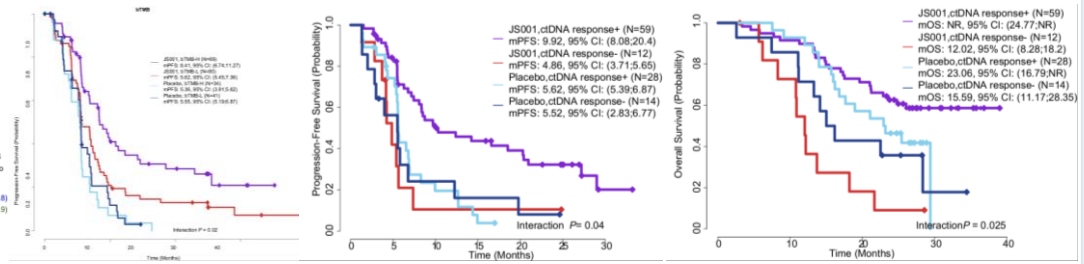
Significant improvement in OS

- mOS **23.8 vs. 17.0 months**, HR=0.69 (95% CI: 0.57-0.93), nominal P=0.01
- 3-year OS rate 32.5% vs. 18.4%
- OS benefits were observed regardless of PD-L1 expression status
- Non-SQ subgroups: mOS **27.8 vs 15.9 months**, HR=0.49 (95% CI: 0.35-0.69), P<0.001



Biomarker analysis

- Patients with mutations in the FA-PI3K-Akt pathway and IL-7 signaling pathway were associated with improved OS in the toripalimab group (interaction P=0.006, and 0.001 respectively)
- High TMB was associated with significantly longer PFS in the toripalimab group among non-squamous NSCLC patients
- Patients with reduced ctDNA levels at cycle 3, day 1 (C3D1) in the combination group exhibited significantly better PFS and OS



Safety

- No new safety concerns emerged following prolonged toripalimab exposure for up to two years
- The incidence of Grade ≥3 adverse events (AEs) and the rate of serious adverse events (SAEs) was comparable between the two groups

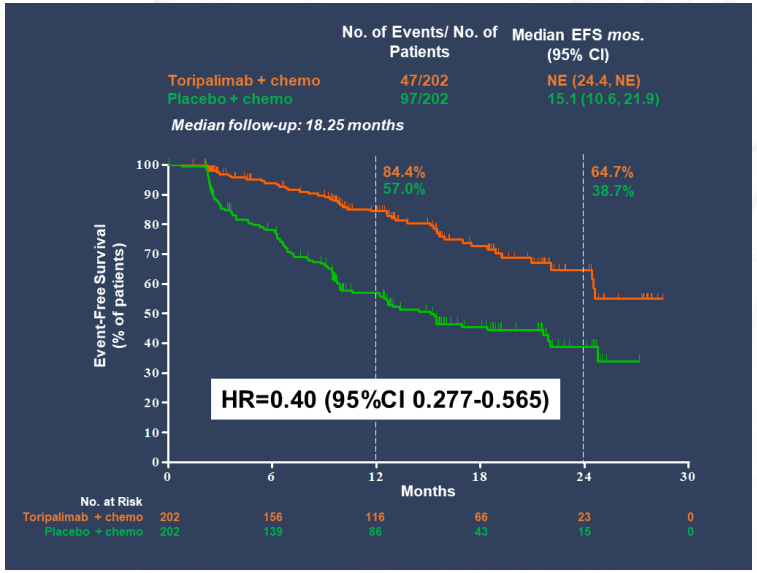
ASCO 2022, ASCO 2023
Zhijie Wang, Lin Wu, Baolan Li, et al. J Clin Oncol. 2022 Oct 7;JCO2200727.
Zhong, J, Fei, K, et al. Sig Transduct Target Ther 9, 369 (2024).

Toripalimab as perioperative treatment of resectable NSCLC

First approved perioperative therapy for lung cancer in China

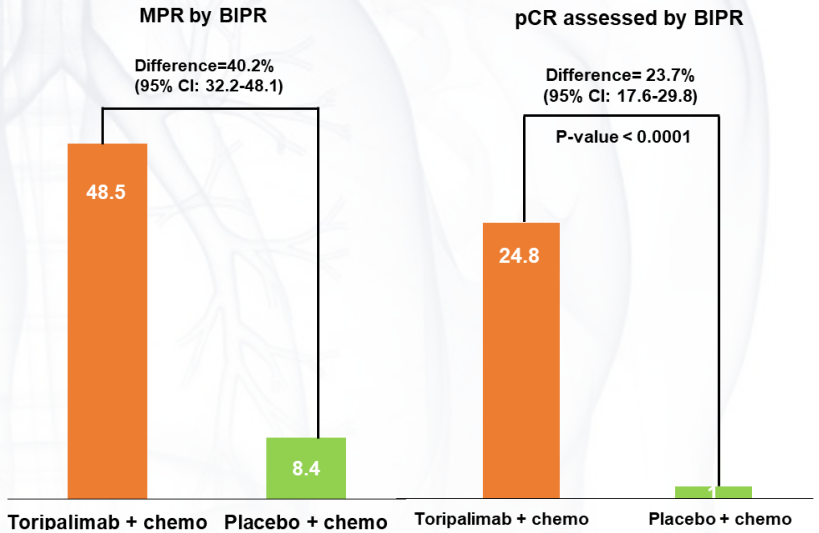
- In December 2023, the NMPA approved sNDA of toripalimab in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC *(Included in the NRDL)*
- NEOTORCH (NCT04158440) is the world' s first phase III clinical study of anti-PD-1 monoclonal antibody for NSCLC perioperative treatment (including neoadjuvant and adjuvant) with positive event-free survival (EFS) results.

Improved EFS and reduced risk of disease recurrence, progression events or death by 60%



- The treatment effects were independent of PD-L1 expression status, while the improvement in EFS was more prominent in the PD-L1 positive patients.
- Toripalimab demonstrated consistent favorable effects in both non-squamous and squamous subtypes.

The MPR and pCR rates were higher compared to the placebo arm



- The MPR rate: 48.5% vs 8.4%, P < 0.0001
- The pCR rate: 24.8% vs 1.0%, P < 0.0001

- **NEOTORCH epitomizes the success of a perioperative immunotherapy**

Study	IO stage
CheckMate-816	Neoadjuvant
Impower 010	Adjuvant
KEYNOTE-091	Adjuvant
NEOTORCH	(Neoadjuvant+Adjuvant) Perioperative

- **NEOTORCH is at the forefront of progress**

Study	Announcement of positive EFS results
NEOTORCH	2023.01.17
KEYNOTE-671	2023.03.01
AEGEAN	2023.03.09

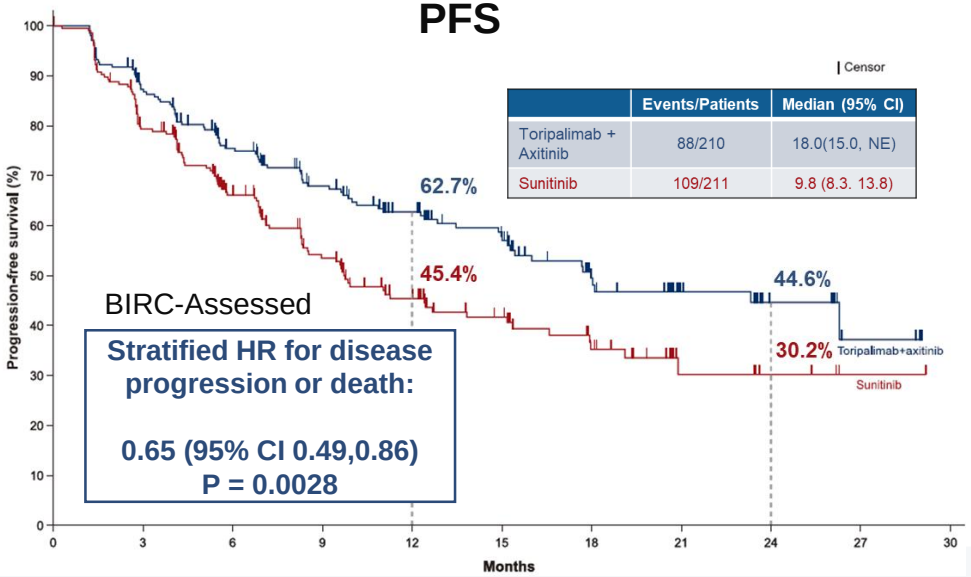
Source: ASCO 2023#8501; JAMA

Toripalimab in 1L RCC

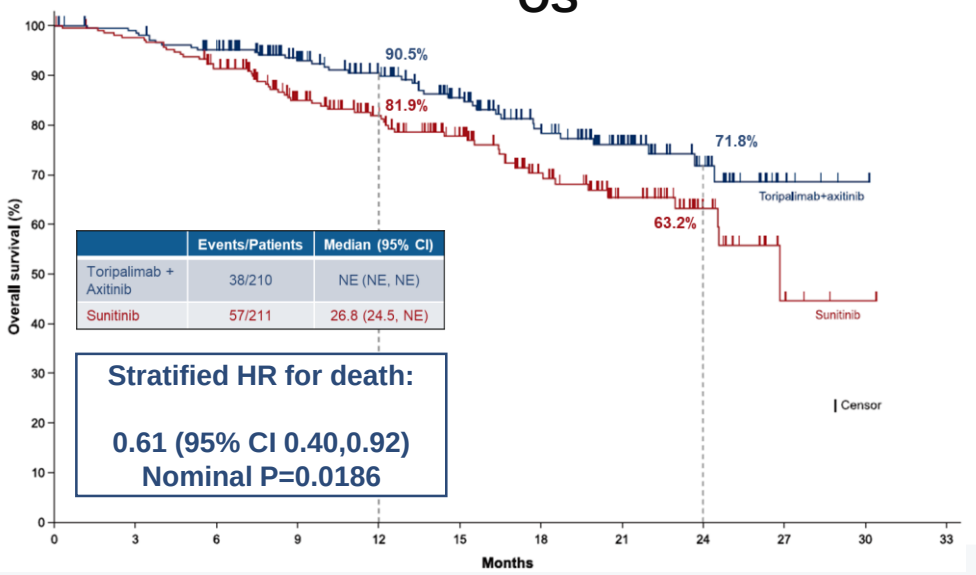
First and only approved immuno-oncology therapy for renal cancer in China

- In April 2024, the NMPA approved sNDA of toripalimab in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic renal cell carcinoma (RCC) *(Included in the NRDL).*
- RENOTORCH study (NCT04394975) is the first pivotal Phase 3 clinical study of immunotherapy for patients with advanced RCC in China.

