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2024 Interim Results

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

Sep, 2024

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2024H1 Financial Review

	2024 H1 (RMB, Million)	2023 H1 (RMB, Million)	YoY (%)	
Total operating income	**786**	670	**+17.37%**	↑
TUOYI® Domestic Sales Revenue	**671**	447	**+50.11%**	↑
Total operating costs	**1,435**	1,773	**-19.07%**	↓
Selling and Distribution Expenses	**428**	373	**+14.59%**	
R&D expenses	**546**	949	**-42.40%**	↓
Administrative Expenses	**240**	232	**+3.19%**	
Net loss attributable to shareholders	**-645**	-997	**+35.33%**	↑
Net loss attributable to the shareholders after deducting non-recurring profit and loss	**-627**	-971	**+35.43%**	↑

Total operating income: The growth was mainly due to the increase of revenue from pharmaceutical products and revenue related to out-licensing overseas. The domestic sales revenue of TUOYI® was approximately RMB671 million, increased by approximately 50%.

Total operating costs: Selling and distribution expenses increased by 15%, with the growth rate significantly lower than the domestic sales growth of TUOYI®. R&D expenses decreased by 42%, primarily because the Group's cost control policy and efforts to optimize resource allocation and focusing on R&D pipelines with greater potential, while successive approval of new indications of TUOYI® also contributed to natural decline of R&D expenditure.

Loss attributable to shareholders decreased to RMB645 million for the Reporting Period, representing a decrease of approximately 35%.

Cash and bank balances, & Held-for-trading financial assets: totaled 3.312 billion, indicating a relatively ample financial reserve.

*The unaudited condensed consolidated interim results are in accordance with the Chinese Accounting Standards(CAS).

2024H1 Snapshot

Rapid Sales Growth

- Revenue from pharmaceutical products increased by approximately **11%** compared to the corresponding period in 2023, in particular: the domestic sales revenue of our core product TUOYI® (toripalimab) was approximately RMB671 million, representing an increase of approximately **50%**.

Pipeline Expansion

- **Tifcemalimab:** A phase III clinical study for treatment of LS-SCLC has been approved to proceed by the NMPA, FDA and PMDA, with FPI completed in 4 regions. A phase III clinical study for the treatment of cHL is now enrolling. Several phase Ib/II clinical studies against multiple types of tumors are underway in China and the US.
- **JS005(anti-IL-17A mAb):** The phase III registrational clinical study for moderate to severe plaque psoriasis has completed enrollment.
- Around **30** drug candidates are undergoing clinical trials, and over **20** drug candidates are at preclinical drug development stage.

Accelerated Registration Process

- **TUOYI®:** During the Reporting Period, **3** sNDAs were approved by the NMPA. As of the date of this announcement,**10** indications approved in China, **6** covered by the national insurance (NRDL), **2** supplemental NDAs under review by the NMPA
- **MINDEWEI:** Officially covered by the NRDL
- **Ongericimab(PCSK9):** **2** sNDAs were accepted by the NMPA, with NDAs for **4** indications under review in total
- **JUNMAIKANG:** **8** indications approved in China, all covered by the NRDL

Global Commercialization

- Toripalimab can now be order at all **33** NCCN institutions in the US.
- Marketing applications of toripalimab under review by EMA(EU), MHRA(UK), TGA(Australia), HAS(Singapore), NPRA(Malaysia) & DO(HKSAR).
- A positive opinion from the CHMP of the EMA was obtained for the MAA of toripalimab.
- Toripalimab achieved international collaboration in more than **50** countries.

Projects Entering the Clinical R&D Stage (As of 30 August 2024)

Phase I/II			Phase III	Approval for marketing/ Emergency use authorization
JS107 Claudin18.2 ADC	**JS015** DKK1	**JS105** PI3K-α	**Tifcemalimab** BTLA	**Toripalimab** PD-1
JS003 PD-L1	**JS203** CD3×CD20	**JS207** PD-1×VEGF	**Bevacizumab** VEGF	**Adalimumab** TNF-α
JS009 CD112R	**JS006** TIGIT	**JS007** CTLA-4	**JS001sc** PD-1	**Deuremidevir Hydrobromide Tablets** RdRp
JS019 CD39	**JS012** Claudin 18.2	**JS014** IL-21	**Ongericimab** PCSK9	**Etesevimab**(Note1) S Protein
JS110 XPO1	**JS101** Pan-CDK	**JS108** Trop2 ADC	**JS005** IL-17A	
JS113 EGFR 4th Gen	**JS111** EGFR exon 20	**JS112** Aurora A		
JS401 ANGPTL3	**JS116** KRAS	**JS201** PD-1×TGF-β		
JS103 Uricase	**JS010** CGRP	**JS026** S Protein		
UBP1213sc BLyS				

Oncology
Metabolism
Immunology
Neurologic
Infectious disease

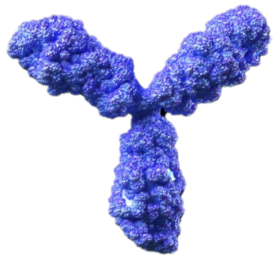
Note 1: Received Emergency Use Authorization (EUA) from the FDA
Note 2: The products listed herein are products that have obtained IND approvals as announced

Broad Technology Platforms

50+

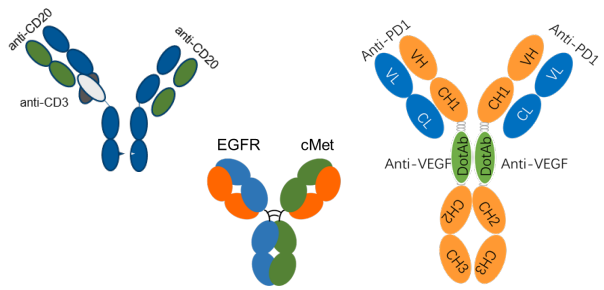
Drug Candidates

mAbs



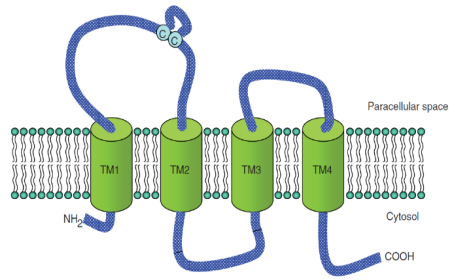
Oncology: Toripalimab (PD-1), Tifcemalimab (BTLA) …; **Immunology:** Adalimumab (TNF-α), JS005 (IL-17A),…; **Metabolism:** Ongericimab (PCSK9); **Neurologic:** JS010 (CGRP); **Infectious disease:** Etesevimab (S protein)

BsAbs



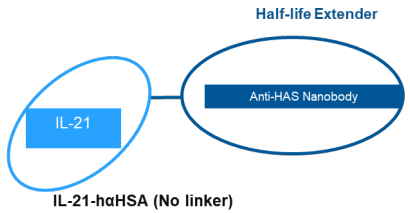
Oncology: JS203(CD20xCD3), JS201 (PD-1 x TGF-β), JS207(PD-1xVEGF)…

ADCs



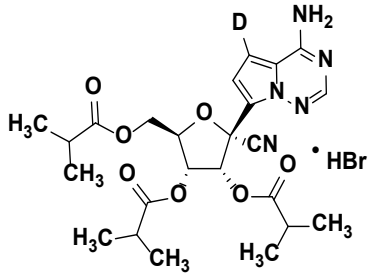
Oncology: JS107 (Claudin18.2 ADC), JS108 (Trop2 ADC)…

Fusion Proteins



Oncology: JS014 (Long-acting IL-21)

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)

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Globalization Roadmap

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, Junshi Biosciences and Coherus announced the FDA approval of LOQTORZI® (toripalimab-tpzi) for the **ALL LINES** of treatments for R/M NPC.

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

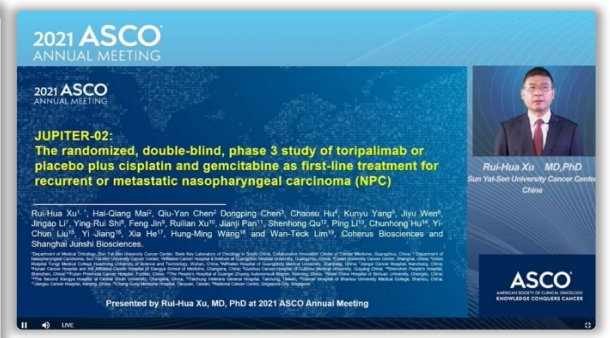
- **1st** innovative biological drug independently developed and manufactured in China approved for marketing by the FDA
- **1st and only** drug approved in US for the treatment of NPC
- Included in the **NCCN guidelines** as a preferred category 1 treatment
- Toripalimab can now be order at all **33** NCCN institutions in the US.
- Coherus expected LOQTORZI® to achieve NPC peak sales **within 2.5 to 3 years,** with the market value reaching **up to $200 million at peak.**

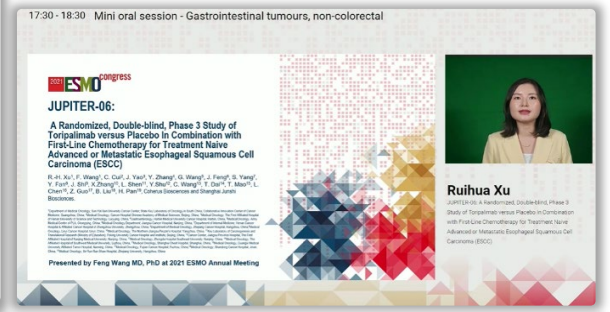
LOQTORZI™
(toripalimab-tpzi)injection

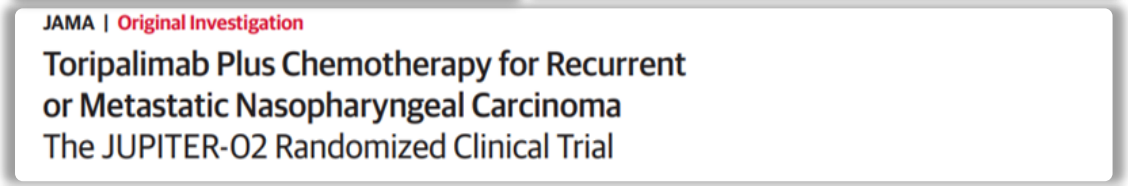
Pursue More Registration Opportunities Worldwide

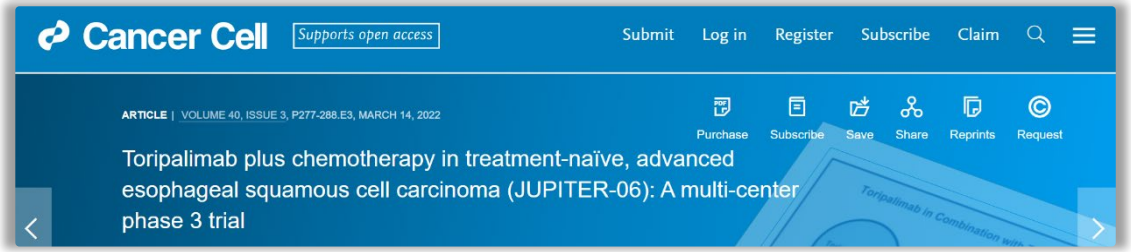
- ***Based on the excellent improvement of survival of toripalimab for the treatments of patients with NPC and ESCC***

- ***Marketing applications have been:***
  - ✓ *Approved in the US*
  - ✓ *Under review in EU, UK, Australia, Singapore, Malaysia and Hong Kong (SAR)*
  - ✓ *Obtained a positive opinion from the CHMP of the EMA*
  - ✓ *Submitted in India, South Africa, Chile, and Jordan*









