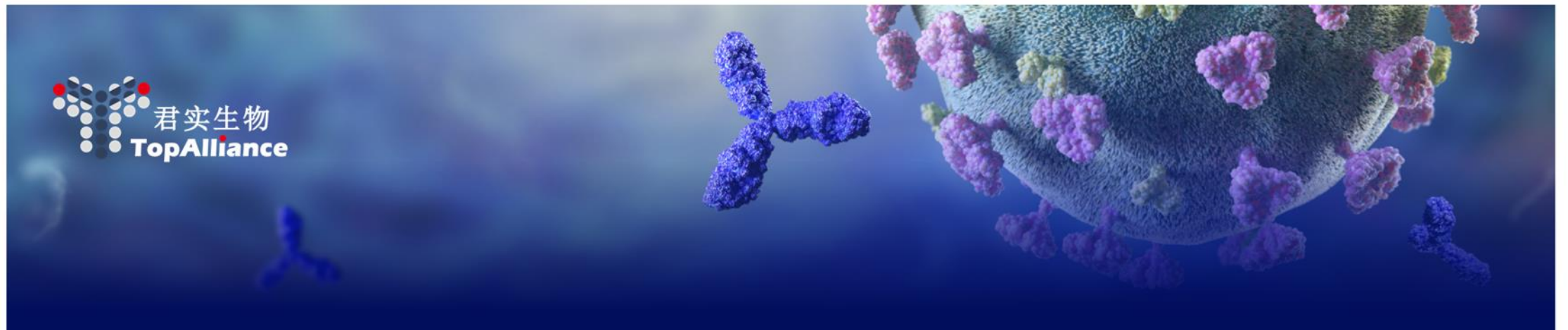


Q3 Results and Investor Presentation

Shanghai Junshi Biosciences Co., Ltd.

November, 2021



Disclaimer

The information, statements and opinions contained in this Presentation and subsequent discussion (if any) do not constitute an offer to sell or solicitation of any offer to subscribe for or purchase any securities or other financial instruments or any advice or recommendation in respect of such securities or other financial instruments in any jurisdiction. In particular, this Presentation is not an offer of securities for sale nor a solicitation of an offer to buy securities.

Potential investors and shareholders of the Company (the “Potential Investors and Shareholders”) are reminded that information contained in this Presentation and subsequent discussion (if any) comprises extracts of operational data and financial information of the Group for the twelve months ended 30 September 2021. The information included in this Presentation and subsequent discussion (if any), which does not purport to be comprehensive nor render any form of financial or other advice, has been provided by the Group for general information purposes only and certain information has not been independently verified. It may not contain all of the information that you may consider material. No representations or warranties, expressed or implied, are made as to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of the information, statements or opinions presented or contained in this Presentation and any subsequent discussions or any data which such information generates. Potential Investors and Shareholders should refer to The Third Quarterly Report for 2021 for the unaudited results of the Group which are published in accordance with the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited

The performance data, the results of operations and the clinical development of the drug candidates of the Group contained in this Presentation and subsequent discussion (if any) are historical in nature, and past performance is no guarantee of the future results of the Group. Any forward-looking statements and opinions contained in this Presentation and subsequent discussion (if any) are based on current plans, beliefs, expectations, estimates and projections at the date the statements are made, and therefore involve risks and uncertainties. The words “aim”, “anticipate”, “believe”, “could”, “continue”, “expect”, “estimate”, “going forward”, “intend”, “may”, “plan”, “predict”, “project”, “potential”, “seek”, “will”, “would”, the negative of these terms and similar expressions, as they relate to us, are intended to identify forward-looking statements. There can be no assurance that any of the matters set out in such forward-looking statements are attainable, will actually occur or will be realised or are complete or accurate. Actual results may differ materially and/or adversely from those stated, implied and/or reflected in such forward-looking statements and opinions. The Group, affiliates, the Directors, officers, employees, agents, representatives and advisers of the Group assume (a) no obligation to correct, update or supplement the forward-looking statements or opinions contained in this Presentation and subsequent discussion (if any), whether as a result of new information, future events or otherwise; and (b) no liability in the event that any of the forward-looking statements or opinions do not materialise or turn out to be incorrect

This Presentation may also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this Presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk

Potential Investors and Shareholders should exercise caution when investing in or dealing in the securities of the Company. Any person who is in doubt about his/her/its position or any action to be taken is recommended to consult his/her/its own professional adviser(s)



PART1: Q3 2021 Highlights

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

Financial Highlights

	YTD 202109 RMB million	YTD 202009 RMB million	Changes
Revenue	2718	1011	169%
R&D expenses	1423	1210	18%
Profit	-392	-1116	N/A
Net cash from operating activities	-540	-1095	N/A
Net cash from financing activities	1770		

- **The increase in total revenue was** mainly due to the significant increase in the out-licensing income and the income generated from new royalty fee during the reporting period.
- **The increase in R&D expenses** was mainly due to: (i) continued increasing investment in in-house R&D projects to ensure the promising progress of pivotal clinical trials and pre-clinical studies; and (ii) the expanded innovative R&D fields, more R&D collaborations and license-in activities which are further developing and enriching our product pipelines.
- **A decrease in the loss** was mainly due to the significant increase in the operating income, which results in a decrease in the loss.
- **The improved net cash flow from operating activities** was mainly due to the significant increase in the operating income, which results in a decrease in the loss.