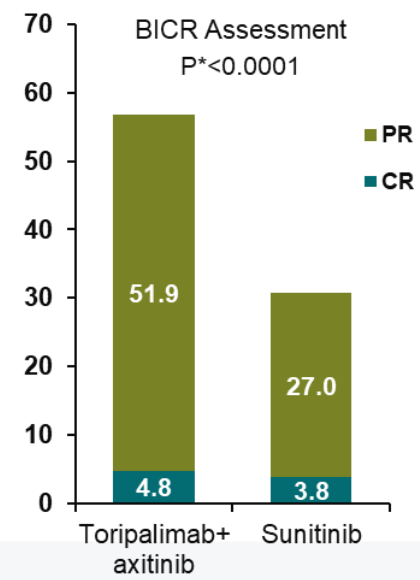
PFS



OS



ORR



- **Compared with sunitinib monotherapy, toripalimab plus axitinib treatment has shown:**
  Significantly prolonged PFS: mPFS18.0 vs. 9.8 months and reduced the risk of disease progression or death by 35% (HR=0.65). The treatment effects were observed across all evaluated subgroups.
  A trend for OS improvement: the descriptive analysis of OS shows that, mOS NE vs. 26.8 months, with a reduction of the risk of death by 39% (HR=0.61)
  Significant improvement in ORR: ORR is 56.7% vs. 30.8% (P<0.0001)

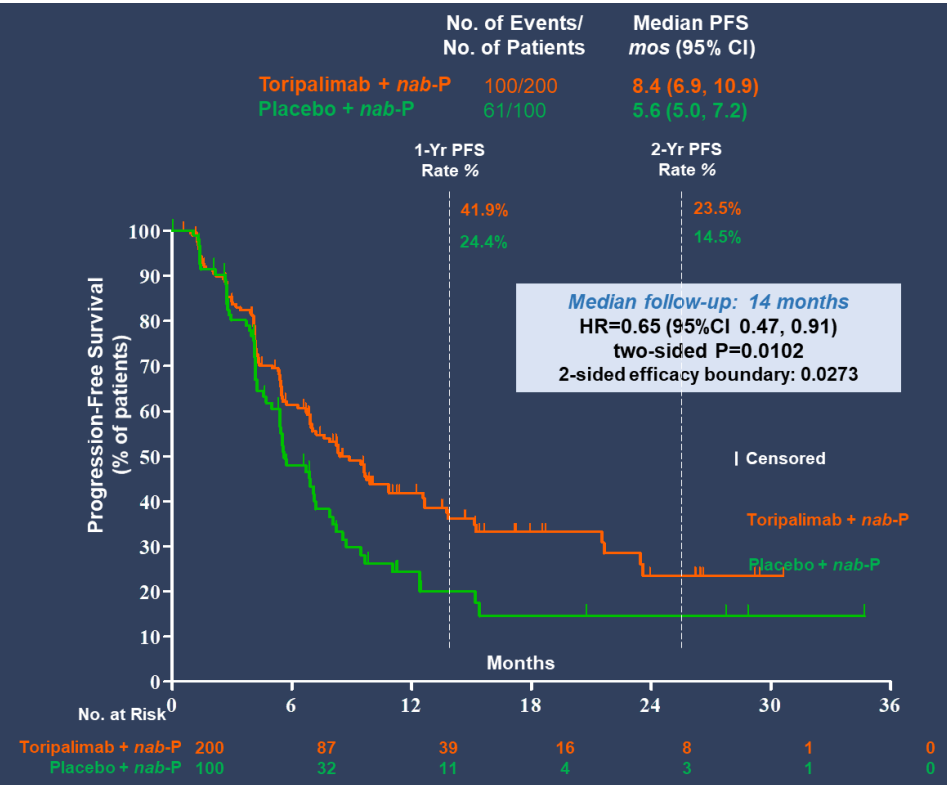
- **Toripalimab + axitinib group had a manageable safety profile with no new safety signal identified.**

Source: ESMO 2023, Annals of Oncology, *P value calculated using Cochran-Mantel-Haenszel method. Data cut-off date: March 31, 2023

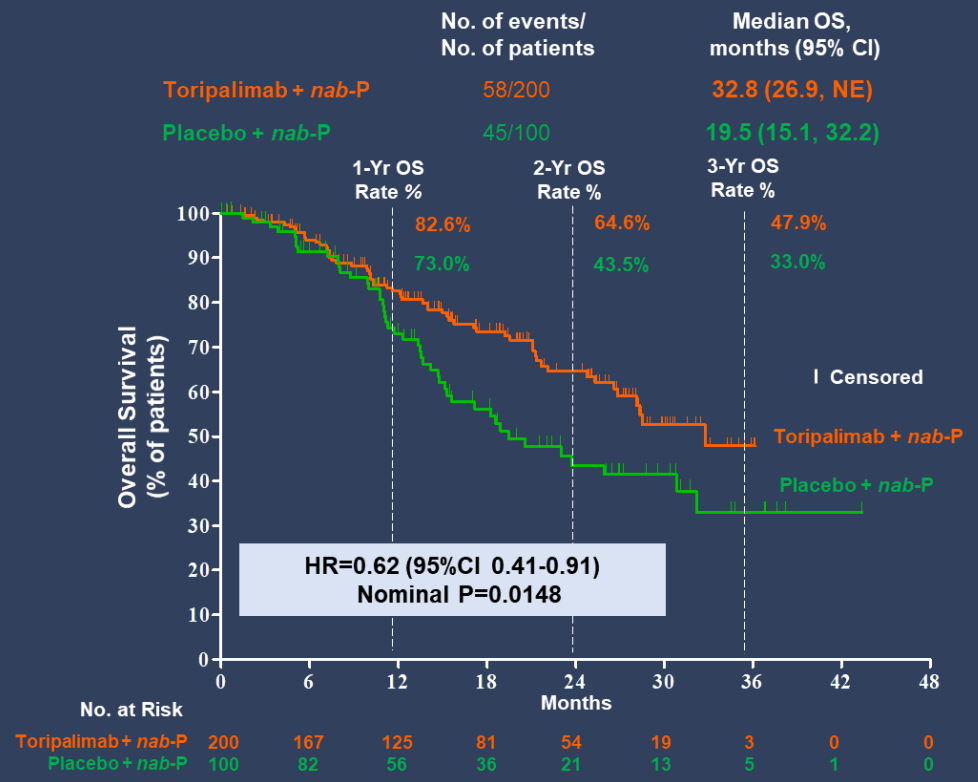
Toripalimab in 1L TNBC

First and only approved immuno-oncology therapy for TNBC in China

- In June 2024, the NMPA approved sNDA of toripalimab in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC *(Included in the NRDL)*.
- TORCHLIGHT study (NCT04085276) is the first Phase 3 registration study in China to achieve a positive outcome in advanced TNBC.



A Statistically significant and clinically meaningful improvement in PFS



A trend towards improved OS

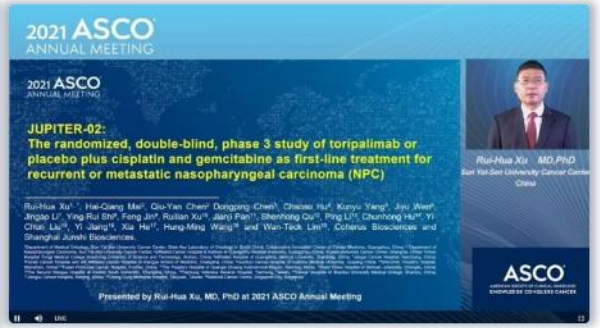
- Median PFS In PD-L1 positive (CPS≥1) metastatic or recurrent TNBC patients: 8.4 vs. 5.6 months, **35% reduction in risk of disease progression or death**
- Median OS in PD-L1 positive subgroup: **32.8** vs. 19.5 months

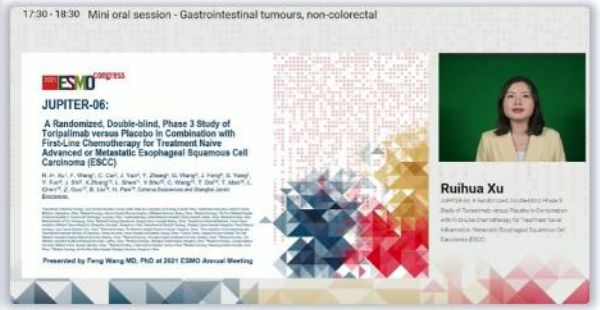
Source: ASCO 2023#LBA1013; Nature Medicine

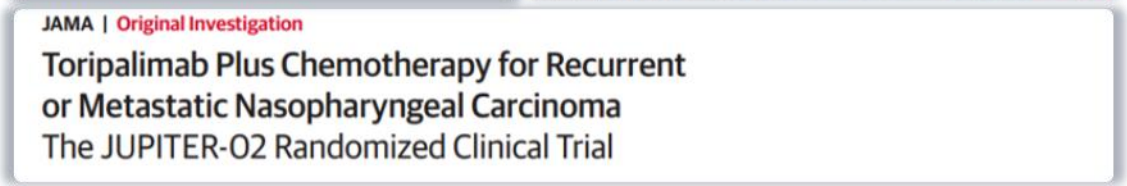
Pursue More Registration Opportunities Worldwide

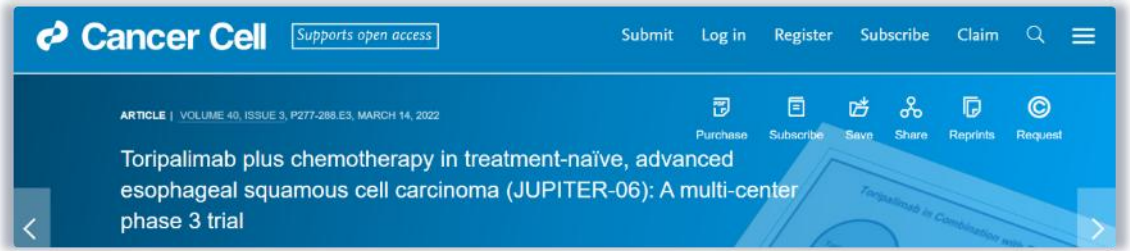
- ***Based on the excellent improvement of survival of toripalimab for the treatments of patients with NPC and ESCC***

- ***Marketing applications have been:***
  - ✓ *Approved in US, EU (all 27 member states, Iceland, Norway and Liechtenstein), India, Hong Kong SAR, Jordan, UK, Australia and Singapore.*
  - ✓ *Submitted/ under review in Brazil, Colombia, South Africa, Chile, Malaysia, Thailand, Indonesia, Philippines, Vietnam, Canada, Pakistan, United Arab Emirates, Morocco, Kuwait, etc.*









1. JUPITER-02: is the first international multi-center Phase III trial to prove the addition of toripalimab to GP as a first-line treatment for r/m NPC patients provided superior PFS and OS than GP alone.
2. JUPITER-06: A randomized, double-blind, Phase 3 clinical trial comparing the efficacy and safety of toripalimab versus placebo in combination with TP as a first-line treatment for patients with advanced or metastatic ESCC.