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

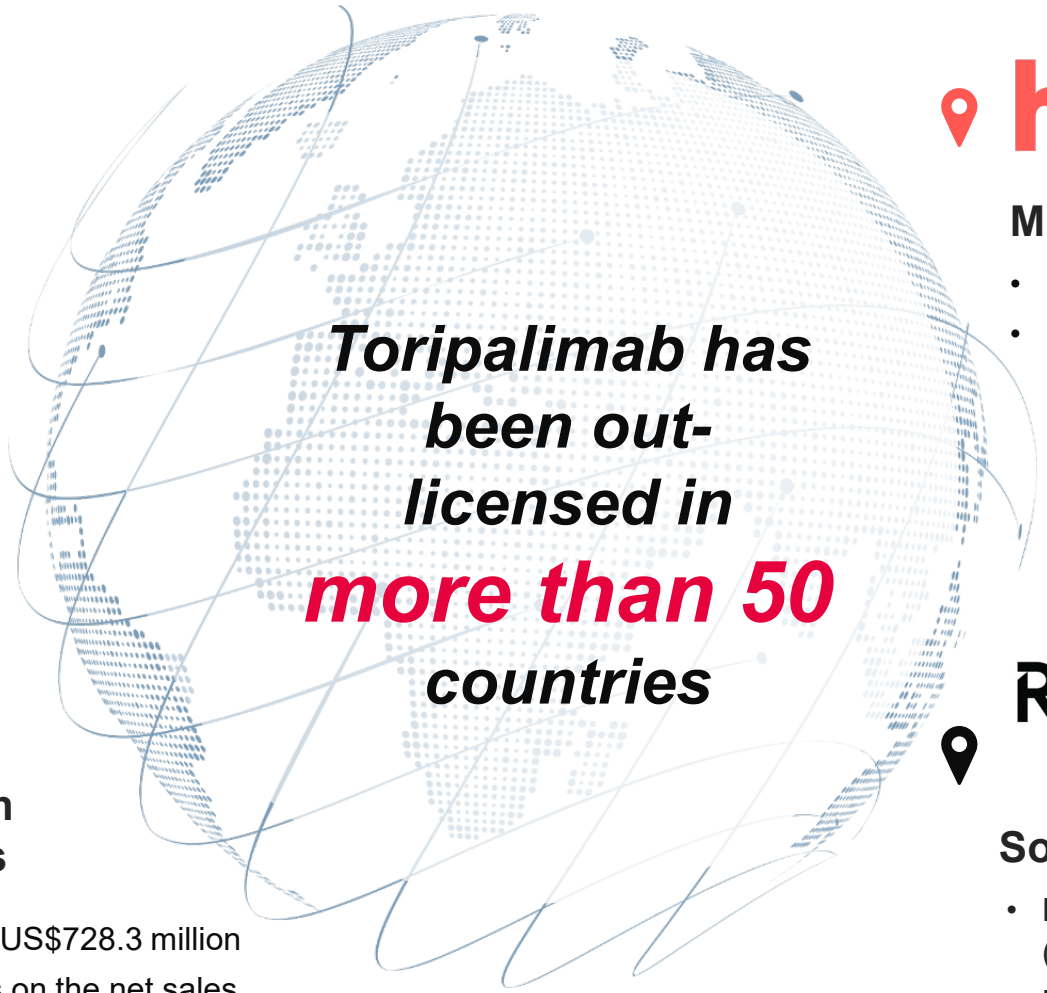
US and Canada

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



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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

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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

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Immuno-Oncology Backbone

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

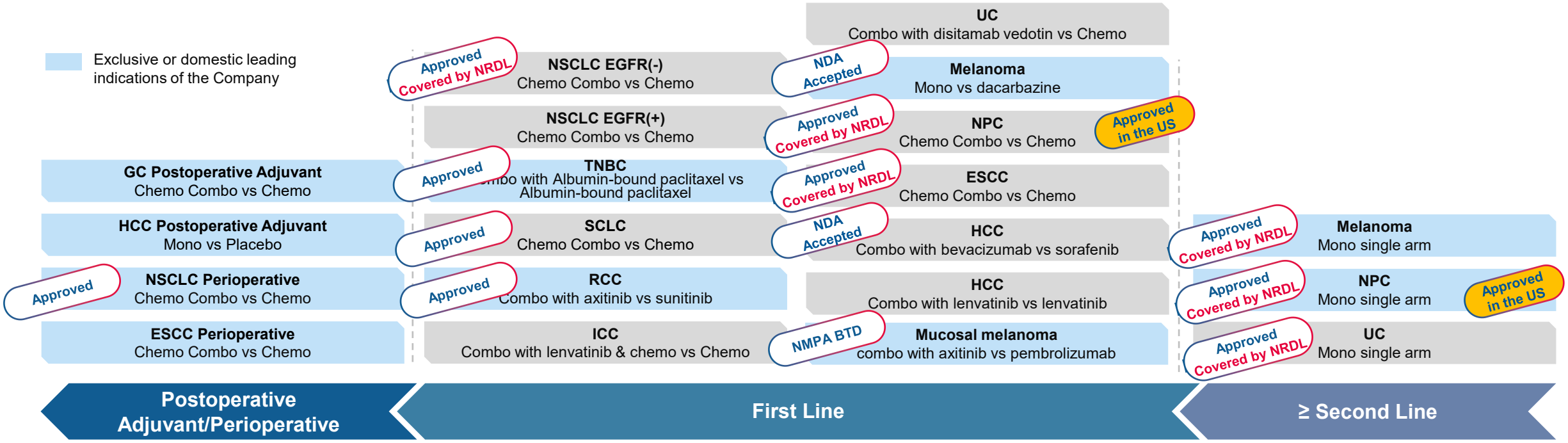
Toripalimab: the PD-1 Inhibitor with Broad Strategic Clinical Layout

Geography Toripalimab is on track to achieve global commercialization, with its approval for commercialization in the US and marketing applications under review in the EU, UK, Australia, Singapore, Malaysia and Hong Kong(SAR).

Frontline Phase 3 clinical trials on postoperative/perioperative treatment settings in gastric, esophageal and liver cancer will be completed in the near future.

Combo Toripalimab is the most widely used PD-1 monoclonal antibody in combination therapies in China. Two phase 3 combination studies for the treatment of urothelial and neuroendocrine cancer are ongoing with strategic partners.

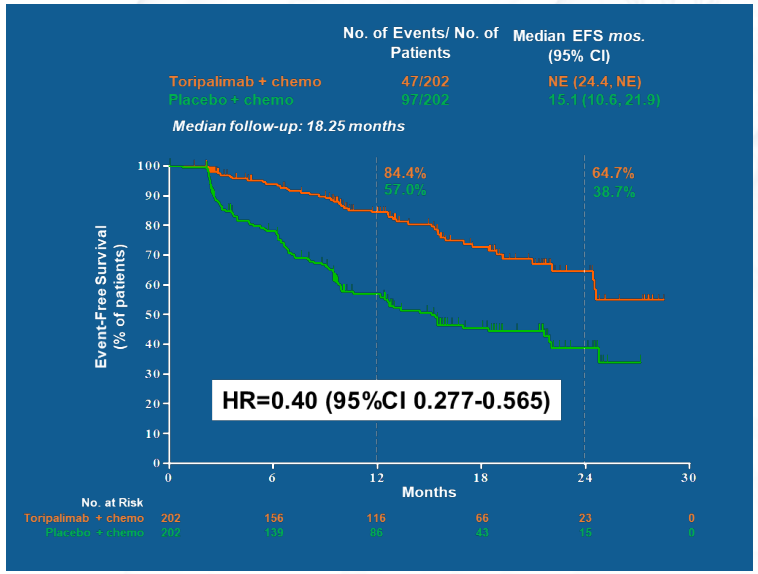
Pivotal registrational clinical trial layout of Toripalimab



The NEOTORCH Study: First Ph3 Registrational Study of Perioperative I-O therapy for Lung Cancer with Positive EFS Result, sNDA Approved by the NMPA

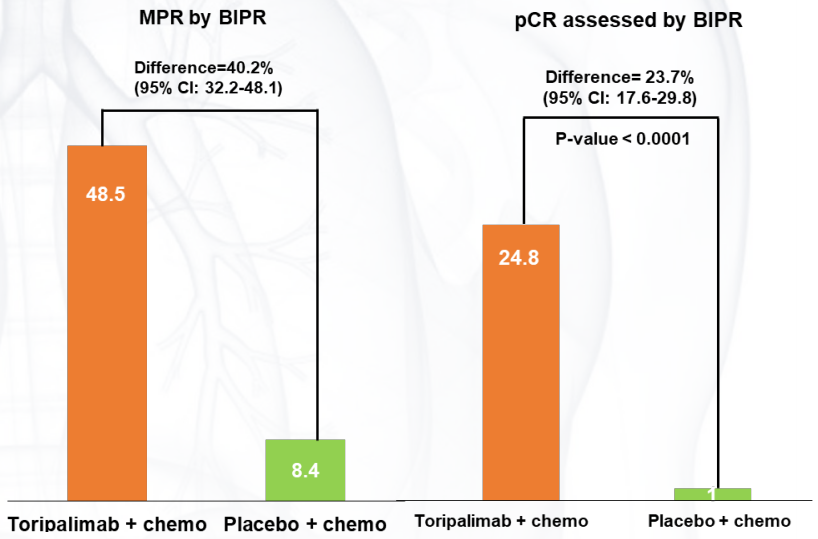
This is the first and only approved perioperative therapy for lung cancer in China.

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**

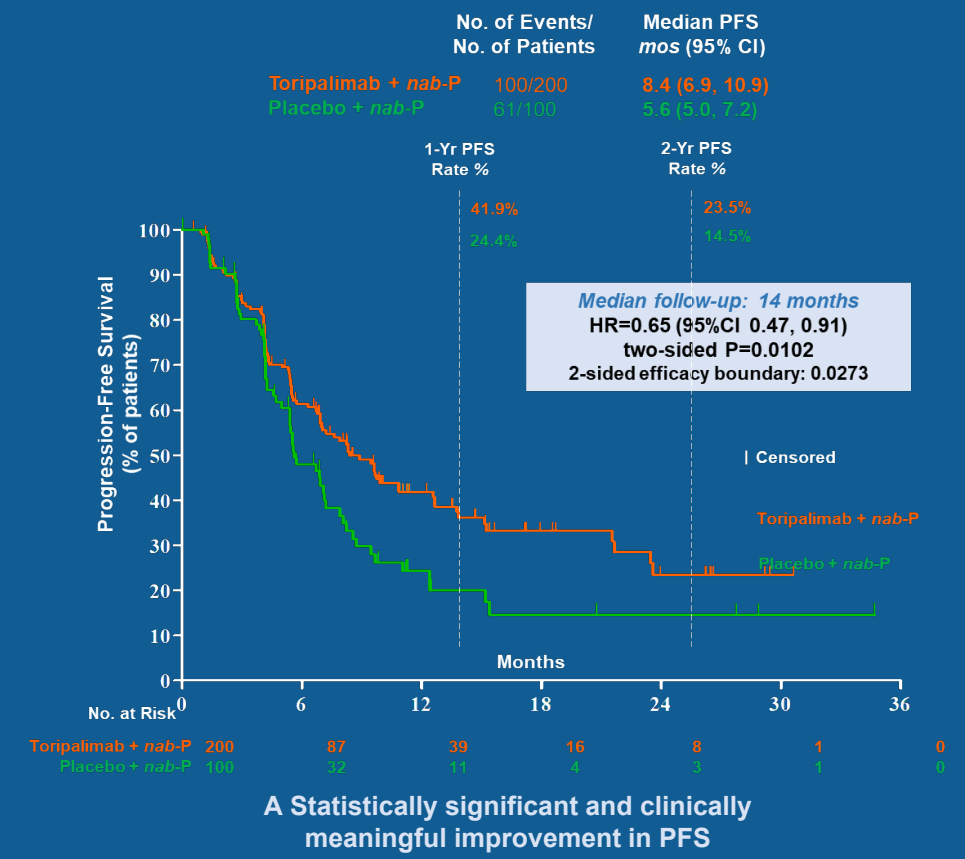
Study	IO stage
CheckMate-816	Neoadjuvant
Impower 010	Adjuvant
KEYNOTE-091	Adjuvant
NEOTORCH	(Neoadjuvant+Adjuvant) Perioperative

- **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

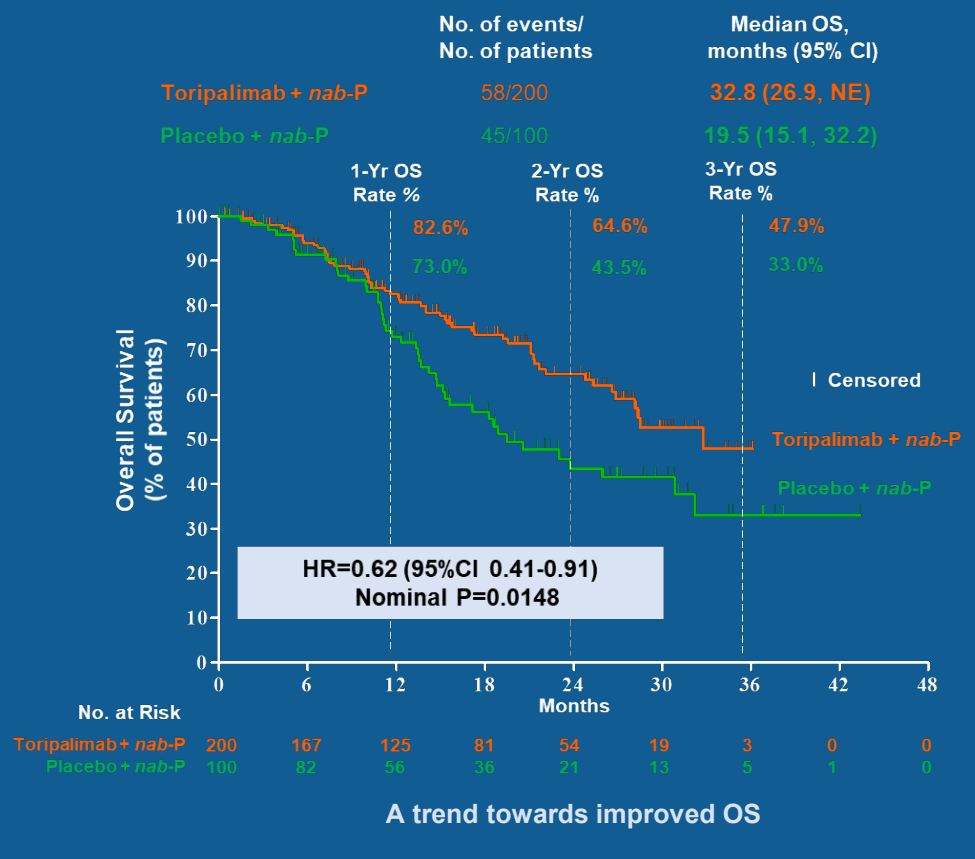
Source: ASCO 2023#8501

The TORCHLIGHT Study: First Ph3 Registrational Study in China to Achieve Positive Outcome in Advanced TNBC immunotherapy, sNDA Approved by the NMPA



A Statistically significant and clinically meaningful improvement in PFS

- 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**



A trend towards improved OS

- Median OS in PD-L1 positive (CPS≥1) subgroup: **32.8** vs. 19.5 months

In February 2023, the phase 3 study of toripalimab in combination with nab-paclitaxel in patients with initial diagnosis of stage IV or recurrent metastatic TNBC (TORCHLIGHT Study) completed the pre-specified interim analysis. **TORCHLIGHT study is the first Phase 3 registration study in China to achieve a positive outcome in advanced TNBC.**

In June 2024, the sNDA for TUOYI® in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1) was approved by the NMPA. This is the 10th indication for toripalimab approved in Chinese mainland.

