



# 2022 Results

## Investor Presentation

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

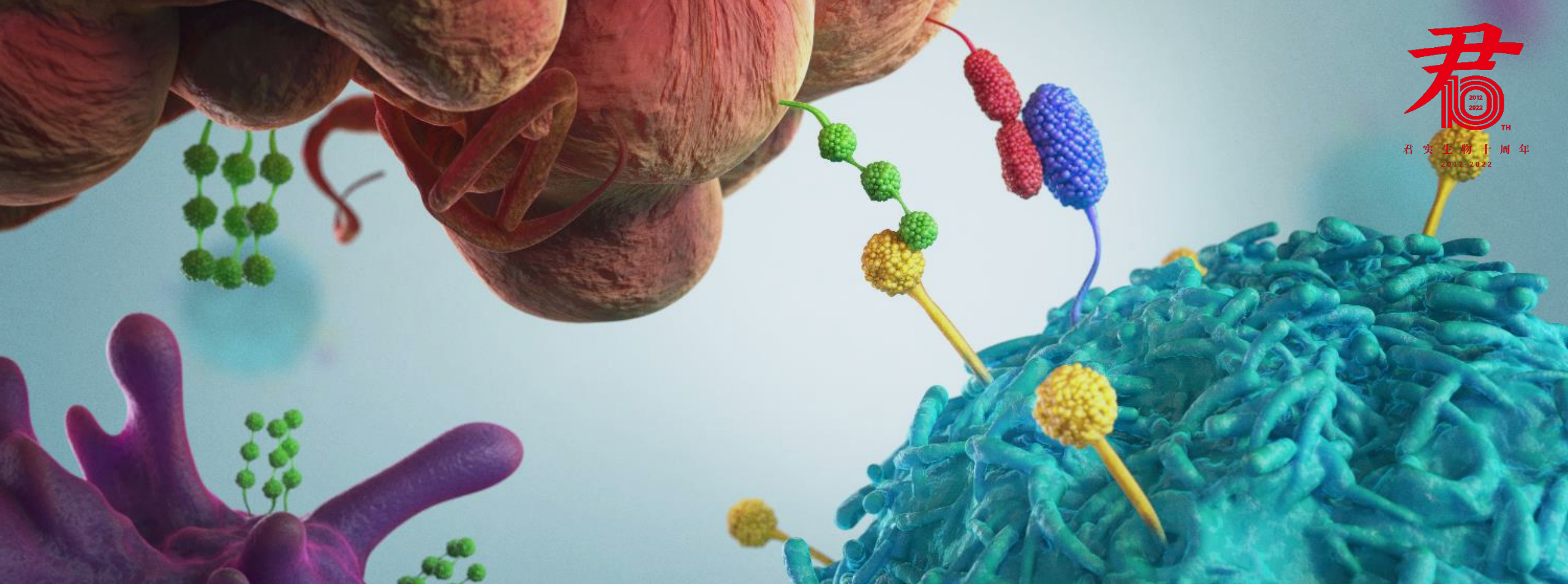
Mar, 2023



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2012-2022

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# Company Overview

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

# 2022 Financial Results

	FY 2022 (RMB, Million)	FY 2021 (RMB, Million)	YoY Change (%)
<b>Total Revenue</b>	<b>1,453</b>	4,025	<b>-63.89%</b>
PD-1 Sales Revenue	<b>736</b>	412	<b>+78.77%</b>
<b>Total Operating Expense</b>	<b>4,103</b>	4,728	<b>-13.23%</b>
Selling and Distribution Expenses	<b>716</b>	735	<b>-2.57%</b>
R&D Expenses	<b>2,384</b>	2,069	<b>15.26%</b>
Administrative Expenses	<b>569</b>	642	<b>-11.36%</b>
<b>Net loss attributable to shareholders</b>	<b>-2,388</b>	-721	/
<b>Net loss attributable to the shareholders after deducting non-recurring profit and loss</b>	<b>-2,450</b>	-884	/

- **Revenue:** The sales revenue of TUOYI® was approximately RMB736 million in FY 2022, which increased 78.77% compared to FY 2021. The sales of TUOYI® in the domestic market are gradually entering into a positive cycle.
- **Selling and Distribution Expenses:** Compared to FY 2021, the expense decreased steadily on the back of effective marketing cost control.
- **R&D Expenses:** Representing a YoY increase of 15.26%. The growth was mainly due to increasing investment in R&D and enrichment of pipelines, the acceleration of current clinical projects and reserve of the R&D team.
- **Administrative Expenses:** Representing a YoY decrease of 11.36%. This decrease was due to the effective implementation of cost control policy and decreased share-based compensation.

# Business Highlights (FY 2022 to present)



**+78.77%**

**2** additional indications for TUOYI® approved by the NMPA; its sales in the domestic market are gradually entering into a positive cycle



**IND**

**10** approved by the NMPA  
**3** approved by the FDA



**Collaborations**

- Coherus
- Hikma
- Rxilient (March, 2023)
- Wigen Biomedicine
- Sun Yat-sen University Cancer Center



**New Drug Approvals**

- **JUNMAIKANG®**: the 1st prescription issued in May 2022; **8** indications approved by the NMPA in total
- **MINDEWEI**: conditionally approved by the NMPA in Jan 2023 for the treatment of adult patients with mild to moderate COVID-19



**Innovation**

- Tifcemalimab<sup>FH</sup>: ASCO, ASH data release
- TUOYI®: TNBC, perioperative treatment for lung cancer data readout
- MINDEWEI: NEJM data release
- siRNA drug JS401: IND accepted



**Capital Markets**

- A Shares included in the SSE 180 Index
- A Shares issuance to target subscribers, the gross proceeds amounted to RMB3,776.50 mn



**Global Development**

- TUOYI® FDA BLA accepted
- EMA MAA accepted
- MHRA MAA accepted
- Keep exploring commercialization in more emerging markets



**+12,000L**

The Shanghai Lingang Production Base constructed with the CGMP standard; commercial production capacity scaled-out

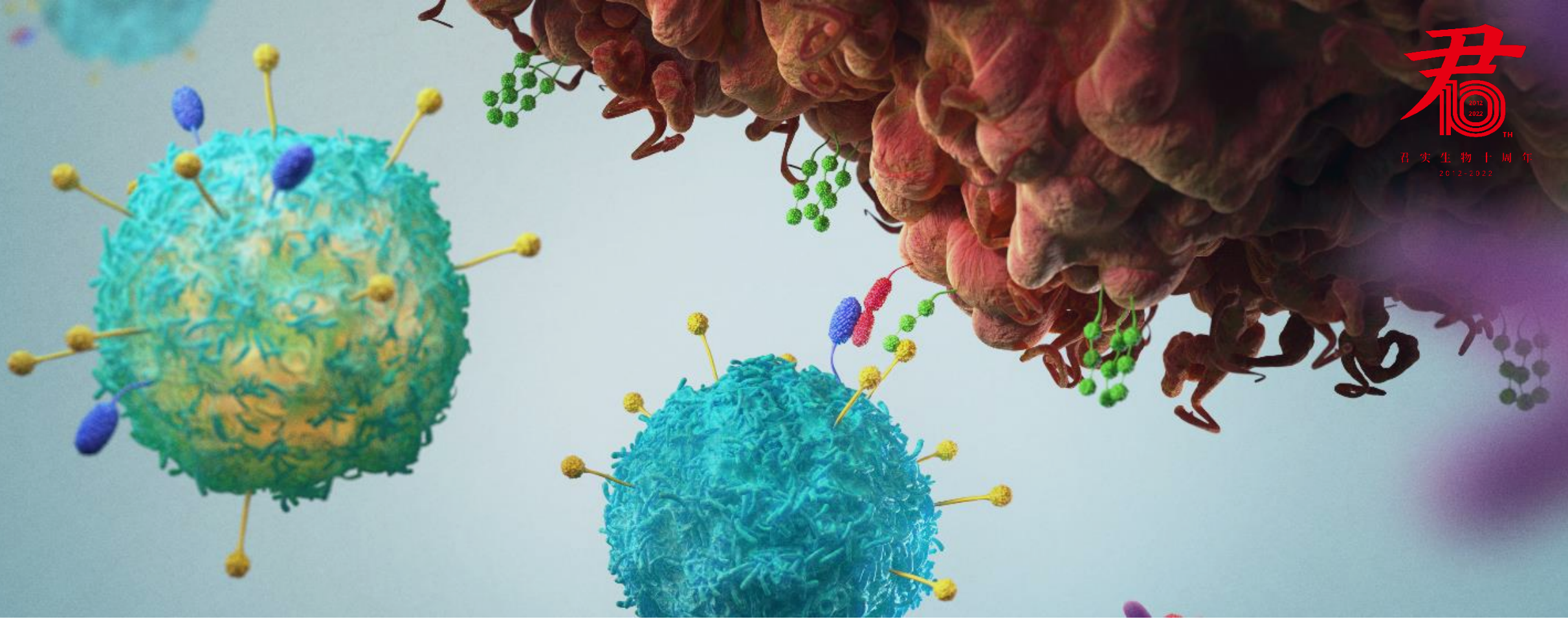


**ESG TOP10%**

Included as a constituent of the Hang Seng (China A-share) Corporate Sustainability Benchmark Index



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# Globalization Roadmap

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

# Make Every Effort to Prepare for FDA's Inspection



Kick-off meeting



Online inspection introduction



In April 2022, the online part of FDA's on-site inspection for the production base was successfully completed.



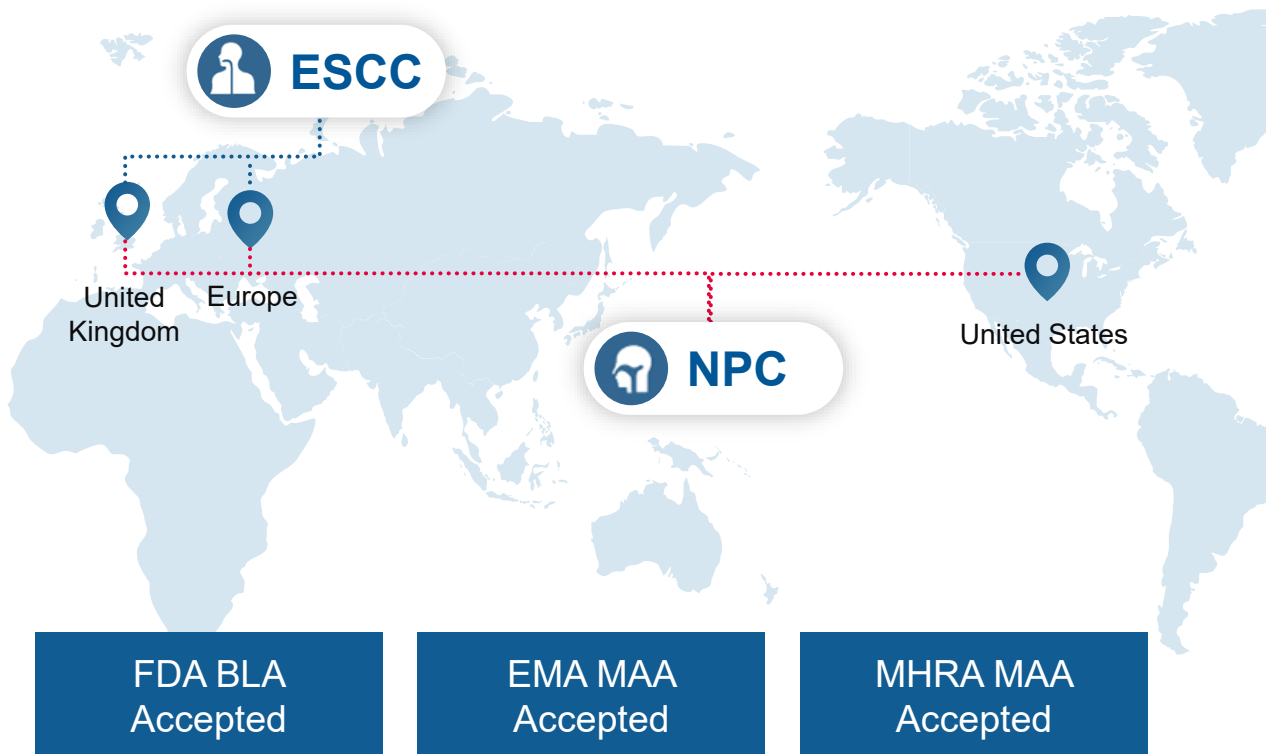
Preparations for the on-site inspection have been successfully completed.