International Collaboration

Coherus BioSciences
Apotex

US and Canada

- Payments of up to an aggregate of US$1.11 billion
- 20% royalty on annual net sales

LEO Pharma

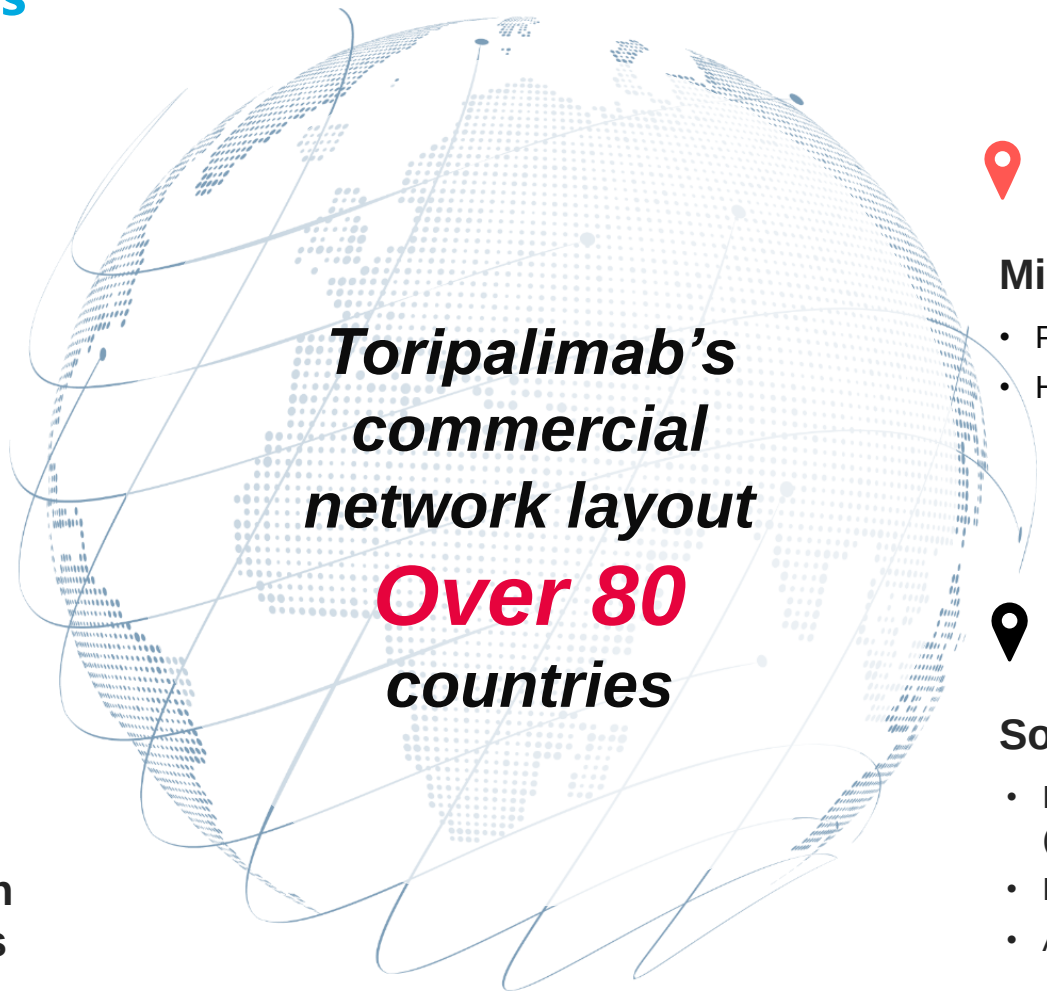
Europe

- Distribution, promotion, sales, etc., in up to 32 countries
- Revenue share of a double-digit percentage on the net sales

Dr. Reddy's

Latin America, India, South Africa, and other countries

- Payments of up to an aggregate of US$728.3 million
- Double-digit percentage of royalties on the net sales



Hikma

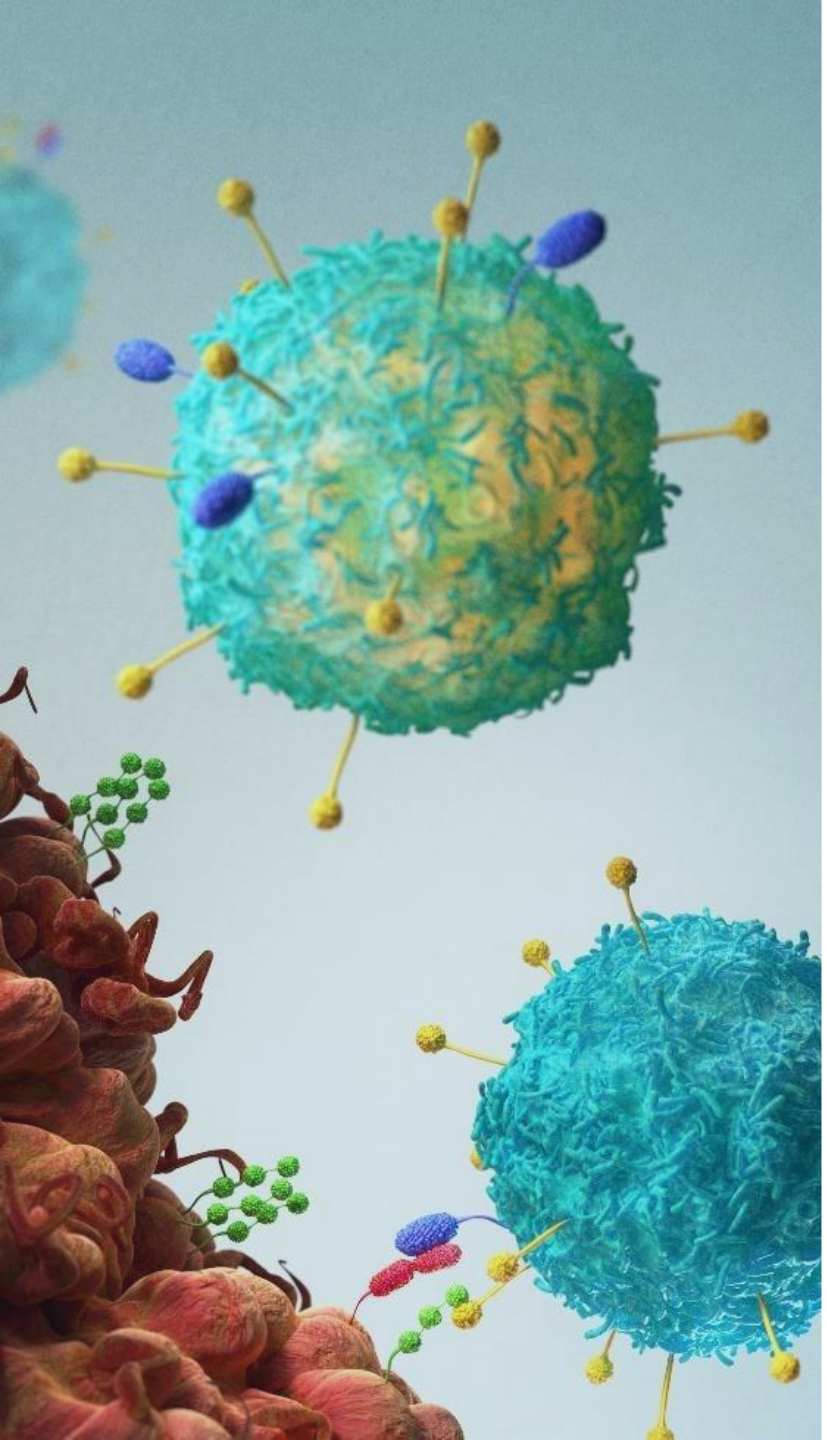
Middle East and North Africa region

- Payments of up to an aggregate of US$12 million
- High-teen tiered royalties of up to 20% of net sales

Rxilient Biotech

Southeast Asia

- Establishment of JV company Excellmab (Junshi owns 40% equity)
- Milestone payment of up to US$4.52 million
- A certain percentage of royalties on net sales

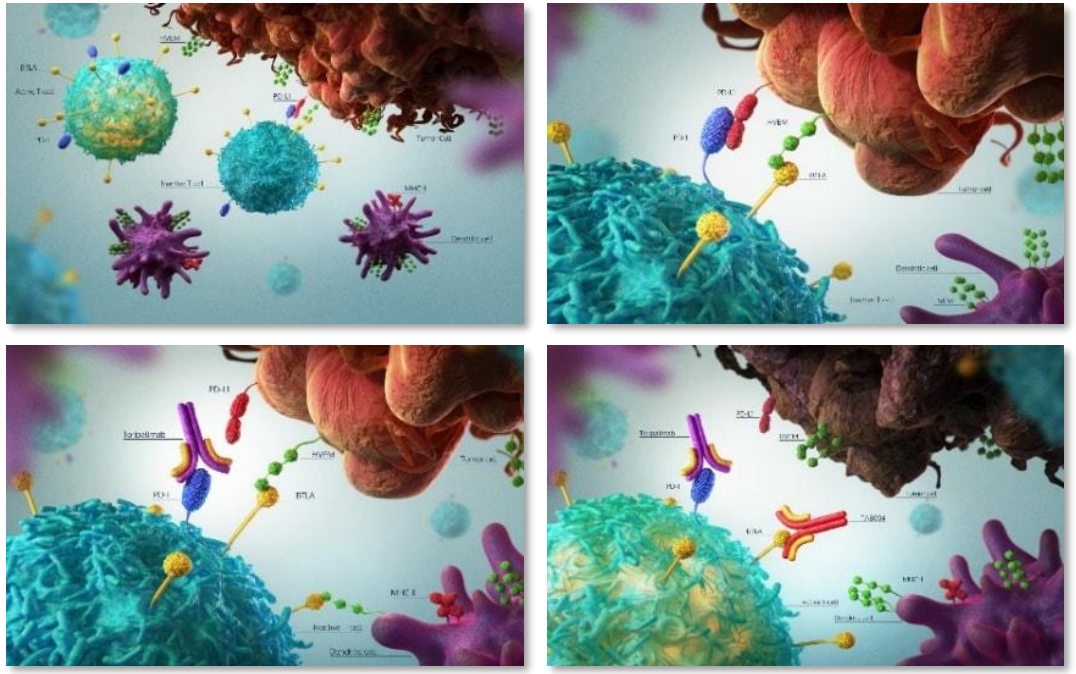


君实生物
TopAlliance

Promising Candidates in Cancer Therapy

Our mission is to provide patients with treatment options that work better and cost less.

Tifcemalimab (TAB004/JS004): MRCT Ph3 is underway



- PD-1 like molecule expressed on activated T and B cells
- BTLA is co-expressed on the surface of activated lymphocytes (B and T cells) with PD-1
- HVEM (ligand on tumor cell) suppresses T-cell proliferation and cytokine release – ***Negative Signalling***
- Tumor expression of HVEM has been associated with poor prognosis and immune escape
- BTLA blockade promotes antigen-specific T cell response and works synergistically with toripalimab (anti-PD-1)

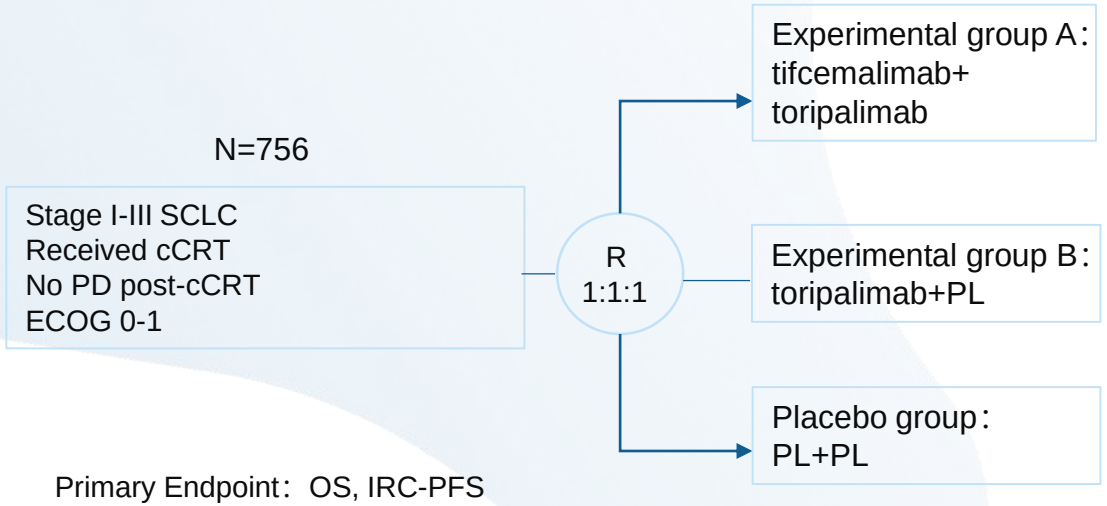
- A phase III study of tifcemalimab in combination with toripalimab as consolidation therapy in patients with LS-SCLC without disease progression following chemo-radiotherapy is being conducted. As the first confirmatory study of anti-BTLA monoclonal antibody, this study is to be carried out in more than 190 research centers in 17 countries and regions around the world and will recruit about 756 subjects. The study has been conducted in more than 150 centers in 15 countries, and enrollment is ongoing.
- As the first phase III study of BTLA-targeted drugs in the hematological neoplasms, tifcemalimab in combination with toripalimab for the treatment of refractory classical Hodgkin lymphoma is designed to evaluate the efficacy and safety of tifcemalimab combined with toripalimab versus investigator-selected chemotherapy in patients with refractory cHL who have failed anti-PD-(L)1 monoclonal antibody therapy. The study will be conducted at approximately 60 sites in China and will enroll approximately 185 patients, and enrollment is ongoing.
- In addition, several phase Ib/II clinical studies of tifcemalimab in combination with toripalimab against multiple types of tumors are underway in China and the US.