Source: ASCO 2023#LBA1013

The RENOTORCH Study: Record-setting Results for 1st line Immunotherapy in Advanced Kidney Cancer with a median PFS of 18.0 months, sNDA Approved by the NMPA

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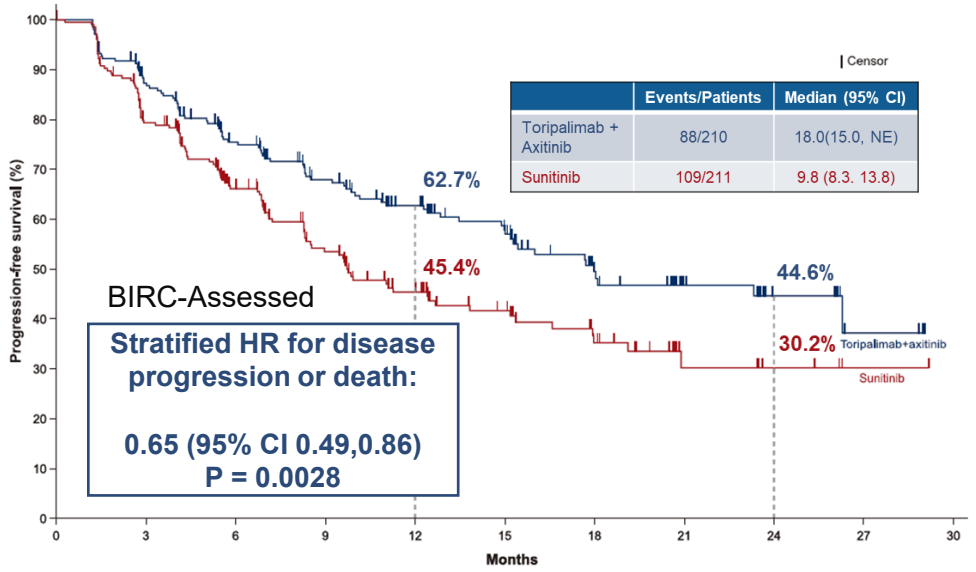
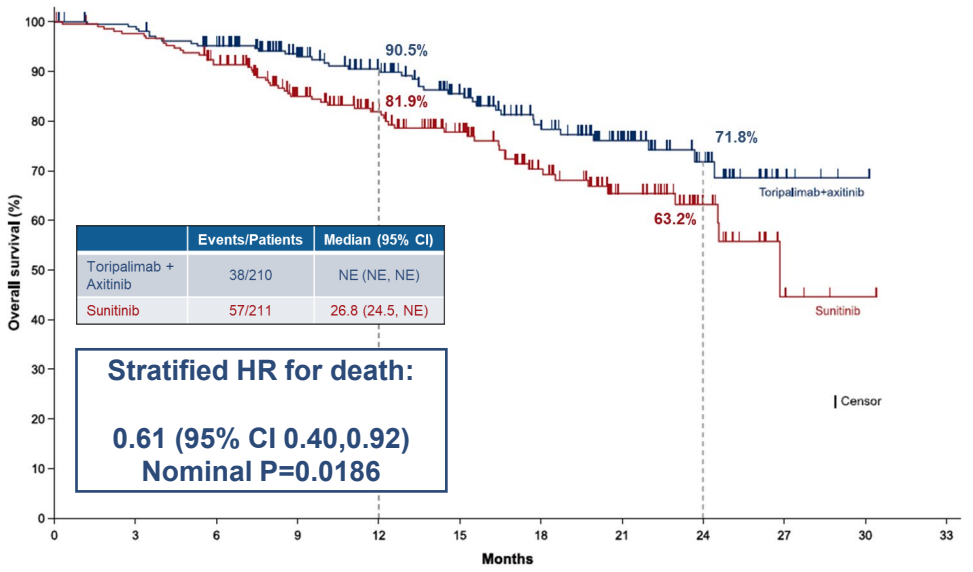
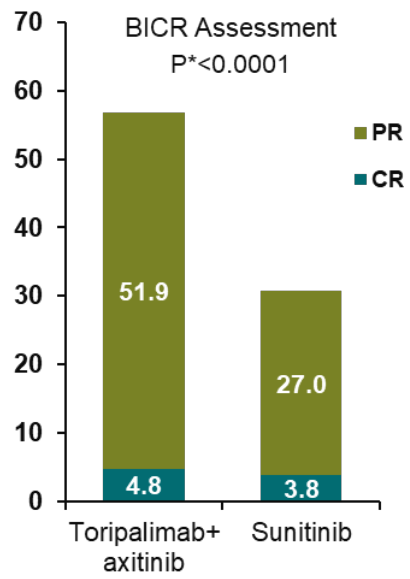
PFS



OS



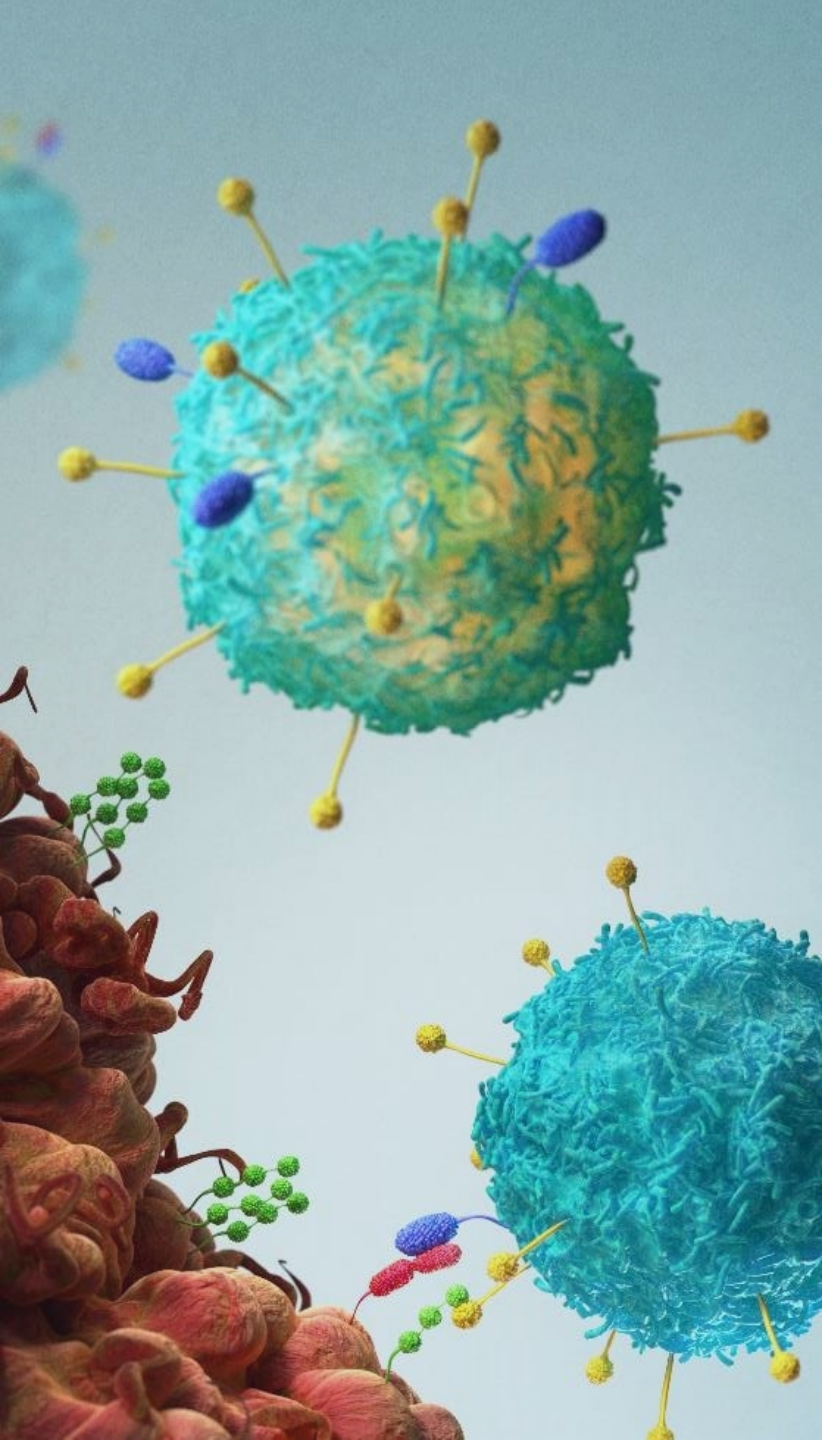
ORR



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



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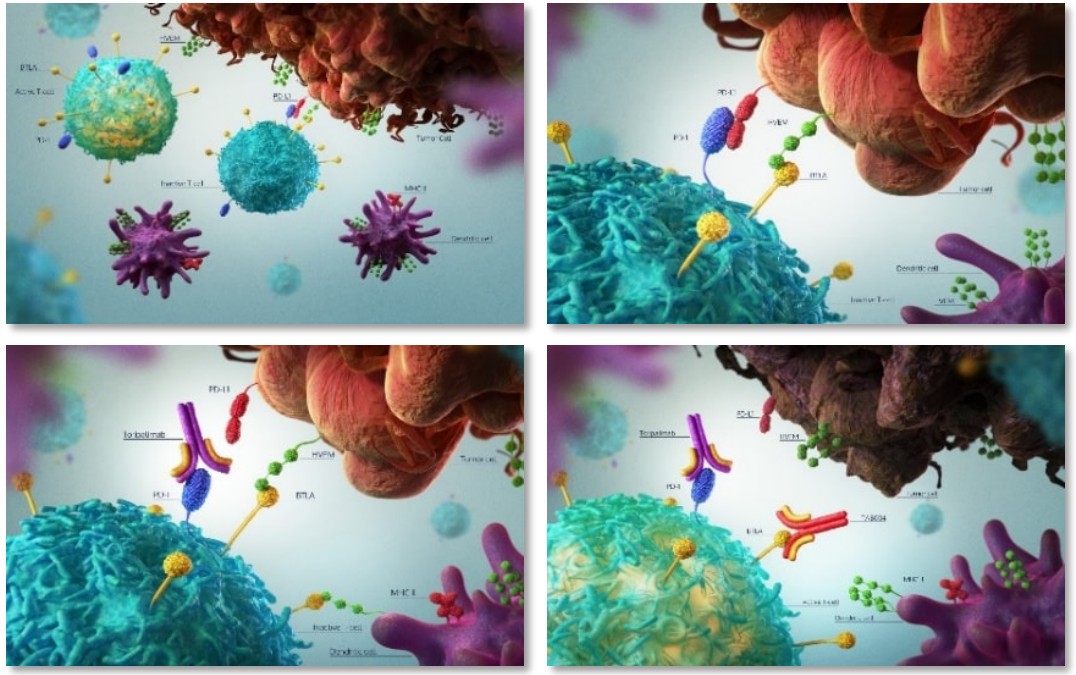
Promising Candidates in Cancer Therapy

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)

