



Annual Report 2023

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

March, 2024

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2023 Business Overview



US FDA approval for the first domestic anti-PD-1 mAb

- US FDA approval for **toripalimab (trade name: TUOYI®/LOQTORZI™)**
- Included in the NCCN guidelines as a preferred category 1 treatment
- Commercial launch in the US
- Marketing applications under review by EU, UK, Australia and Singapore health authorities
- Marketing applications submitted in India, South Africa, Chile, and Jordan
- The first domestic oncology drug to be included in Project Orbis
- Achieved international collaboration in more than 50 countries



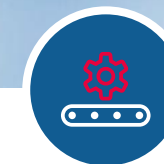
Steady growth in Sales Revenue

- **TUOYI®**: 7 indications approved in China, 6 covered by the national insurance (NRDL), 3 supplemental BLAs under review by the NMPA
- **MINDEWEI**: conditionally approved by the NMPA; officially covered by the NRDL
- **JUNMAIKANG**: 8 indications approved in China, all covered by the NRDL



Efficiently pushed forward R&D pipelines

- **Tifcemalimab (BTLA)**:
 - Maintenance therapy for limited stage small cell lung cancer (LS-SCLC): Multi-regional Ph3 Trial initiated, completed FPI and the first drug administration
 - Chemo- and IO- refractory classical Hodgkin's Lymphoma (cHL): Ph3 Trial initiated in China
- **Ongericimab(PCSK9)**: BLAs for 2 indications under review by the NMPA
- **JS005 (IL-17A)**: Ph3 registrational clinical study for moderate to severe plaque psoriasis initiated



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; responsible for the production of the commercial batches of toripalimab in the US at this stage
- **Shanghai Lingang production base**: A production capacity of 42,000L (21*2,000L)
- 12 internal quality audits conducted and 12 external quality inspections/audits received

2023 Financial Results

	FY 2023 (RMB/MN)	FY 2022 (RMB/MN)	YoY (%)
Total Operating Income	1,503	1,453	+3.38%
PD-1 Sales Revenue	919	736	+24.93%
Total Operating Expense	3,812	4,103	-7.09%
Selling Expenses	844	716	+17.98%
R&D Expenses	1,937	2,384	-18.74%
Administrative Expenses	536	569	-5.74%
Net loss attributable to shareholders	-2,283	-2,388	/
Net loss attributable to the shareholders after deducting non-recurring profit and loss	-2,298	-2,450	/

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

Projects Entering the Clinical R&D Stage (as of March 28, 2024)

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

● Oncology
 ● Metabolism
 ● Immunology
 ● Neurologic
 ● Infectious disease

1: Received Emergency Use Authorization from the FDA

2: The products listed herein are products that have obtained IND approvals as announced

Broad Technology Platforms

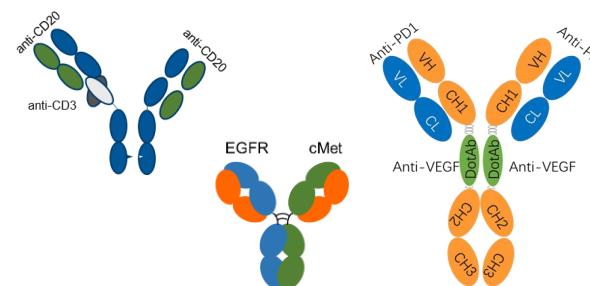
50+
Drug Candidates

mAbs



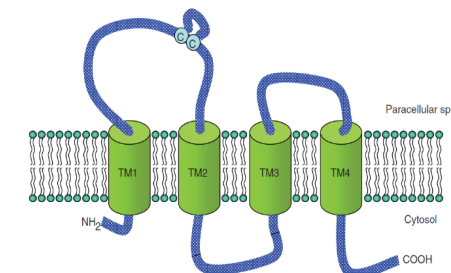
Oncology: Toripalimab (PD-1), Tifcemalimab (BTLA) ...; **Immunology:** Adalimumab (TNF- α), JS005 (IL-17A),...; **Metabolism:** Ongericimab (PCSK9); **Neurologic:** JS010 (CGRP); **Infectious disease:** Etesevimab (S protein)

BsAbs



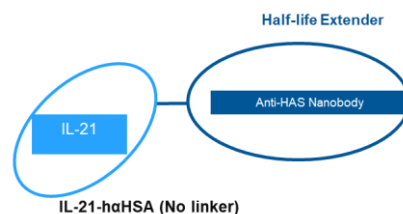
Oncology: JS203(CD20xCD3), JS201 (PD-1 x TGF- β), JS207(PD-1xVEGF)...

ADCs



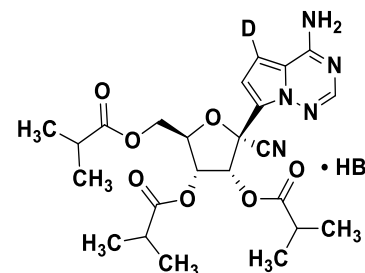
Oncology: JS107 (Claudin18.2 ADC), JS108 (Trop2 ADC)...

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

siRNA R&D Platform

- Our siRNA R&D platform is initially established with eight basic supporting systems that improve our developing efficiency
- Improve two crucial elements of siRNA drug developments: drug delivery system, and chemical structure modification

Metabolism: JS401(ANGPTL3 siRNA)

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 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
- Included in the **NCCN guidelines** as a preferred category 1 treatment



LOQTORZI™: Coherus Commercial Strategy

Expected to achieve NPC peak sales **within 2.5 to 3 years**, with the market value reaching **up to \$200 million at peak**.



Strong KOL advocacy: During MHNCS 2024, Coherus held over 50 1v1 in-person meeting with the nation's top opinion leaders. And over 90% of them affirmed that LOQTORZI™ + chemo will become the new standard of care in NPC.

Achieved preferred listing on both the ASCO and NCCN: LOQTORZI™ is the only PD-1 with a Category 1 designation with NCCN for first line use of NPC

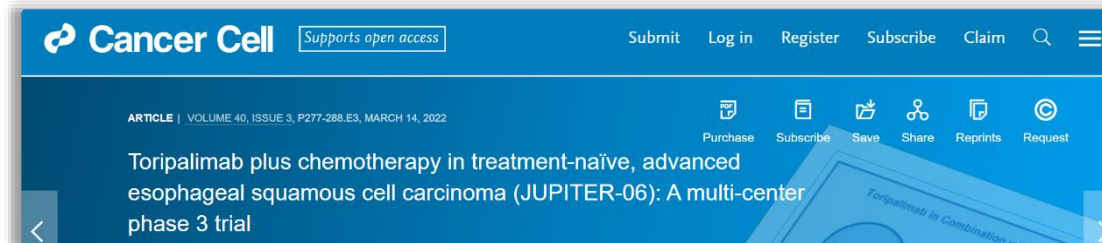
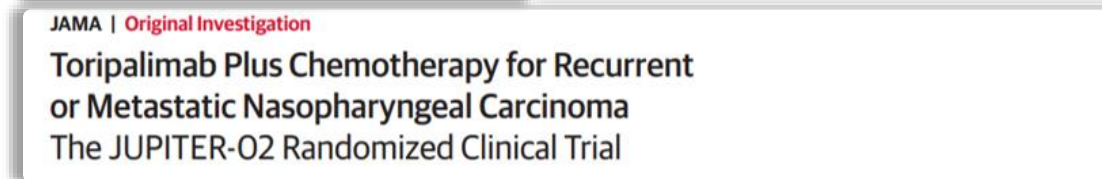
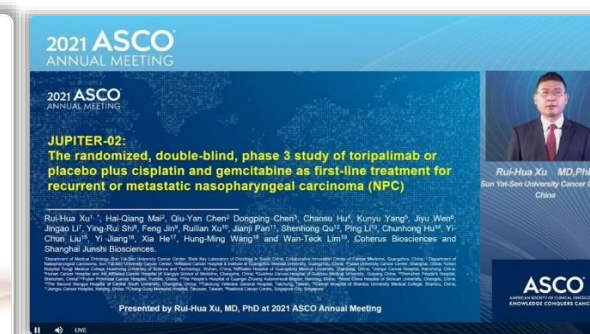
Confirmed Payer Coverage: Label with payers representing **~95%** of targeted lives

Deployed digital tools to identify NPC patients in real time: Enabling LOQTORZI sales calls and hyper targeted branded digital advertising to occur with the right doctor at the right time, contributing over **60%** of accounts that have ordered LOQTORZI™

Physicians are prescribing: Since launch, 59 accounts comprised of both clinics and hospitals have purchased LOQTORZI™. And 55% of the NCCN designated cancer centers have already added LOQTORZI™ to formulary with the remaining centers in P&T review.

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 and Singapore
 - ✓ 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.