Tifcemalimab: Ph3 Clinical Trials Overview

Indications	Drugs	Pre-Clinical	Phase I	Phase II	Phase III	Locations
Limited stage small cell lung cancer	tifcemalimab+toripalimab					International multi-center
Classic Hodgkin Lymphoma	tifcemalimab+toripalimab					China

JUSTAR-001

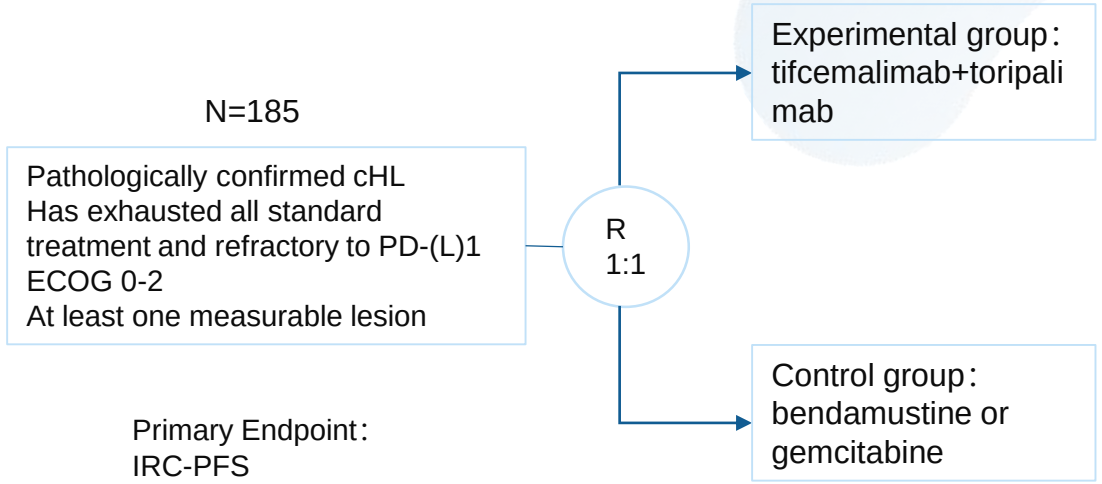
Planned to be carried out in more than 190 research centers in over 17 countries.
Enrollment is underway.



Primary Endpoint: OS, IRC-PFS

JS004-III-cHL

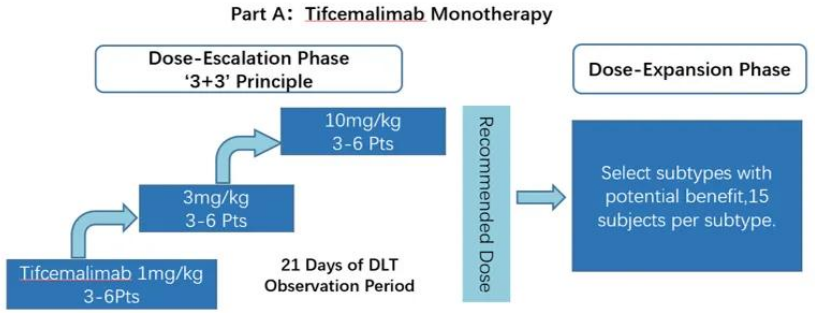
Planned to be carried out in more than 60 research centers in China.
Enrollment is underway.



Primary Endpoint:
IRC-PFS

Tifcemalimab in R/R Lymphomas: Monotherapy/Combo with Toripalimab

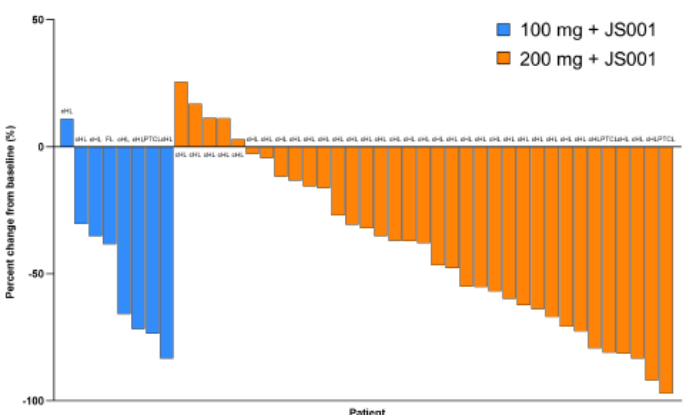
By the cutoff date of July 19, 2023, a total of 71 patients were enrolled, including 25 in part A (mono) and 46 in part B (combo). The median prior treatment lines were 4 in part A and 3 in part B. 54 (76%) progressed upon prior anti-PD-1/L1 therapy with 13 in part A and 41 in part B.



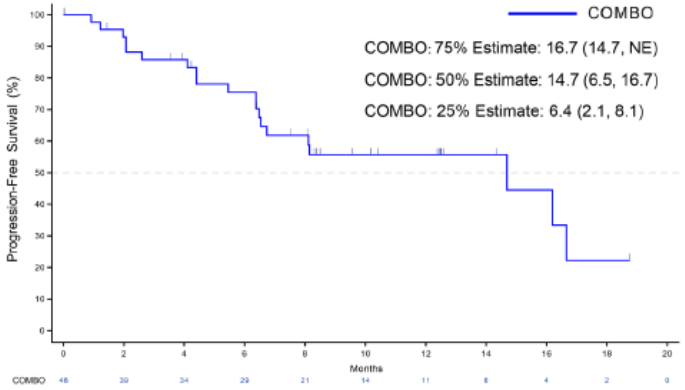
DLT, dose-limiting toxicity; Pt, patient.

Results

- As of July 19, 2023, the median follow-up time was 57 weeks.
- **Among 25 patients receiving the monotherapy**, 1 PR (follicular lymphoma) and 7 SD were observed; the median progression- free survival (PFS) was 2.1 months.
- **Among 46 patients receiving combination therapy,** 1 CR, 16 PR (ORR 37.0%), and 20 SD (DCR 80.4%) were observed and the estimated median PFS was 14.7 months.
- Among 34 cHL patients receiving the RP2D, all of them were heavily treated with anti-PD-1/L1 antibodies, 12 PR (ORR 35.3%) and 17 SD (DCR 85.3%) were observed and an estimated median PFS was 16.2 months.
- No DLT was observed in either monotherapy or combination dose escalation cohort.



Best response of target lesion(s) in Combo



Progression-free survival status in Combo

NCT04477772 is a multi-center, open-label, dose-escalation and dose-expansion Phase I clinical study aimed at evaluating the efficacy and safety of tifcemalimab monotherapy or in combination with toripalimab in patients with relapsed/refractory lymphoma. Source: ASH 2023.

Tifcemalimab in 1L ES-SCLC: Combination with toripalimab and chemotherapy achieved an ORR of 86.0% and a DCR of 100%

- Phase Ib/II study：evaluate the safety and efficacy of tifcemalimab combined with toripalimab and chemotherapy **as a 1st line treatment for patients with advanced lung cancer.**

- As of March 26 2024, 44 patients were enrolled, the median age of the patients was 65.5 (range 48-73) years, and 84.1% (37/44) were males.

Cohort 5

- Aged ≥18 years
- Pathologically confirmed ES-SCLC
- ECOG PS of 0-1
- Without previous systemic anti-tumor therapy for ES-SCLC
- Adequate organ function

↓

Part A: safety run-in phase

Tifcemalimab 200 mg IV Q3W + Toripalimab 240 mg IV Q3W + EP chemotherapy*, Q3W

↓

Part B: extension phase

Tifcemalimab 200 mg IV Q3W + Toripalimab 240 mg IV Q3W + EP chemotherapy*, Q3W, for 4 cycles

↓

Part C: maintenance therapy phase

Tifcemalimab 200 mg IV Q3W + Toripalimab 240 mg IV Q3W, until disease progression, intolerable toxicity, or completion of 2 years treatment

* Etoposide d1-3, 100 mg/m² + carboplatin d1, AUC=5 or cisplatin d1, 75 mg/m²

Results

- As of March 26 2024, the median follow-up duration was 4.2 months.
- Among the 43 evaluable patients, the ORR, DCR and median DoR of tifcemalimab combined with toripalimab and chemotherapy were 86.0%, 100%, and 4.3 months, respectively.
- Median PFS and OS were 5.4 (95% CI 4.2, 7.5) months and NE (95% CI 7.5, NE),respectively.

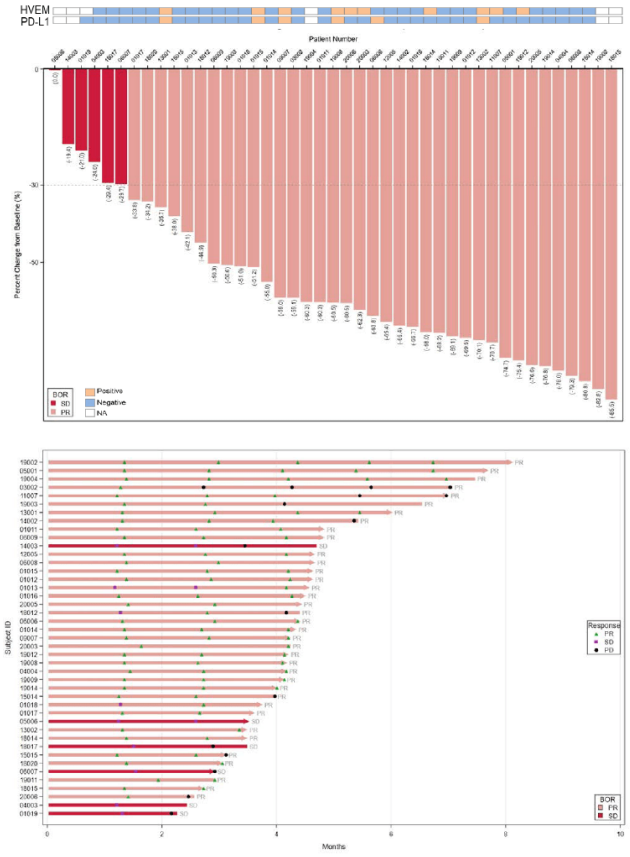


Figure 4. KM plot of PFS

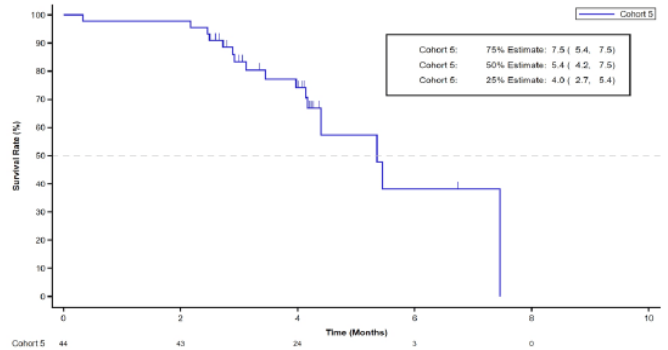
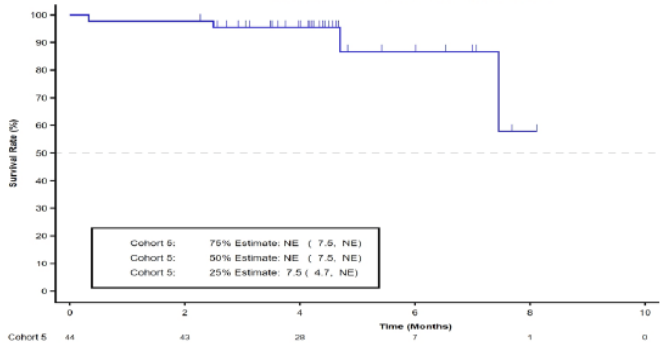