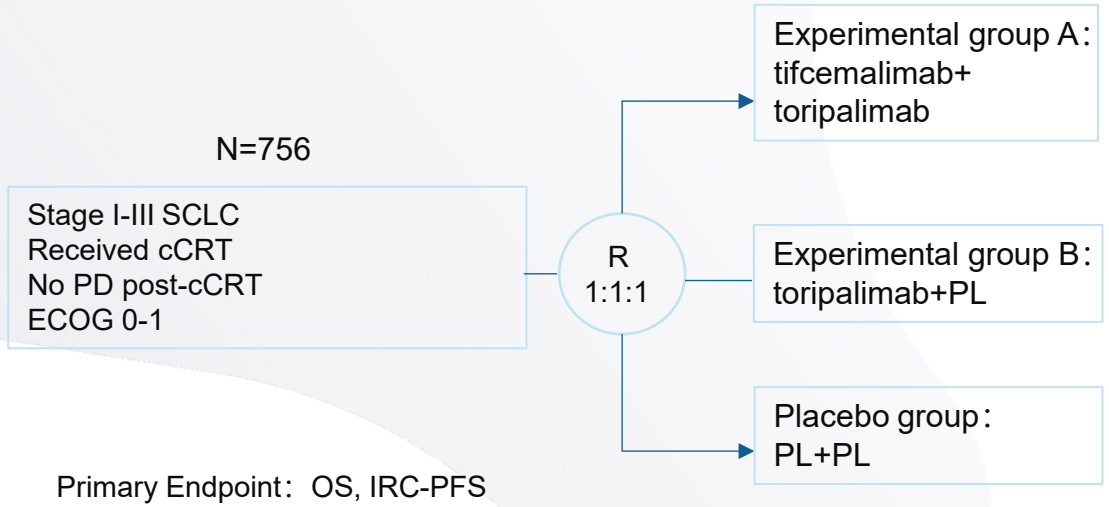
- A phase III study of tifcemalimab in combination with toripalimab as consolidation therapy in patients with LS-SCLC without disease progression following chemo-radiotherapy is being conducted. As the first confirmatory study of anti-BTLA monoclonal antibody, this study is to be carried out in more than 190 research centers in 17 countries and regions around the world and will recruit about 756 subjects. Up to now, this study has completed the first patient enrollment (FPI) and the first drug administration in China, the United States, Europe and Japan.
- A phase III clinical study of tifcemalimab in combination with toripalimab for cHL is being conducted. As the first phase III clinical study of drugs targeting BTLA in the field of hematological tumors, this study is to be carried out in more than 50 research centers in China, and will recruit about 185 subjects.
- 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

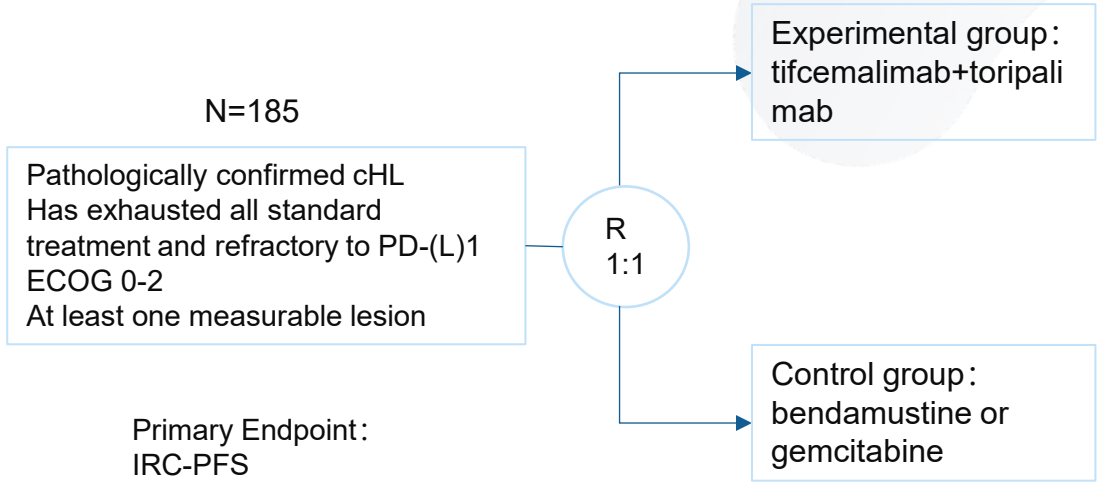
This study has completed the first patient enrollment (FPI) and the first drug administration in **China, the United States, Europe and Japan**



Primary Endpoint: OS, IRC-PFS

JS004-III-cHL

Planned to be carried out in more than 50 research centers in China. Enrollment is underway.



Primary Endpoint: IRC-PFS

Tifcemalimab shown promising efficacy in patients with advanced malignancies

Phase Ia: Tifcemalimab monotherapy in advanced solid tumors[1]

- By April 31, 2022, the median follow-up was 32 weeks.
- Among 19 evaluable patients, 1 confirmed PR (melanoma) and 7 SD (2 CRC, 2 HNSCC, 1 NET, 1 NSCLC and 1 Sarcoma) were observed.
- The median duration of SD was 18 weeks (9-45 weeks).
- 1 melanoma patient has continued PR for more than 24 months, and had previously progressed upon nivolumab and BRAF/MEK inhibitors treatments.
- No Dose Limiting Toxicity (DLT) was observed.

Figure 6. Changes in target lesion(s) over time

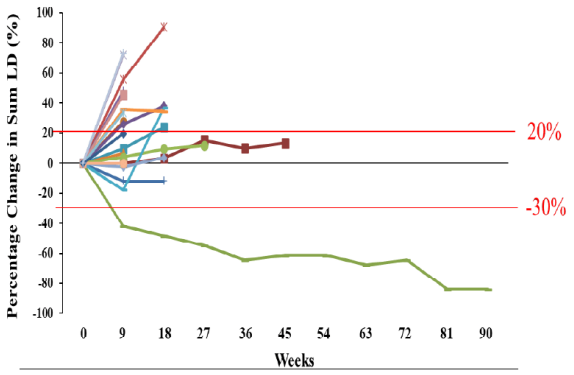
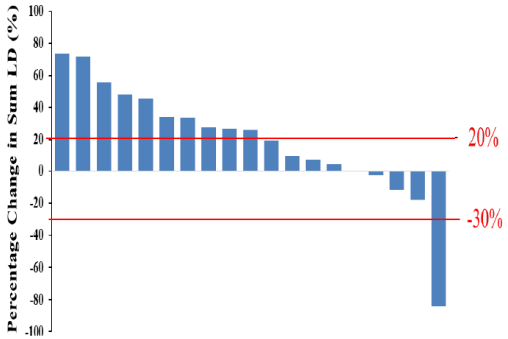


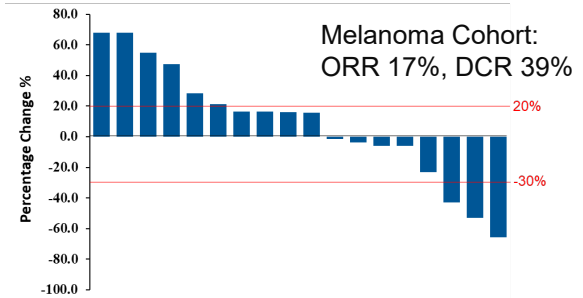
Figure 7. Best response of target lesion(s)

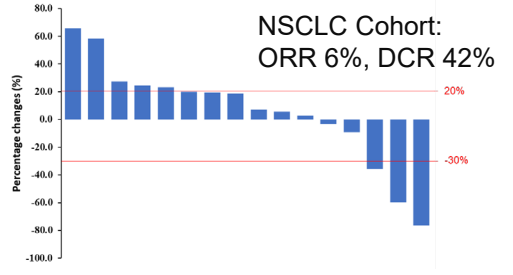


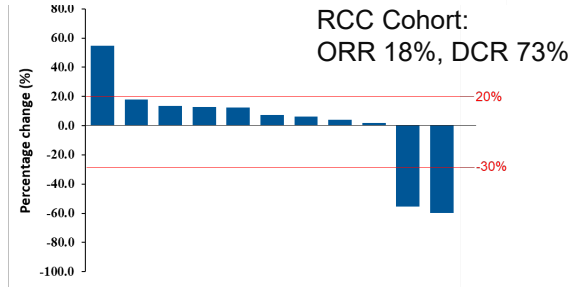
Phase I: Tifcemalimab in combination with toripalimab for the treatment of advanced malignancies in heavily pretreated patients[2]

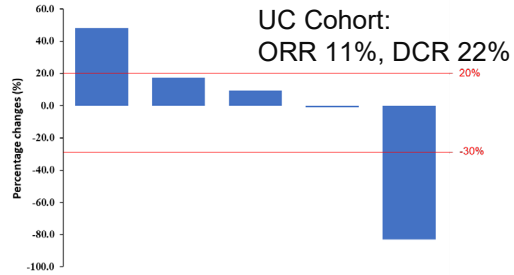
From July 2021 to February 2024, enrollment was completed with 16 patients treated in dose escalation and 75 patients treated in cohort expansion. Patients were heavily pre-treated with a median of 4 prior lines of therapy. 69 (75.8%) patients received prior anti-PD-(L)1 therapy.

- By the cut-off date of April 17, 2024, the median follow-up was 2.8 months.
- As assessed by the investigator, there was 1 complete metabolic response (classical Hodgkin's lymphoma), 6 partial response (3 melanoma, 1 RCC, 1 NSCLC and 1 UC) and one iPR (RCC) and 18 patients with stable disease. Seven of the 8 responses are still ongoing by the cut off date.





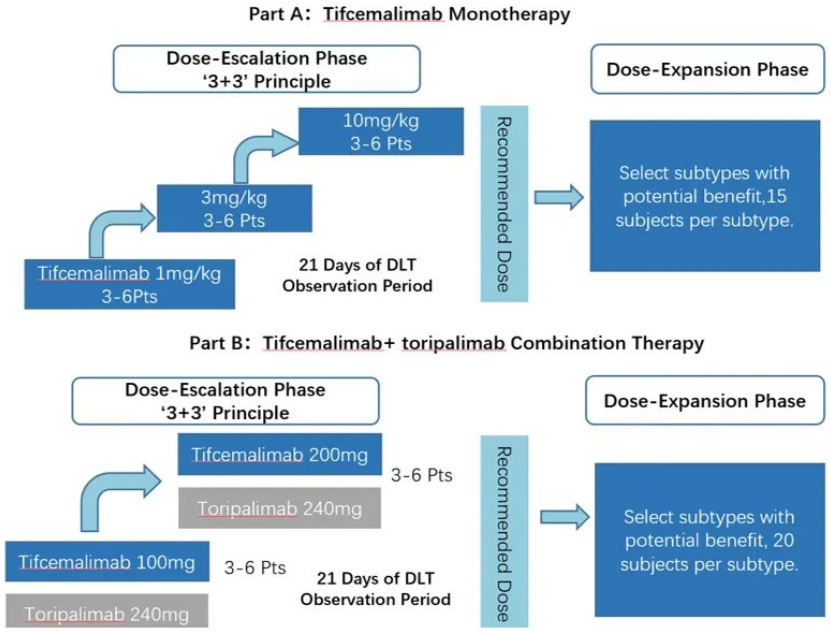




NCT04137900, led by Professor Aung Naing at MD Anderson in the United States, evaluated the safety and efficacy of tifcemalimab in patients with advanced malignancies. The study included two parts: tifcemalimab monotherapy (Parts A and B) and combination therapy with toripalimab (Parts C and D).1. ASCO 2022 presented preliminary data from the Phase I monotherapy clinical trial in patients with advanced solid tumors. 2. ASCO 2024 released data from the dose-escalation and cohort expansion phases of the combination therapy with tifcemalimab and toripalimab.

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

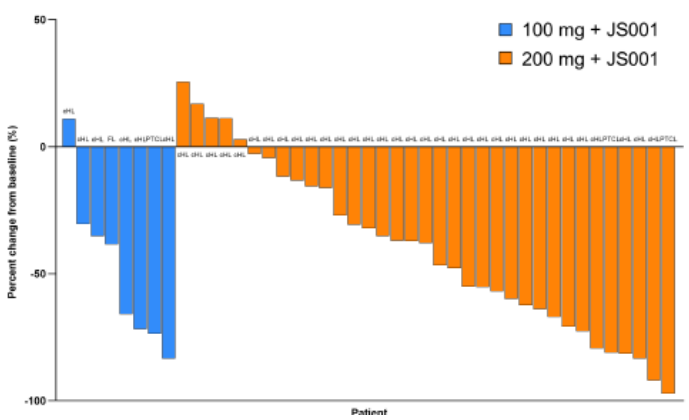
By the cutoff date of July 19, 2023, a total of 71 patients were enrolled, including 25 in part A (mono) and 46 in part B (combo). The median prior treatment lines were 4 in part A and 3 in part B. 54 (76%) progressed upon prior anti-PD-1/L1 therapy with 13 in part A and 41 in part B.