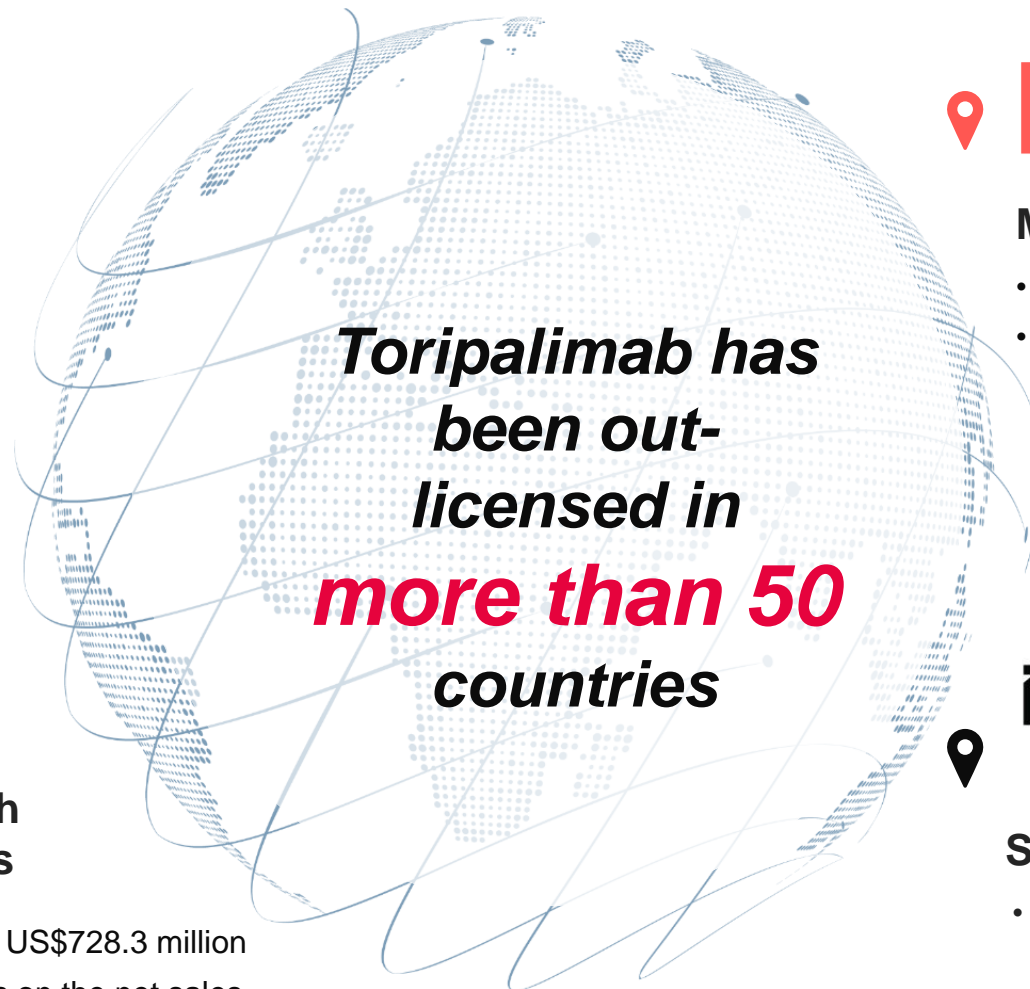
US and Canada

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



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



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



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

Academic Achievement

The milestones achieved in clinical studies of our product and candidate are included in presentations of many international academic conferences and journals.





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 and Singapore.

Frontline



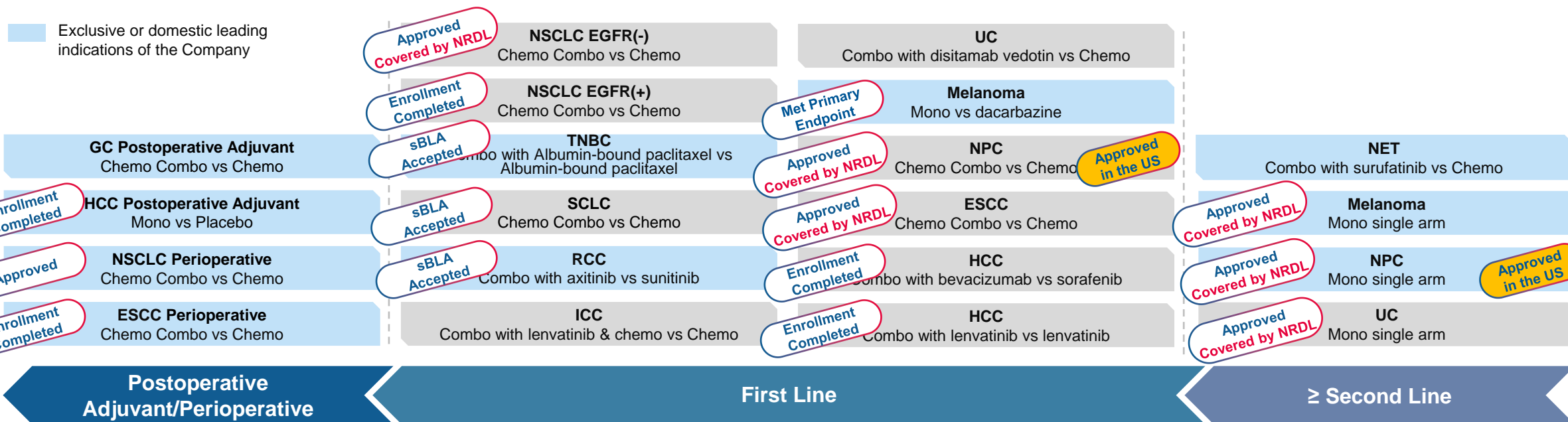
Phase 3 clinical trials on postoperative/perioperative treatment settings in lung, gastric, esophageal and liver cancer will be completed in the near future.

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.

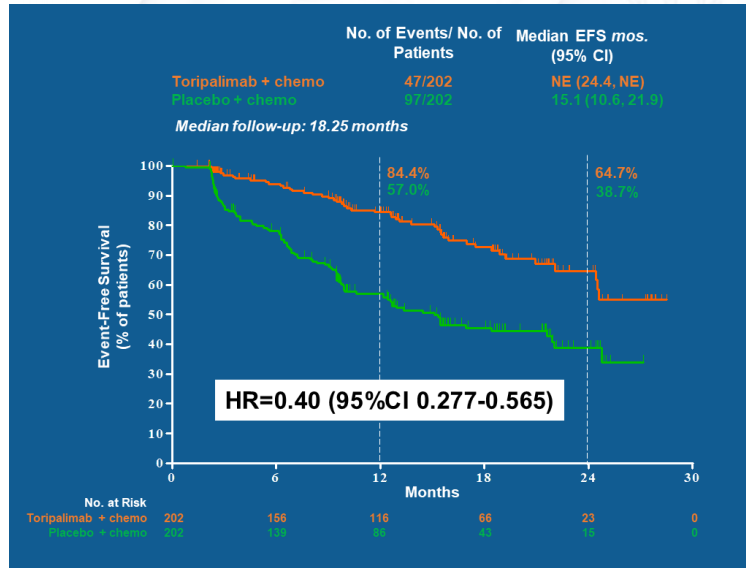
Pivotal registrational clinical trial layout of Toripalimab



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

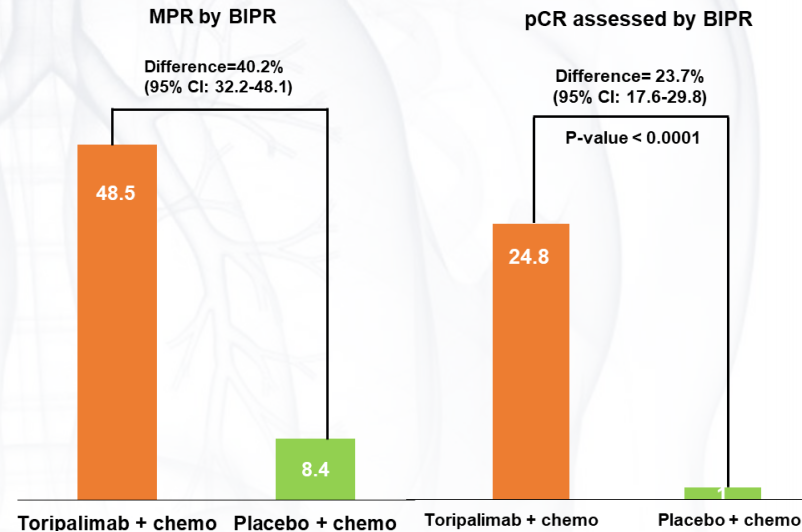
This is the first and only approved perioperative therapy for lung cancer in China.