Business Highlights



	Q1		Q2		Q3			2021Q4 and beyond		
Toripalimab	China	1L NPC Combo with chemo NMPA NDA Accepted	1L MM Combo with axitinib NMPA BTD	2L UC Mono NMPA NDA approved	1L SCLC Enrollment completion	1L ESCC Combo with paclitaxel/cisplatin NMPA NDA accepted				
		3L NPC Mono NMPA NDA approved	Entered into an exclusive promotion agreement with AstraZeneca	1L ESCC Combo with paclitaxel/cisplatin Reached pre-specified primary endpoints	HCC adjuvant Enrollment completion	CSCO R&D progress in multiple tumor types				
	Overseas	1L MM Combo with axitinib FDA FTD	Explore oversea market through cooperation with Coherus	AACR 2021 3 research results selected		NPC FDA BTD	1L NSCLC WCLC 2021	1L ESCC ESMO 2021	Digestive system tumors Neo Adjuvant ASTRO 2021	NPC FDA BLA accepted
		1L MM Combo with axitinib Phase III	NPC FDA rolling submission& rolling review	ASCO 2021 Plenary session Oral Presentations		NPC FDA rolling submission completed	Nature Medicine Cover Article NPC JUPITER-02			
Etesevimab	COVID-19 Combo with bamlanivimab FDA EUA				NEJM JS016+ LY-CoV555 Phase 3 clinical data	Post-exposure prophylaxis for COVID-19 FDA EUA	An additional 388,000 doses purchased by the U.S; EU agreed to purchase up to 220,000 doses			
Other product candidates	TAB006/JS006 TIGIT NMPA IND approved	JS201 PD-1/TGF-β NMPA IND accepted	JS110 XPO1 NMPA IND approved	JS007 CTLA-4 NMPA IND approved	JS111 EGFR Exon 20ins The dosing of the first patient completed	UBP1213sc BLyS NMPA IND accepted	JS110 XPO1 The dosing of the first patient completed	JS026 COVID-19 NMPA IND accepted		
	TAB006/JS006 TIGIT FDA IND approved	JS103 Pegylated uricase derivative NMPA IND accepted	JS111 EGFR Exon 20ins NMPA IND approved	JS014 IL-21 NMPA IND accepted	JS201 PD-1/TGF-β The dosing of the first patient completed	JS014 IL-21 NMPA IND approved	JS012 Claudin18.2 NMPA IND accepted	JS019 CD39 NMPA IND accepted		
	JS110 XPO1 NMPA IND accepted	JS007 CTLA-4 NMPA IND accepted	JS103 Pegylated uricase derivative NMPA IND approved							
	JS111 EGFR Exon 20ins NMPA IND accepted									
Other corporate development	A shares & H shares included in Northbound Trading under SH-HK Stock Connect and the Stock Connect Southbound Trading		A shares included in the STAR 50 index, the FTSE Global Equity Index H shares included in several Hang Seng Indexes		New H shares issued		Alliance with Immorna	A shares will be included in the MSCI China A Onshore Index		
							Collaborate with Vigonvita to jointly develop oral nucleoside analog against COVID-19	Collaborate with the IMCAS to jointly develop ZIKV Vaccine		

R&D Progress of Toripalimab

Therapeutic Area	Medicine Codes	Clinical Trial Number	Indications	Pre-Clinical	Phase I	Phase II	Phase III	NDA	Locations	Note	
Oncology	JS001 Toripalimab	NCT03013101	Melanoma (2L, mono)	Approved on 17 December 2018						China	
		NCT02915432	Nasopharyngeal carcinoma (3L, mono)	NDA approved by NMPA in February 2021, BLA submitted to FDA Accepted						China	FDA BTD and ODD
		NCT03113266	Urothelial carcinoma (2L, mono)	NDA Approved by NMPA in April 2021						China	
		NCT03581786	Nasopharyngeal carcinoma (1L, combo with chemo)	NDA Accepted, BLA submitted to FDA Accepted						Global	FDA BTD NMPA Priority Review
		NCT03829969	ESCC (1L, combo with chemo)	NDA Accepted						China	
		NCT03856411	EGFR negative NSCLC (1L, combo with chemo)	Pivotal registered clinical trial						China	Phase III data readout
		NCT03924050	EGFR mutated TKI failed NSCLC (combo with chemo)	Pivotal registered clinical trial						China	
		NCT04772287	NSCLC (neoadjuvant)	Pivotal registered clinical trial						China	
		NCT04012606	SCLC (1L, combo with chemo)	Pivotal registered clinical trial						China	Completed subjects enrollment
		NCT04848753	ESCC (neoadjuvant)	Pivotal registered clinical trial						China	
		NCT03430297	Melanoma (1L, mono)	Pivotal registered clinical trial						China	
		NCT04085276	TNBC (combo with albumin-bound paclitaxel)	Pivotal registered clinical trial						China	
		NCT04523493	HCC (1L, combo with lenvatinib)	Pivotal registered clinical trial						Global	
		NCT04723004	HCC (1L, combo with bevacizumab)	Pivotal registered clinical trial						Global	
		NCT03859128	HCC (adjuvant)	Pivotal registered clinical trial						China	Completed subjects enrollment
		NCT02915432	Gastric carcinoma (3L, mono)	Pivotal registered clinical trial						China	
		NCT04394975	Renal cell carcinoma (1L, combo with axitinib)	Pivotal registered clinical trial						China	
		NCT04568304	Urothelial carcinoma (1L, PD-L1+)	Pivotal registered clinical trial						Global	
		/	Mucosal melanoma (combo with axitinib)						U.S.	FDA FTD ODD ; NMPA BTD	
		NCT03474640	Sarcoma						U.S.	FDA ODD	