We, together with Coherus remain in close communication with the FDA to advance the on-site inspection to the extent possible, aiming to promote the commercialization of toripalimab in the United States as soon as possible.

# Pursue More Registration Opportunities Worldwide

- Based on the excellent clinical efficacy of toripalimab in the treatments for patients with **ESCC, NPC**
- Marketing applications have been accepted in US, UK and EU



\*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.

\*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



Toripalimab has been out-licensed in **more than 30 countries**

### Collaborate with Coherus in the US and Canada

- ✓ In February 2021, the Company granted Coherus the exclusive license of toripalimab and two option programs in the U.S. and Canada. The Company also grants priority negotiation rights to Coherus for two additional checkpoint inhibitor antibodies. In Jan 2022, Coherus has initiated the process to exercise its option to license JS006 (TIGIT-targeted antibody) in the US and Canada.
- ✓ Payments of up to an aggregate of US\$1.11 billion
- ✓ 20% royalty on annual net sales

### Collaborate with Hikma in the Middle East and North Africa region

- ✓ In December 2022, the Company granted Hikma an exclusive license to develop and commercialize toripalimab in all 20 Middle East and North Africa markets including Jordan, Kingdom of Saudi Arabia, United Arab Emirates, Qatar, Morocco and Egypt etc., as well as the priority negotiation rights for future commercialization of the three development-stage drug candidates in one or more countries in the Hikma Territory.
- ✓ Payments of up to an aggregate of US\$12 million
- ✓ high-teen tiered royalties of up to 20% of net sales

### Collaborate with Rxilient Biotech in Southeast Asia

- ✓ In March 2023, the Company and Rxilient Biotech announced the collaboration on the development and commercialization of toripalimab in 9 Southeast Asian countries through a joint venture company, Excellmab. Excellmab will also obtain a right of first negotiation for the commercialization of four other products under research as stipulated in the License Agreement in the cooperation territory.
- ✓ Excellmab will be responsible for the development, medical affairs, production of finished products, and commercialization of toripalimab within the cooperation territory. The profits available for distribution by Excellmab will be distributed in proportion to the respective shareholdings of the parties (Junshi owns 40% equity of Excellmab)
- ✓ Milestone payment of up to approximately US\$4.52 million, plus a certain percentage of royalties on net sales

# Overseas Clinical Trials Progress: FDA, EMA, MHRA

Therapeutic Area	Name of Drug	Target	Indications	Pre Clinical	Phase I	Phase II	Phase III	NDA	Overseas Interests Partner	
Oncology	Toripalimab (JS001)	PD-1	NPC, liver cancer, ICC, esophageal cancer, HNSCC, gastric cancer, etc.	Marketing applications accepted by the FDA, the EMA, the MHRA						Coherus (United States and Canada) Hikma (20 countries in the Middle East and North Africa region) Rxilient (9 countries in Southeast Asia)
	Tifcemalimab (TAB004/JS004)	BTLA	Lung cancer, Melanoma, lymphoma, etc.							
	JS006 (TAB006)	TIGIT	Tumors							Coherus (United States and Canada)
	JS009 (TAB009)	CD112R/PVRIG	Tumors							
	JS105	PI3K-α	Breast cancer, renal cell carcinoma							
	JS110	XPO1	Multiple myeloma etc.							
Anti-infection	Etesevimab (JS016)	S protein	COVID-19	EUA has been obtained in more than 15 countries and regions worldwide						Eli Lilly and Company (Except for the Greater China region)

# Academic Achievements During the Reporting Period

## March 2022

### *Cancer Cell, IF: 38.585*

Toripalimab in combination with TP chemotherapy for the first-line treatment of advanced or metastatic ESCC (JUPITER-06)

### *ASCO Plenary Series*

Toripalimab in combination with chemotherapy for the first-line treatment of advanced NSCLC without EGFR/ALK mutation (CHOICE-01)

## April 2022

### *Annual meeting of the AACR*

Toripalimab in combination with chemotherapy for first-line treatment of recurrent or metastatic NPC (JUPITER-02)

## May 2022

### *The Innovation*

Toripalimab in combination with chemotherapy for the first-line treatment of biliary tract cancer.

## June 2022

### *Annual meeting of the ASCO*

Almost **40** results of multi-tumor studies in relation to toripalimab and tificemalimab were released

## July 2022

### *Annals of Oncology, IF: 51.769*

Toripalimab versus HDI - $\alpha$ 2b as an adjuvant therapy for resected mucosal melanoma

## September 2022

### *Annual meeting of the ESMO*

Toripalimab in combination with chemotherapy as a neoadjuvant treatment for resectable stage III NSCLC (NeoTAP01)

## October 2022

### *Journal of Experimental & Clinical Cancer Research, IF: 12.658*

Toripalimab in combination with chemotherapy as a neoadjuvant treatment for resectable locally advanced HNSCC

## December 2022

### *ESMO-IO*

The data of four Phase I/II studies of toripalimab in lung cancer was presented at the congress, involving multiple combination therapy strategies

### *Journal of Clinical Oncology, IF: 50.739*

Toripalimab in combination with chemotherapy for first-line treatment of ESCC in patients with low PD-L1 expression

### *Annual meeting of ASH*

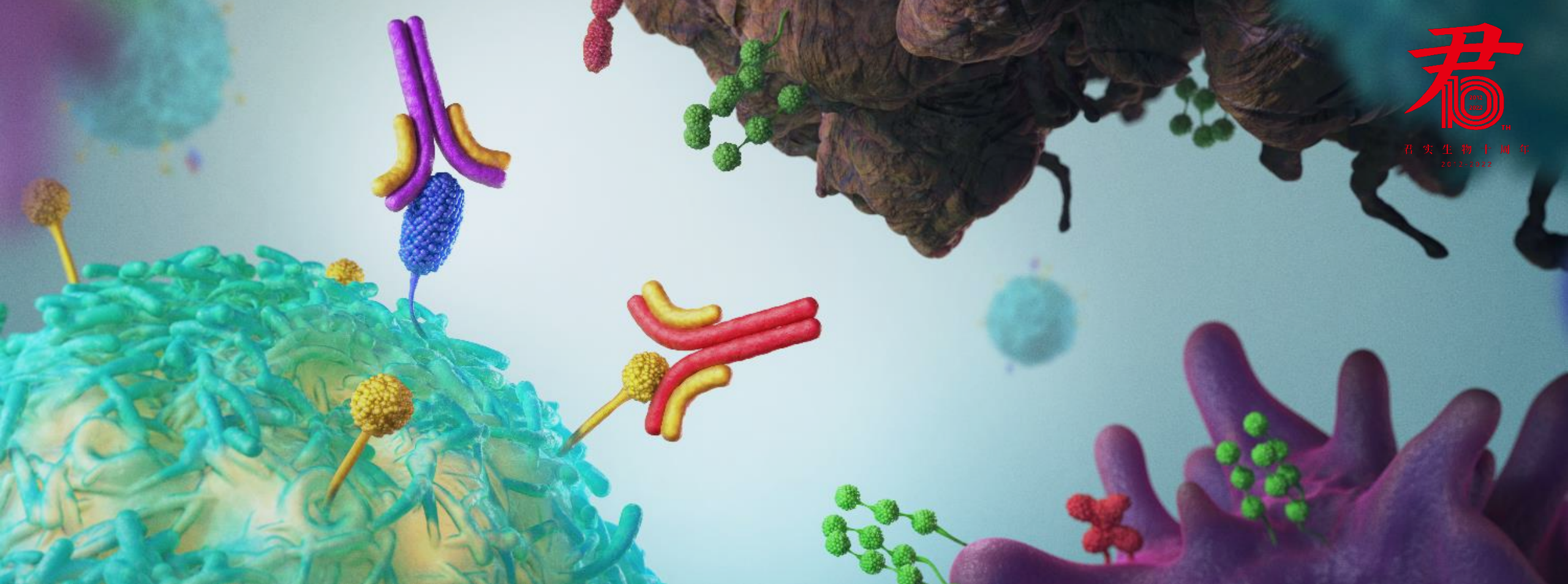
Tificemalimab for relapsed or refractory lymphoma

### *NEJM, IF: 176.082*

MINDEWEI versus PAXLOVID for the early treatment of patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19



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# Continuous Dedication to Innovation and R&D

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

# R&D Pipelines Covering Various Therapeutic Areas

(As of 30 March 2023)

Pre Clinical		Phase I		Phase II	Phase III	Approved
JS011 Undisclosed	JS013 CD93	JS006 TIGIT	JS007 CTLA-4	Tifcemalimab BTLA	Senaparib PARP	Toripalimab PD-1
JS018 IL-2	JS104 Pan-CDK	JS009 CD112R	JS014 IL-21	JS005 IL-17A	Bevacizumab VEGF	Adalimumab TNF- $\alpha$
JS114 Nectin4 ADC	JS115 BCMA ADC	JS015 DKK1	JS105 PI3K- $\alpha$		Ongericimab PCSK9	Deuremidevir Hydrobromide Tablets RdRp
JS120 IDH1	JS121 SHP2	JS107 Claudin18.2 ADC	JS111 EGFR exon 20			Etesevimab* S protein
JS122 FGFR2	JS123 ATR	JS112 Aurora A	JS113 EGFR 4th Gen			
JS205 EGFR x cMet	JS206 IL-2 x PD-1	JS001sc PD-1	JS110 XPO1			
JS207 PD-1 x VEGF	JS208 Undisclosed	JS203 CD3 x CD20	JS019 CD39			
JS209 CD112R x TIGIT	JS211 PD-L1 x Undisclosed	JS003 PD-L1	JS012 Claudin18.2			
JS401 ANGPTL3	VV993 3CL protease	JS101 Pan-CDK	JS108 Trop2 ADC			
JS008 Undisclosed	JT109 Vaccine for Zika virus	JS116 KRAS	JS201 PD-1 x TGF- $\beta$			
		JS010 CGRP	JS103 Uricase			
		UBP1213sc BLYS	JS026 S protein			

● Oncology
 ● Metabolism
 ● Immunology
 ● Neurologic
 ● Infectious disease

\*Received FDA Emergency Use Authorization

# Multiple IND Applications Accepted/Approved

## China

### 11 IND Applications Accepted/Approved by the NMPA

- 2022 Feb ● JS112 (Aurora A), IND approved
- Mar ● JS001sc (PD-1), IND approved
- Mar ● JS107 (Claudin18.2), IND approved
- May ● JS105 (PI3K- $\alpha$ ), IND approved
- Jun ● JS113 (EGFR 4th Gen), IND approved
- Jun ● JS116 (KRAS<sup>G12C</sup>), IND approved
- Jul ● JS203 (CD20 x CD3), IND approved
- Aug ● TAB009/JS009 (CD112R), IND approved
- Oct ● JS015 (DKK1), IND approved
- 2023 Jan ● JS401 (ANGPTL3), IND accepted
- Mar ● JS010 (CGRP), IND approved