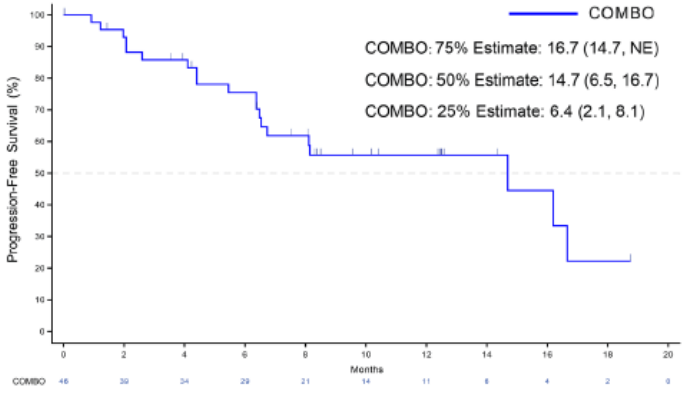
DLT, dose-limiting toxicity; Pt, patient.

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 refractory ES-SCLC: ORR of 40% in chemo refractory IO naive pts

- Phase I/II combination study of tifcemalimab with toripalimab in patients with refractory extensive-stage small cell lung canicer (ES-SCLC).
- As of Mar 14, 2023, 43 patients with **refractory ES-SCLC** were enrolled. 15 (34.9%) patients IO-refractory, 19 (44.2%) had received 2 lines of prior therapies.

Cohort 1
- Aged ≥18 years
- Pathologically confirmed NSCLC
- ECOG PS of 0-1
- Failure or intolerance to prior standard treatments
- Received ≤1 PD-(L)1 inhibitor
- No EGFR mutation/ALK fusion
- Adequate organ function

Cohort 2
- Aged ≥18 years
- Pathologically confirmed ES-SCLC
- ECOG PS of 0-1
- Failure or intolerance to prior standard treatments
- Immunotherapy (IO) naïve or received ≤1 PD-(L)1 inhibitor
- Adequate organ function

Part A: safety run-in phase
Tifcemalimab 200 mg IV Q3W + Toripalimab 240 mg IV Q3W

Part B: extension phase
Tifcemalimab 200 mg IV Q3W + Toripalimab 240 mg IV Q3W

Continue until disease progression, intolerable toxicity, or other treatment discontinuation criteria were met. Treatment may continue after PD if the patient is clinically stable per investigator

Results

- By the cut-off date, the median follow-up time is 26.4 weeks.

- In all patients (EAS=40): **ORR was 27.5%, DCR was 55.0%.**
- **In the IO naive patients (EAS=20): ORR was 40.0%,** DCR was 70.0%, median DoR was 6.9 months, and among them, three (15.0%) responders to tifcemalimab plus toripalimab have lasted over 6 months, median PFS was 5.5 months.
- Among 20 non-IO naïve patients, including 15 patients with prior IO treatment and 5 patients with unknown IO treatment status, 2 patients and 1 patient, respectively, achieved PR.

- For safety, 38 (88.4%) patients experienced TEAEs, 32(74.4%) experienced TRAEs. Grade≥3 TEAEs and TRAEs occurred in 16 (37.2%) and 7 (16.3%) patients, respectively. No patient withdrew from tifcemalimab or toripalimab treatment due to TEAE.

Figure 2. Maximum tumor reduction in IO naïve patients (EAS=20)

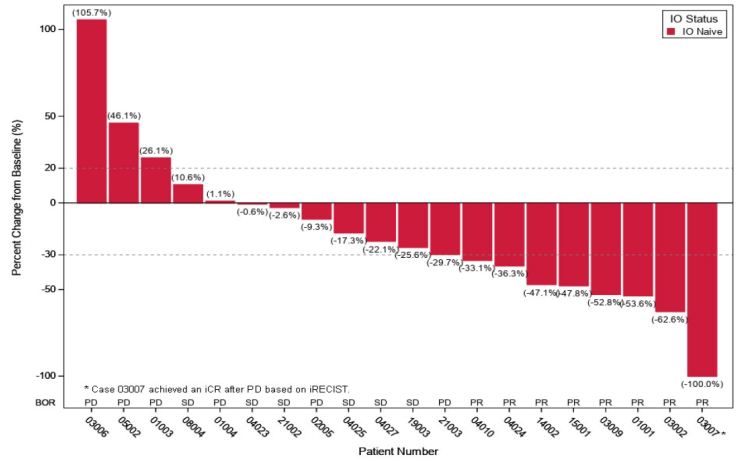
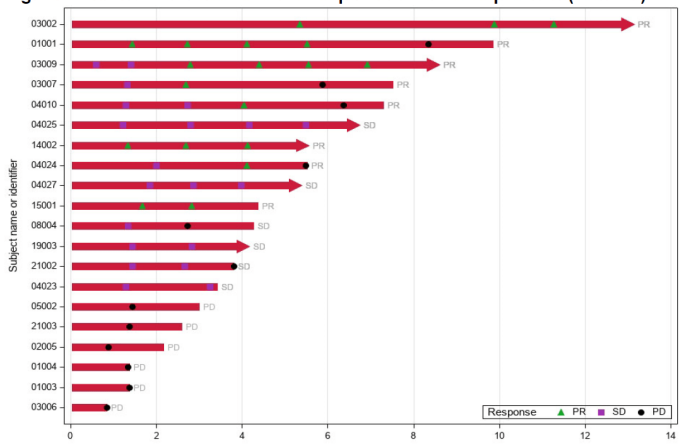


Figure 4. Duration of treatment and response in IO naïve patients (EAS=20)



Source: ASCO 2023#8579

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.

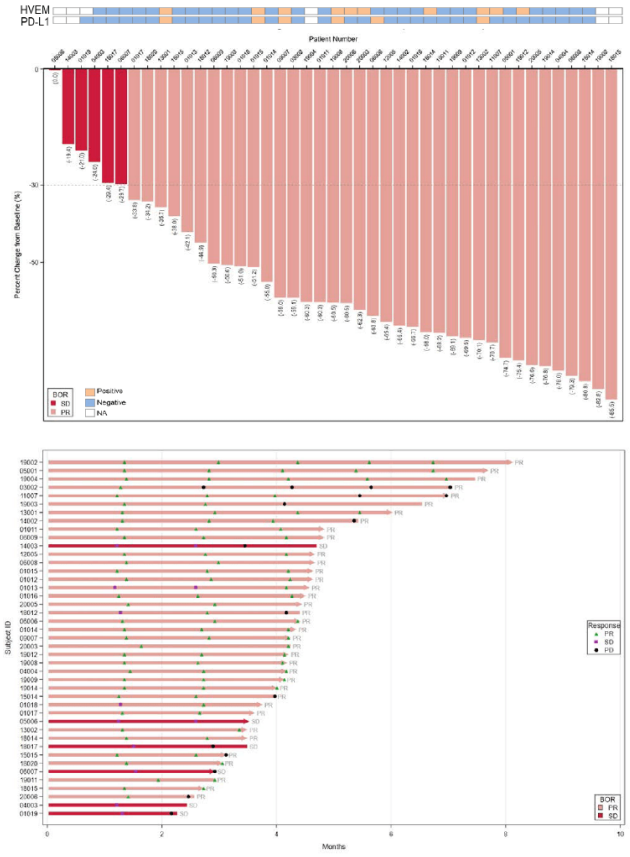


Figure 4. KM plot of PFS

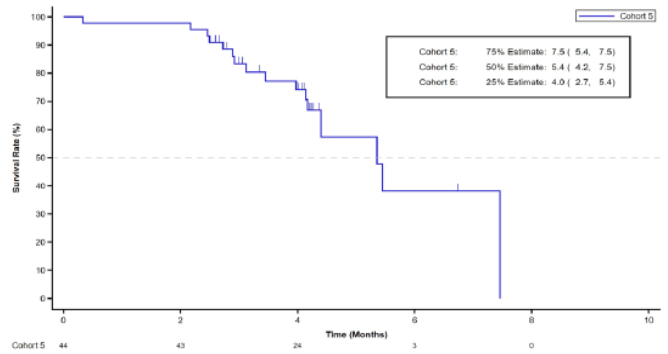
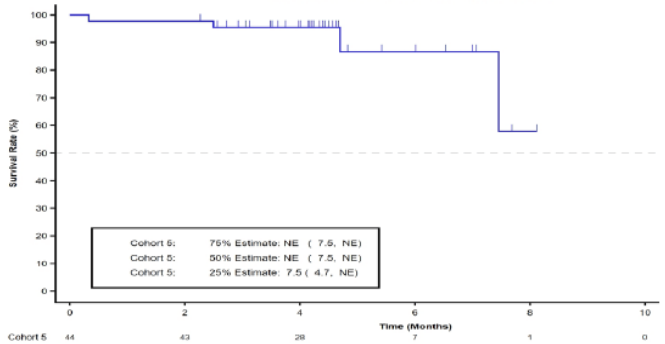


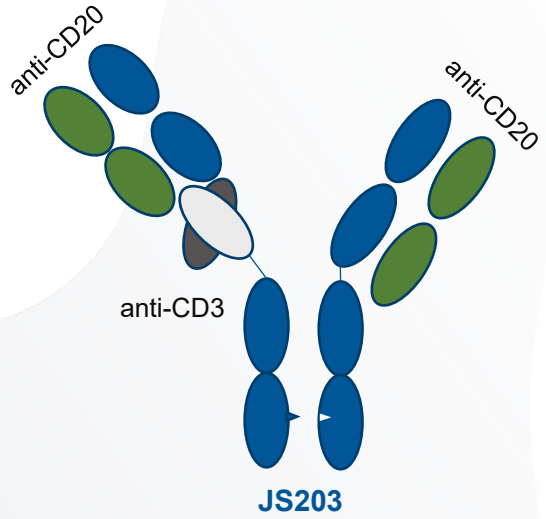
Figure 5. KM plot of OS



Source: ASCO 2024#8089

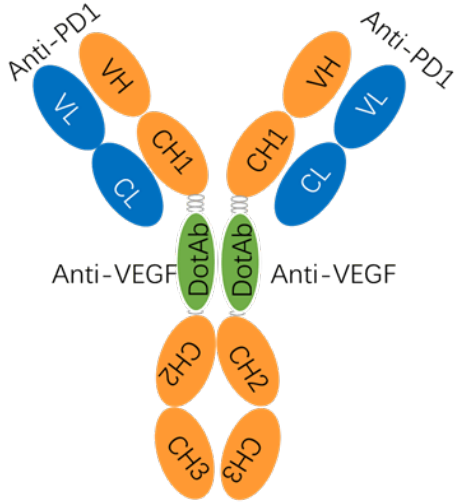
Multiple Bispecific Antibody Programs

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 clinical stage.**

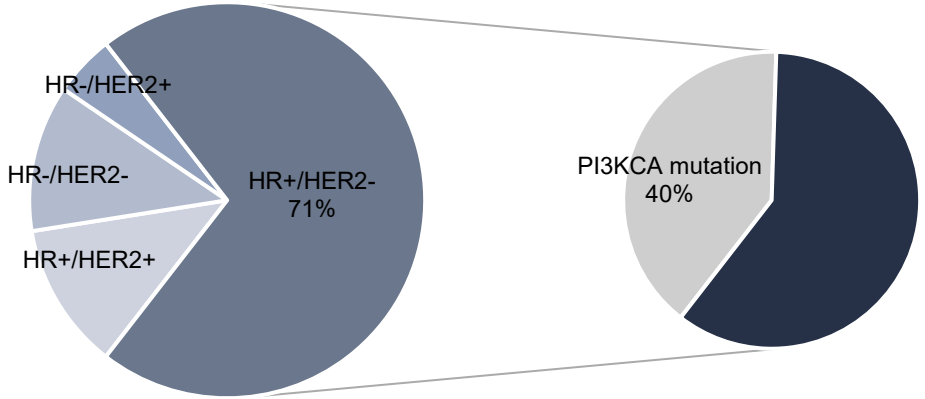
JS207
PD-1 x VEGF Bispecific Antibody



- Given the strong correlation between VEGF-A and PD-1 expression in the TME, the simultaneous blockade of these two targets by JS207 as a single agent might achieve enhanced antitumor activity, with an improved safety profile, compared to the combo therapy.
- **JS207 is currently in phase I clinical stage.**

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 female (post-menopausal) patients with HR-positive, HER-2 negative, PIK3CA-mutated, advanced breast cancer who are experiencing disease progression during or after treatment with endocrine-based regimens.
- 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.**

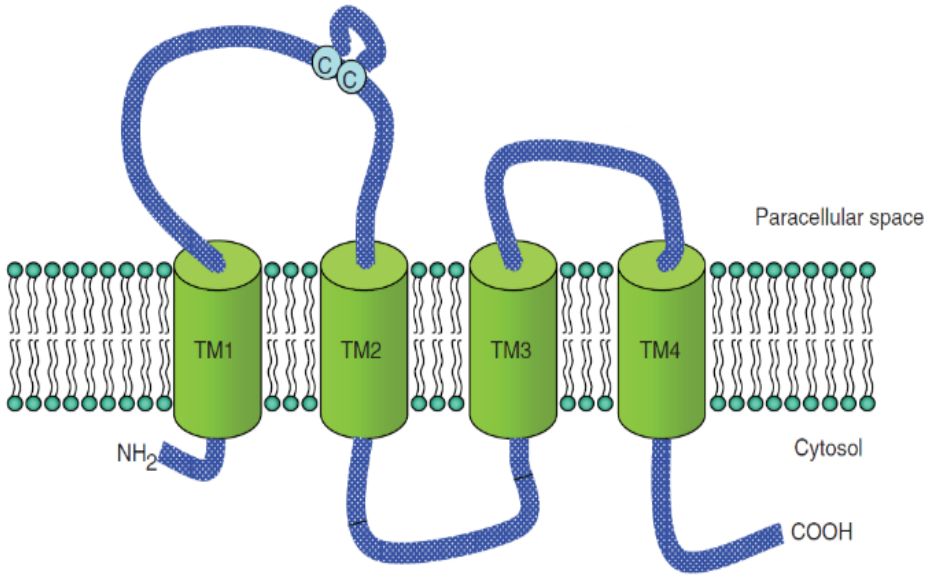


- According to GLOBOCAN 2020, breast cancer had the highest incidence rates worldwide, with 2.26 million new cases and 0.68 million deaths in 2020.
- According to data from Novartis, HR+/HER2- represents 71% of breast cancer patients, and ~40% of people with HR+/HER2- breast cancer have a PIK3CA mutation in their tumor
- There is only one PI3K-α inhibitor, Piqray® (Alpelisib, a product of Novartis), approved for commercialization in the world, and no PI3K-α inhibitor has been approved for marketing in China.