Figure 5. KM plot of OS



Source: ASCO 2024#8089

JS207：PD-1 x VEGF Bispecific Antibody

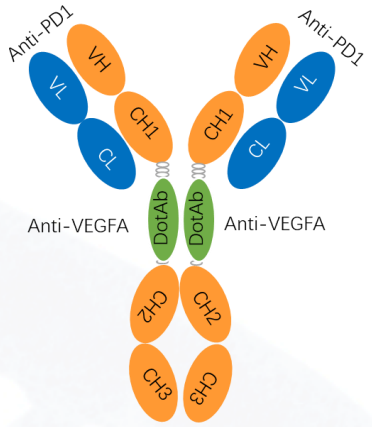
Rationale & Mechanism of Action

- Given the strong correlation between VEGF-A and PD-1 expression in the TME, the simultaneous blockade of these 2 targets by JS207 as a single agent might achieve higher target binding specificity and produce enhanced antitumor activity, with an improved safety profile, compared to the combo therapy.
- Blocking PD-1/PD-L1 interaction can activate cytotoxic T lymphocytes.
- Neutralizing VEGF can inhibit the proliferation of vascular endothelial cells, improve the tumor microenvironment, and increase the infiltration of cytotoxic T lymphocytes in the tumor microenvironment.
- Synergistic effect of anti-angiogenesis and ICB.

Differentiations from competitor compounds

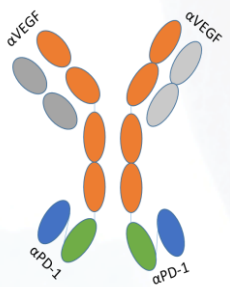
- JS207 is engineered on the backbone of toripalimab, a clinically validated and differentiated anti-PD-1 with global approvals.
- The anti-PD-1 portion of JS207 has a Fab structure rather than a scFv in AK112 (Akesobio & Summit Therapeutics), to maintain its binding affinity to PD-1 to provide tumor microenvironment targeting.
- The anti-VEGF has a similar binding affinity to human VEGF as bevacizumab, with similar anti-tumor efficacy in animal models.
- The structure of JS207 resembles a traditional monoclonal antibody, with a good stability profile and high harvest yield (~5 g/L).
- **JS207 is currently in phase II/III clinical stage.**

JS207:
anti-PD-1 (Fab)
+ anti-VEGF (VHH)



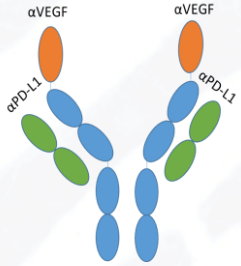
MW:180kDa
Junshi Biosciences

AK112 : anti-PD-1 (scFv)
+ anti-VEGF (Fab).



MW:200kDa
Akesobio & Summit Therapeutics

HB0025: anti-PD-L1 (Fab)
+ VEGFR1-D2 (ECD)



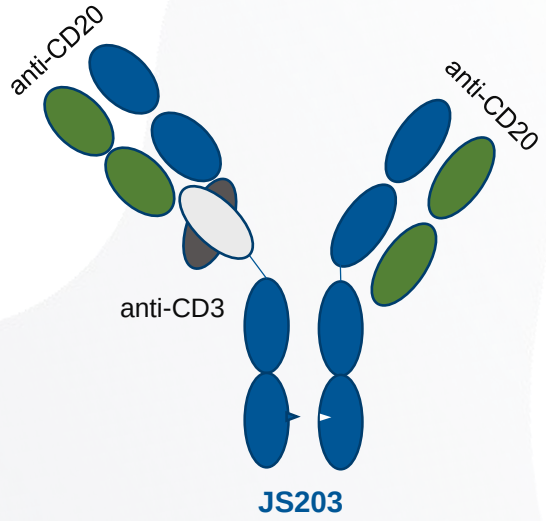
MW:170kDa
Harbour Biomed

PM8002: anti-PD-L1 (Fab)
+ anti-VEGF (VHH)

MW:170kDa
Biotheus (acquired by BioNTech)

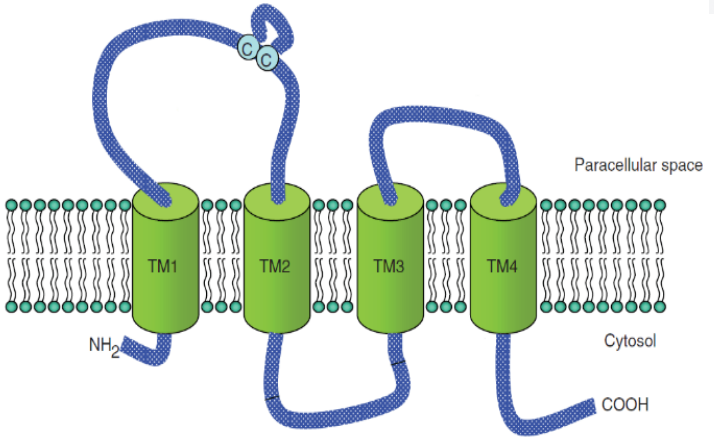
Bispecific Antibody & Antibody-Drug Conjugate

JS203
CD20 x CD3 Bispecific Antibody



- JS203 is a recombinant humanized anti-CD20/CD3 bispecific antibody self-developed by Junshi, for the treatment of relapsed/refractory B-cell non-Hodgkin's lymphoma.
- Pre-clinical animal models showed that JS203 had a strong anti-tumor effect while it was well tolerated.
- **JS203 is currently in phase I/II clinical stage. Pivotal registrational clinical trial is expected to be initiated in 2025.**

JS107
Anti-Claudin18.2 ADC

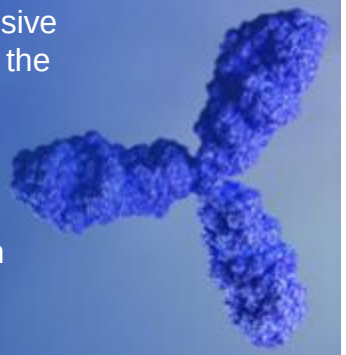


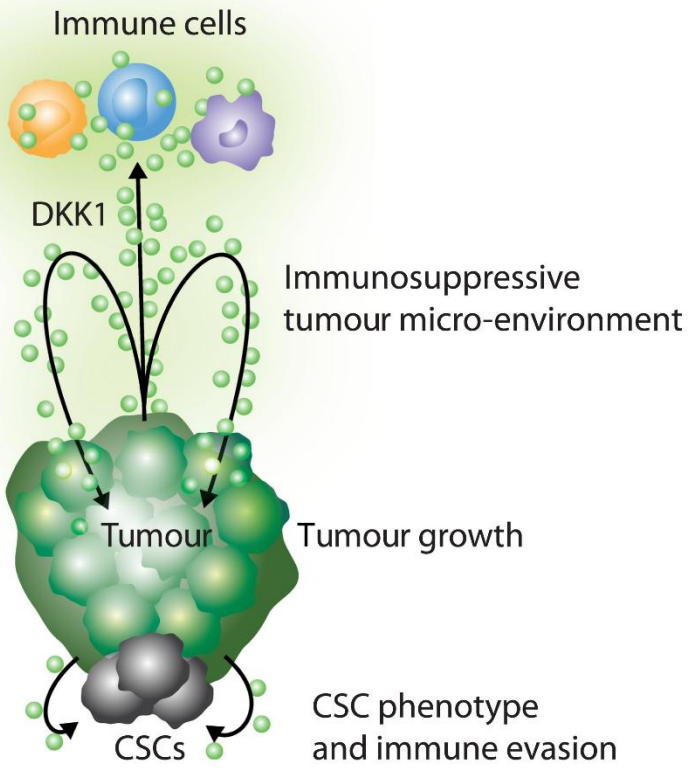
schematic of a claudin18 monomer

- JS107 is a recombinant humanized anti-Claudin18.2 monoclonal antibody-MMAE (Monomethyl auristatin E) conjugate for injection developed independently by Junshi. It is an antibody-drug conjugate (ADCs) targeting tumor-related protein Claudin18.2 and is intended to be used for the treatment of advanced malignant tumors, such as gastric cancer and pancreatic cancer.
- The pre-clinical in vivo animal models showed that JS107 exhibits significant anti-tumor effect. In addition, JS107 has a good safety profile in animals.
- **The phase I/II clinical trials on the JS107's monotherapy and combination treatment are currently underway. Phase III clinical trial is expected to be initiated in 2025.**

JS015: Anti-DKK1 Monoclonal Antibody

- DKK1 (Dickkopf-1) is a secreted protein of the DKK family, which is highly expressed in multiple gastric cancer, gastroesophageal junction cancer, myeloma, liver cancer, lung cancer, ovarian cancer and other tumor cells, and can inhibit the canonical Wnt signaling pathway through negative feedback signals.
- JS015 binds to human DKK1 with high affinity, and can effectively block the interaction between DKK1 and its ligand LRP5/6 and activate the Wnt signaling pathway. JS015 can inhibit the immunosuppressive effect of DKK1 in the tumor microenvironment, thereby improving the ability of immune system to kill tumor cells.
- The pre-clinical in vivo pharmacodynamics showed that JS015 monotherapy, JS015 in combination with toripalimab injection, in combination with paclitaxel exhibit significant anti-tumor effect. In addition, JS015 is well tolerated by animals.
- JS015 is currently in phase II clinical stage.