## US

### 3 IND Applications Approved by the FDA

- 2022 Apr ● TAB009/JS009 (CD112R), IND approved
- Jul ● JS105 (PI3K- $\alpha$ ), IND approved
- Aug ● JS110 (XPO1), IND approved

# Tifcemalimab Debuted Its Promising Early Clinical Results, Ph3 Initiation Expected In the Near Future

## ASCO 2022

### #2643: Phase Ia dose-escalation study of the anti-BTLA antibody tifcemalimab as a monotherapy in patients with advanced solid tumors

- Among 19 evaluable patients as of April 30, 2022, **1 confirmed PR (Melanoma) and 7 SD** were observed with the median duration of SD at 18 weeks (1 melanoma patient who had previously progressed upon nivolumab and BRAF/MEK inhibitors treatments, has continued PR for more than 18 months since received Tifcemalimab, demonstrating its long-term effectiveness)

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

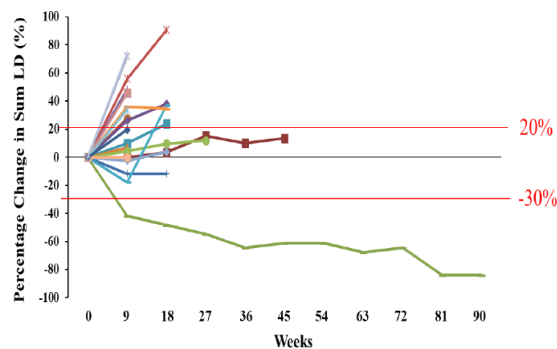
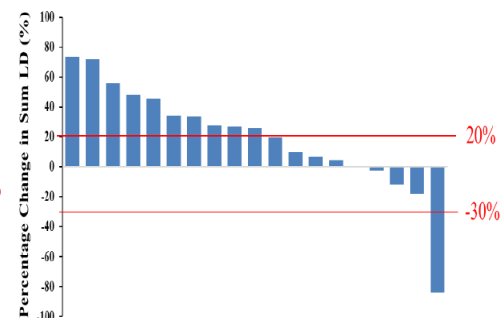


Figure 7. Best response of target lesion(s)



### #7578: Phase I study of the anti-BTLA antibody tifcemalimab as a single agent or in combination with toripalimab in relapsed/refractory lymphomas

- As of Apr 26, 2022, among 25 evaluable patients receiving monotherapy, 1 PR (follicular lymphoma) and 7 SD were observed (Lugano criteria)
- Among 6 patients receiving the combination (all progressed upon prior anti-PD-1 therapy), **3 PR (ORR 50%) and 1 SD (DCR 67%)** were observed

## ASH 2022

### #1613: Phase I study of the anti-BTLA antibody tifcemalimab as a single agent or in combination with toripalimab in relapsed/refractory lymphomas

Figure 2. Changes in target lesion(s) over time (Mono)

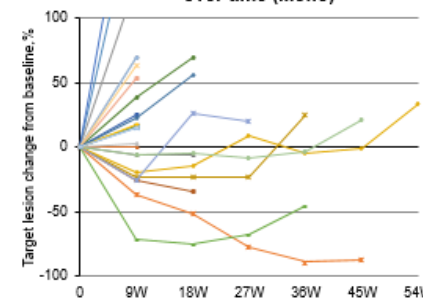


Figure 3. Best response of target lesion(s) (Mono)

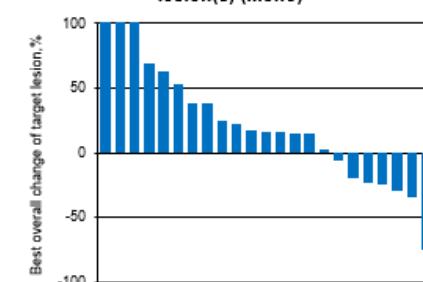


Figure 4. Changes in target lesion(s) over time (Combo)

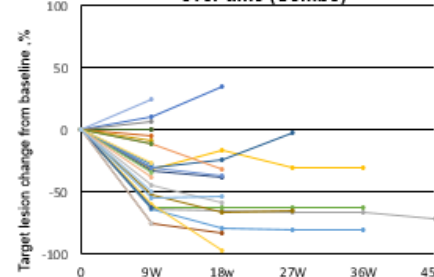
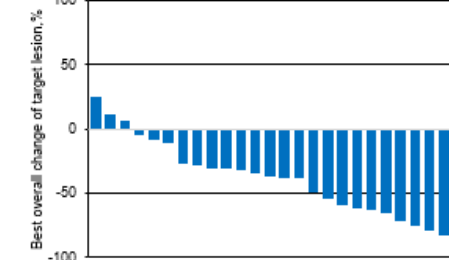


Figure 5. Best response of target lesion(s) (Combo)



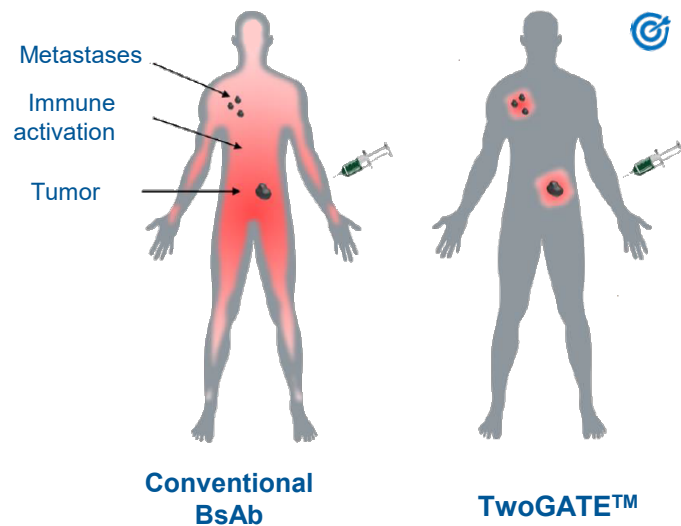
- As of Oct 26, 2022, among 25 evaluable patients receiving monotherapy, 1 PR (follicular lymphoma) and 7 SD were observed (Lugano 2014 criteria)
- Among 28 patients receiving the combination (24 patients progressed upon prior anti-PD-1), **1 CR, 10 PR (ORR 39.3%) and 13 SD (DCR 85.7%)** were observed

# The Next-generation of T-cell Engaging Cancer Immunotherapies: TwoGATE™

Junshi and Revitope collaborate in the research and development of the next-generation of T-cell engaging cancer immunotherapies. Revitope will be responsible for designing up to 5 unique T-cell immunotherapeutic drugs against targets selected by the Company.



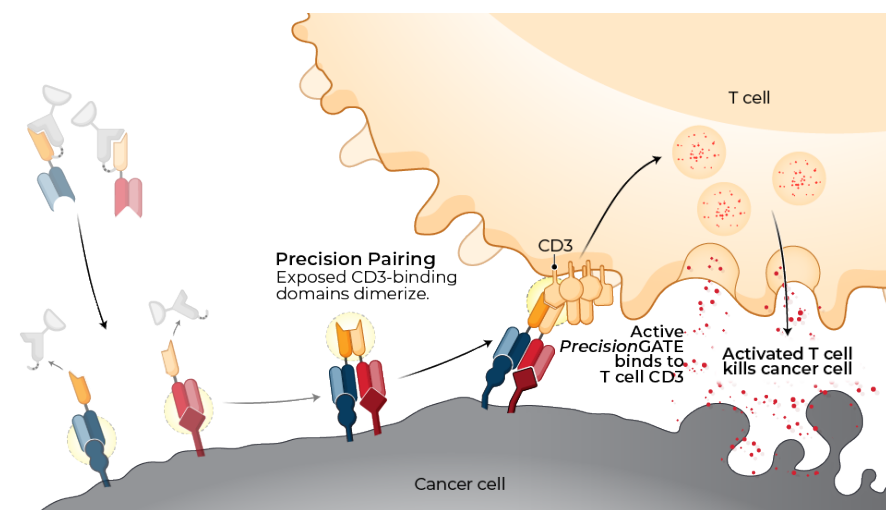
## Background



As conventional bispecific antibody therapeutics can generate unwanted and substantial **“on-target, off-tumor”** toxicity, Revitope’s two-component T-cell engaging antibody circuits are designed to permit specific recruitment and activation of T-cells exclusively by **tumor cells**, thereby **reducing systemic toxicity**.



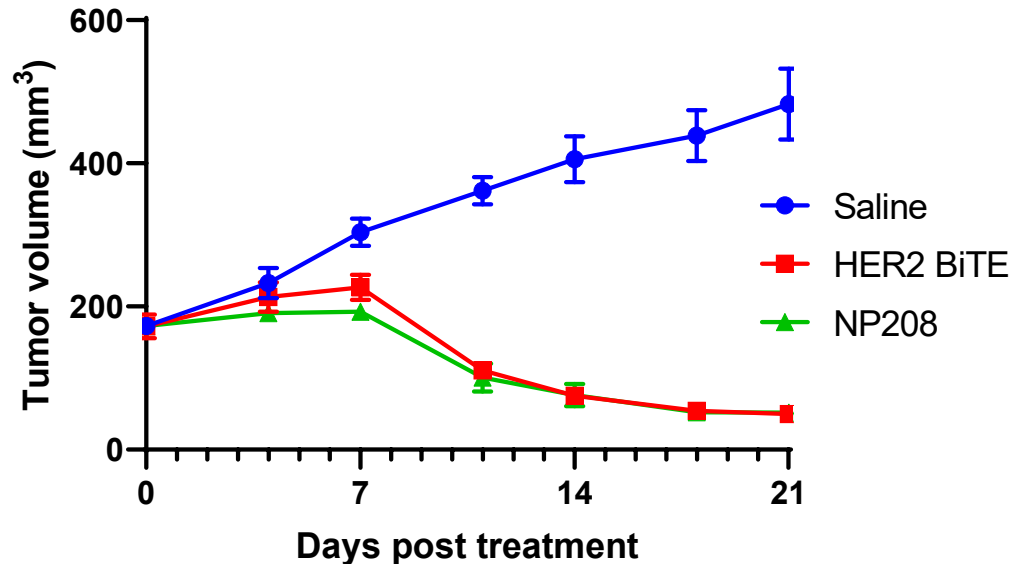
## MoA



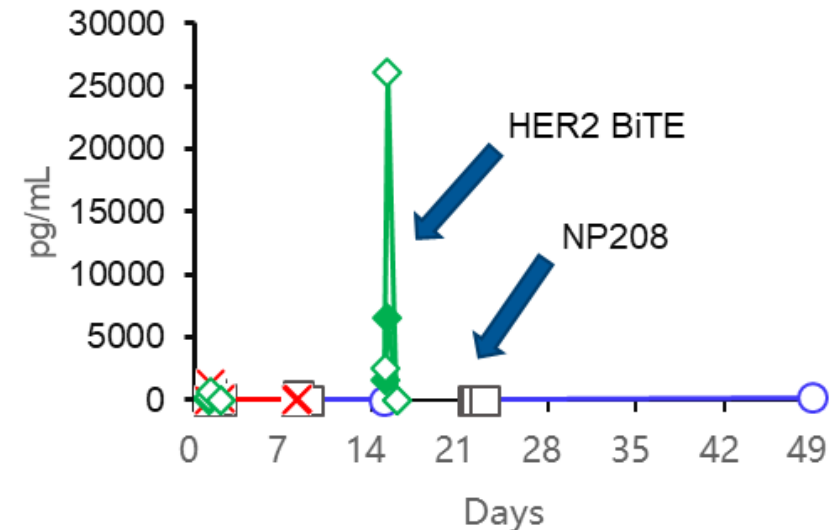
**TwoGATE™** therapies **split** the CD3 paratope (the T-cell recognition domain) into two halves. Only when the two molecules come together through **binding to their different tumor targets on the same tumor cell** can the two halves of the CD3 binding domain **recombine and create** a fully functional anti-CD3 domain.