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

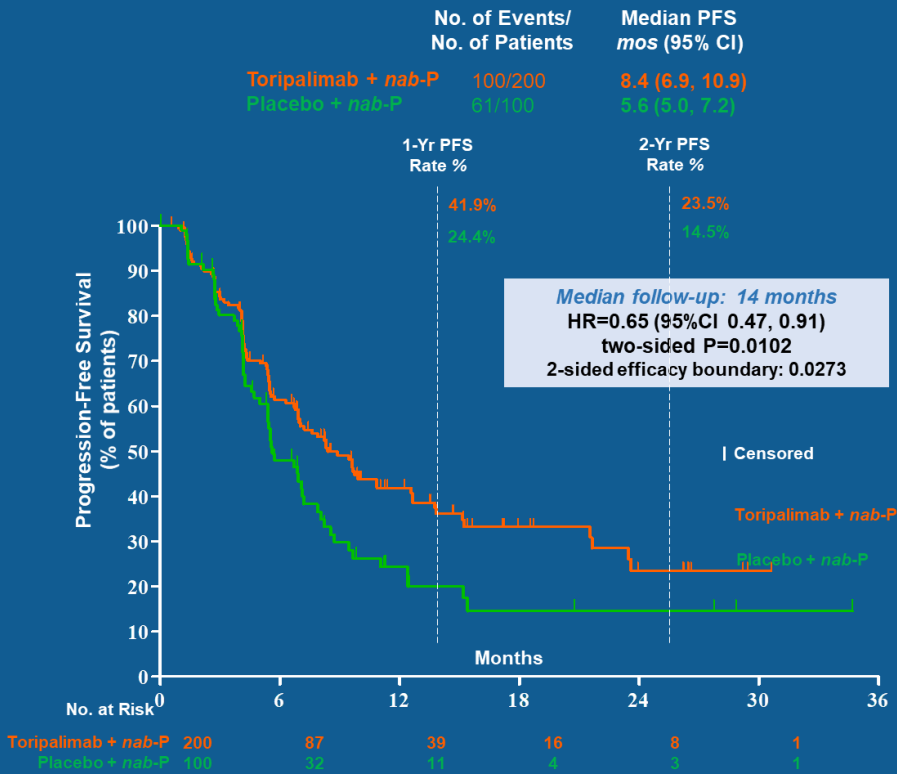
Study	IO stage
CheckMate-816	Neoadjuvant
Impower 010	Adjuvant
KEYNOTE-091	Adjuvant
NEOTORCH	(Neoadjuvant+Adjuvant) Perioperative

- NEOTORCH is at the forefront of progress

Study	Announcement of positive EFS results
NEOTORCH	2023.01.17

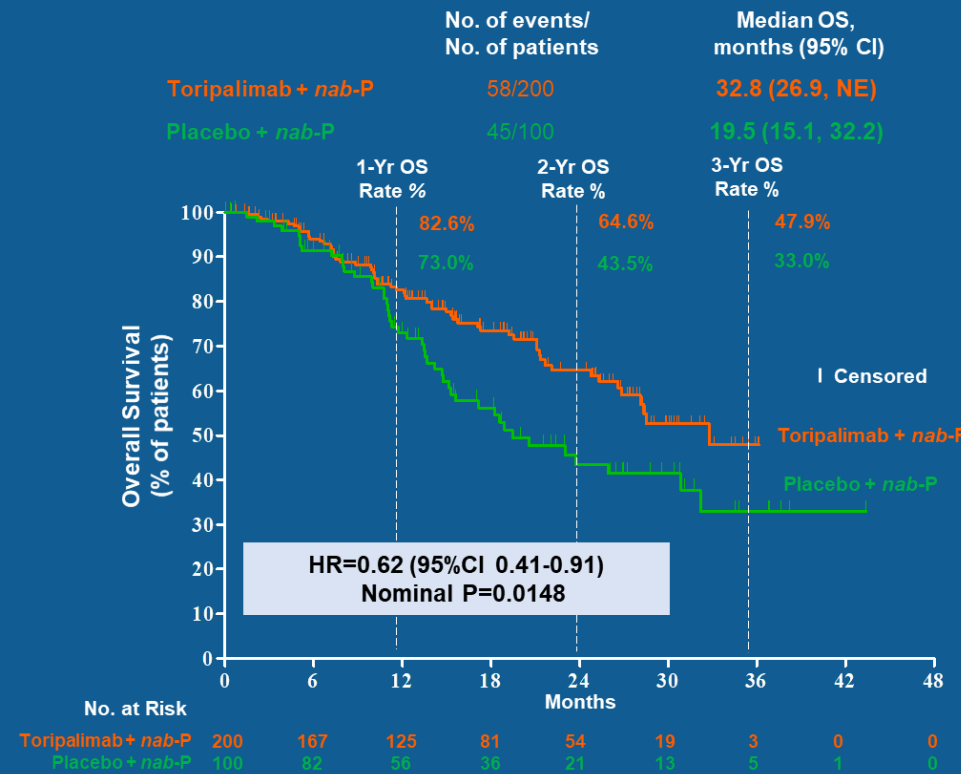
KEYNOTE-671	2023.03.01
AEGEAN	2023.03.09

The TORCHLIGHT Study: First Ph3 Registrational Study in China to Achieve Positive Outcome in Advanced TNBC immunotherapy, sBLA Accepted 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

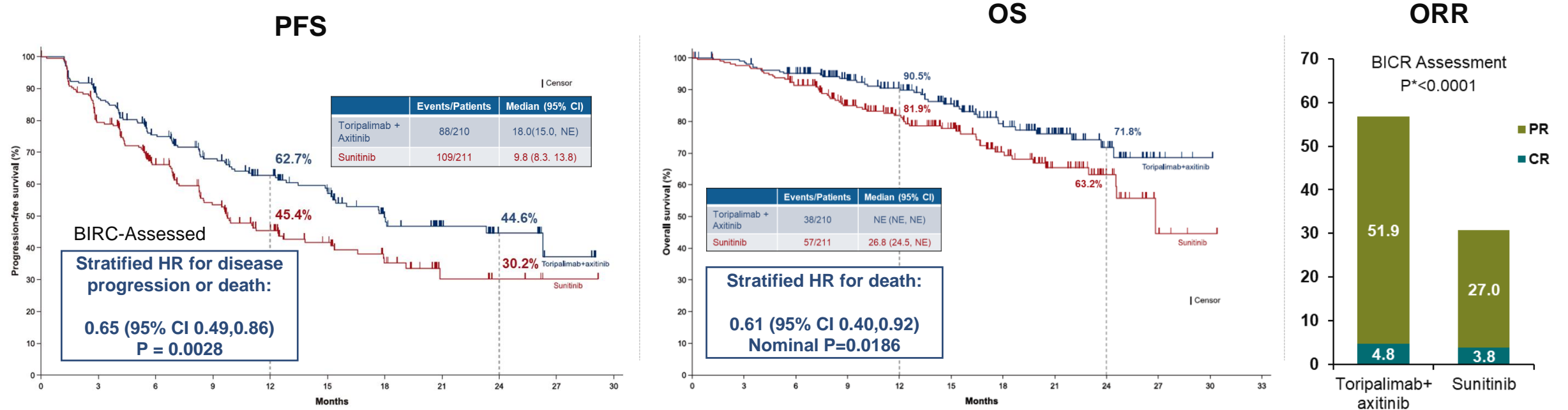
- Median OS in PD-L1 positive (CPS≥1) subgroup: **32.8** vs. 19.5 months

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.**

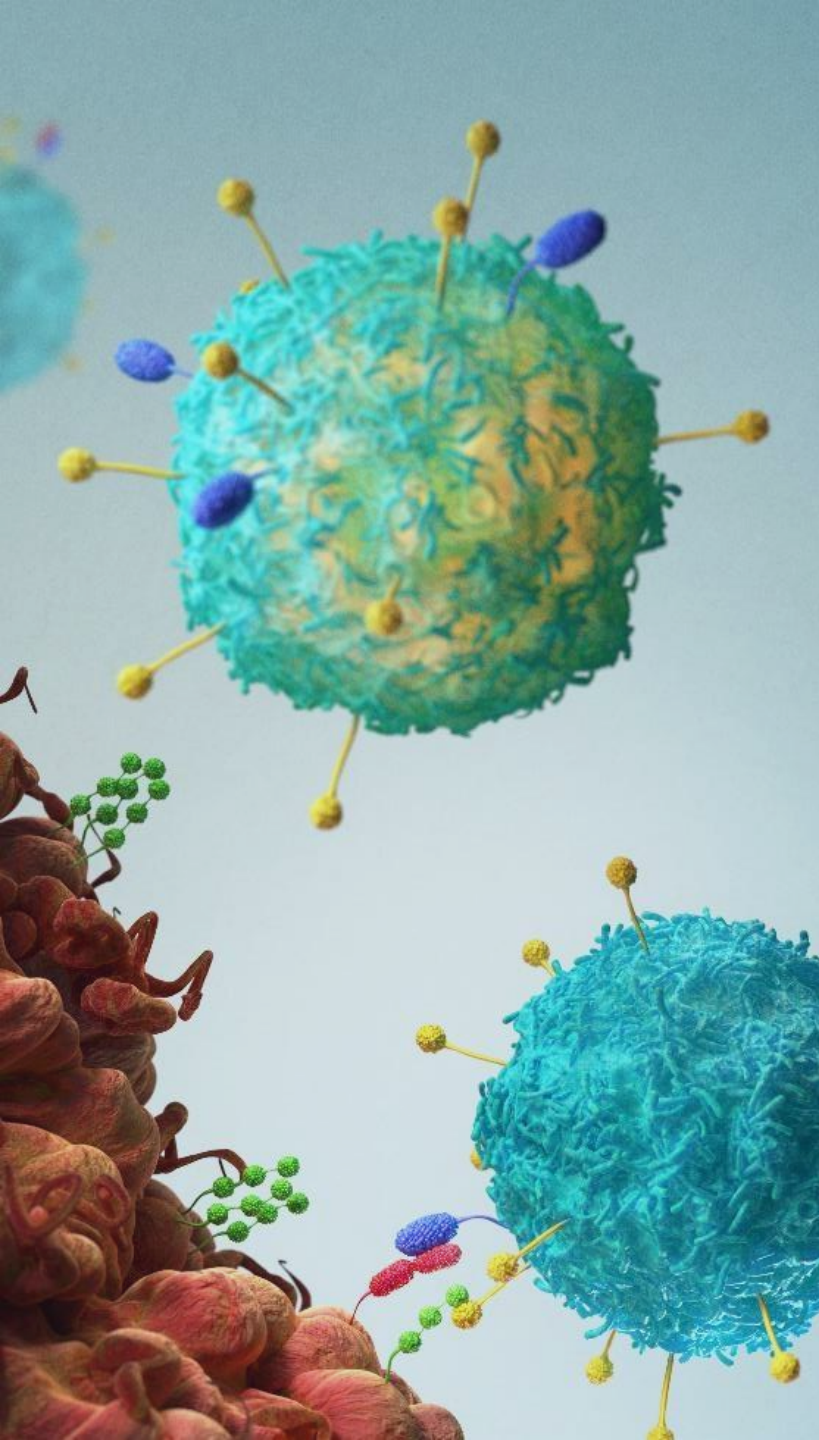
In May 2023, the supplemental new drug application for toripalimab in combination with nab-paclitaxel for the treatment of PD-L1 positive (CPS ≥ 1) untreated metastatic or recurrent metastatic TNBC has been accepted by the NMPA.