R&D Pipelines Covering a Wide Variety of Therapeutic Areas

Pre-clinical

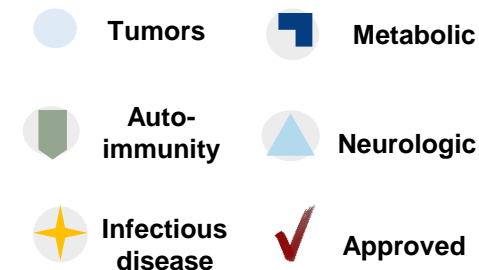
Phase I

Phase II

Phase III

Approved/
Under Review

JS009 CD112R/PVRIG Tumors	JS209 CD112R+TIGIT Tumors	JS112 Aurora A Small cell lung cancer	JS113 EGFR 4th Gen Non-small cell lung cancer	JS003 PD-L1 Tumors	JS007 CTLA-4 Lung cancer, melanoma	JS004(TAB004) BTLA Lung cancer, Melanoma, etc	JS109 PARP Ovarian cancer (1L maintenance)	Toripalimab PD-1 Tumors ✓
JS011 Undisclosed Tumors	JS001 SC PD-1/L1 Tumors	JS203 CD3+Undisclosed Tumors	JS114 Nectin4 ADC Tumors	JS006(TAB006) TIGIT Tumors	JS014 IL-21 Tumors	JS005 IL-17A Psoriatic, spondylitis	Bevacizumab VEGF Non-small cell lung cancer	Adalimumab Rheumatoid arthritis
JS013 CD93 Tumors	JS107 Claudin18.2 ADC Gastrointestinal cancer	JS207 PD-1+Undisclosed Tumors	JS115 BCMA ADC Multiple myeloma	JS012 Claudin 18.2 Gastric cancer	JS101 Pan-CDK Breast cancer, etc.		Ongericimab PCSK9 Hyperlipidemia	Etesevimab* S protein COVID-19 ✨
JS015 Undisclosed Tumors	JS104 Pan-CDK Breast cancer, etc.	JS211 PD1+Undisclosed Tumors	JS116 KRAS Tumors	JS019 CD39 Tumors	JS110 XPO1 Multiple myeloma, etc.			
JS018 IL-2 Tumors	JS105 PI3K-α Breast cancer, renal cell cancer	JS401 Undisclosed (RNAi) Metabolic diseases	JS008 Undisclosed	JS108 TROP2 ADC Triple negative breast cancer	JS201 PD-1/TGF-β Tumors			
JS206 IL2+PD-1 Tumors		JS010 CGRP Migraine ▲	VV116 Oral nucleoside analog COVID-19 ✨	JS111 EGFR exon 20 Non-small cell lung cancer	JS103 Uricase Hyperuricacidemia			
				JS026 S protein COVID-19 ✨	UBP1213 BLyS Systemic lupus erythematosus			



*Received Emergency Use Authorization from FDA



PART2: Helping Patients Worldwide

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

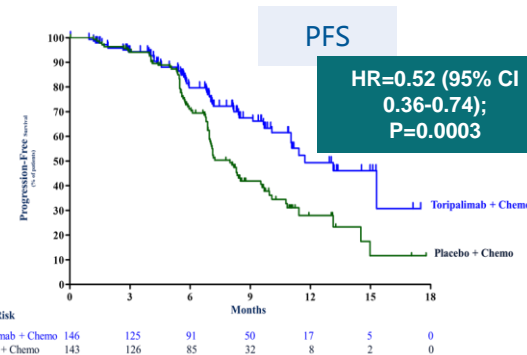
Toripalimab in NPC

- In Feb 2021, the supplemental NDA application of toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, r/m NPC was accepted by the NMPA.
- **The data of toripalimab in 1L NPC was featured at ASCO 2021 in the plenary session on Sunday, June 6, 2021.**
- JUPITER-02 is the first international 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.
- US FDA has **accepted for review the BLA** for toripalimab in combination with gemcitabine and cisplatin for the first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma (“NPC”) and toripalimab monotherapy for the second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.
- The FDA has granted **Priority Review Designation** for the toripalimab BLA and set a Prescription Drug User Fee Act ("PDUFA") action date for April 2022.
- The FDA is **not currently planning to hold an advisory committee** meeting to discuss the application.

□ Efficacy

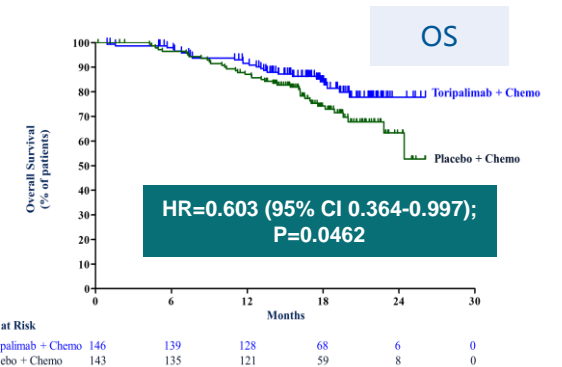
- Significant improvement in PFS: mPFS 11.7 vs. 8.0 months
- mOS: not mature, but a 40% reduction in risk of death was observed in the toripalimab arm over the placebo arm
- A second interim OS analysis will be performed at pre-specified final PFS analysis followed by the final OS analysis