# TwoGATE™: 3rd Generation T-cell Engager Platform



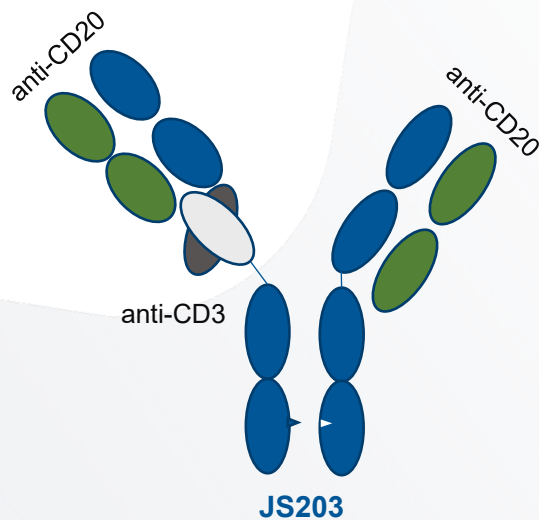
Tumor volume growth curves of the mice after treatment



IL-6 serum levels after treatment

- TwoGATE™ is the 3rd Generation T-cell engager platform developed by Junshi and Revitope.
- Combining Revitope's unique tumor-specific safety gating mechanisms and Junshi's in-house targets, TwoGATE™ are designed to avoid cytokine release risks in peripheral blood (CRS) and instead direct a focused and powerful tumor-specific T cell response.
- TwoGATE™ molecules show similar anti-tumor efficacies as 1<sup>st</sup> bispecific T-cell engager HER2 BiTE.
- The results from toxicity studies performed in cynomolgus monkeys display that, compared with HER2 BiTE, TwoGATE™ molecules significantly reduce the risk for CRS.
- **The IND for the first product generated from this platform is expected to be submitted in 2023**

## JS203 CD20 x CD3 Bispecific Antibody



CD20 is a B lymphocyte restricted differentiation antigen and one of the most successful targets for B-cell lymphoma treatment.

CD3 is an important marker on the surface of T cell. The main mechanism of T cell engaging bispecific antibodies is using CD3 as a mediator to activate T cells to specifically attack tumor cells.

- JS203 is a recombinant humanized anti-CD20/CD3 bispecific antibody self-developed by Junshi, mainly for the treatment of relapsed/refractory B-cell non-hodgkin lymphoma.
- Pre-clinical in vivo pharmacodynamics shows that JS203 has a significant anti-tumor effect. In addition, JS203 is well tolerated by animals.
- **In July 2022, the IND application for JS203 was approved by the NMPA. The enrollment of the Phase 1 clinical trial of JS203 is currently underway.**

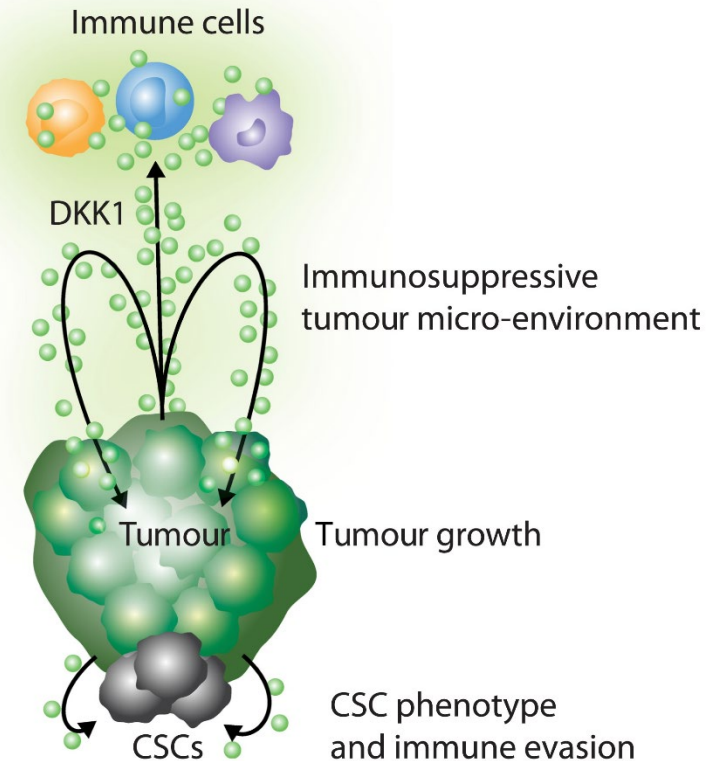
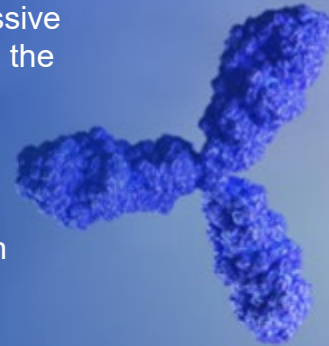
## JS207 PD-1 x VEGF Bispecific Antibody

- Given the strong correlation between VEGF-A and PD-1 expression in the TME, the simultaneous blockade of these 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.
- **JS207 is in preclinical studies and the IND application is expected to be submitted in 2023.**

- 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 immune checkpoint blocking

# JS015: Anti-DKK1 Monoclonal Antibody

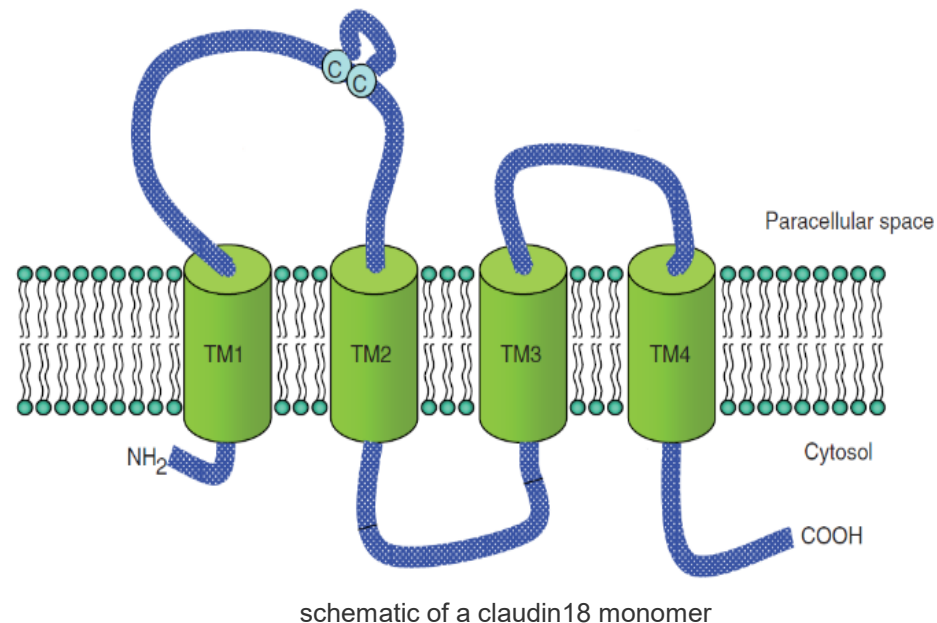
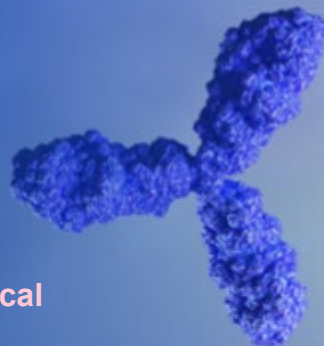
- DKK1 (Dickkopf-1) is a secreted protein of the DKK family, which is highly expressed in multiple gastric cancer, gastroesophageal junction cancer, myeloma, liver cancer, lung cancer, ovarian cancer and other tumor cells, and can inhibit the canonical Wnt signaling pathway through negative feedback 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.
- **In October 2022, the IND application for JS015 was approved by the NMPA. The enrollment of the Phase 1 clinical trial of JS015 is currently underway.**



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.

# JS107: Anti-Claudin18.2 ADC

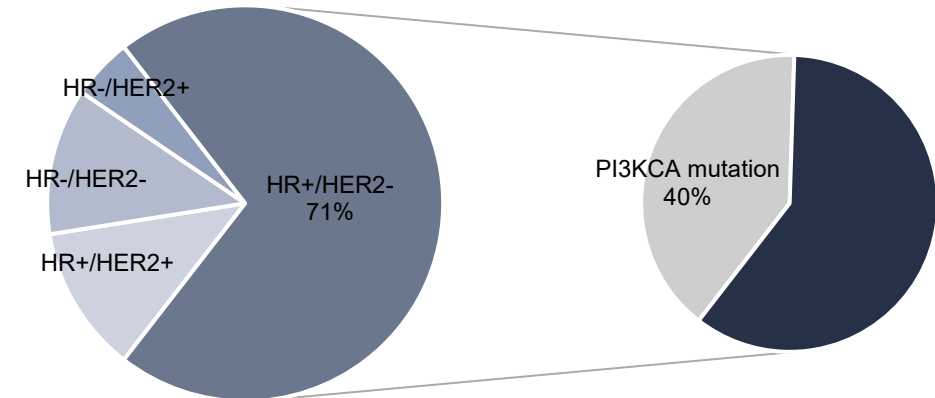
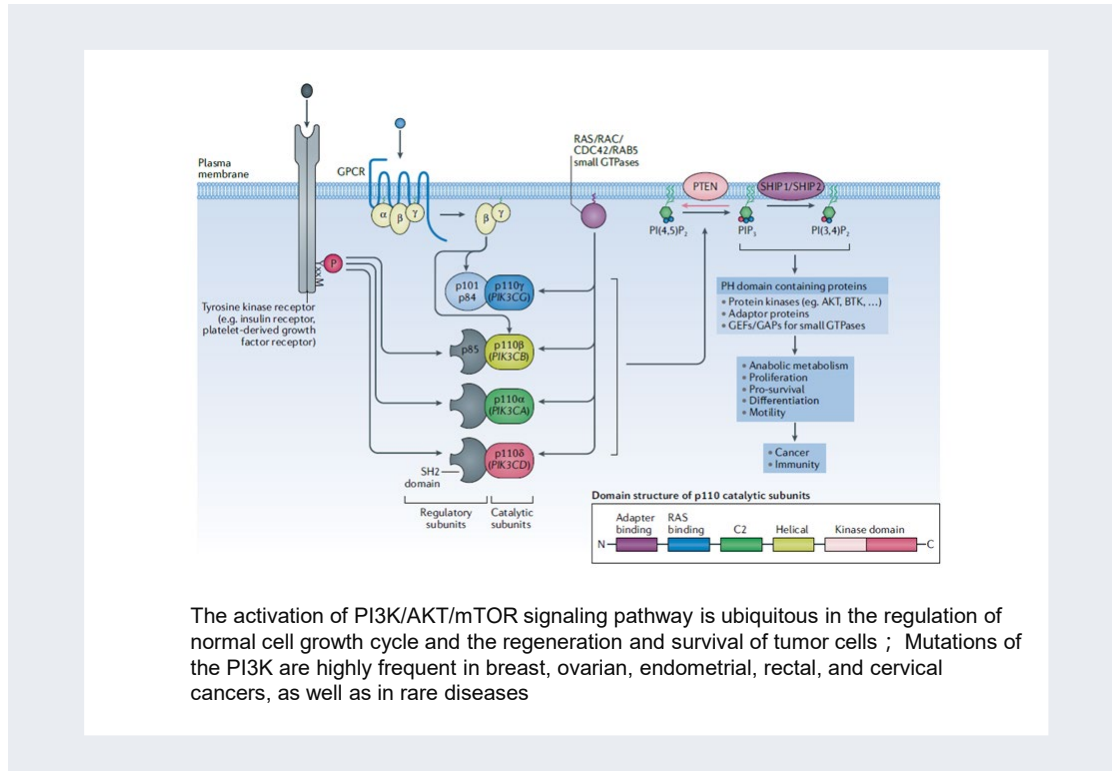
- JS107 is a recombinant humanized anti-Claudin18.2 monoclonal antibody-MMAE (Monomethyl auristatin E) conjugate for injection developed independently by the Company. It is an antibody-drug conjugate (ADCs) targeting tumor-related protein Claudin18.2, and is intended to be used for the treatment of advanced malignant tumors, such as gastric cancer and pancreatic cancer.
- The pre-clinical in vivo pharmacodynamics showed that JS107 exhibits significant anti-tumor effect. In addition, animals have a good tolerance to JS107 and JS107 exhibits good safety.
- **In March 2022, the IND application for the JS107 has been approved by the NMPA. The enrollment of the Phase 1 clinical trial of JS107 is 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.