In June 2023, the results were presented as LBA at the ASCO 2023.

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



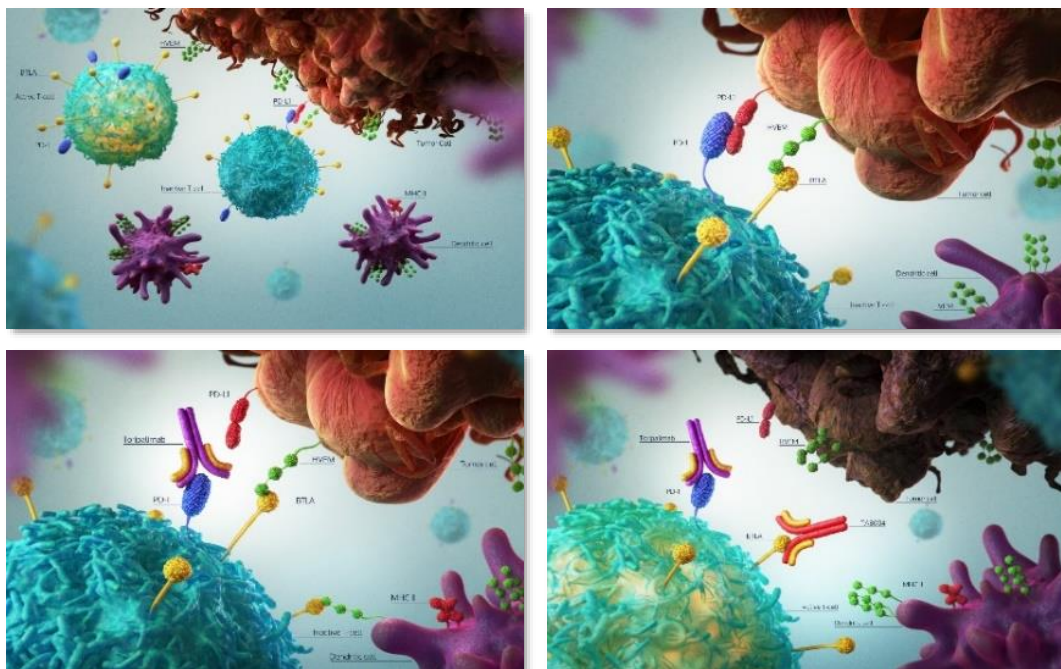
- Compared with sunitinib monotherapy, toripalimab plus axitinib treatment has shown:
 - Significantly prolonged PFS: mPFS 18.0 vs. 9.8 months and reduced the risk of disease progression or death by 35% (HR=0.65). The treatment effects were observed across all evaluated subgroups.
 - A trend for OS improvement: 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.



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 Initiated



- 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)

- In June 2023 and August 2023, the FDA and the NMPA agreed that a randomized, double-blind, placebo-controlled, multi-regional Phase III clinical study of tifcemalimab in combination with toripalimab as **consolidation therapy in patients with LS-SCLC without disease progression following chemo-radiotherapy may proceed**. This study is the first registration study of an anti-BTLA monoclonal antibody, with the plan to be carried out in more than 170 research centers in 15 countries and regions around the world, including China, the United States, and Europe, this study will recruit about 756 subjects. At present, this study has completed the world's first patient enrollment (FPI) and the first drug administration, and has made sound progress at the enrollment stage.
- In December 2023, the Phase III clinical study of Tifcemalimab in combination with toripalimab for the treatment of **classical Hodgkin's Lymphoma (cHL)** has been officially launched in China. The study is planned to be carried out in about 50 research centers in China and recruit about 185 patients.
- 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: Promising Early Clinical Results Debut

Phase Ia: monotherapy in advanced solid tumors

Clinical Activity:

Among 19 evaluable patients as of April 30, 2022, **1 confirmed PR (Melanoma)**, **7 SD** were observed, the median duration of SD was **18 weeks**, 1 melanoma patient had previously progressed upon nivolumab and BRAF/MEK inhibitors treatments, has **continued PR for more than 24 months**

Safety and Tolerability:

No Dose Limiting Toxicity (DLT) was observed

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

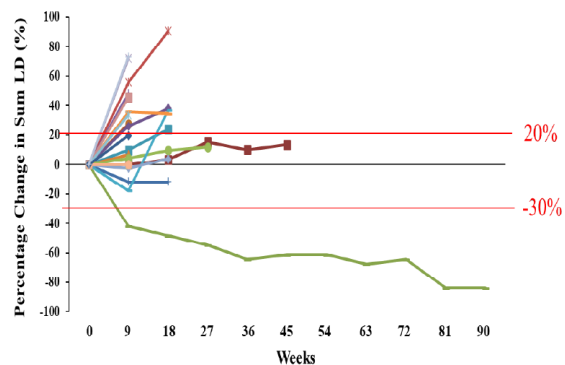
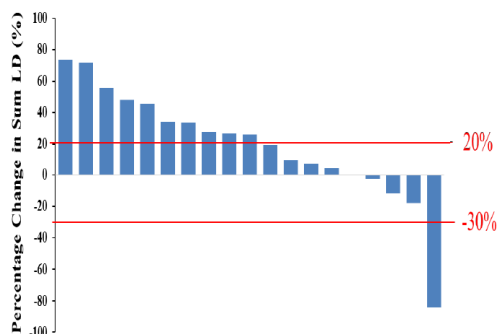


Figure 7. Best response of target lesion(s)



Phase I: monotherapy or in combination with toripalimab in relapsed/refractory lymphomas

Clinical Activity:

As of April 26, 2022,

Among 25 evaluable patients receiving monotherapy: **1 PR, 7 SD**
 Among 6 patients receiving the combination therapy (all progressed upon prior anti-PD-1 therapy): **3 PR (ORR 50%), 1 SD (DCR 67%)**

Safety and Tolerability:

No DLT was observed

Figure 5. Best response of target lesion(s)
Monotherapy

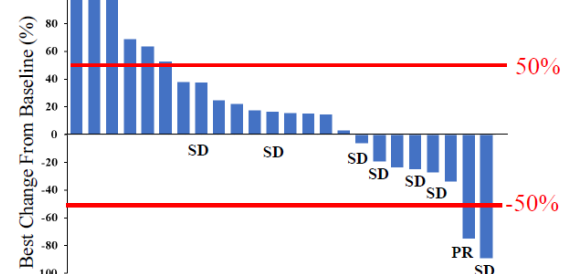
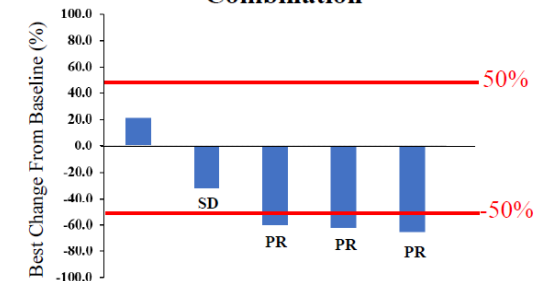


Figure 7. Best response of target lesion(s)
Combination



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

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. 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 \geq 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.

Table 4. Antitumor activity

Antitumor activity	Patients (n=43)	IO naïve (n=23)
Evaluable subjects (EAS)	40	20
Best overall response, n (%)		
Complete response	0	0
Partial response	11 (27.5)	8 (40.0)
Stable disease	11 (27.5)	6 (30.0)
Progressive disease	18 (45.0)	6 (30.0)
ORR (CR+PR), n (% , 95% CI)	11 (27.5, 5.3-27.9)	8 (40.0, 19.1-63.9)
DCR (CR+PR+SD), n (% , 95% CI)	22 (55.0, 31.2-62.3)	14 (70.0, 45.7-88.1)
Median DoR, months (95% CI)	6.9 (1.4-6.9)	6.9 (1.4-6.9)
Median TTR, months (95% CI)	2.7 (1.3-4.0)	2.7 (1.3-4.0)
Median PFS, months (95% CI)	2.8 (1.4-5.5)	5.5 (1.4-6.4)
Median OS, months (95% CI)	14.9 (8.8-16.0)	9.4 (8.8-16.0)
12-month OS rate, % (95% CI)	51.7 (20.7-75.9)	47.3 (14.3-75.0)