	No. of Events/ Total No. of Patients	Median Progression-free Survival, months (95% CI)	1-Yr Progression- free Survival Rate, % (95% CI)
Toripalimab + Chemo	49/146	11.7 (11.0, NE)	49.4 (36.4, 61.1)
Placebo + Chemo	79/143	8.0 (7.0, 9.5)	27.9 (18.0, 38.8)



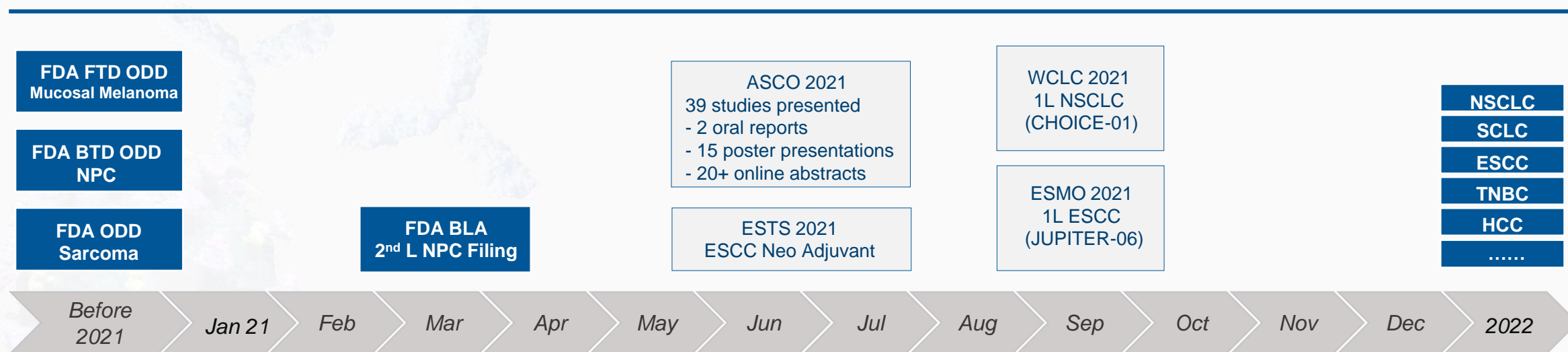
Interim Analysis Data cut-off Date: May 30, 2020

	No. of Deaths/ Total No. of Patients	Median Overall Survival (95% CI) mo	1-Yr Overall Survival Rate % (95% CI)	2-Yr Overall Survival Rate % (95% CI)
Toripalimab + Chemo	25/146	NE (NE, NE)	91.6 (85.6, 95.1)	77.8 (68.0, 85.0)
Placebo + Chemo	39/143	NE (22.8, NE)	87.1 (80.4, 91.7)	63.3 (49.8, 74.1)



9-month OS update after PFS Interim Analysis on Feb 18, 2021

International Recognition and Overseas Progress of Toripalimab



WCLC 2020 NSCLC

Journal of Clinical Oncology
IF=44.544
r/m NPC (POLARIS-02)

Therapeutic Advances in Medical Oncology
IF=8.168
GS

AACR 2021
3 studies selected
- HCC Neo Adjuvant
- ESCC Neo Adjuvant
- SCLC Maintenance

Nature Medicine
IF=53.440
r/m NPC (JUPITER-02)

FDA BTD 1st L NPC Filing

ASTRO 2021 Digestive system tumors Neo Adjuvant

FDA BLA NPC Accepted

Meet primary endpoint at interim analysis 1L NSCLC

Progress of overseas clinical trials

Academic achievements

Prevalence

Indications	China	Northern American	Europe	South-Eastern Asia	Others
LC	883,100	328,224	582,924	134,378	676,165
HCC	338,106	39,797	68,095	82,593	267,040
ESCC	313,121	23,544	57,655	13,998	191,432
NPC	186,908	7,756	17,323	101,117	69,403
TNBC	139,010	118,911	213,812	49,179	258,160
Melanoma	22,281	368,049	517,196	8,954	176,338

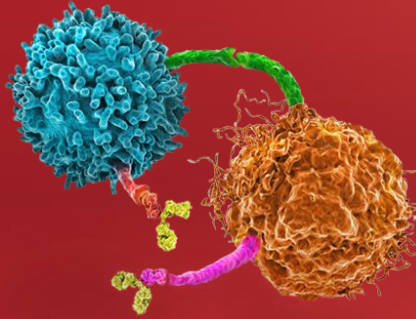
Source : WHO 2020

The Study of Toripalimab as 1L Treatment in NPC Becomes a Cover Article in the Nature Medicine

Sept. 15, 2021, Junshi announced publication of a cover article in the *Nature Medicine* (IF: 53.440) featuring clinical data from the pivotal study “JUPITER-02”, a phase 3 randomized JUPITER-02 trial evaluating toripalimab, Chinese-developed innovative biological drug, in combination with standard chemotherapy for the first-line treatment of R/M NPC. Professor Ruihua Xu is the lead principal investigator of the study.

It is the first time to recommend domestic innovative drug research since Nature Medicine was founded 26 years ago.





Junshi Biosciences grants Coherus the exclusive license to Toripalimab and two option programs in the U.S. and Canada. Junshi also grants certain negotiation rights to Coherus for two additional checkpoint inhibitor antibodies.