# JS105: Oral Small Molecule Inhibitor Targeting PI3K- $\alpha$

- JS105 is an oral small molecule inhibitor targeting PI3K- $\alpha$  cooperated with Risen and is primarily used in the treatment of female (post-menopausal) and male 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 good safety.
- **In May 2022 and July 2022, the IND application for JS105 was approved by the NMPA and the FDA, respectively. The enrollment of the Phase 1 clinical trial of JS105 is currently underway.**

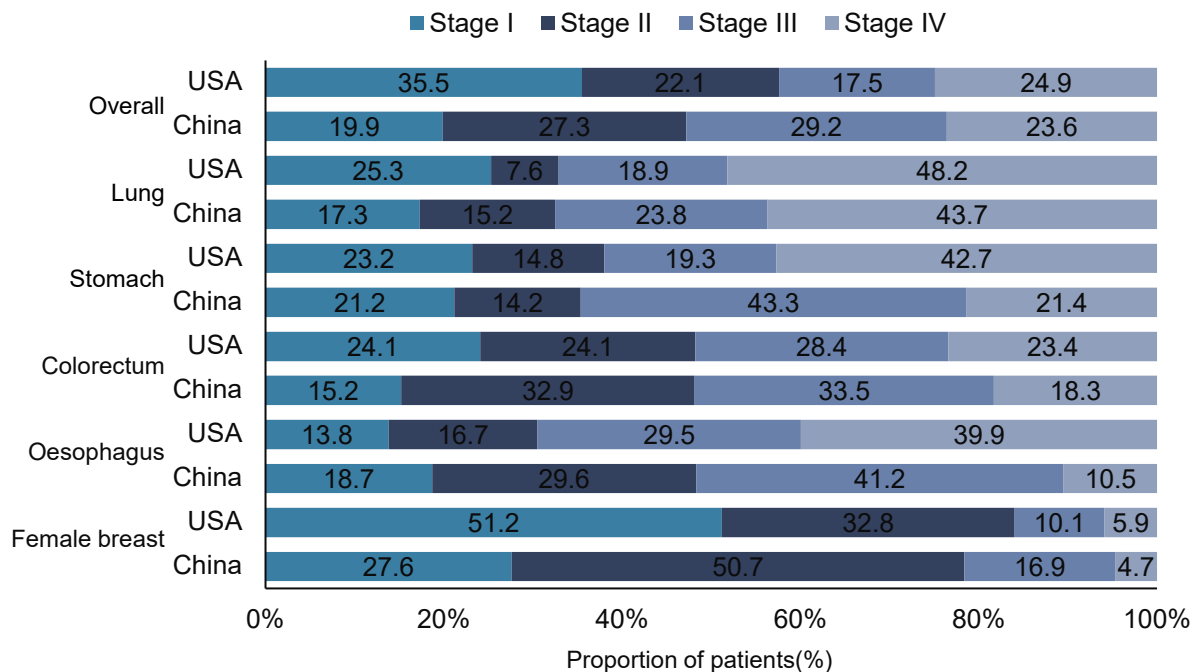


- According to GLOBOCAN 2020, breast cancer had the highest incidence rates worldwide, with 2.26 million new cases and 0.68 million deaths in 2020.
- According to data from Novartis, HR+/HER2- represents 71% of breast cancer patients, and ~40% of people with HR+/HER2- breast cancer have a PIK3CA mutation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

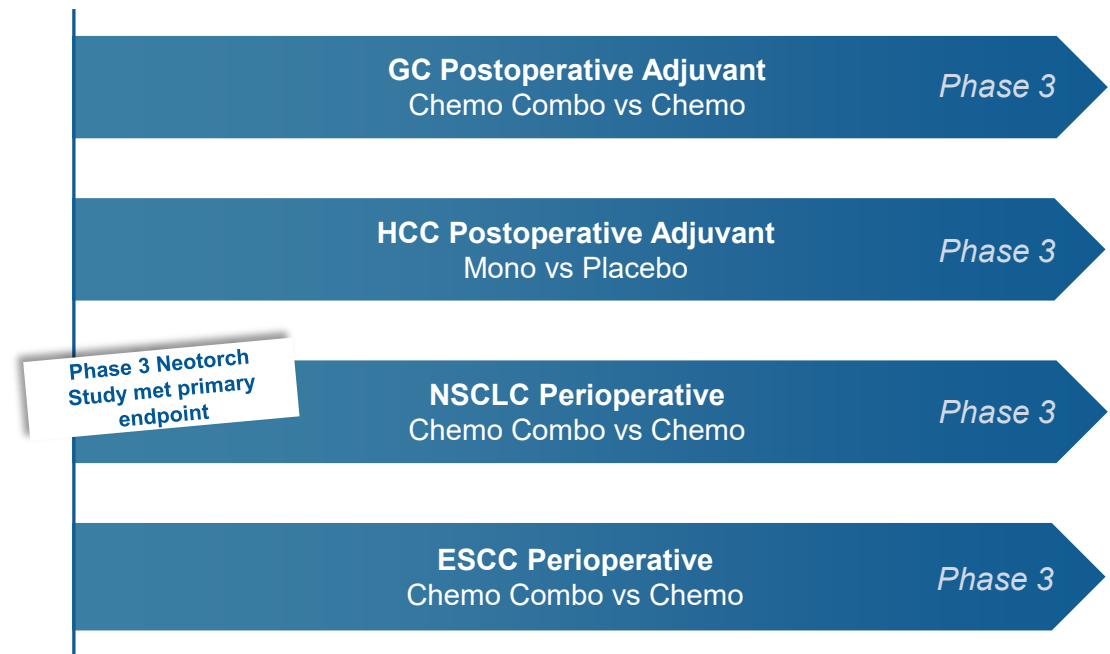
# Promote the Use of Toripalimab in Frontline Treatment: the Strongest Postoperative Adjuvant/Perioperative Deployment in China

- The data from the China National Central Cancer Registry<sup>1</sup> shows that, 56.5% of the cancer patients were diagnosed at stage II or III (where postoperative adjuvant/ perioperative therapy can be better applied) among top 5 cancers China. Therefore, with the improvement of cancer prevention awareness and early cancer detection, target group will continue to grow, leading to a market with large potential.
- Junshi has promoted the use of toripalimab in frontline treatment, with focus on postoperative adjuvant/perioperative therapy. **The clinical trials cover most common cancer types in China**, including gastric cancer, liver cancer, lung cancer, and esophageal squamous cell carcinoma, all of which are currently in Phase 3. The phase 3 study (Neotorch study) of Toripalimab in combination with platinum-containing doublet chemotherapy as **perioperative treatment for operable NSCLC patients has met the primary endpoint.**

## Stage Distribution for Top 5 Cancers in China



## Postoperative Adjuvant/Perioperative Pipeline of Toripalimab



# Toripalimab + Chemotherapy as Perioperative Treatment for NSCLC:Met Primary Endpoint in Ph3

- **Neotorch is the world's first phase 3 registered study of perioperative immunotherapy for lung cancer with positive EFS result.** In January 2023, the phase 3 clinical study of toripalimab in combination with platinum-containing doublet chemotherapy versus placebo in combination with platinum-containing doublet chemotherapy for patients with operable NSCLC has finished the pre-specified interim analysis. The IDMC has determined that the primary endpoint of EFS has met the pre-defined efficacy boundary.
- Compared with chemotherapy alone, toripalimab in combination with chemotherapy as perioperative treatment for phase 3 operable NSCLC patients and toripalimab monotherapy for consolidation therapy thereafter may significantly extend EFS of patients. The safety data of toripalimab is in line with known risks, without identification of new safety warnings
- The research findings of Neotorch have been accepted at the ASCO Monthly Plenary Series (April). The exceptional therapeutic efficacy and robust potential of toripalimab will herald a new era of perioperative immunotherapy for NSCLC in China.
- **The company has submitted application for the pre-NDA communication for such indication to the NMPA.**

## Neotorch epitomizes the success of a perioperative immunotherapy

Study	IO stage
CheckMate-816	Neoadjuvant
Impower 010	Adjuvant
KEYNOTE-091	Adjuvant
<b>Neotorch</b>	<b>(Neoadjuvant+Adjuvant) Perioperative</b>

## Neotorch is at the forefront of progress

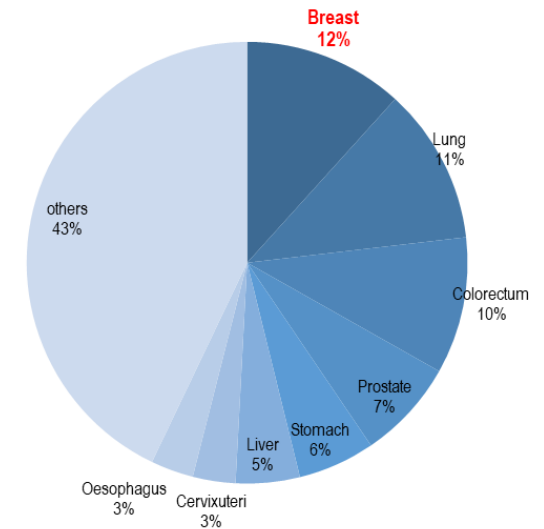
Study	Announcement of positive EFS results
<b>Neotorch</b>	<b>2023.01.17</b>
KEYNOTE-671	2023.03.01
AEGEAN	2023.03.09

# Toripalimab + Chemotherapy for Advanced TNBC: Met Primary Endpoint in Ph3

- **Breast cancer is the most common cancer worldwide**, TNBC accounts for about 15% to 20% of all breast cancer cases, which is a more aggressive type of tumor with higher recurrence risk and poor prognosis. **No immunotherapy drugs has been approved for advanced TNBC in China, and chemotherapy is still the main treatment.**
- In February 2023, the phase 3 study of toripalimab in combination with paclitaxel for injection (albumin-bound) 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 an advanced TNBC immunotherapy.** Based on the interim results, compared with paclitaxel for injection (albumin-bound), toripalimab in combination with paclitaxel for injection (albumin-bound) in patients with initial diagnosis of stage IV or recurrent metastatic TNBC can significantly prolong the PFS of patients with PDL1-positive, and at the same time, the secondary endpoint of all comers and PD-L1-positive population, i.e. the overall survival (OS), also showed a clear trend of improvement. The safety data of toripalimab is in line with known risks, without identification of new safety warning.
- **The company has submitted application for the pre-NDA communication for such indication to the NMPA.**

- 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.
- In China, 0.42 million new cases and 0.12 million deaths due to breast cancer were reported in 2020, accounting for 18.4% and 17.1% of global cases, respectively.