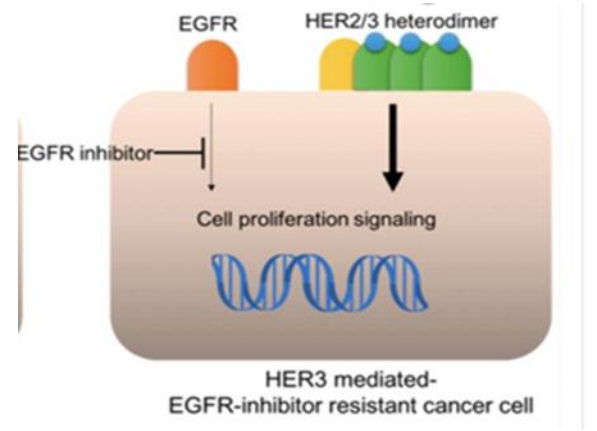


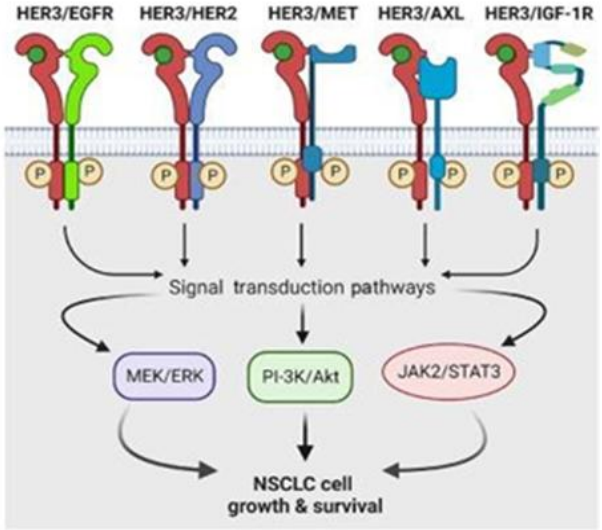


DKK1 signals to tumor cells and immune cells, resulting in an immunosuppressive tumor micro-environment, tumor growth, metastasis, a cancer stem cell (CSC) phenotype and immune evasion.

JS212: EGFR×HER3 Bispecific ADC

- JS212 is an antibody-drug conjugate (ADC), which is a conjugate of a recombinant humanized bispecific antibody targeting both EGFR and HER3, linked through Exatecan, with an inhibitor of payload.
- JS212, with its high affinity and specific binding to the antigens EGFR and HER3, block the binding of EGFR to its ligands and the binding of HER3 to its ligands, thereby inhibiting signaling pathways. EGFR and HER3 are highly expressed on the surfaces of many tumor. By targeting these two receptors simultaneously and blocking their synergistic signaling pathways, JS212 exerts a more potent antitumor effect.
- The pre-clinical in vivo animal models showed that JS212 exhibits significant anti-tumor effect. In addition, JS212 has a good safety profile in animals.
- JS212 has received IND approval in China.





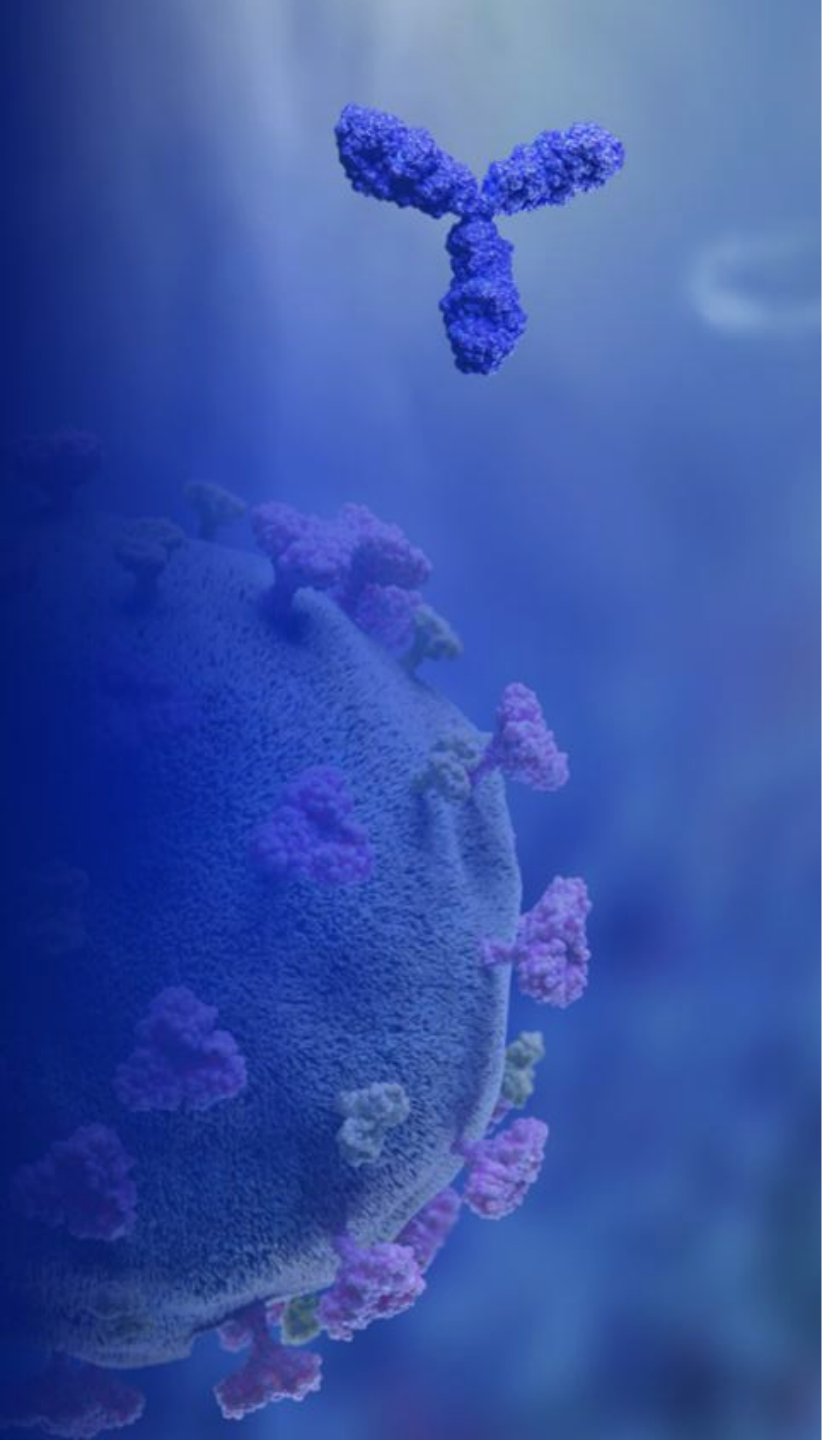
Small Molecule Inhibitor for Cancer Therapy

JS105:
Oral Small Molecule Inhibitor Targeting PI3K-α

- **JS105** is an oral small molecule inhibitor targeting PI3K-α in collaboration with Risen and is intended for the treatment of solid tumors with PI3K-α mutation, i.e. breast cancer, cervical cancer and other gynecological tumors.
- Pre-clinical studies have shown that JS105 is effective in animal models of breast cancer, and also in other solid tumors such as cervical cancer, kidney cancer, colorectal cancer and esophageal cancer. JS105 has also demonstrated a good safety profile in animals.
- **The phase I/II clinical studies on the JS105's monotherapy and combination treatment are currently underway. The phase III clinical trial is expected to start in 2025.**

JS110: XPO1 inhibitor

- **JS110** is a small molecule inhibitor of the nuclear export protein XPO1, which is clinically intended to treat patients with advanced tumors, i.e. endometrial cancer.
- Due to its unique mechanism of action - targeting nuclear export proteins, it is expected to bring new treatment options for patients with advanced malignancies.
- Initial data suggest that JS110 has good efficacy in Myelofibrosis (MF) that was refractory or intolerant to JAK inhibitors both monotherapy and in combination with ruxolitinib, and the therapies have smaller gastrointestinal toxicity and better patient compliance.
- **JS110 is currently in phase I clinical stage.**



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Innovation Beyond Oncology

Our mission is to provide patients with treatment options that work better and cost less.

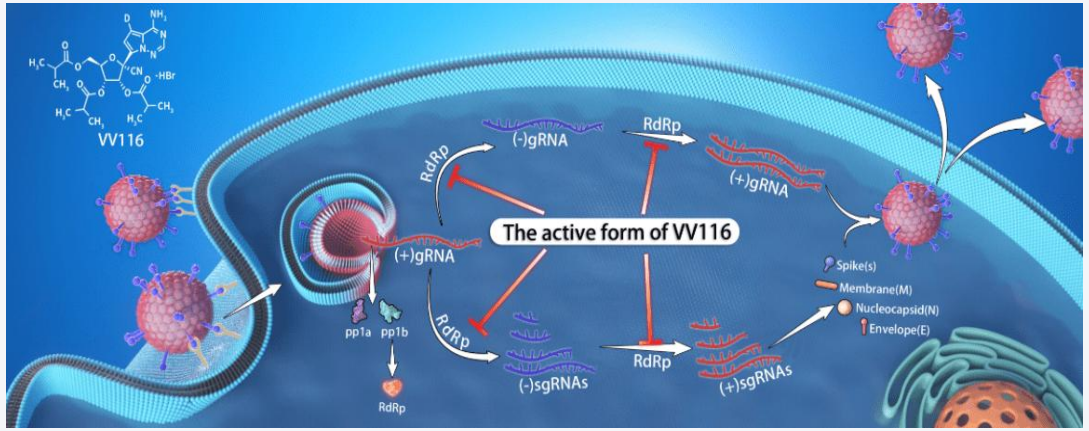
MINDEWEI (VV116/JT001): Oral Nucleoside Drug against COVID-19

- In October 2021, Junshi and Vigonvita Life Sciences, reached a collaboration to jointly develop and commercialize the oral nucleoside anti-SARS-CoV-2 drug VV116 (JT001) globally*.
- In December 2021, VV116 (JT001) was approved for the treatment of moderate to severe COVID-19 patients in Uzbekistan.
- In January 2023, NMPA conditionally approved for marketing JT001/VV116 in China (commercial name MINDEWEI) for the treatment of adult patients with mild to moderate COVID-19 based on JT001-015 study. In January 2025, MINDEWEI's conditional approval converted to regular approval.
- The results of two Phase 3 clinical studies of MINDEWEI were published in ***the New England Journal of Medicine (IF: 158.5)*** and ***the Lancet Infectious Diseases (IF:56.3).***
- MINDEWEI was officially included in the NRDL since January 2024.

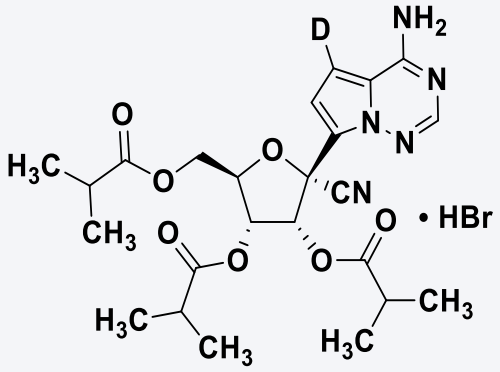
JT001-015

- FPI: 2022.10.21
- BLA accepted: 2023.01.17
- BLA approved: 2023.02.18

88 days + ***11*** days = ***99*** days



MINDEWEI (VV116) targets the conserved viral RdRp, playing a crucial role in viral replication and transcription.