*Data-driven sales——
the core of overseas market*

Key Contents of the Agreement



- An aggregate of US\$1.11 billion of upfront payments, exercise fees and milestone payments
- 20% royalty on annual net sales
- Exclusive rights of toripalimab in US and Canada
- Options to JS006 and JS018-1
- Negotiation rights for two additional checkpoint inhibitor antibodies
- Establishing a joint development committee
- A maximum of US\$25 million R&D expenses per project per year

Upcoming Catalysts



- **Clinical Data:** Data from toripalimab pivotal clinical program, TIGIT/PD-1 combination and other potential combination trials
- **Publications:** Abstracts in medical conferences such as ASCO and SITC, 5-year publication plan in both mono and combo settings
- **FDA Filings:** BLA filing of NPC with BTD, multiple additional filings and PDUFA actions in rare and prevalent indications
- **Commercial Launches:** Multiple U.S. launches expected between 2022 and 2026

Toripalimab in Lung Cancer

The global prevalence of lung cancer in 2020: China(883,100), Northern America(328,224), Europe (582,924), Others(810,543)

NSCLC (1L, chemo combo)

Total enrollment: 465 patients

Primary Endpoint: PFS

Key Sec. Endpoints: OS, ORR

Status:

- Dec 2020: Met primary endpoint of PFS at interim analysis
- Sep 2021: Data been presented at WCLC

EGFR mutated TKI failed NSCLC (1L, chemo combo)

Total enrollment: 350 patients

Primary Endpoint: PFS

Key Sec. Endpoints: OS, ORR

Status:

- Enrollment completion expected by year end
- Data expected in 2022

NSCLC (neoadjuvant)

Total enrollment: 406 patients

Primary Endpoint: mPR

Key Sec. Endpoints: EFS

Status:

- Enrollment completion expected by year end
- Final data expected in 2022

SCLC (1L, chemo combo)

Total enrollment: 420 patients

Primary Endpoint: PFS, OS

Key Sec. Endpoints: ORR

Status:

- Enrollment complete
- Final data expected in 2022

Additional Toripalimab Studies with Data through 2022

ESCC (1L, chemo combo)

Total enrollment:	500 patients
Primary Endpoint:	PFS, OS
Key Sec. Endpoints:	ORR

Status:

- Feb 2021: Met primary PFS and OS endpoints at interim analysis
- Sep 2021: Data been presented at ESMO

Global prevalence: China(313,121), Northern America (23,544), Europe(57,655), Others(205,430)

TNBC (1L, chemo combo)

Total enrollment:	660 patients
Primary Endpoint:	PFS
Key Sec. Endpoints:	OS, ORR

Status:

- Enrollment completion expected by year end
- Final data expected in 2022

Global prevalence: China(139,010), Northern America (118,911), Europe(213,812), Others(307,339)

HCC (adjuvant)

Total enrollment:	402 patients
Primary Endpoint:	RFS
Key Sec. Endpoints:	TTR, OS

Status:

- Enrollment completed
- Data readout expected in 2022

Global prevalence : China(338,106), Northern America (39,797), Europe(68,095), Others(349,633)

HCC (1L, lenvatinib combo)

Total enrollment:	519 patients
Primary Endpoint:	PFS, OS
Key Sec. Endpoints:	ORR

Status:

- Enrollment completion expected by year end
- Data readout expected in 2022



PART3: Global Covid-19 Response

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

Many firsts, China speed

- Compressing the normal pre-clinical research time of antibody from 18 months to less than **4** months
- The **1st** report to evaluate the function of NAb against SARS-CoV-2 in nonhuman primates
- The **1st** clinical trial on a NAb for COVID-19 carried on healthy subjects
- The **1st** NAb for COVID-19 to enter the clinical trial in China
- The **1st** Chinese-developed innovative biological drug approved for use in the U.S.
- The **1st** Chinese innovative drug recommended by NIH
- The **1st** Chinese-developed monoclonal antibody purchased by the U.S. government

Gained EUA in many countries and regions, purchased by many countries

- As of this announcement, more than **15** countries and regions have granted EUA for the JS016 and LY-CoV555 together.
 - 2021/02, the therapy is authorized for treatment
 - 2021/09, the therapy is authorized for post-exposure prophylaxis
- 2021/09, The U.S. government has made an additional purchase for the therapy, with **388,000** doses; European Commission has agreed to purchase up to **220,000** doses of JS016 and LY-CoV555

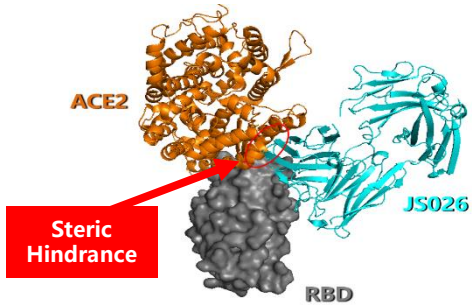
Active against multiple variants (including Delta variants)

- According to the paper *Tackling COVID-19 with neutralizing monoclonal antibodies* published in *CELL* in June 2021, as well as *the Reduced sensitivity of SARS-CoV-2 variant delta to antibody neutralization* published in *Nature* in June 2021, the combination therapy is effective against **B.1.1.7/Alpha variants** (first identified in Britain) as well as **B.1.617.1/Kappa** and **B.1.617.2/Delta variants** (first identified in India).