**Breast cancer had the highest incidence rates worldwide**



Source: WHO 2020



# Toripalimab: the domestic PD-1 inhibitor with the widest strategic layout

**Geography**

The applications for commercialization have already been submitted in the US, EU and UK. Toripalimab is on track to achieve global commercialization.

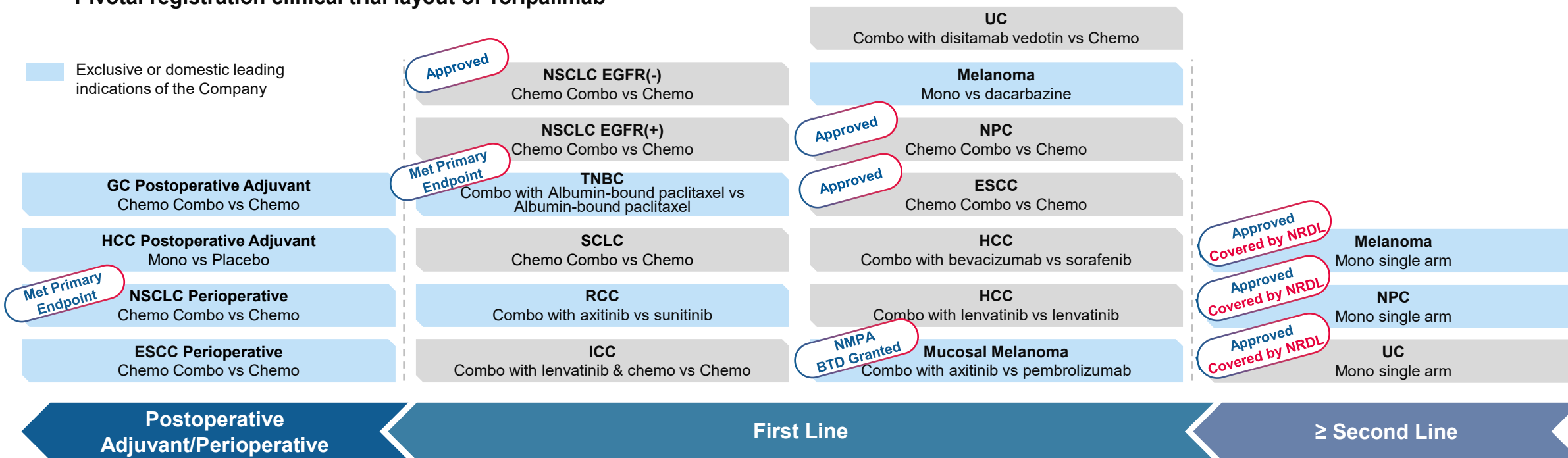
**Frontline**

Several Phase 3 clinical trials on postoperative adjuvant/perioperative treatment will be completed. Toripalimab is well-prepared to address unmet clinical needs.

**Combo**

Toripalimab is the most widely used domestic PD-1 monoclonal antibody in combination therapy with excellent safety profile. And we have built strong connections with a large number of potential strategic partners.

## Pivotal registration clinical trial layout of Toripalimab



# Treatments for Autoimmune, Metabolic and Neurological Diseases

- **Indications:** psoriatic, spondylitis
- **Origins:** In-house, developed independently by Junshi
- **Commercial Rights:** Global
- **Clinical Stage:** Phase 2 in China
- The Phase 2 clinical trial on non-radiographic axial spondyloarthritis is in progress. The two Phase 2 clinical trials on moderate to severe psoriasis and ankylosing spondylitis have been completed unblinding after a database lock, the efficacy results of which reached expectations with good safety.
- **The communication for registrational clinical trials has started, and the Phase 3 registrational clinical study is about to commence.**

- **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.**

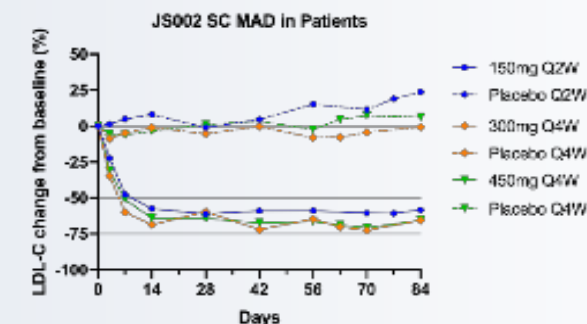
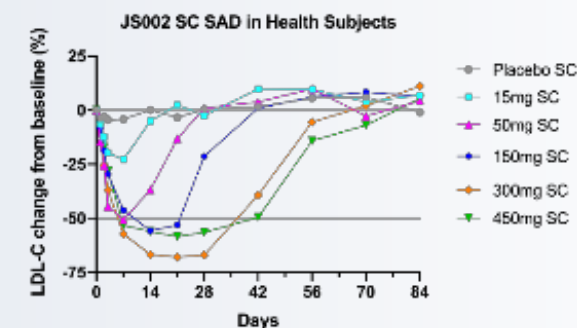
## JS005 Anti-IL-17A mAb

- **Indications:** hyperlipidemia
- **Origins:** In-house, developed independently by Junshi
- **Commercial Rights:** Global
- **Clinical Stage:** Phase 2/3 in China

- The Phase 3 clinical studies of primary hypercholesterolemia and mixed hyperlipidemia had been successfully completed, and met primary endpoints.
- **The Company plans to submit an NDA application for JS002 to the NMPA in 2023.**

## Ongericimab (JS002) Anti-PCSK9 mAb

## JS010 Anti-CGRP mAb



Notes: This is the primary analysis data, the final result is subject to the publication

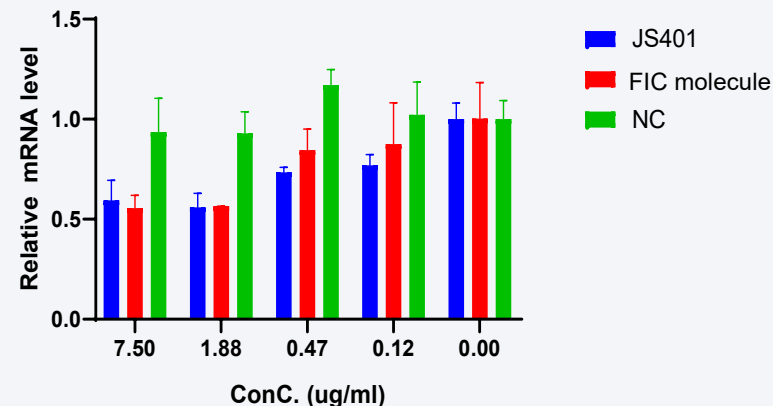
# siRNA Drug targeting ANGPTL3: JS401

## The advantages of our siRNA technology platform

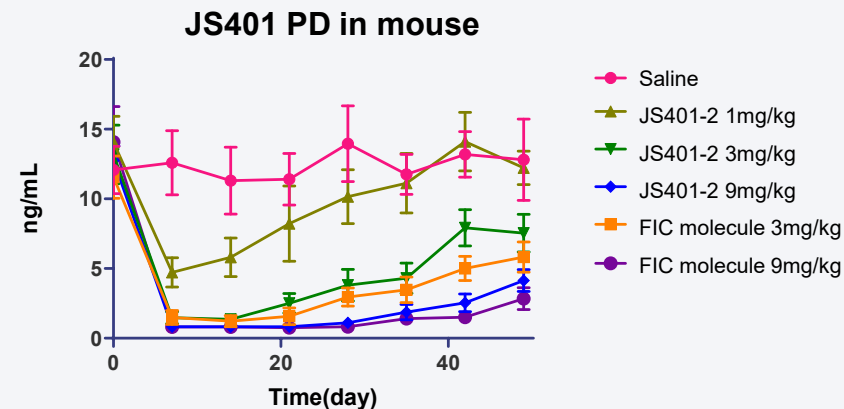
- Applying bioinformatics and AI technology to bring rational siRNA design, generating siRNA sequences with high inhibitory effect.
- Through our unique modifications, the stability of siRNA is enhanced with lower side effects. After generating siRNA sequence with inhibitory activity, it can be combined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

- JS401 is a siRNA drug targeting ANGPTL3 mRNA jointly developed by us 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 February 2023, the IND application for JS401 was accepted by the NMPA.**



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



君实生物十周年  
2018-2023

# Anti-infectives Field

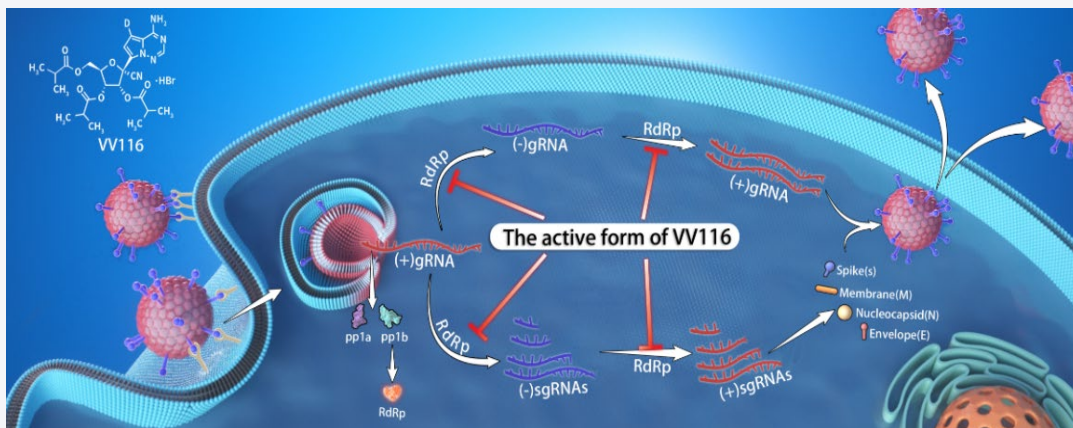
*Our mission is to provide patients with treatment options that work better and cost less.*

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

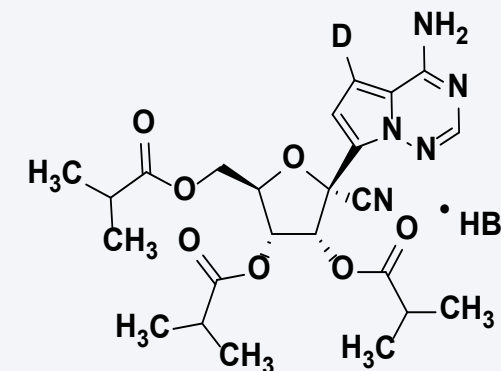
- In October 2021, Junshi and **Vigonvita Life Sciences**, reached a cooperation and will jointly undertake the clinical development and industrialization of the oral nucleoside anti-SARS-CoV-2 drug **VV116 (JT001)** on a global scale\*.
- In December 2021, **VV116 (JT001)** was approved for the treatment of moderate to severe COVID-19 patients in Uzbekistan.
- In January 2023, **NMPA conditionally approved for marketing JT001/VV116** for the treatment of adult patients with mild to moderate COVID-19 based on JT001-015 study.