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

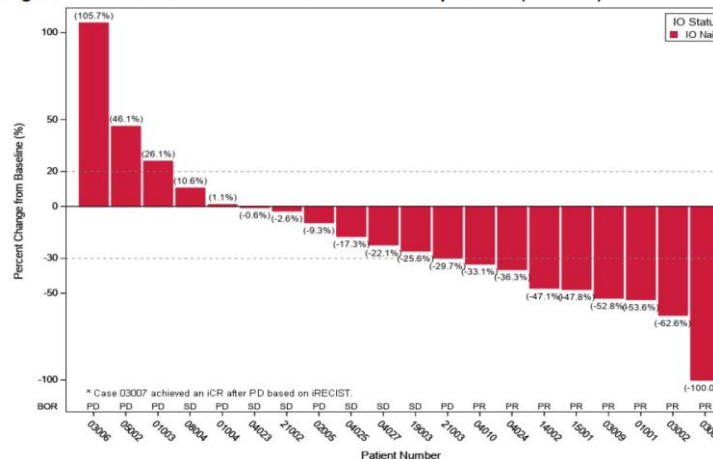
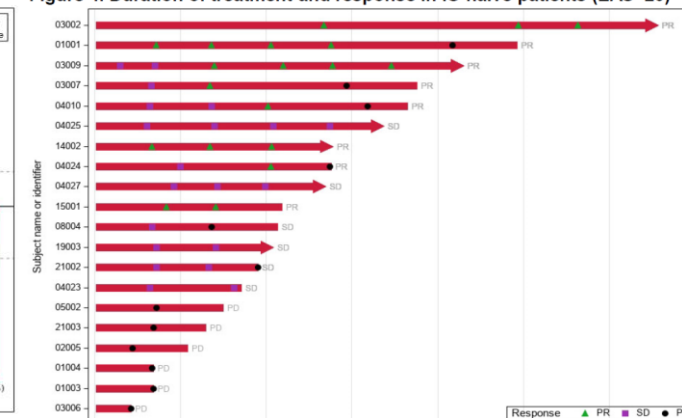


Figure 4. Duration of treatment and response in IO naïve patients (EAS=20)



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

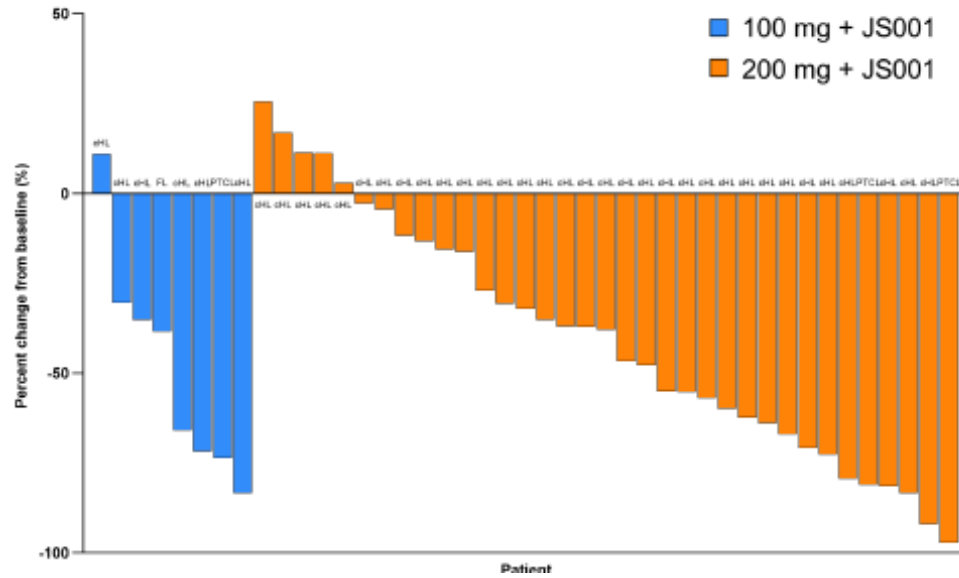
As of July 19, 2023, with median follow-up time of 57 weeks,

Among 25 patients receiving the monotherapy:

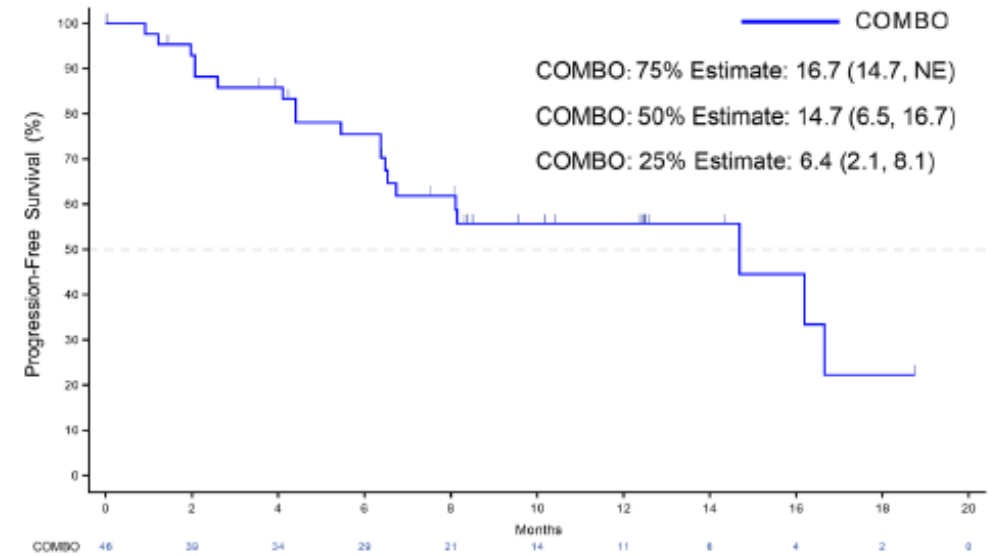
- 1 PR, 7 SD, mPFS: 2.1 months

Among 46 patients receiving combination therapy,

- 1 CR, 16 PR (ORR 37.0%), 20 SD (DCR 80.4%), mPFS 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 the mPFS was 16.2 months





Best response of target lesion(s) in Combo



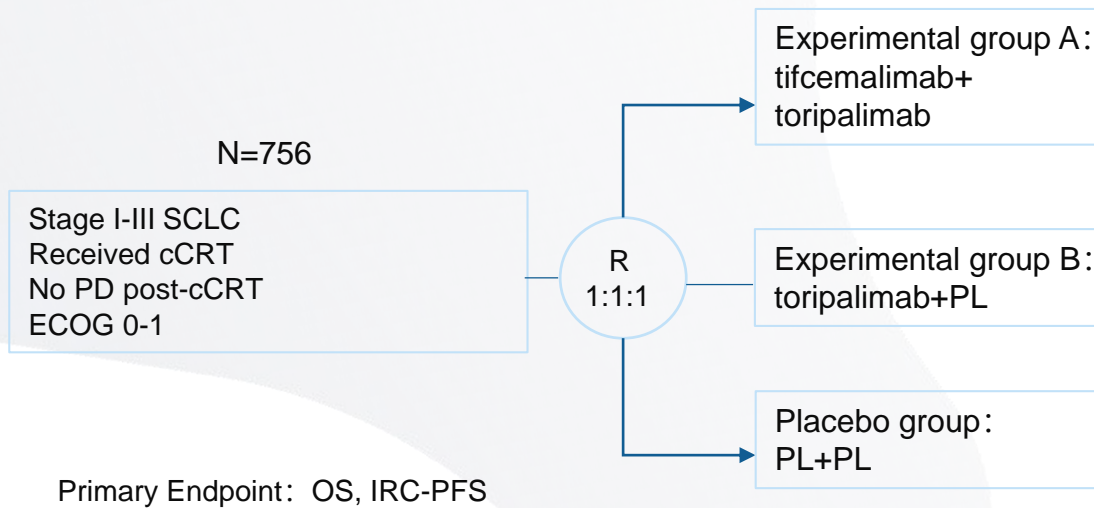
Progression-free survival status in Combo

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

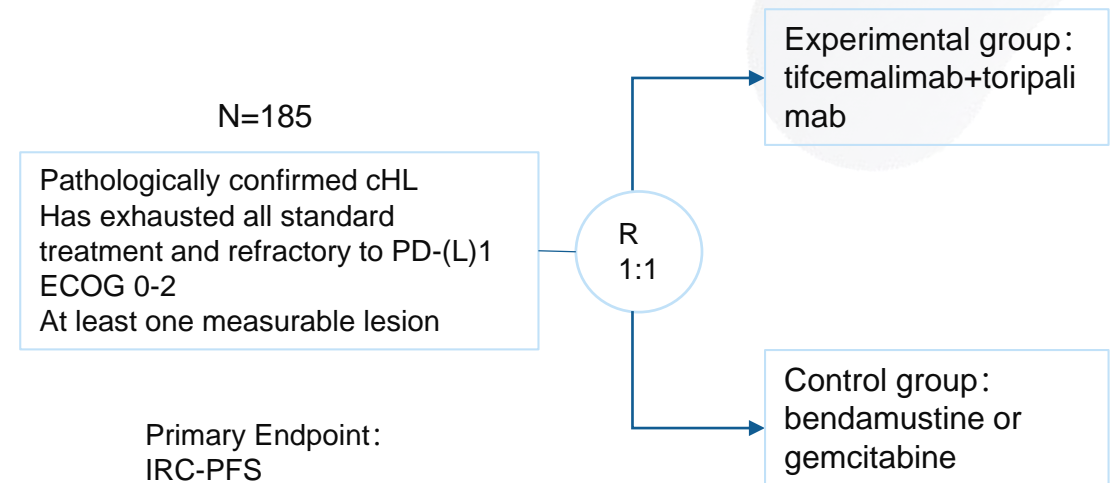
JS004-III-SCLC

About 30 international clinical trial sites including **China, the United States and Europe** have been initiated, and it is planned to complete the enrollment in **2026 H1**