Covid-19 NAb ——Etesevimab

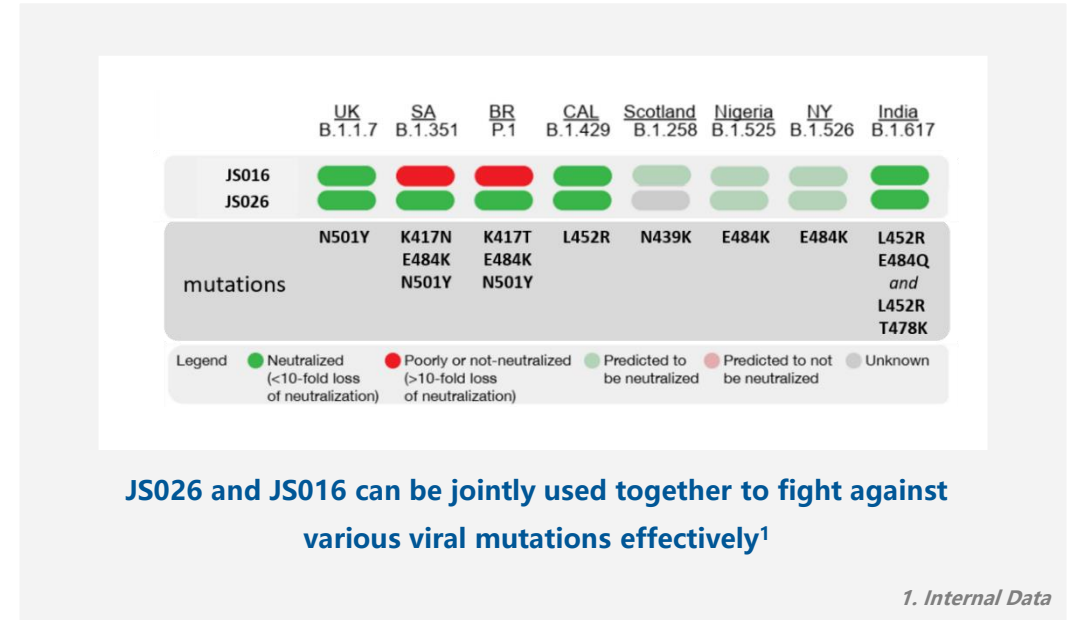
JS026: a new Deploy for COVID-19 Antibody Drug



- JS026 injection is a recombinant fully human monoclonal antibody, which is mainly used to prevent and treat the COVID-19.
- JS026 targets the S1 subunit of the SARS-CoV-2 spike protein, binding to the RBD with high affinity, blocking the binding between RBD and the ACE2 in the host cell surface receptor, thereby further blocking the infection of host cells by SARS-CoV-2.
- In October 2021, the IND application for JS026 has been accepted by NMPA.

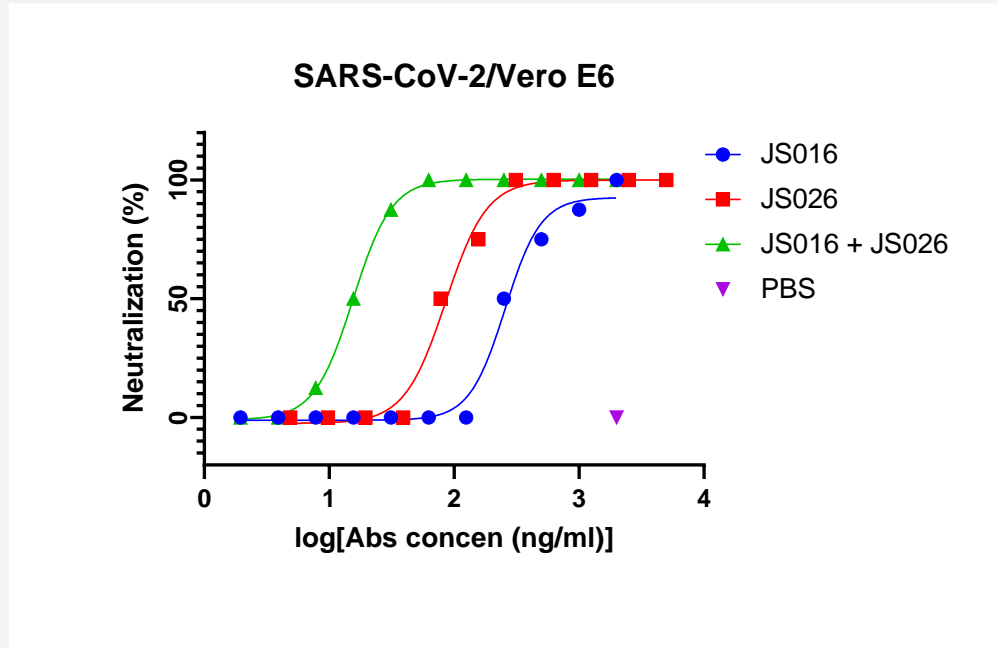
JS026 in combination with JS016 can be jointly used together to fight against various viral mutations effectively

- JS026 shows excellent broad-spectrum virus-neutralizing activities
- JS026 has neutralizing activity against B.1.1.7 and B.1.351 variants
- The binding epitopes of JS026 do not overlap with that of JS016. Therefore, JS026 can be used in combination with JS016 to avoid viral escape.