MINDEWEI (VV116) Chemical Structure

*Cooperation territory: the whole world except for the following four territories, namely the five Central Asian countries, Russia, North Africa, and the Middle East

Source: Xie, Y., Yin, W., Zhang, Y. et al. Design and development of an oral remdesivir derivative VV116 against SARS-CoV-2. Cell Res (2021). https://doi.org/10.1038/s41422-021-00570-1

Metabolic Treatment: JUNSHIDA(JS002, Ongericimab), Anti-PCSK9 mAb

- **Indications:** hyperlipidemia
- **Origins:** In-house, developed independently by Junshi Biosciences
- **Commercial Rights:** Cooperated with Bochuang Pharmaceuticals (Chinese Mainland)
- **Clinical Stage**: **NDA approved in China**

In October 2024, the NDA for ongericimab was approved by the NMPA for the treatment of:

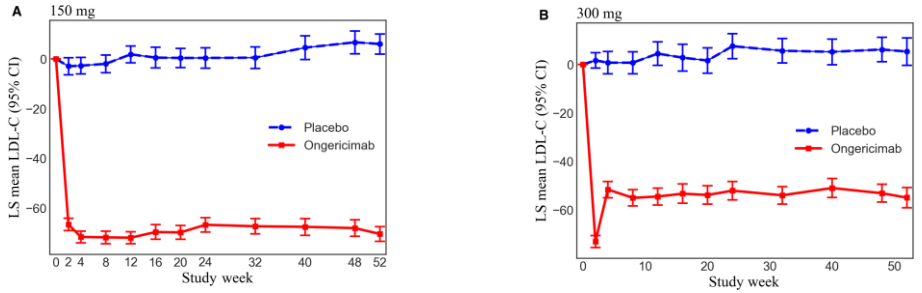
- Primary hypercholesterolemia and mixed dyslipidemia*.

In April 2024, the sNDA for ongericimab was accepted by the NMPA for the treatment of:

- Heterozygous familial hypercholesterolemia
- Primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated.

*Indication: based on dietary control, in combination with statins or statins and ezetimibe for the treatment of adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia, who fail to achieve low-density lipoprotein cholesterol (LDL-C) goals after receiving moderate or higher doses of statins treatment

	Ongericimab 150 mg every 2 weeks (n=272)	Placebo every 2 weeks (n=131)	Ongericimab 300 mg every 4 weeks (n=265)	Placebo every 4 weeks (n=134)
LDL-C				
LS mean % change from baseline to week 24 (95% CI) *	−67.4 (−70.3 to −64.4)	0.4 (−3.7 to 4.5)	−53.5 (−57.1 to −49.8)	7.7 (2.7 to 12.7)
LS mean difference (95% CI)	−67.7 (−72.5 to −63.0)		−61.2 (−67.1 to −55.2)	
P value	<0.0001		<0.0001	
LS mean %change from baseline to week 52 (95% CI)	−70.5 (−73.4 to −67.5)	6.1 (2.0 to 10.1)	−55.0 (−59.2 to −50.8)	5.4 (−0.3 to 11.0)
LS mean difference (95% CI)	−76.5 (−81.3 to −71.7)		−60.3 (−67.2 to −53.5)	
P value	<0.0001		<0.0001	



The results indicated that treatment with ongericimab, at doses of 150 mg every 2 weeks or 300 mg every 4 weeks, both resulted in significant reductions in LDL-C levels over 60% compared with placebo. The observed reduction was sustained for 52 weeks, similar to or numerically higher than the reduction achieved with the approved PCSK9 antibodies

In terms of safety, the overall safety profile of ongericimab was good, with a TEAE incidence comparable to that of placebo

Source: AHA 2023, Wang X, Qiu M, Cheng Z, et al. Efficacy and Safety of Ongericimab in Chinese Patients With Primary Hypercholesterolemia and Mixed Dyslipidemia. J Am Heart Assoc. 2024 May 31:e033669. doi: 10.1161/JAHA.123.033669.

Treatments for Autoimmune

Adalimumab

UBP1211

- **Indications:** rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis and pediatric Crohn's disease
- **Origins:** Developed by Junshi Biosciences, Mabwell Bio and its subsidiaries

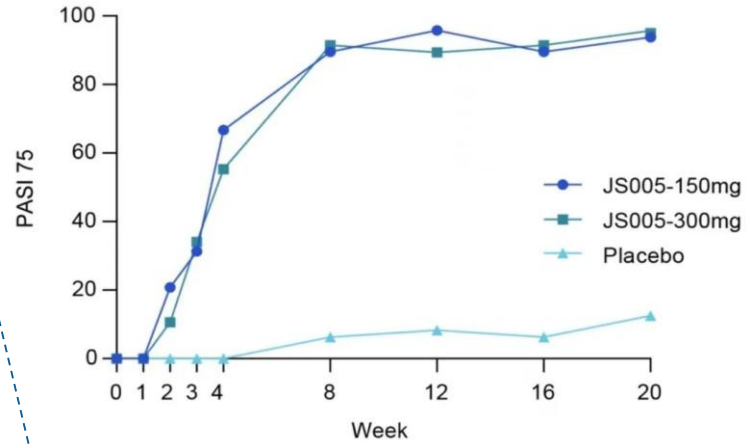
- All of the 8 indications are included in the **NRDL**.
- Anti-TNF-α mAb is a new generation treatment of immune mediated inflammatory diseases with the special characteristics of being highly efficient, safe, and can be administrated conveniently.

JS005

Anti-IL-17A mAb

- **Indications:** psoriatic, spondylitis
- **Origins:** In-house, developed independently by Junshi
- **Commercial Rights:** Global

- **Phase III clinical stage:** moderate to severe plaque psoriasis, **all subjects have been enrolled**
- **Phase II clinical stage**: ankylosing spondylitis, **all subjects have been enrolled , now being followed**



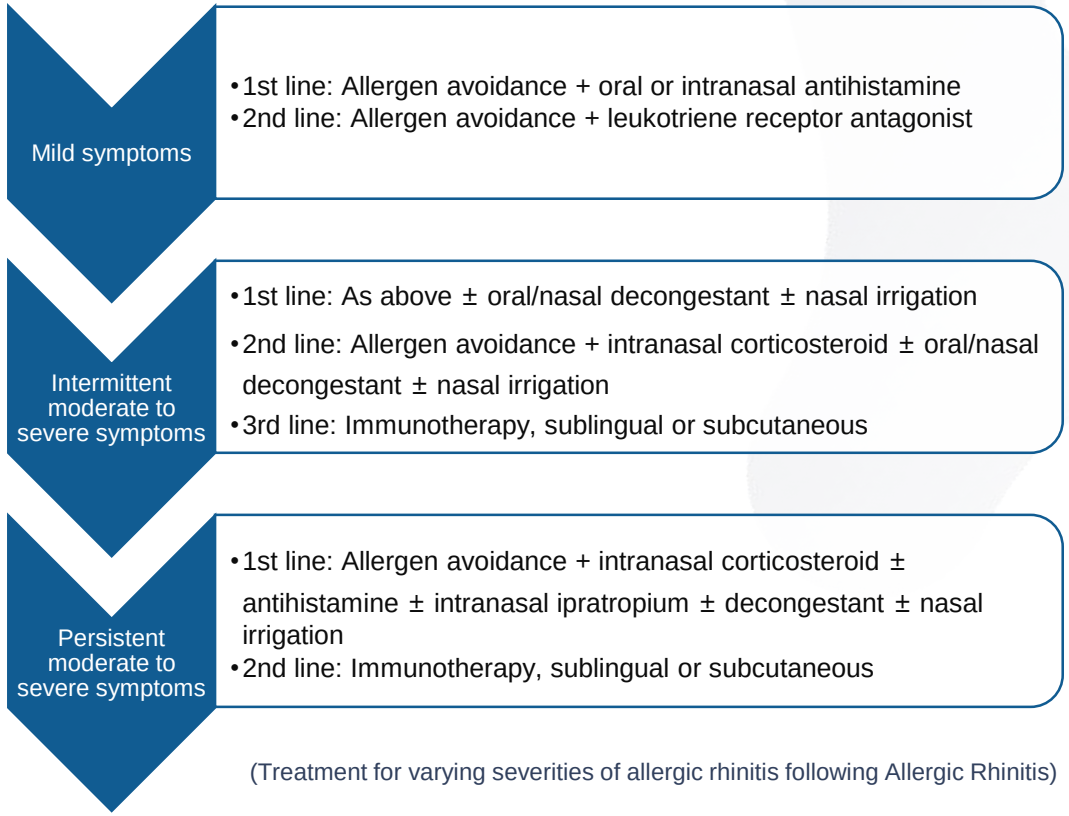
The proportions of patients achieved PASI 75 at week 12 were significantly higher in the JS005 150mg group (95.8%, p<0.0001) and 300mg group (89.4%, p<0.0001) than in the placebo group (8.3%)

Source: ACR 2023. Cai L, Mu Z, Tao X, Zhang L, Zhang C, …, Zhang J. A Phase Ib/II Randomized, Double-blind, Placebo-controlled Study of Novel anti-IL-17A Monoclonal Antibody JS005 in Patients with Moderate to Severe Psoriasis [abstract]. Arthritis Rheumatol. 2023; 75 (suppl 9). December 21, 2023.