Source: Vanhaesebroeck B, et al. Nature Reviews Drug Discovery, 2021, 20(10): 741-769., Novartis investor presentation

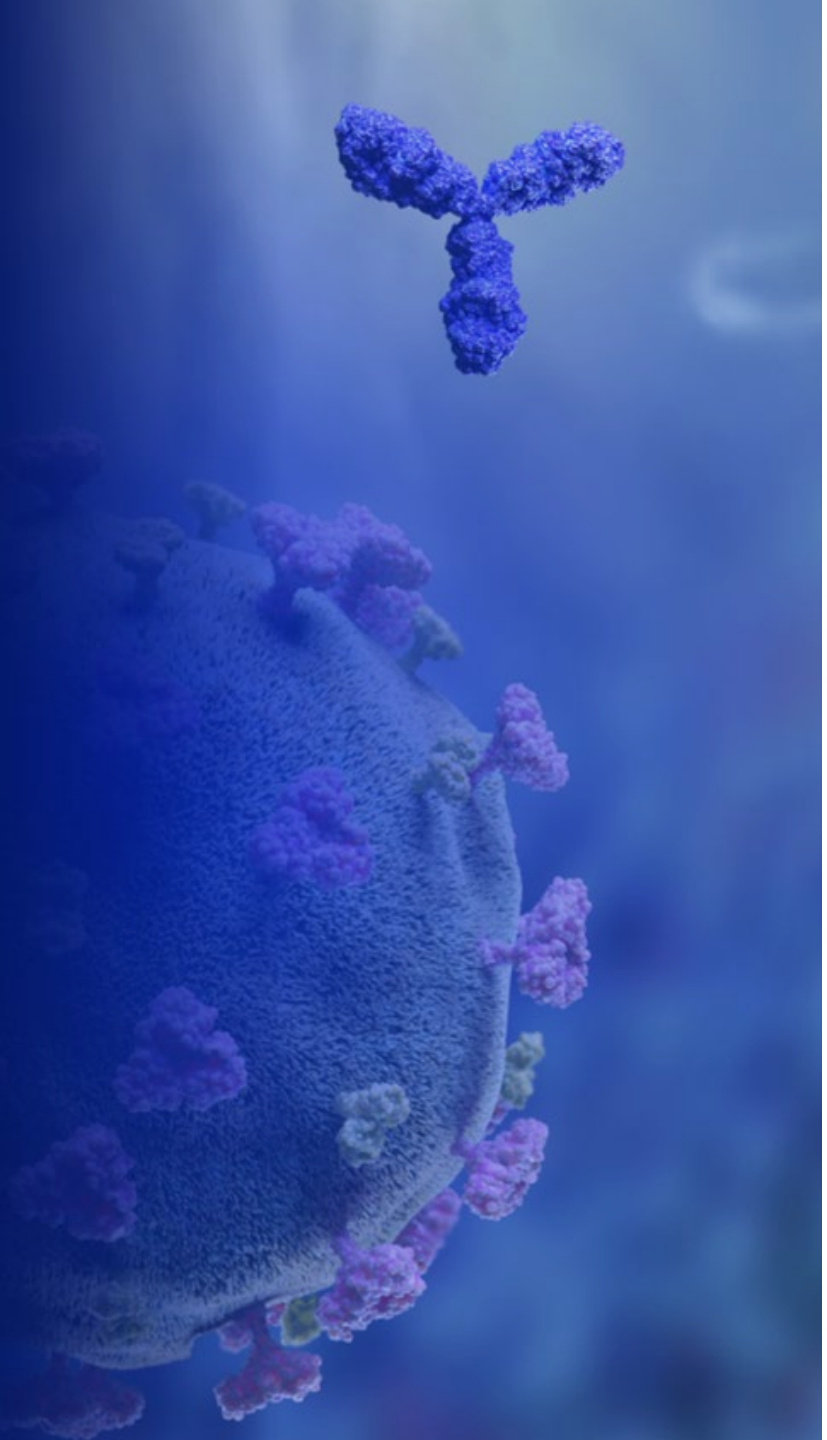
JS107: Anti-Claudin18.2 ADC

- 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 studies on the JS107's monotherapy and combination treatment are currently underway.**



schematic of a claudin18 monomer

JS107 can bind to Claudin18.2 on the surface of tumor cells, enter into tumor cells through endocytosis, and release the small molecule toxin MMAE, which has a strong lethality to tumor cells.



君实生物
TopAlliance

Innovation Beyond Oncology

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

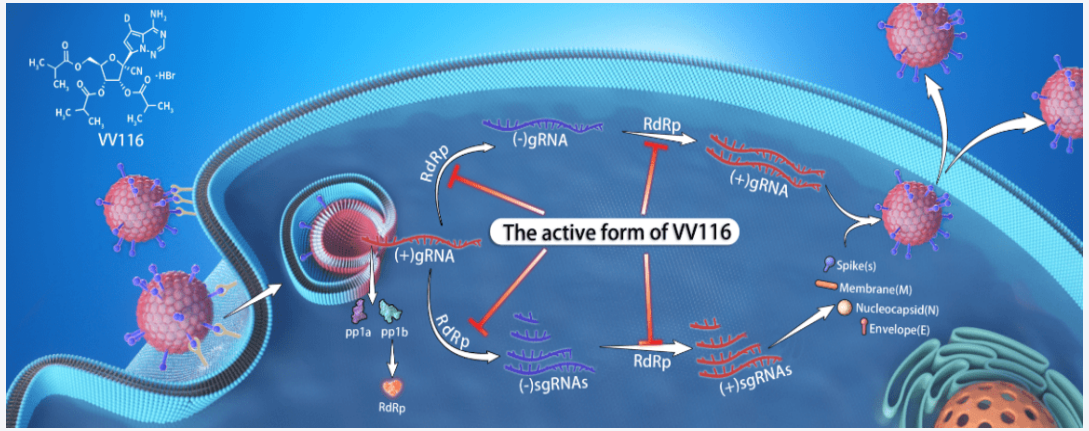
Deuremidevir Hydrobromide Tablets (VV116/JT001): Oral Nucleoside Drug against COVID-19

- 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. MINDEWEI was officially included in the NRDL since January 2024.
- 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)***.

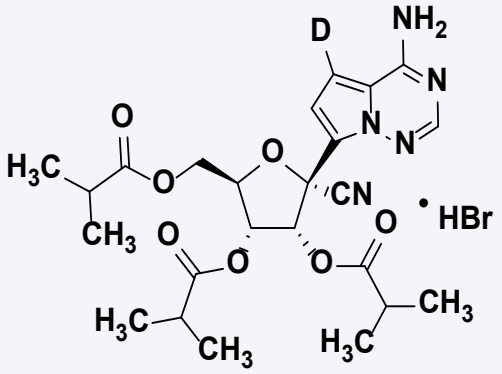
JT001-015

- 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

Ongericimab (JS002): Anti-PCSK9 mAb

- **Indications:** hyperlipidemia
- **Origins:** In-house, developed independently by Junshi
- **Commercial Rights:** Global
- **Clinical Stage**: **NDA accepted in China**

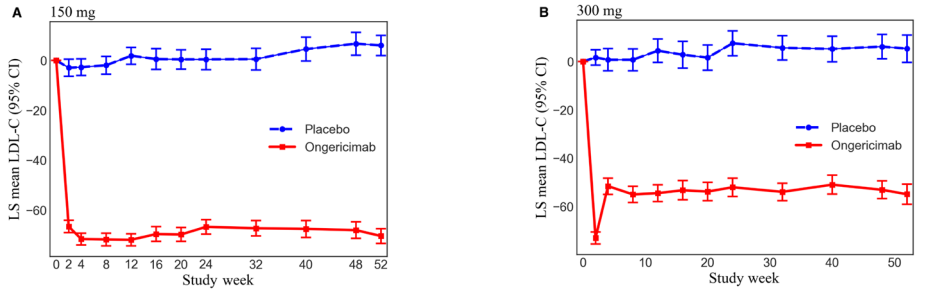
In April 2023, the NDA for ongericimab was accepted by the NMPA for the treatment of:

- Primary hypercholesterolemia and mixed dyslipidemia (combined with statins);
- Homozygous familial hypercholesterolemia.

In April 2024, the NMPA has accepted two sNDA for ongericimab for the treatment of:

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

	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 ranging from 60.3% to 76.5% 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 (45%–75%).

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.

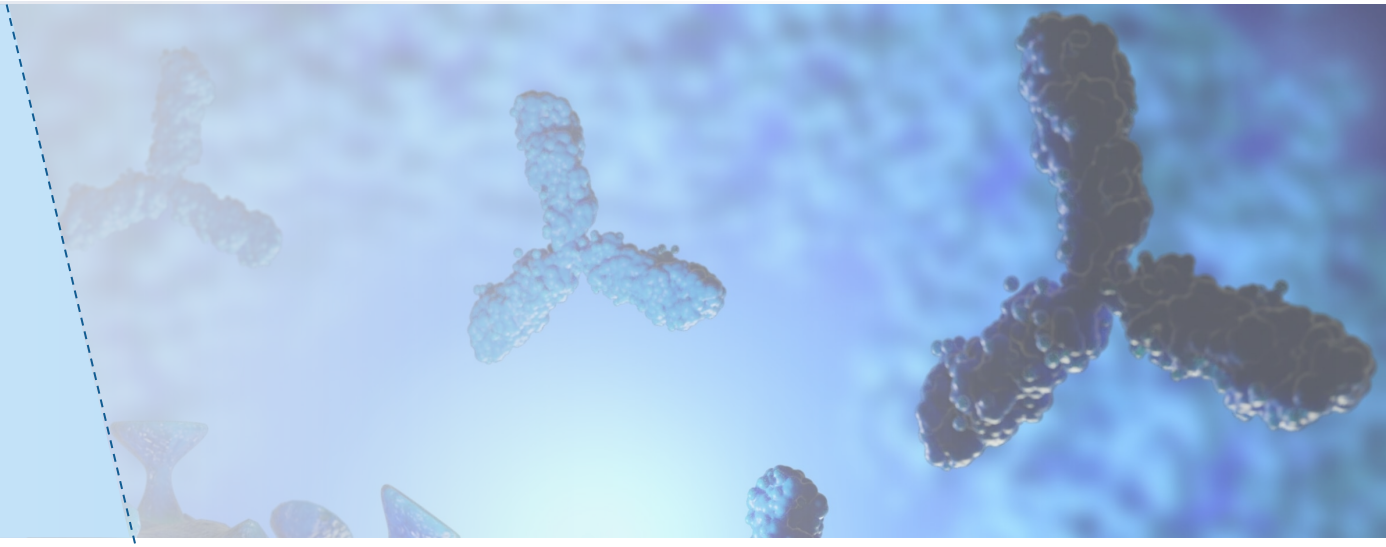
Autoimmune and Neurological Diseases

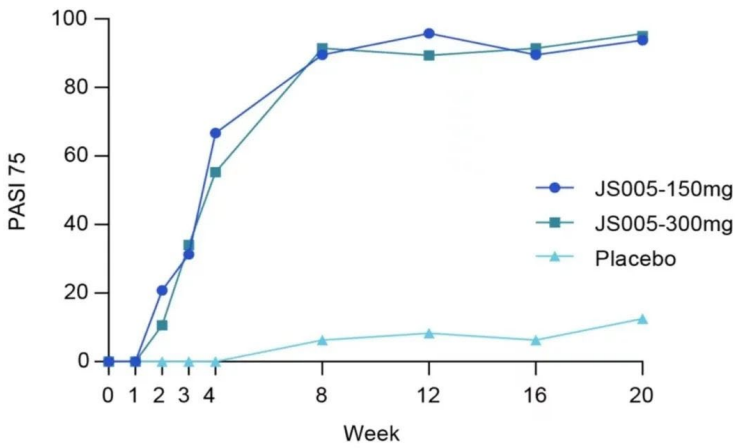
JS005

Anti-IL-17A mAb

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

- **Currently in Phase 3 clinical stage:** moderate to severe plaque
- **All subjects have been enrolled**





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%)

JS010

Anti-CGRP mAb

- **Indications:** preventive treatment of migraine in adults
- **Origins**: In-house, developed independently by Junshi
- **Commercial Rights:** Global

- **Currently in Phase 1 clinical stage.**

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.