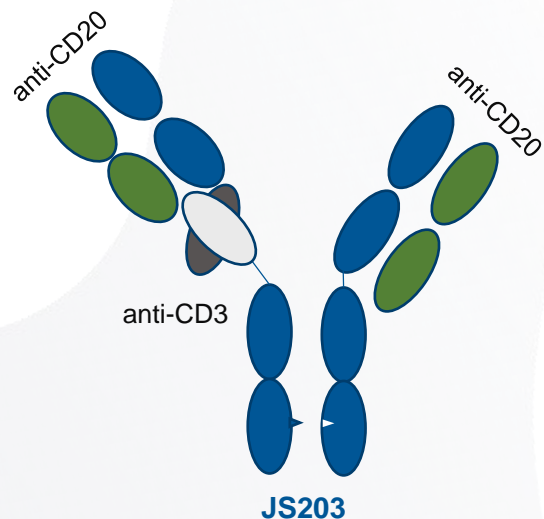
JS004-III-cHL

Nearly half of all clinical trial sites in China have been initiated, and it is planned to complete enrollment by **2024**



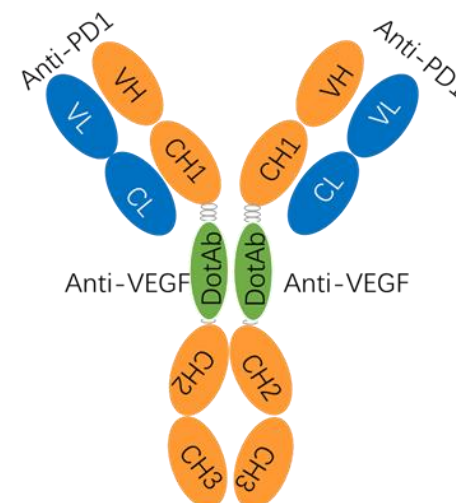
Multiple Bispecific Antibody Programs

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, and we plan to commence preparations for pivotal study in the latter half of this year.**

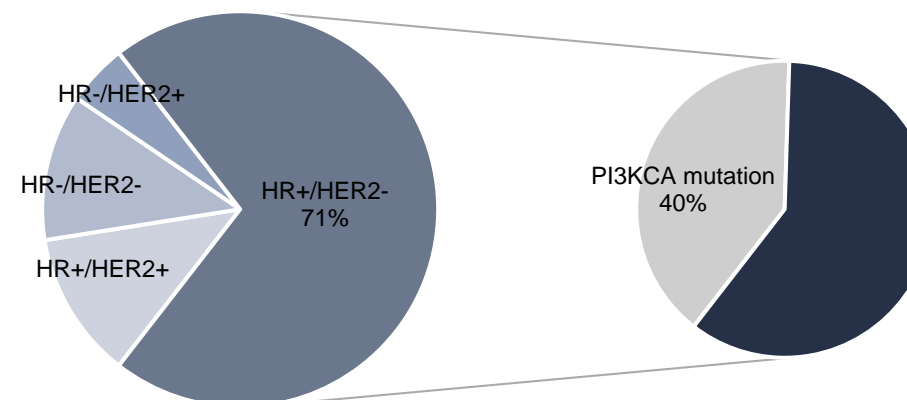
JS207 PD-1 x VEGF Bispecific Antibody



- 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.
- **At the end of August 2023, JS207 received approval for clinical trial by the NMPA and has achieved FPI within a month.**

JS105: Oral Small Molecule Inhibitor Targeting PI3K- α

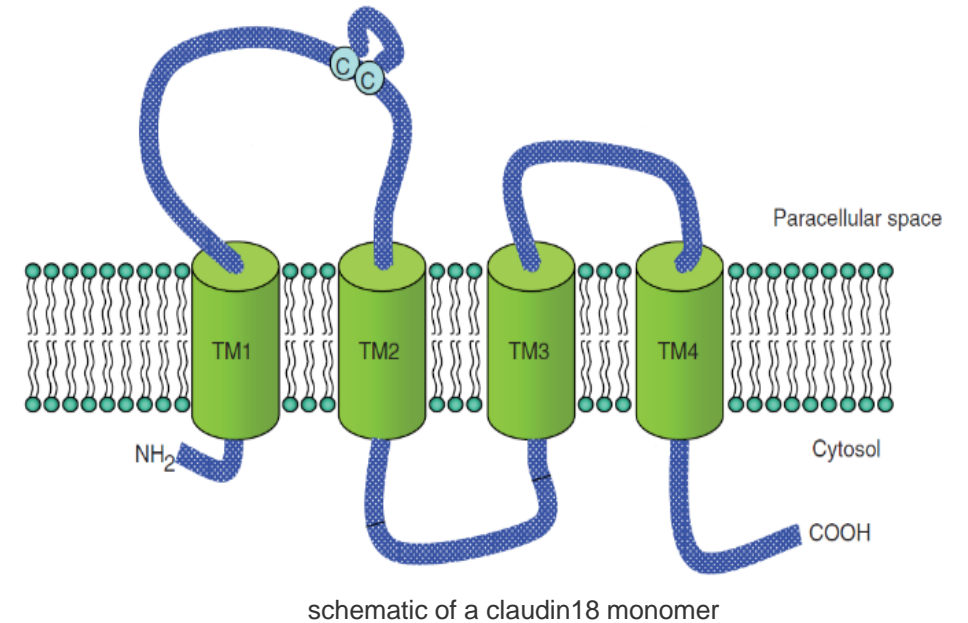
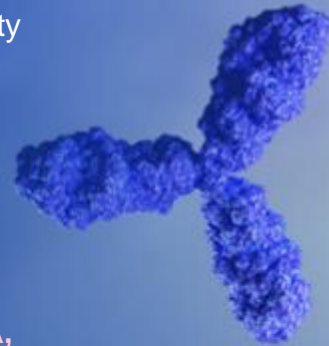
- JS105 is an oral small molecule inhibitor targeting PI3K- α in collaboration with Risen and is intended for the treatment of female (post-menopausal) patients with HR-positive, HER-2 negative, PIK3CA-mutated, advanced breast cancer who are experiencing disease progression during or after treatment 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.
- **In May 2022 and July 2022, the IND application for JS105 was approved by the NMPA and the FDA, respectively.**
- **In November 2023, the IND application for JS105 in combination with other anti-tumor therapies was approved by the NMPA, and the phase I/II clinical studies on the 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.

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.
- **In March 2022, the IND application for the JS107 has been approved by the NMPA.**
- **In June 2023, the IND application for JS107 in combination with other anti-tumor therapies was approved by the NMPA, which further expanded the scope of exploration of JS107 in anti-tumor treatment. The phase I/II clinical studies on the JS107's monotherapy and combination treatment are currently underway.**



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.

Innovation Beyond Oncology

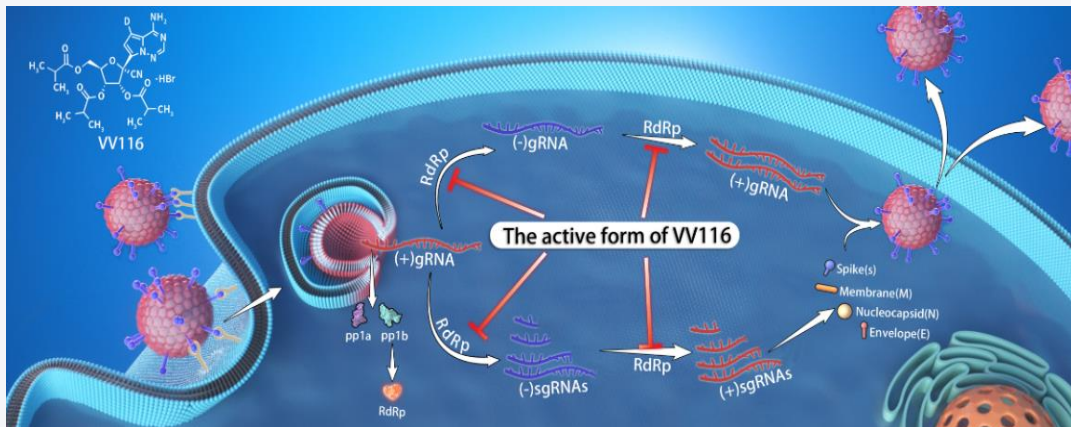
Our mission is to provide patients with treatment options that work better and cost less.

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

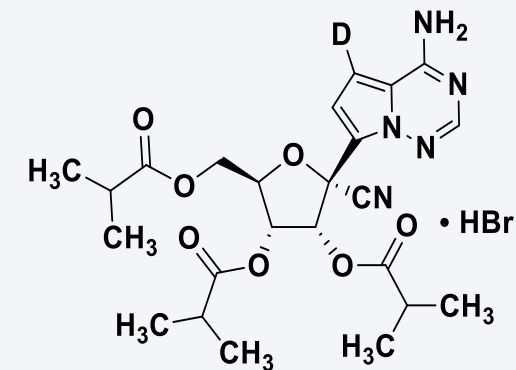
- In October 2021, Junshi and Vigonvita Life Sciences, reached a collaboration to jointly develop and commercialize the oral nucleoside anti-SARS-CoV-2 drug VV116 (JT001) globally*.
- In December 2021, VV116 (JT001) was approved for the treatment of moderate to severe COVID-19 patients in Uzbekistan.
- 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 | } 88 days | } 99 days |
| • NDA accepted: | 2023.01.17 | | |
| • NDA approved: | 2023.02.18 | } 11 days | |



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



MINDEWEI (VV116) Chemical Structure

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 BLA for ongericimab was accepted by the NMPA for the treatment of:

- primary hypercholesterolemia (including familial and non-familial heterozygous) and mixed dyslipidemia;
- homozygous familial hypercholesterolemia in adults or adolescents aged 12 or above.