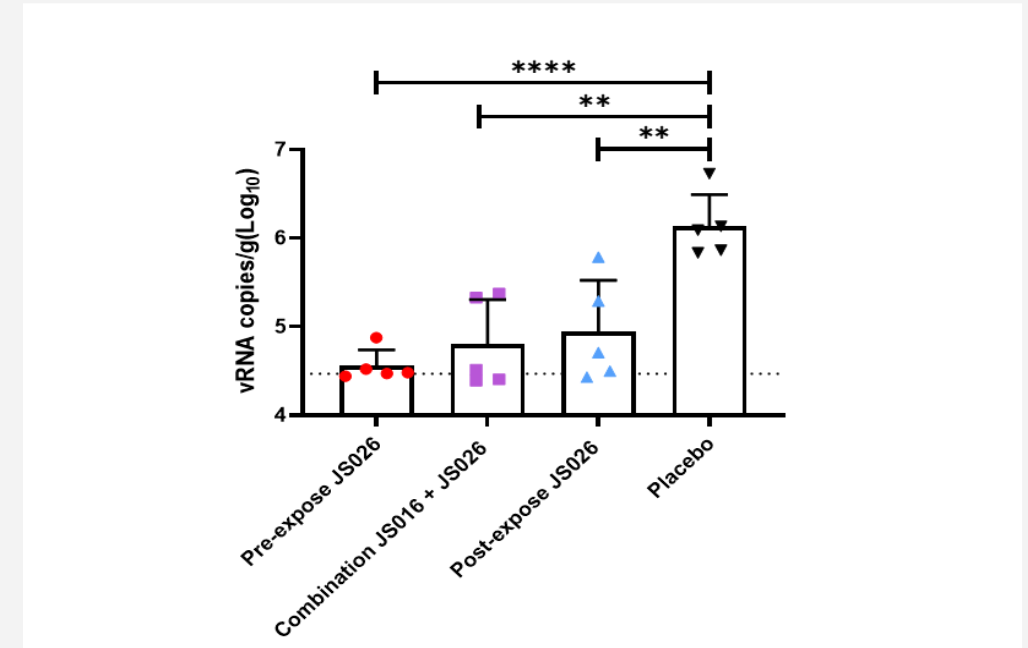
JS026 Shows Excellent Virus-neutralizing Activities

in vitro wild type virus neutralization assay of JS026



- Both JS016 and JS026 show excellent neutralizing activity against live SARS-CoV-2 virus. Besides, the neutralizing activity of JS026 was superior to JS016. The combination of these two antibodies will offer synergistic benefits and improve neutralization of biological activity

in vivo live virus neutralization assay of JS026

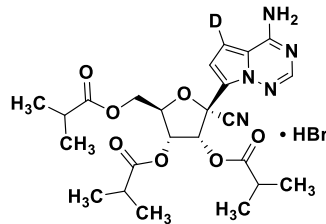


- JS026 used alone or in combination with JS016 can significantly reduce viral load in the lungs of mice and show remarkable therapeutic effects as compared with the placebo group.

Promising oral Nucleoside drug Against COVID-19: VV116

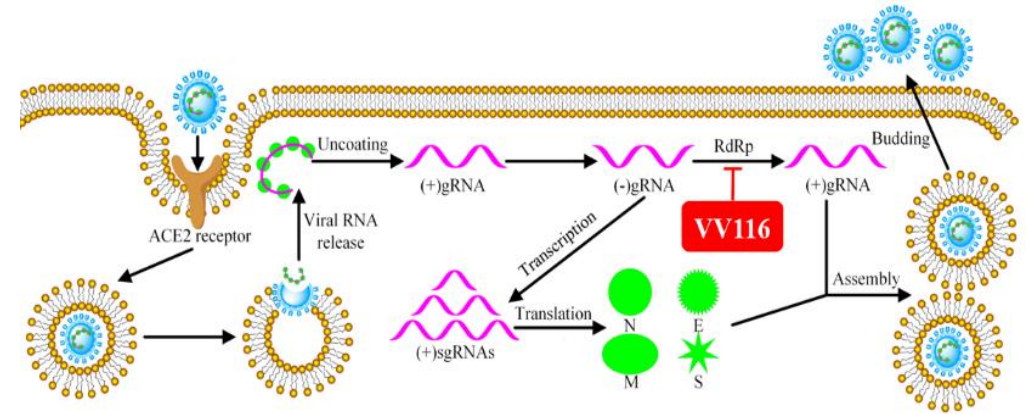
- On 4 October 2021, Junshi announced that the company and **Vigonvita Life Sciences**, incubator of SUSIMM, have reached a cooperation and will jointly undertake the clinical development and industrialization of the oral nucleoside anti-coronavirus candidate **VV116** on a global scale
- **The IND applications** of VV116 have been submitted to the drug regulatory authorities in **China and Uzbekistan** respectively. At present, **the IND application has been approved in Uzbekistan.**

VV116



Positive preclinical results

- **VV116 has a high barrier to drug resistance, which means it is effective against WT and various variants (eg Beta, Delta)**
- **VV116 shows excellent in vitro efficacy**
- **VV116 has high oral bioavailability**
 - **80% and 90% in rats and dogs, respectively**
- **VV116 significantly reduces the viral RNA copies and infectious virus titers in the lungs**
 - Preclinical pharmacodynamics studies have shown that VV116 exhibits significant anti-coronavirus effects both in vivo and in vitro.
 - In mouse models, VV116 can reduce the lung virus titer below the detection limit and show strong anti-coronavirus efficacy.
- **The results of in vitro bacterial reverse mutation test and chromosome aberration test are negative and there is no genetic toxicity**



RdRp: Responsible for viral RNA synthesis, highly conserved active-site region, an important target for anti-SARS-CoV-2

[nature](#) > [cell research](#) > [letter to the editor](#) > [article](#)

Letter to the Editor | [Open Access](#) | [Published: 28 September 2021](#)