JS005(Anti-IL-17A mAb): Significant Advantages over Competitive products

- **Rapid response:** During the treatment cycle, JS005 achieves comparable PASI 75/90 response rates approximately **4 weeks earlier than competitive products**.
- **Comparable efficacy**: At week 12, JS005 demonstrates PASI 75/90 response rates similar to those of competitive products.
- **Lower incidence of infectious adverse events:** The study in Chinese participants shows that JS005 exhibits a lower incidence of infection-related adverse events compared to competitive products with same target, with no additional safety signals found.

		JS005	Overseas Product 1 with same target	Overseas Product 2 with same target	Domestic drug candidate 1 with same target	Domestic drug candidate 2 with same target
PASI 75 Response Rate	At Week 4	60-70%	< 40%	~60%	~50-55%	< 40%
	At Week 8	~90%	< 70%	~80%	86.5%	~80%
	At Week 12	91.1%-95.6%	67%-98.0%	81%-90%	86.5%	90.7%
PASI 90 Response Rate	At Week 4	20~30%	< 20%	< 30%	~20%	Undisclosed
	At Week 8	~65%	~25%-40%	~60%	~54%	Undisclosed
	At Week 12	75.6%-80.0%	39%-81%	65%-71%	62.2%	74.4%
AEs-Infection and Infestations	-	10.6-14.6%	28.7%	27%	35.5%	UK (Upper respiratory tract infection 14.0%)

Note: The data is based on indirect comparisons across clinical trials.

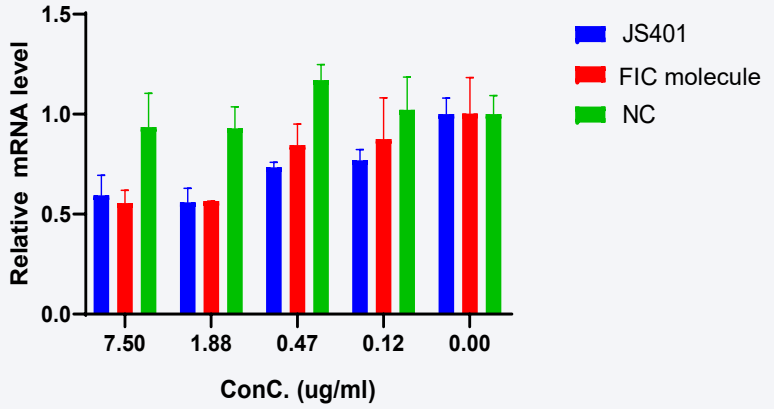
JS401: siRNA Drug targeting ANGPTL3

The advantages of our siRNA technology platform

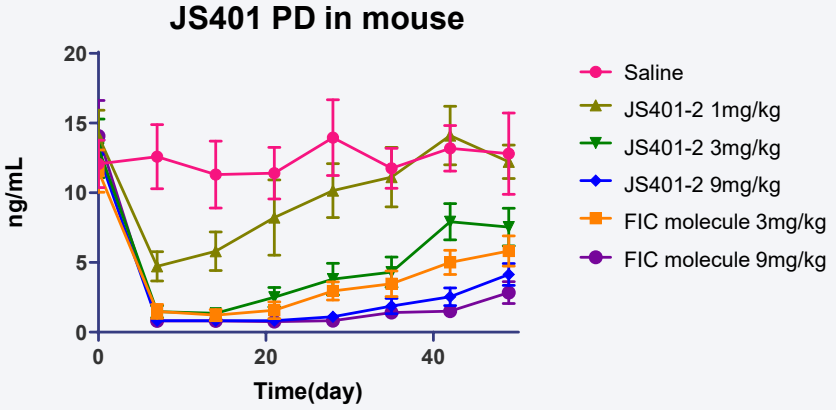
- Applying bioinformatics and AI technology to bring rational siRNA design, generating siRNA sequences with high inhibitory effect.
- Through our unique modifications, the stability of siRNA is enhanced with lower side effects. After generating siRNA sequence with inhibitory activity, it can be combined with targeted delivery molecules to form an siRNA drug with specific inhibition.
- The synthesis and purification platform, as well as the pilot production platform of siRNA drugs will also be established in the near future to further improve R&D.

JS401: controlling triglycerides & cholesterol levels long term

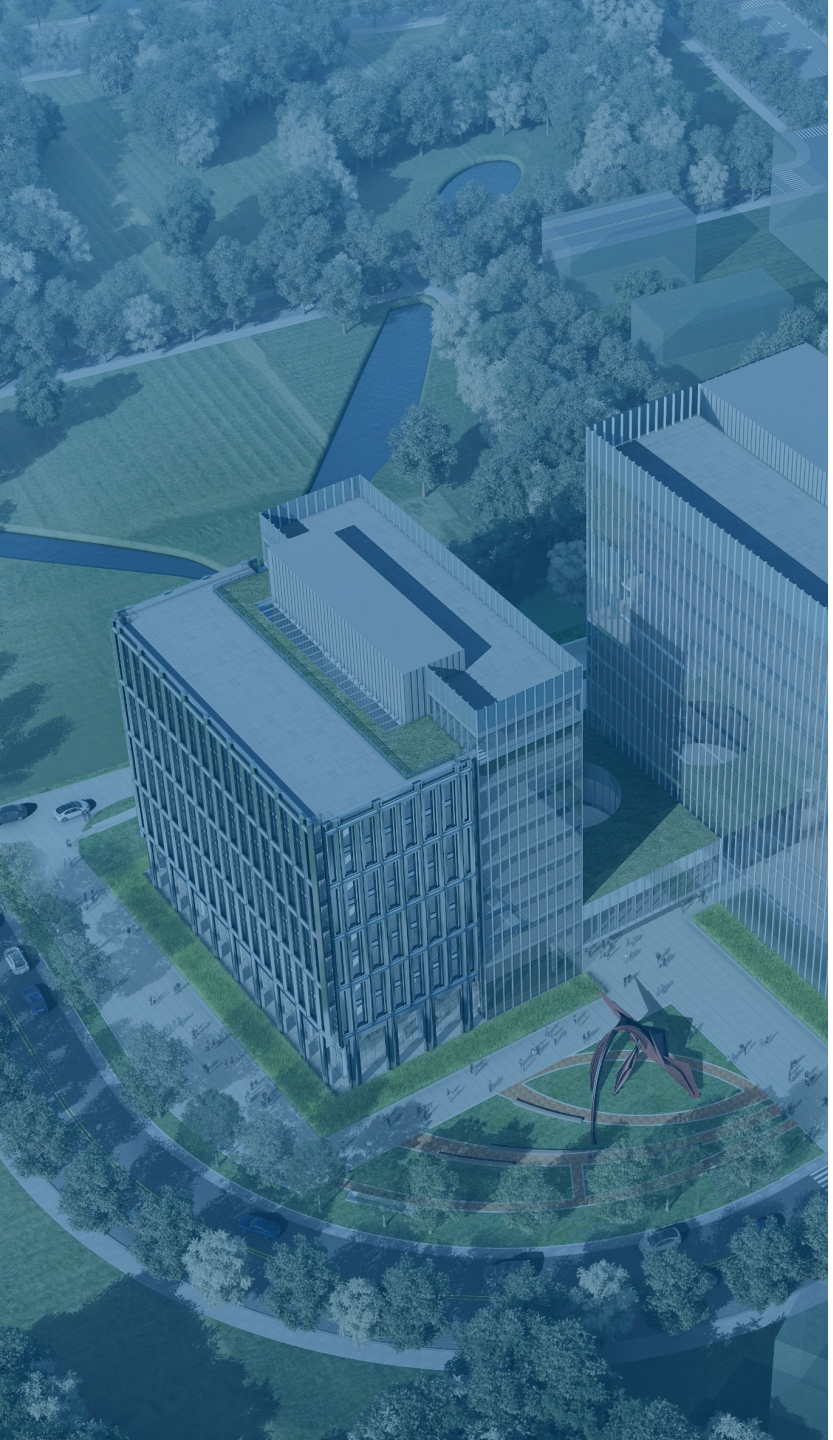
- JS401 is a siRNA drug targeting ANGPTL3 mRNA jointly developed by Junshi and Risen Shanghai, which is intended to be mainly used for the treatment of hyperlipidemia.
- Compared with monoclonal antibody drugs, siRNA drugs can effectively control triglycerides and cholesterol levels for a longer period of time.
- **In April 2023, the IND application for JS401 was approved by the NMPA. Currently, JS401 is in Phase 1 clinical stage.**



Comparable in vitro activity of free uptake in monkey hepatocytes to the FIC molecule



Comparable protein inhibitory activity in transgenic mice to the FIC molecule



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Commercialization

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

Fast Sales Growth in 2024 H1

Total Operating Income

786 MN

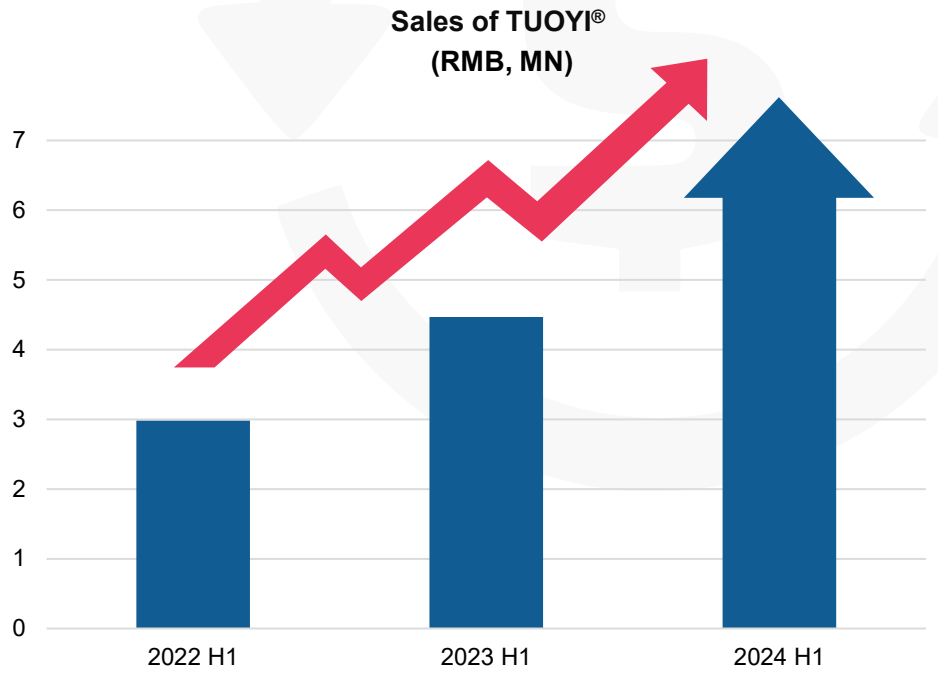
YoY **17.37** %

Sales of TUOYI®

671 MN

YoY **~ 50** %

The commercialization efficiency continued to improve, the sales revenue of the core product, TUOYI®, increased rapidly, and our income-generating capacity has been further strengthened.



Improvement in Commercialization Efficiency

TUOYI®: six indications included in the NRDL

- Starting from 2024, TUOYI® has three new indications included in the new edition of the NDRL, and there are currently a total of six indications being included in the NRDL.
- The only anti-PD-1 mAb used in the treatment of melanoma and NPC in the NRDL.
- TUOYI® has been sold in **more than 5,000** medical institutions and **more than 2,000** specialty pharmacies and community pharmacies nationwide.

MINDEWEI: officially included in the NRDL

- MINDEWEI was 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 and an internal team for MINDEWEI based on the coverage of its existing internal hospital sales team for TUOYI®. All members of the new sales promotion team have extensive experience in promotion in the field of respiratory infections.

JUNMAIKANG: stable sales revenue in the future

- Under the continuous promotion of our commercialization partners, JUNMAIKANG was newly used in **55** hospitals during the Reporting Period. As of the end of the Reporting Period, JUNMAIKANG completed the tendering process on the procurement platform as well as healthcare and insurance connection in **26** provinces, and has been used in **243** hospitals, covering **1,303** pharmacies.