Table 1. Results of Ongericimab on Lipid Parameters in Patients with Primary Hypercholesterolemia and Mixed Dyslipidemia on Background Lipid-lowering Therapy (Percent Change from Baseline to Week 24)

Treatment group	LDL-C	Non-HDL-C	Apo B	Total Cholesterol	Lipoprotein(a)	Triglyceride	HDL-C
Ongericimab 150mg vs. Placebo every 2 weeks							
Placebo Q2W ^a (n=131)	0.4	-1.6	-1.1	0.4	14.7	5.9	6.5
Ongericimab 150 mg Q2W ^a (n=272)	-67.4	-62.0	-58.8	-40.9	-52.8	-13.4	16.6
LS mean difference ^b (95% CI)	-67.7 (-72.49, -62.99)	-60.3 (-64.74, -55.94)	-57.7 (-61.86, -53.56)	-41.2 (-44.51, -37.93)	-67.5 (-90.27, -44.74)	-19.28 (-26.83, -11.73)	10.02 (6.94, 13.11)
Ongericimab 300mg vs. Placebo every 4 weeks							
Placebo Q4W ^a (n=134)	7.7	4.3	4.9	5.1	2.8	6.4	7.1
Ongericimab 300 mg Q4W ^a (n=265)	-53.5	-48.8	-45.3	-31.4	-42.0	-4.1	13.8
LS mean difference ^b (95% CI)	-61.2(-67.09, -55.21)	-53.1(-58.60, -47.53)	-50.1(-55.32, -44.94)	-36.5(-40.60, -32.37)	-44.79 (-52.11, -37.47)	-10.54 (-19.88, -1.21)	6.71 (3.53, 9.88)

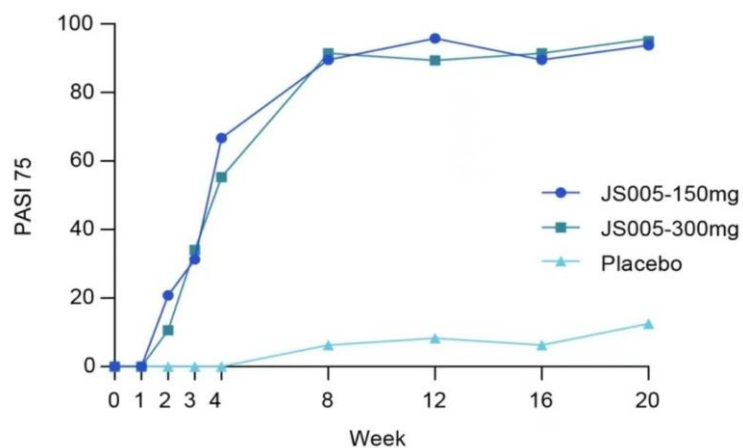
a. The data presented are least-squares mean, which was calculated from the repeated measures model which includes treatment group, stratification factor(s), scheduled visit and the interaction of treatment with scheduled visit as covariates.

b. Treatment differences were calculated within each treatment regimen using its own placebo as the reference.

- At the 2023 AHA Scientific Sessions, the data for efficacy and safety of Ongericimab in Chinese patients with primary hypercholesterolemia and mixed dyslipidemia was released.
- The results shown that subcutaneously injecting Ongericimab could significantly reduce low-density lipoprotein cholesterol (LDL-C) of patients, reducing the LDL-C of the vast majority of patients with ultra-high (extreme) risk in cardiovascular diseases to the target level and maintaining stable decreases during 52 weeks of treatment, while significantly improving other blood lipid parameters.

JS005 Anti-IL-17A mAb

- **Indications:** psoriatic, spondylitis
- **Origins:** In-house, developed independently by Junshi
- **Commercial Rights:** Global
- **Ph3 Registrational clinical trial initiated:** Severe plaque psoriasis



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
- **Clinical Stage:** Phase 1 in China
- **In March 2023, the IND application for JS010 has been approved by the NMPA. JS010 is currently in Phase 1 clinical stage.**

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.

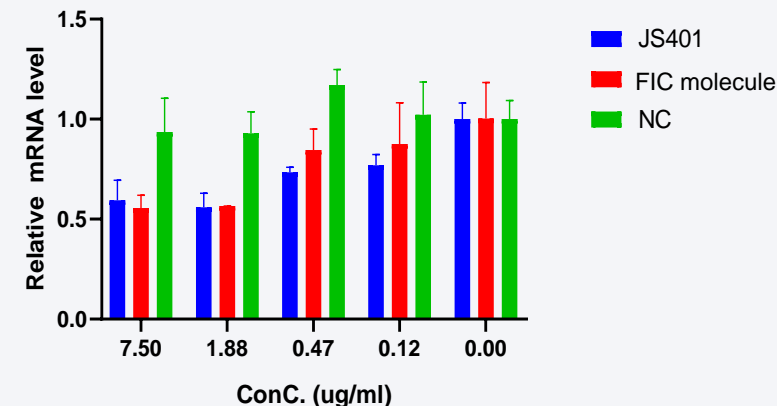
JS401: siRNA Drug targeting ANGPTL3

The advantages of our siRNA technology platform

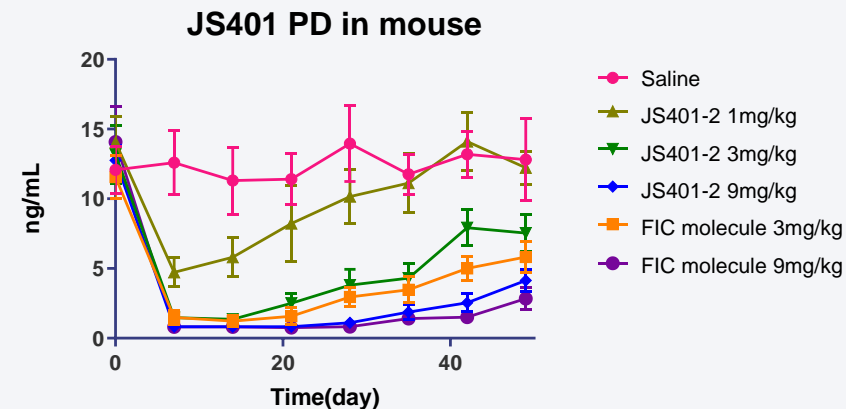
- Applying bioinformatics and AI technology to bring rational siRNA design, generating siRNA sequences with high inhibitory effect.
- Through our unique modifications, the stability of siRNA is enhanced with lower side effects. After generating siRNA sequence with inhibitory activity, it can be combined 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

Commercialization

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

Steady Growth in Sales

Total Operating Income

1,503 MN

YoY

3.38 %

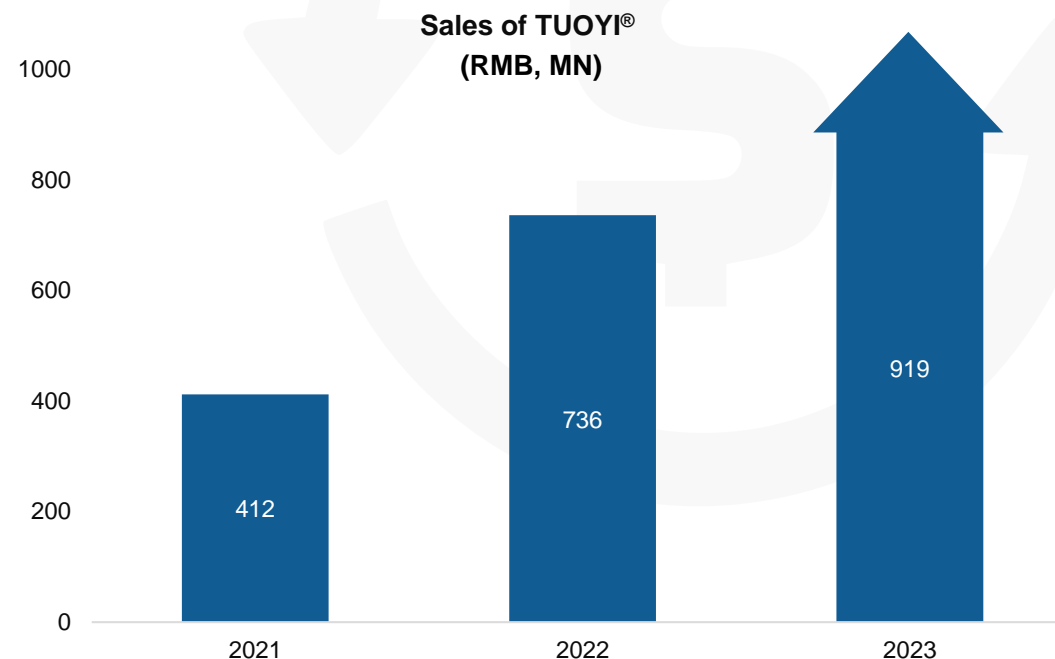
Sales of TUOYI®

919 MN

YoY

24.93 %

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.



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 NRDL, 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 about 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 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.