Other Treatments

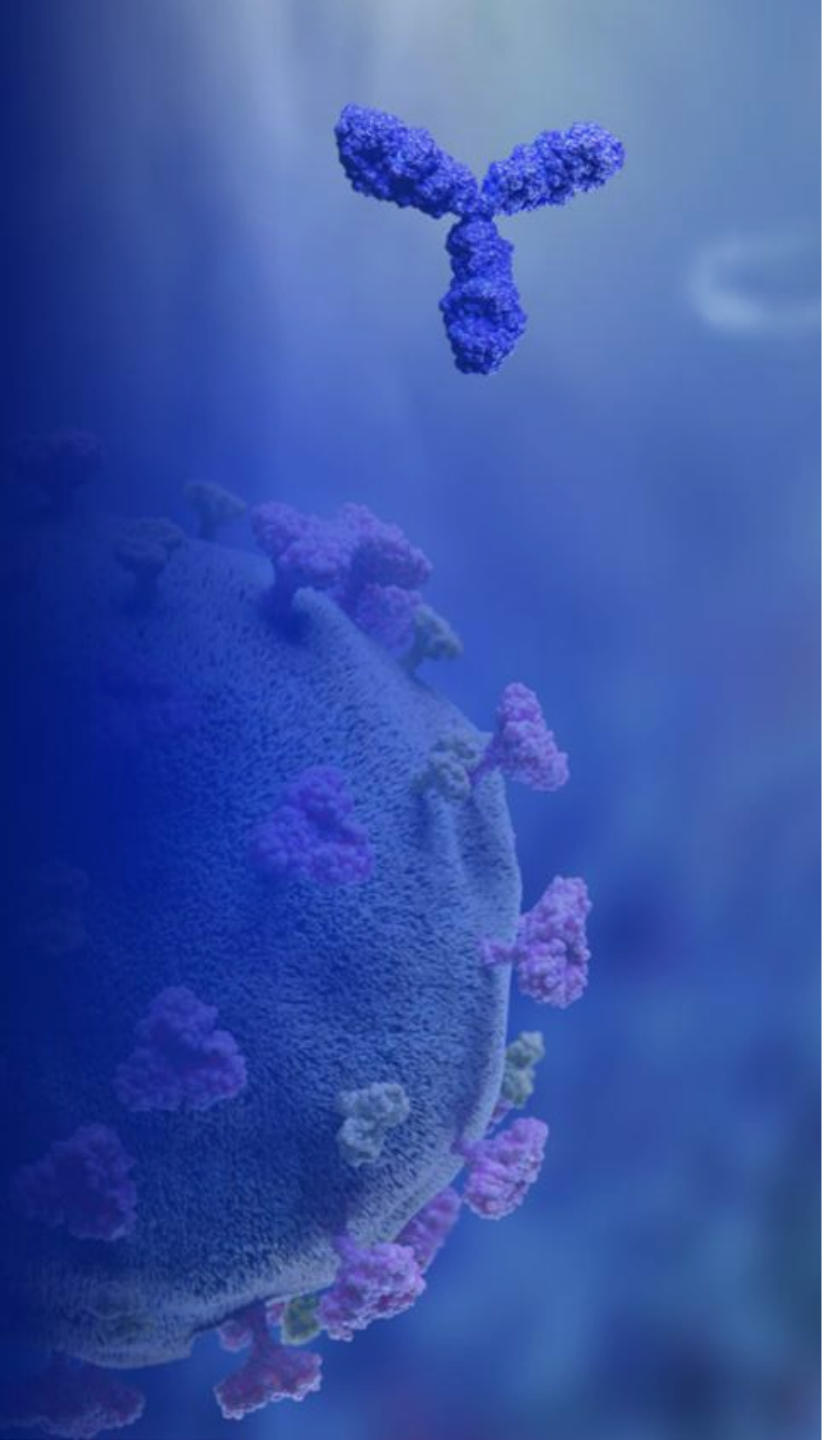
JT002
Small Nucleic Acid Nasal Spray

- JT002 is an innovative immunomodulatory small nucleic acid nasal spray, developed by Junshi and JSIAMA, for the treatment of allergic rhinitis.
- Allergic rhinitis (AR) has become a global health problem, affecting 10% to 20% of the world's population, Chinese adults self-reported prevalence in AR is also on the rise.
- It is the world’s first nasal spray immunomodulatory small nucleic acid drug that was independently developed and has entered the clinical trial stage. JT002 has currently completed phase I clinical trials in China, demonstrating superior safety, tolerability, and target-mediated biological activity.
- **JT002 has entered the phase II clinical trial stage in the first half of 2025.**



(Treatment for varying severities of allergic rhinitis following Allergic Rhinitis)

Source: Allergic rhinitis: diagnosis and management. ZA Siddiqui, A Walker, MM Pirwani, M Tahiri, I Syed Feb 23, 2022.



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Commercialization

Our mission is to provide patients with treatment options that work better and cost less.

Steady Growth in Sales

Total Operating Income

1,948 MN

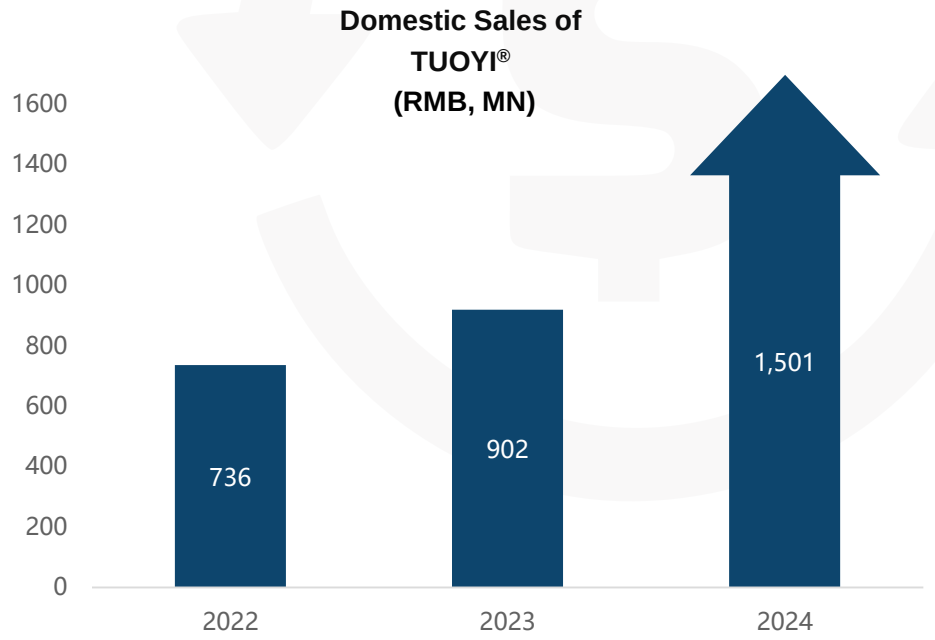
YoY **29.67%**

Domestic Sales of TUOYI®

1,501 MN

YoY about **66 %**

The revenue from sales of pharmaceutical products has gradually accounted for a greater share in operating income, which demonstrates that our income-generating capacity has been further strengthened.



* The date will be provided in accordance with the Chinese Accounting Standards(CAS).

Improvement in Commercialization Efficiency

TUOYI®: ten indications included in the NRDL

- Starting from 2025, TUOYI® has four new indications included in the new edition of the NDRL, currently ten indications being included in the NRDL.
- The only anti-PD-1 mAb used in the treatment of melanoma, perioperative NSCLC, RCC, TNBC in the NRDL.
- TUOYI® has been sold in more than **6,000 medical institutions and more than 3,000 specialty pharmacies and community pharmacies** nationwide.

MINDEWEI: officially included in the NRDL

- Officially included in the NRDL since January 2024.
- As at the end of the Reporting Period, MINDEWEI has been used in **more than 2,300** hospitals, including community healthcare service centers, secondary hospitals and tertiary hospitals, **covering all provinces in the territory.**
- Continuously explored sales models, and included a new sales promotion model based on the coverage of its existing internal hospital sales team. All members of the new sales promotion team have extensive experience in promotion in the field of respiratory infections.

JUNSHIDA: approval for NDA

- NDA approved in October 2024
- In October 2023, the Company signed an agreement with Bochuang Pharmaceuticals, under which Bochuang Pharmaceuticals would be responsible for the subsequent commercialization of Ongericimab in Chinese mainland and make corresponding payments to the Company

JUNMAIKANG: stable sales revenue in the future

- Under the continuous promotion of our commercialization partners, JUNMAIKANG completed the tendering process on the procurement platform as well as healthcare and insurance connection in **27 provinces** as at the end of the Reporting Period, and has been used in **319 hospitals**, covering **1,379 pharmacies**.

Upgrading Production Capacity, Transforming into Intelligent Manufacturing Through Digitalization

Shanghai Lingang

Production Base

- Under construction in accordance with **CGMP standard**
- **42,000L** fermentation capability in the first phase of the project
- **NMPA GMP certification**
- Passed the on-site inspection conducted by Lilly and **provided overseas clinical samples of JS016**
- **Digital "smart" factory**
- Responsible for the production of commercial batches of TUOYI® jointly with Wujiang production base

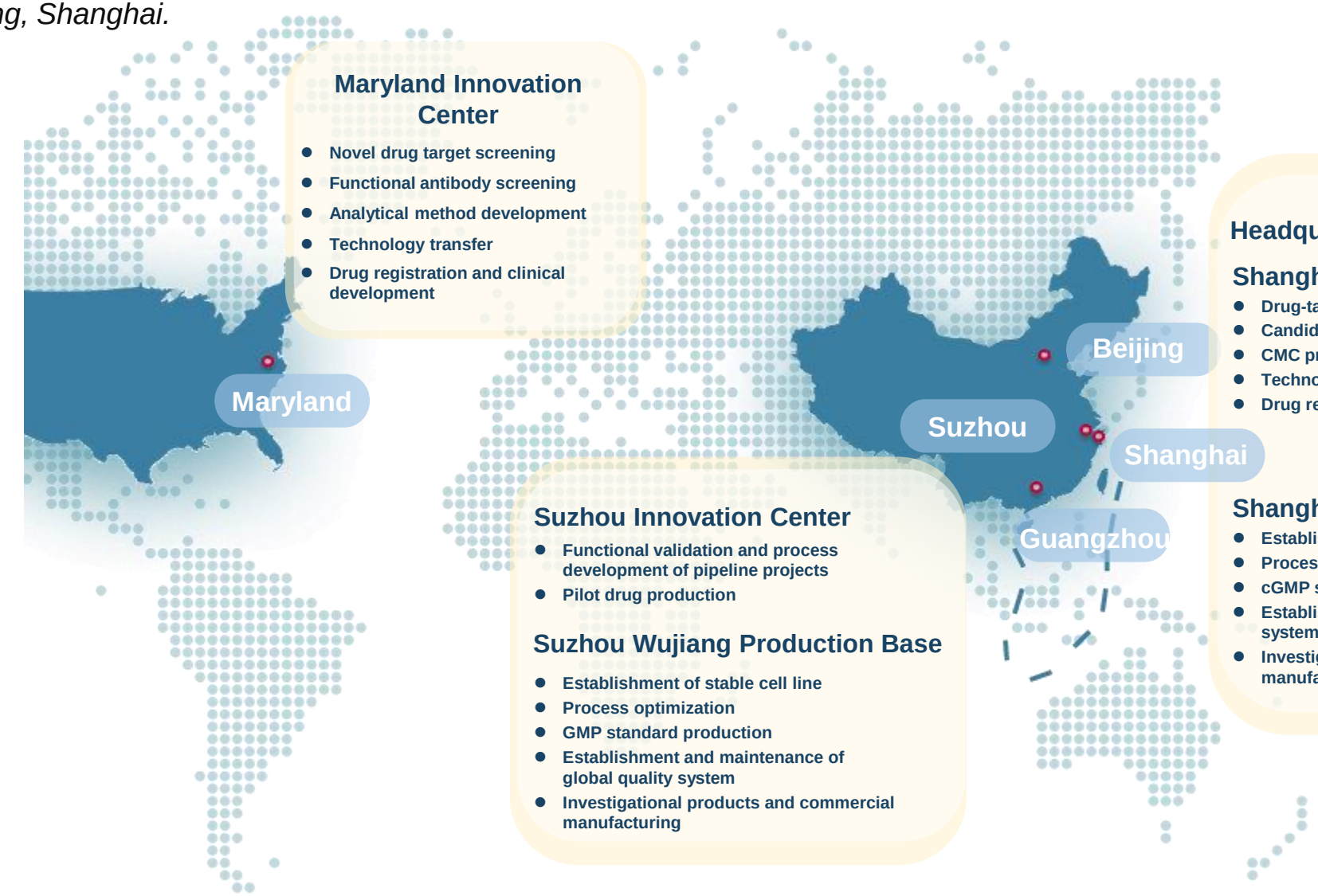
Suzhou Wujiang

Production Base

- **4,500L** fermentation capability
- **FDA PLI completed**
- **EMA GMP on-site inspection completed**
- **GMP certification by NMPA, FDA, EMA**
- Responsible for the production of the commercial batches of toripalimab in US, India and HK at this stage

In China, For Global

We have established three R&D centers in Shanghai, Suzhou, and Maryland, and two biological drug production bases in Wujiang, Suzhou and Lingang, Shanghai.



Maryland Innovation Center

- Novel drug target screening
- Functional antibody screening
- Analytical method development
- Technology transfer
- Drug registration and clinical development

Suzhou Innovation Center

- Functional validation and process development of pipeline projects
- Pilot drug production

Suzhou Wujiang Production Base

- Establishment of stable cell line
- Process optimization
- GMP standard production
- Establishment and maintenance of global quality system
- Investigational products and commercial manufacturing

Headquarters

Shanghai Innovation Center

- Drug-target identification and verification
- Candidate molecule screening and optimization
- CMC process and analytical method development
- Technology transfer
- Drug registration and clinical development

Shanghai Lingang Production Base

- Establishment of stable cell line
- Process optimization
- cGMP standard
- Establishment and maintenance of global quality system
- Investigational products and commercial manufacturing

THANK YOU

Our mission is to provide patients with treatment options that work better and cost less.

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