Production capacity support our business continues to expand

Shanghai Lingang
Production Base

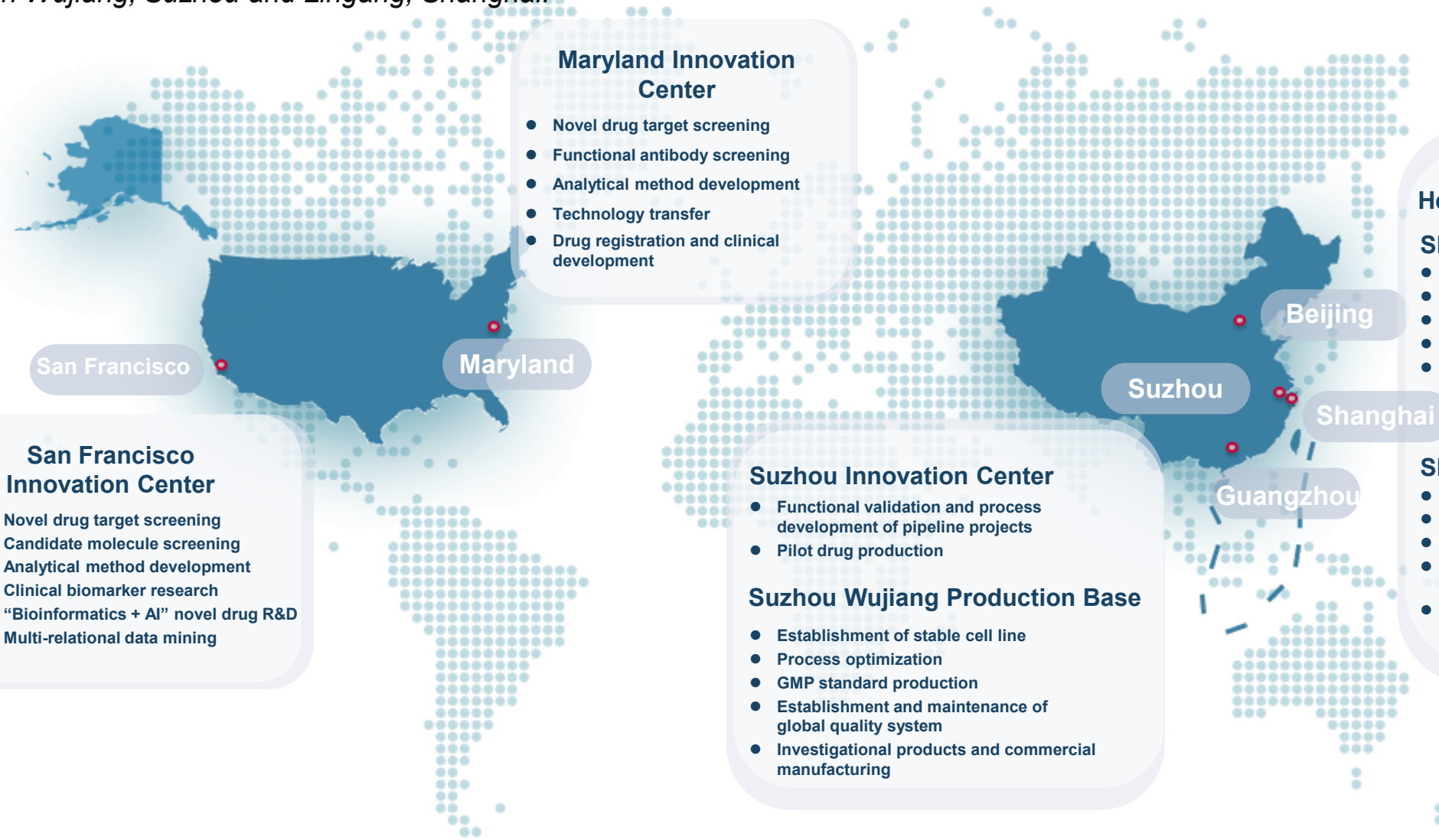
- Under construction in accordance with **CGMP standard**
- **42,000L** fermentation capability in the first phase of the project
- **NMPA GMP certification**
- Passed the on-site inspection conducted by Lilly and **provided overseas clinical samples of JS016**
- **Digital "smart" factory**
- Responsible 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 the NMPA, EMA and FDA**

In China, For Global

We have established four R&D centers in Shanghai, Suzhou, San Francisco 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

San Francisco Innovation Center

- Novel drug target screening
- Candidate molecule screening
- Analytical method development
- Clinical biomarker research
- "Bioinformatics + AI" novel drug R&D
- Multi-relational data mining

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

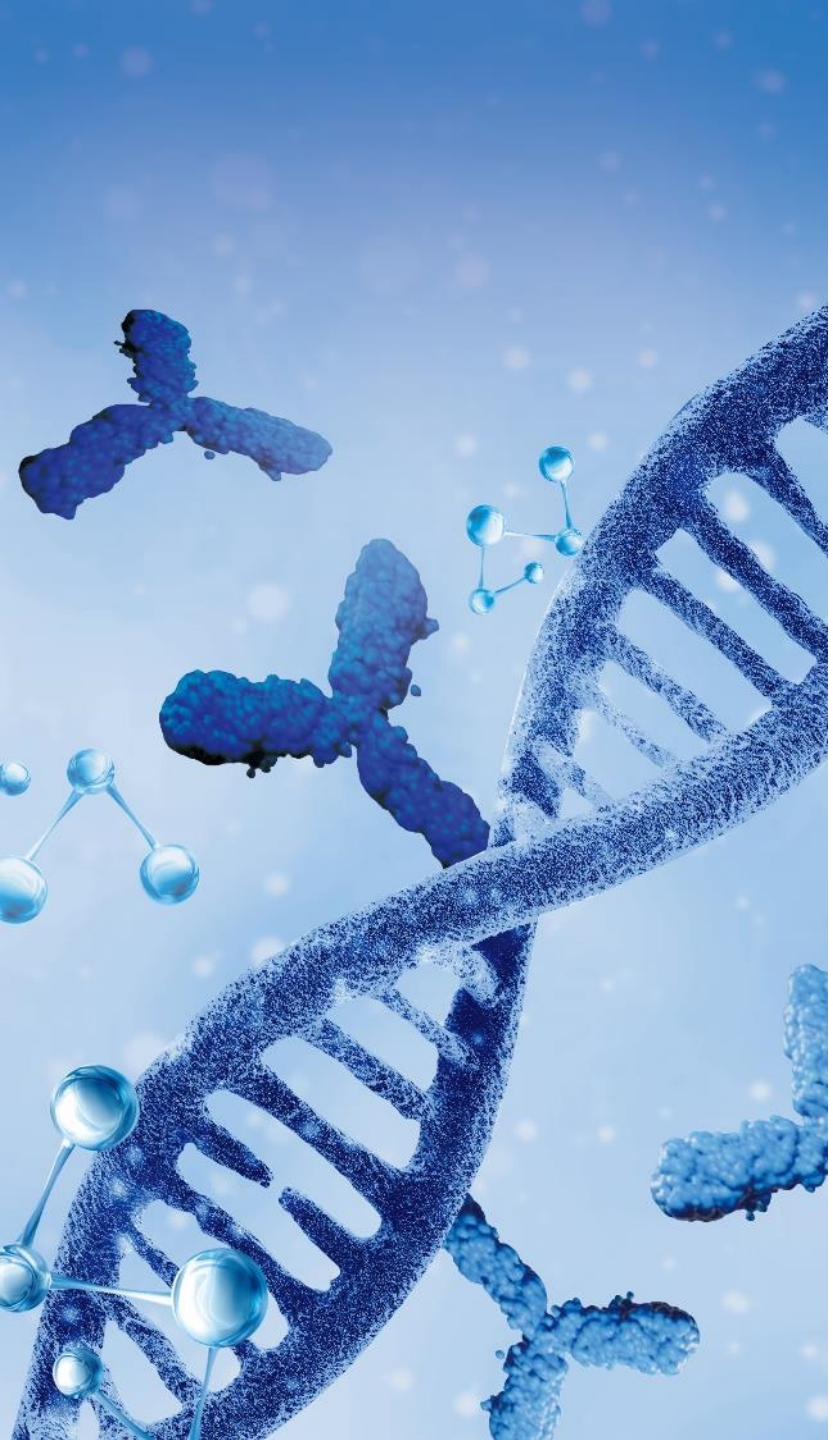
Headquarters

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



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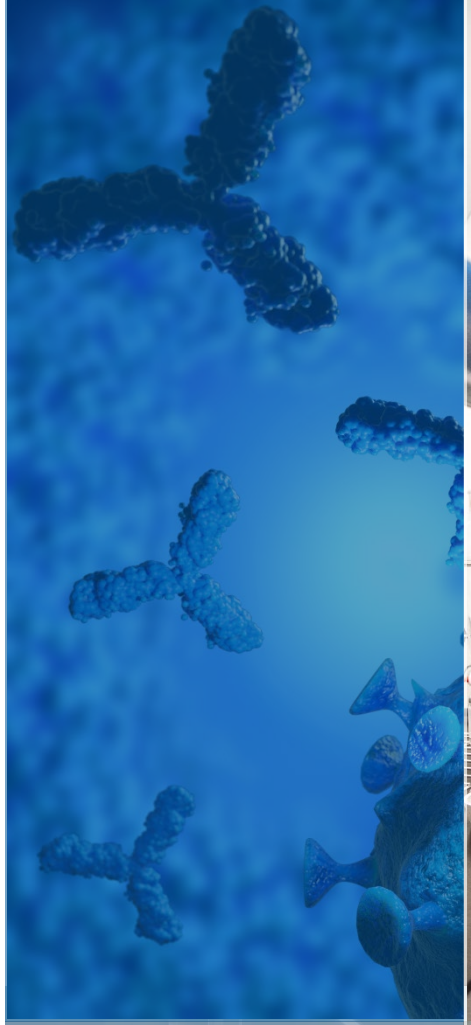
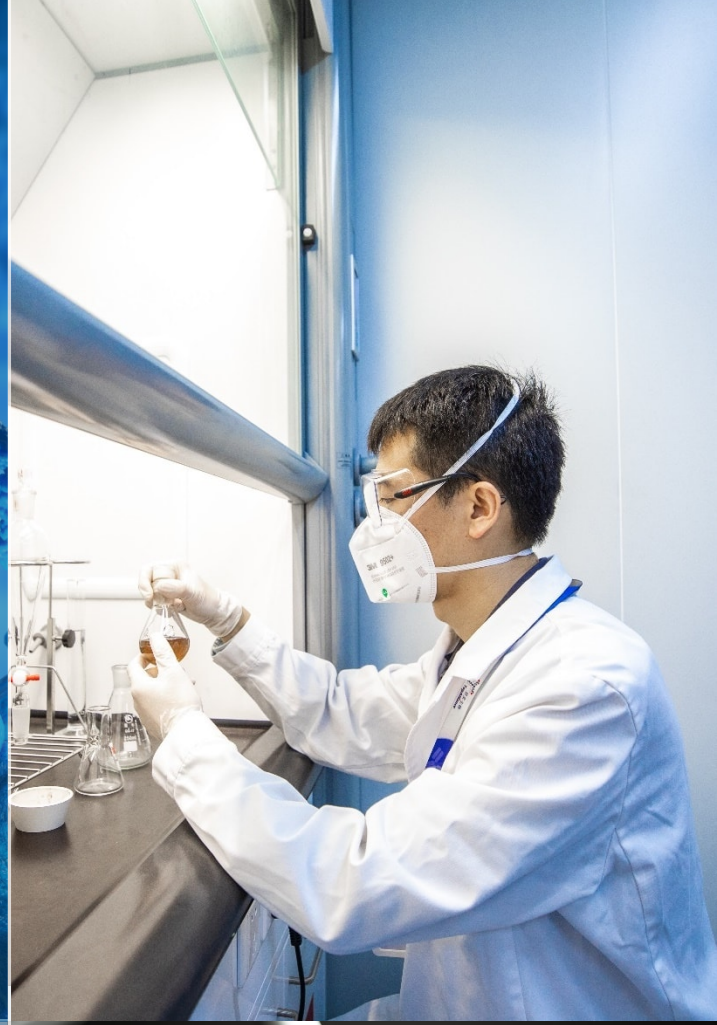
Outlook

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

2024 Catalysts

Domestic Commercialization	• Toripalimab (PD-1) TNBC (PD-L1+) ✓ • Toripalimab (PD-1) 1L RCC ✓ • Toripalimab (PD-1) 1L SCLC ✓ • Ongericimab (PCSK9) PH/MHL • Ongericimab (PCSK9) HoFH	
Overseas Commercialization	• EU • Singapore • Australia • Malaysia • HKSAR	• India • South Africa • Chile • Jordan
Data readouts & sNDA submissions	• Toripalimab (PD-1) ESCC perioperative • Toripalimab (PD-1) 1L HCC ✓ • Ongericimab (PCSK9) HeFH ✓ • Ongericimab (PCSK9) statin intolerance ✓	
Pivotal studies	• Tifcemalimab (BTLA) cHL enrollment complete • JS005 (IL-17A) enrollment complete ✓ • JS105 (PI3K-α) initiate • JS001sc(PD-1) initiate ✓	
Academic publications	Plan to submit research findings for **7** products/candidates from **22** clinical trials to a variety of international academic conferences/journals	





THANK YOU

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