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 **26 provinces** as at the end of the Reporting Period, and has been used in **173 hospitals**, covering **1,316 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
- Passed the GMP compliance inspection
- 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

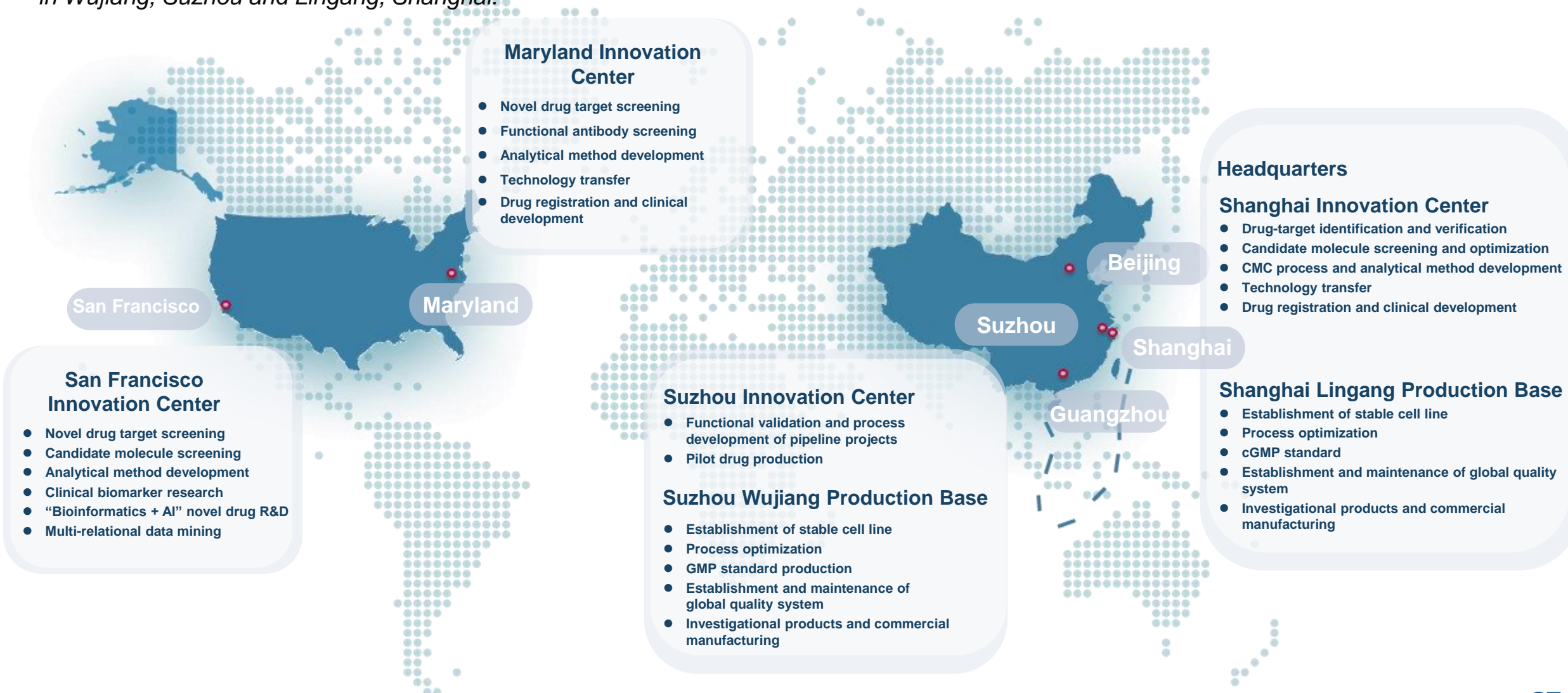
Suzhou Wujiang Production Base

- **GMP certification**
- Construction completed in 2016
- **4,500L** fermentation capability
- **FDA PLI completed**
- **EMA GMP on-site inspection completed**
- Responsible for the production of the commercial batches of toripalimab in the United States at this stage



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.





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
- Ongerlicimab (PCSK9) PH/MHL
- Ongerlicimab (PCSK9) HoFH

Overseas Commercialization

- EU
- Singapore
- Australia
- India
- South Africa
- Chile
- Jordan

Data readouts & sNDA submissions

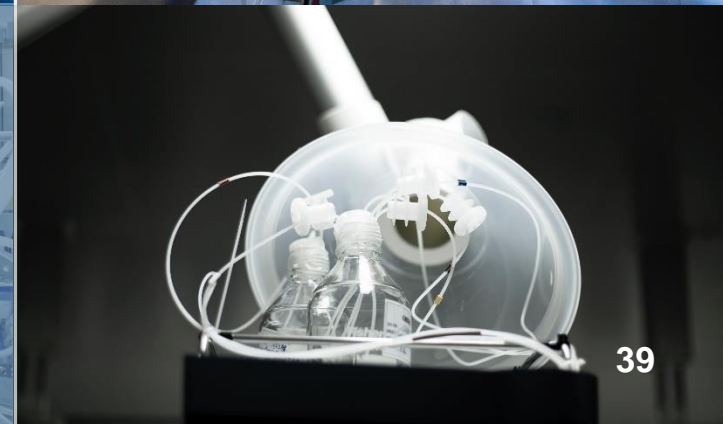
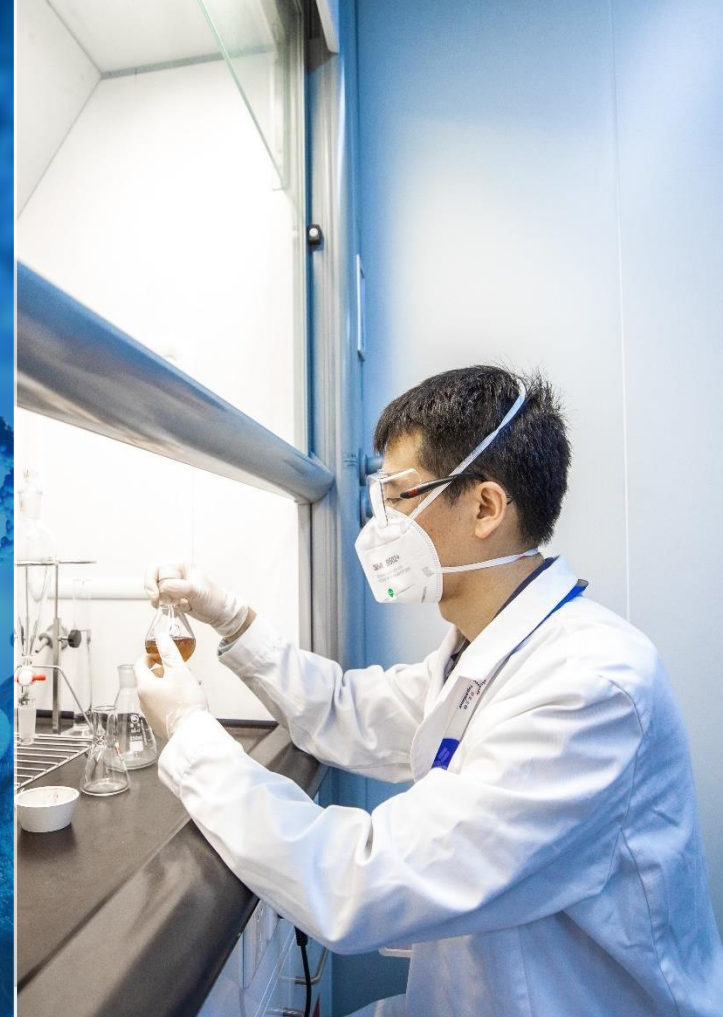
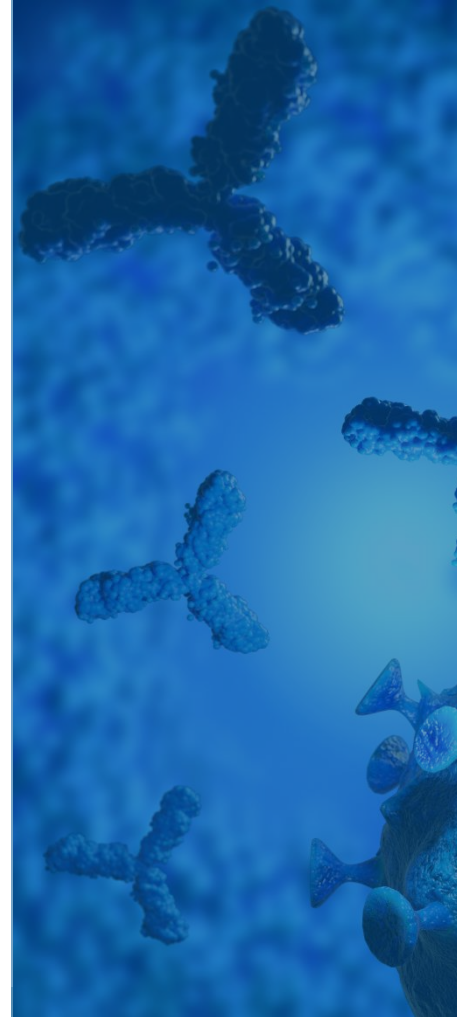
- Toripalimab (PD-1) ESCC perioperative
- Toripalimab (PD-1) 1L HCC
- Ongerlicimab (PCSK9) HeFH
- Ongerlicimab (PCSK9) statin intolerance

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



让生命
再出发

THE JOURNEY
AHEAD

THANK YOU