## JT001-015

- |                 |            |           |           |
|-----------------|------------|-----------|-----------|
| • FPI:          | 2022.10.21 | } 88 days | } 99 days |
| • NDA accepted: | 2023.01.17 |           |           |
| • NDA approved: | 2023.02.18 | } 11 days |           |



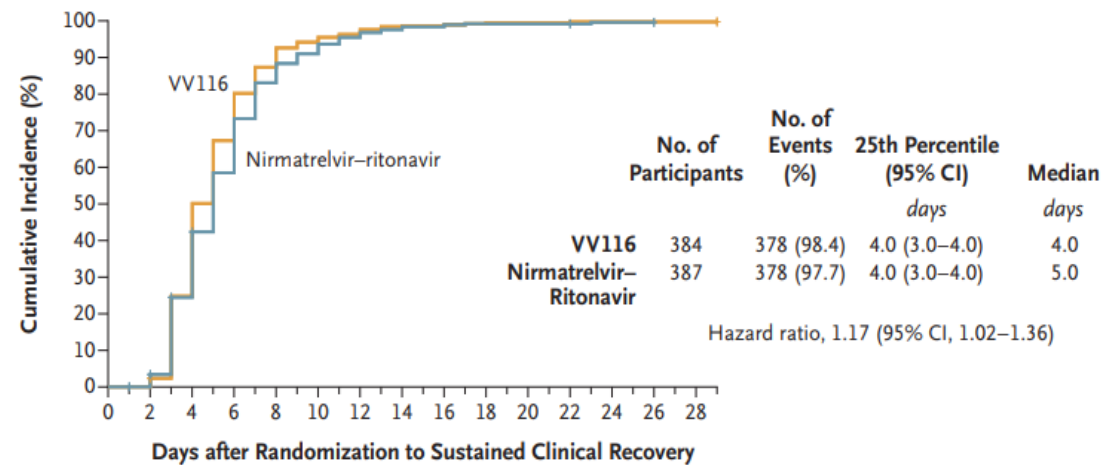
**VV116 targets the conserved viral RdRp, playing a crucial role in viral replication and transcription.**



**VV116 Chemical Structure**

# JT001-010: Noninferior to Paxlovid, with Fewer Safety Concerns

- ✓ NEJM (IF: 176.079) published the study results of the phase 3 trial comparing the efficacy and safety of VV116 (JT001) and Paxlovid in the treatment of symptomatic patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19 including death. **It is the first time that NEJM published the clinical trial results of China-developed anti-SARS-CoV-2 drug.**
- ✓ The study is **the first “head-to-head” phase 3 clinical study of small molecule oral anti-SARS-CoV-2 drug in Chinese COVID-19 patients during the Omicron outbreak.** The results indicated that the primary endpoint of the study realized the designed noninferiority endpoint, and **VV116 group had a shorter time to sustained clinical recovery with less safety concerns as compared with Paxlovid.**



No. at Risk	
VV116	384 384 285 124 48 22 14 6 5 3 2 2 1 1 1 1
Nirmatrelvir-ritonavir	387 386 287 157 64 34 17 9 6 3 3 3 1 1 0 0

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## VV116 versus Nirmatrelvir-Ritonavir for Oral Treatment of Covid-19

Z. Cao, W. Gao, H. Bao, H. Feng, S. Mei, P. Chen, Yueqiu Gao, Z. Cui, Q. Zhang, X. Meng, H. Gui, W. Wang, Y. Jiang, Z. Song, Y. Shi, J. Sun, Y. Zhang, Q. Xie, Y. Xu, G. Ning, Yuan Gao, and R. Zhao

### Primary Endpoint

In the FAS population, VV116 versus Paxlovid achieved noninferiority in the ‘time to sustained clinical recovery’ (HR=1.17, 95%CI: 1.02~1.36), and **the median time to sustained clinical recovery was shorter (4 days vs. 5 days).**

### Secondary Endpoints

VV116 and Paxlovid showed similar results in respect of ‘time to sustained resolution of all target symptoms’ and ‘time to a first negative SARS-CoV-2 test’, with a median time of 7 days. At each preset time point, **the proportion of patients with clinical recovery was larger in the VV116 group than that in the Paxlovid group.** No patients in either group had progression to severe/critical COVID-19 or had died.

# JT001-010: Noninferior to Paxlovid, with Fewer Safety Concerns

- The incidence of AEs in VV116 group was lower than that in the Paxlovid group (all-grade AEs: 67.4% vs. 77.3%, Grade 3 or 4 AE: 2.6% vs. 5.7%).
- Paxlovid has multiple drug-drug interactions, while VV116 does not inhibit or induce major drug-metabolism enzymes, or inhibit major drug transporters, and is therefore less likely to interact with the drugs for combination therapy.



**VV116 showed fewer safety concerns than Paxlovid**

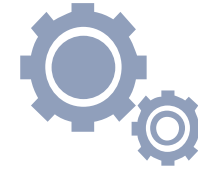
	VV116 (N = 384)	Paxlovid (N = 387)
<b>Any adverse event</b>	259 (67.4%)	299 (77.3%)
<b>Adverse event with maximum grade of <math>\geq 3</math></b>	10 (2.6%)	22 (5.7%)
<b>Serious adverse event</b>	1 (0.3%)	2 (0.5%)

# JT001-015: Benefit Mild to Moderate COVID-19 Patients with/without High Risk of Progression to Severe COVID-19

- JT001-015 is a multi-center, double-blind, randomized, placebo-controlled phase 3 clinical study (NCT05582629) evaluating the efficacy and safety of VV116 among mild to moderate COVID-19 patients with or without high risk of progression to severe COVID-19. The primary endpoint of the study was the time to sustained clinical symptoms resolution, while the secondary endpoints included the time to sustained clinical symptoms alleviation, percentage of participants with disease progression to severe or critical COVID-19 or death by any cause by day 28, changes in SARS-CoV-2 nucleic acid and viral load, safety, and etc.
- In January 2023, JT001-015 study completed its pre-defined interim analysis and met the pre-defined primary efficacy endpoint.
- **On January 28<sup>th</sup> 2023, VV116 was conditionally approved by the NMPA for the treatment of adult patients with mild to moderate COVID-19 based on JT001-015 study.**



As of the data cut-off date of the interim analysis, among 1,277 randomized and treated subjects:



## Efficacy

- ✓ The **primary endpoint**, or the time from first administration to sustained clinical symptoms resolution (The score of 11 COVID-19 related clinical symptom =0 and lasted for 2 days) of the VV116 group was significantly shortened when compared with that of the placebo group (median time difference of 2 days)
- ✓ **The time to sustained clinical symptoms alleviation** was significantly shortened
- ✓ The **change of viral load** from baseline and other virological indicators were better than those of the placebo group



## Safety

- ✓ The incidence of AE for VV116 group was low during the treatment, which was comparable to those of the placebo group

- Since the initial patient selection on October 21<sup>st</sup> 2022, more than 30 centers nationwide have overcome many difficulties to achieve the success of this study. While actively saving patients, preventing severe diseases, and reducing mortality, we quickly and efficiently completed the enrollment of more than 1,300 patients within 3 months.
- With its good efficacy and safety, VV116 is expected to become **one of the first-line COVID-19 drugs**. And it can benefit both mild to moderate COVID-19 patients and patients with high risk factors for severe COVID-19.





君实生物 Kingbio  
2015-2022

# Commercialization

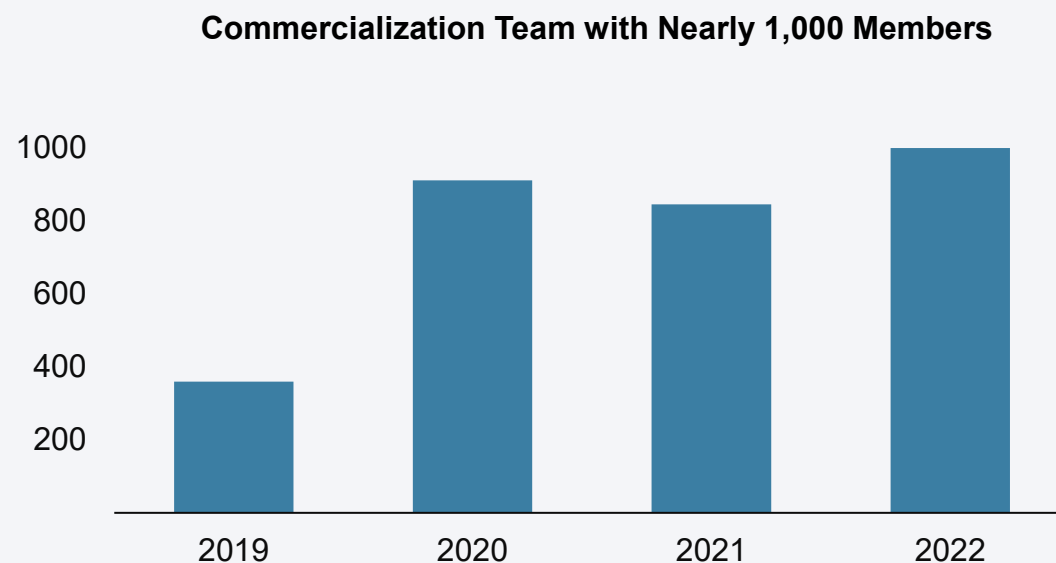
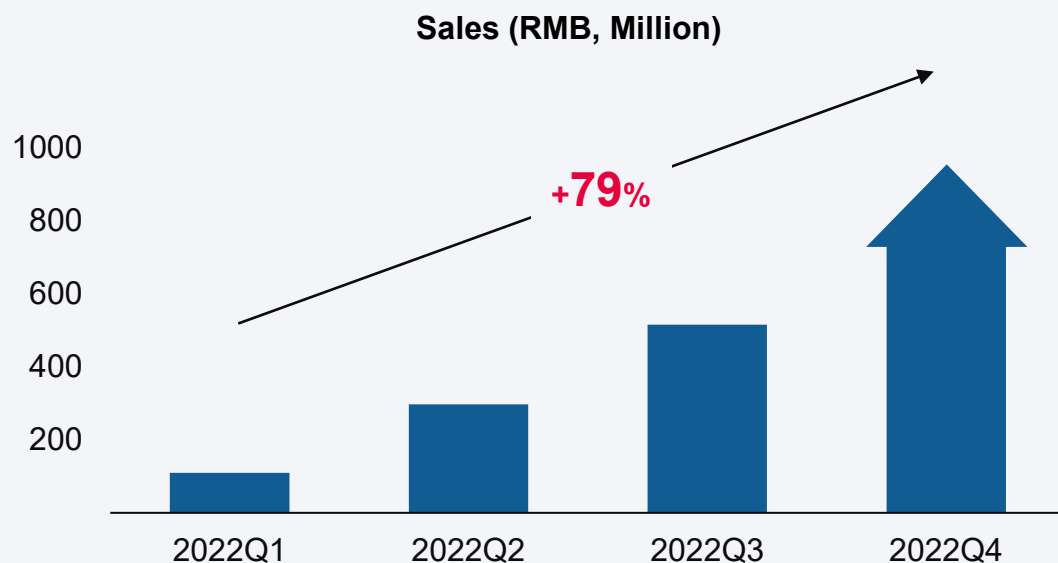
*Our mission is to provide patients with treatment options that work better and cost less.*


# TUOYI®: Steady Progress in Commercialization

TUOYI® sales revenue in FY 2022

736 ¥, MN <sup>YoY Growth</sup> 78.77%

With the improvement in commercialization capabilities and the approval of two new major indications for TUOYI® during the Reporting Period, the sales of TUOYI® in domestic market have gradually entered a positive cycle.





2L melanoma, 3L NPC and 2L UC included in NRDL  
The **only** anti-PD-1 mAb used in the treatment of melanoma and NPC in the NRDL

Three indications  
of TUOYI® included  
in the NRDL



Included in  
supplementary  
medical insurance,  
reducing the  
burden on patients

The indications that have been included in the NRDL, were entitled to supplementary reimbursement in **137** regions or cities through the urban commercial insurance across the country

The newly approved indications of 1L ESCC, 1L NPC and 1L NSCLC were entitled to supplementary reimbursement of commercial insurance in **93**, **104** and **93** cities, respectively

TUOYI® has been successfully included in the special drug catalogues of commercial insurance in **33** regions and cities

## Keep Improving Sales of TUOYI®

TUOYI® has been sold in **more than 4,000** medical institutions and **nearly 2,000** professional pharmacies and social pharmacies nationwide.

With the acceleration in clinical research, there will be more pivotal registered clinical studies on first-line treatment, perioperative treatment and postoperative adjuvant treatment of TUOYI® gradually completed, and more new indications will enter sNDA stage.

Promising  
competitiveness in  
commercialization



# Upgrading Production Capacity, Transforming into Intelligent Manufacturing Through Digitalization



## Shanghai Lingang Production Base

- Under construction in accordance with **CGMP standard**
- **42,000L (+12,000L)** 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



君实生物十周年  
2012-2022



# Outlook

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

# Upcoming Catalysts in 2023

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## Commercialization

- Toripalimab (PD-1) – FDA review
  - Toripalimab (PD-1) – EMA pre-approval inspection
- 

## Regulatory Submissions

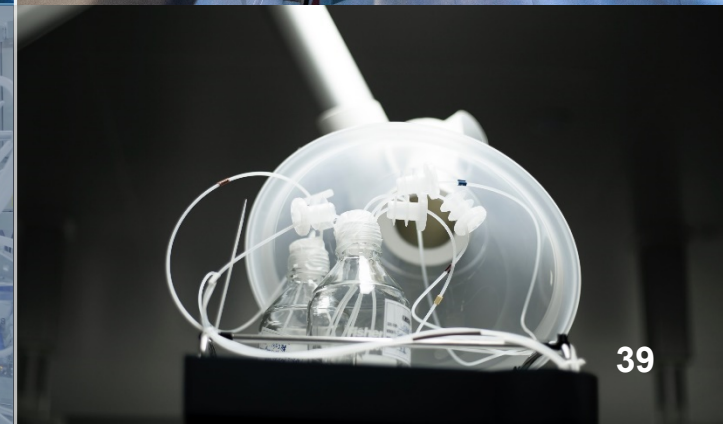
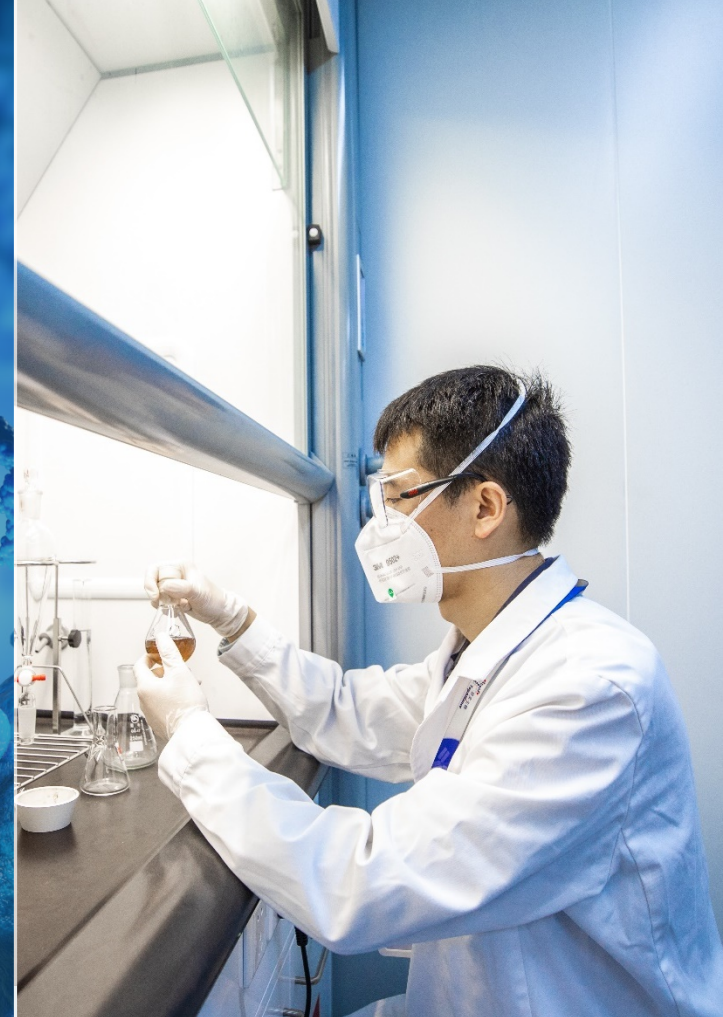
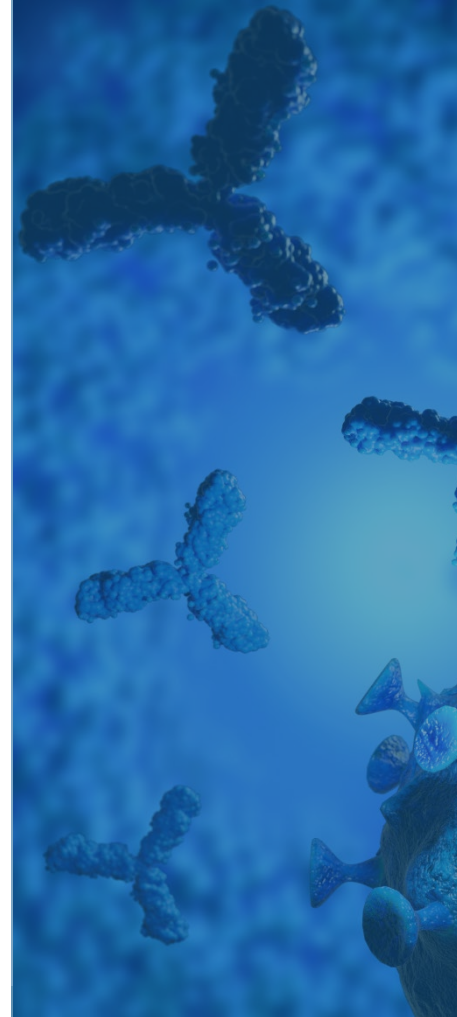
- Senaparib/JS109 (PARP)
  - Ongericimab/JS002 (PCSK9)
  - Toripalimab (PD-1) - NSCLC Perioperative
  - Toripalimab (PD-1) - TNBC
  - Toripalimab (PD-1) - 1L RCC
- 

## Registrational Phase 3 Initiations

- Tifcemalimab (BTLA)
  - JS005 (IL-17A)
- 

## IND Applications for New Products

- JS207 (PD-1+VEGF)
  - JS401 (ANGPTL3 siRNA)
- 





## Accelerate Clinical Trials

- Expand TUOYI® indications: postoperative adjuvant, perioperative, and frontline treatment; explore more commercialization opportunities in the US, UK, EU, MENA and SEA markets
- Accelerate clinical trials of FIC drugs including tificemalimab in China and the US
- Accelerate Ph3 trials of senaparib, bevacizumab and ongericimab to get NDA/BLA approvals
- Bring more innovative drugs to clinical stage

## Promote Innovation, and explore more novel therapies

- Establish R&D platforms for nucleic acid drugs, ADCs, bispecific and multispecific antibody drugs, etc.
- Discover IO/IO combination treatments like TUOYI® + tificemalimab, TUOYI® + JS009+JS006 to improve the clinical efficacy
- Collaborate with international partners to enrich our pipelines, and expand our businesses in the EU and US, including working with leading pharma specialized in small molecule drug

## Upgrade our commercialization capabilities

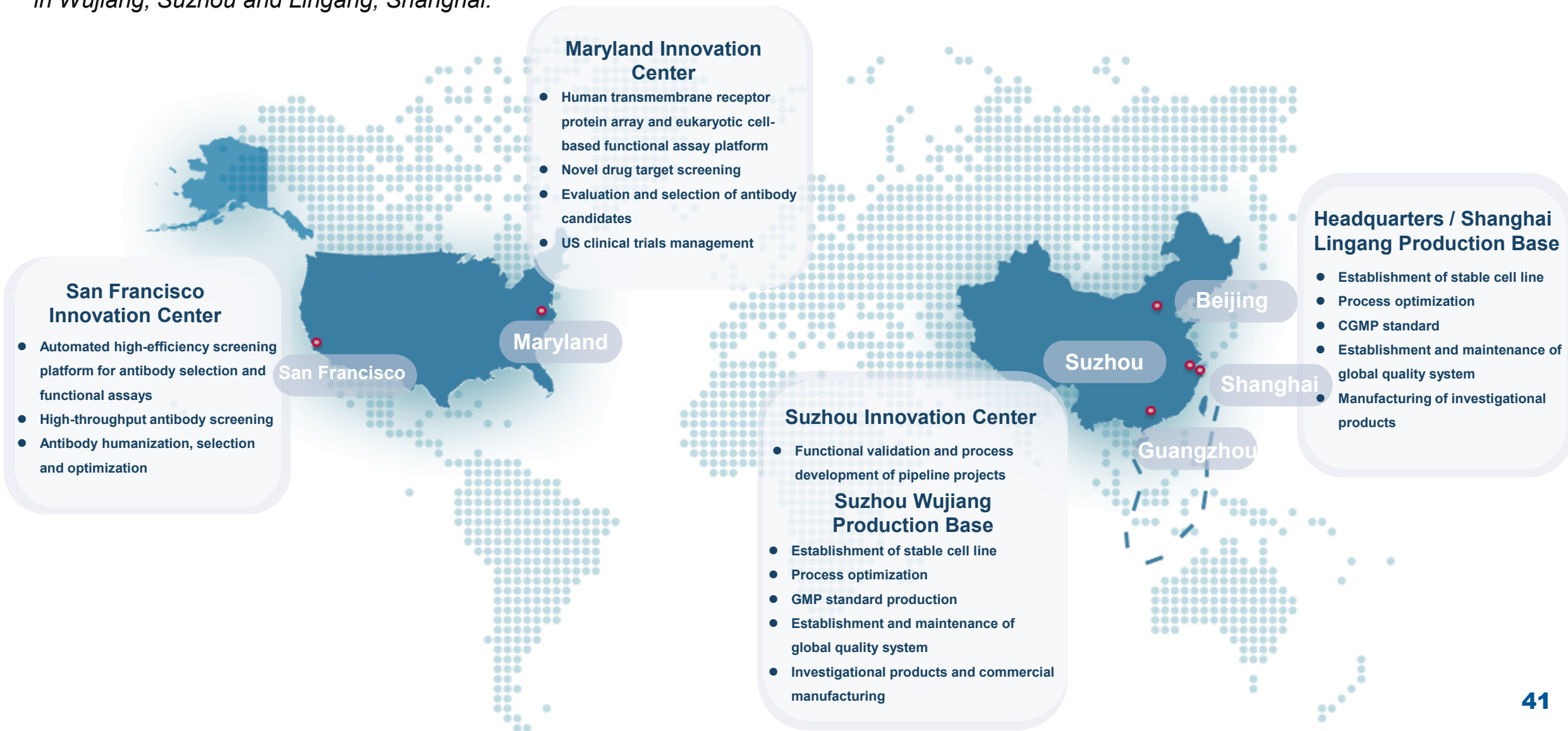
- With more large indications of TUOYI® approved, the benefits of forward-looking positioning in multi-indication perioperative clinical research starts to materialize. Together with the production capacity upgrade, the domestic sales of TUOYI® entered into a positive cycle
- Increase the penetration of the drug and provide doctors with clinical trial results of TUOYI® for postoperative adjuvant, perioperative, and other frontline treatment

## International Development

- With the goal of building a global biopharmaceutical company rooted in China, we will continue to expand the company's overseas clinical team, improve our global clinical trial strategy, and conduct more international multi-center clinical trials (MRCTs) to achieve global approvals of our key product pipelines

# 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.







君实生物十周年  
2012-2022

让生命  
再出发

THE JOURNEY  
AHEAD

**THANK YOU**