Design and development of an oral remdesivir derivative VV116 against SARS-CoV-2

[Yuanchao Xie](#), [Wanchao Yin](#), [Yumin Zhang](#), [Weijuan Shang](#), [Zhen Wang](#), [Xiaodong Luan](#), [Guanghui Tian](#), [Haji A. Aisa](#), [Yechun Xu](#), [Gengfu Xiao](#), [Jia Li](#), [Hualiang Jiang](#), [Shuyang Zhang](#), [Leike Zhang](#) & [H. Eric Xu](#) & [Jingshan Shen](#)

[Cell Research](#) (2021) | [Cite this article](#)



PART4: Domestic Commercialization — Based on Needs of Patients

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

Promote the Use of TUOYI® in Frontline Treatment: the Strongest Adjuvant/Neo Adjuvant Deployment in China

the Company's exclusive or the domestic leading indications

Met pre-specified primary endpoint (Interim analysis)

NSCLC EGFR(-)
Chemo Combo vs Chemo

NSCLC EGFR(+)
Chemo Combo vs Chemo

TNBC
Combo with Albumin-bound paclitaxel vs Albumin-bound paclitaxel

SCLC
Chemo Combo vs Chemo

RCC
Combo with axitinib vs sunitinib

UC PD-L1(+)
Chemo Combo vs Chemo

Melanoma
Mono vs dacarbazine

NDA Submitted

NPC
Chemo Combo vs Chemo

NDA Submitted

ESCC
Chemo Combo vs Chemo

HCC
Combo with avastin vs sorafenib

HCC
Combo with lenvatinib vs lenvatinib

NMPA BTD

Mucosal Melanoma
Combo with axitinib vs pembrolizumab

Approved

Melanoma
Mono single arm

Approved

NPC
Mono single arm

Approved

UC
Mono single arm

GC
Mono single arm

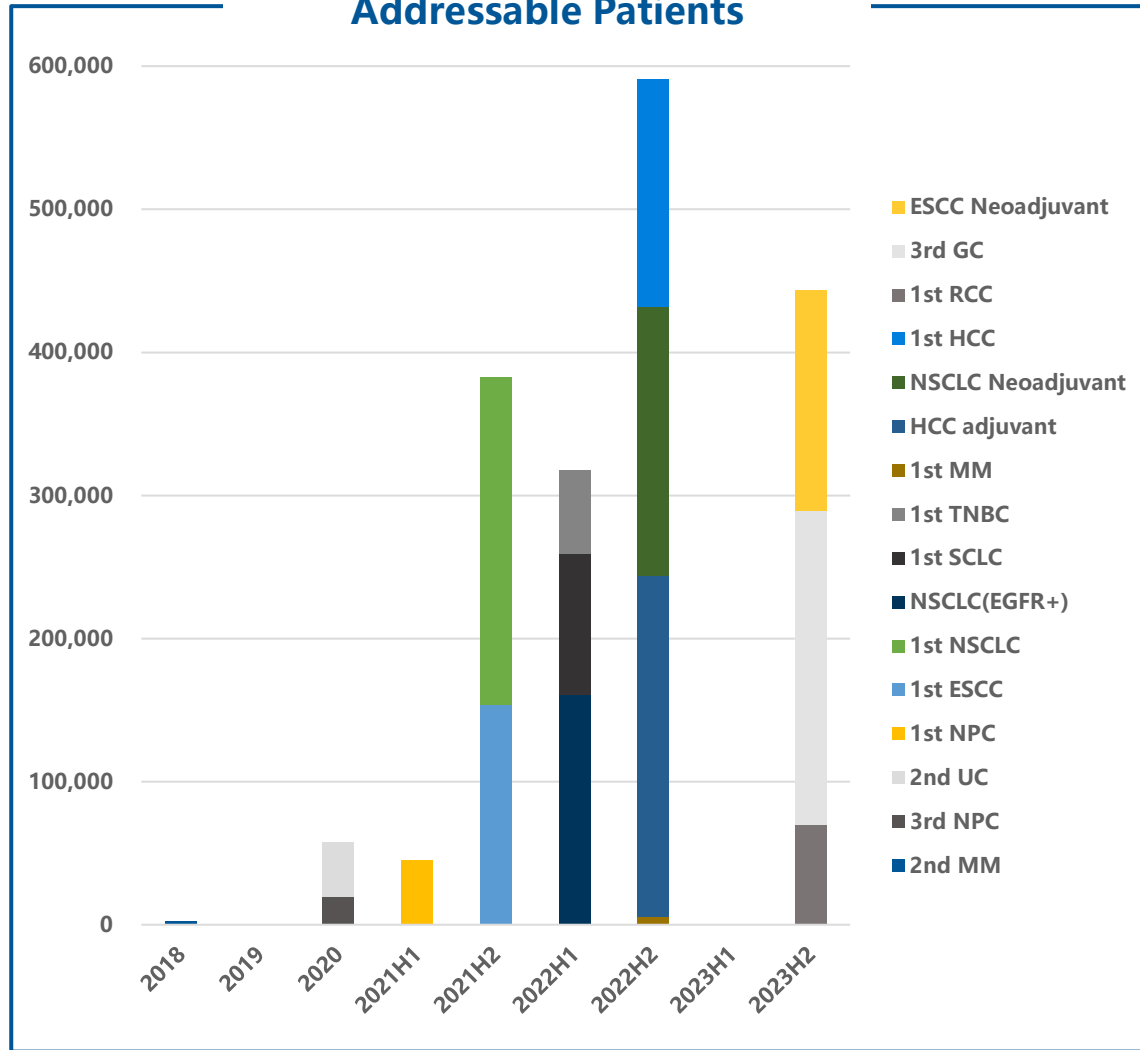
Adjuvant/Neo Adjuvant

First Line

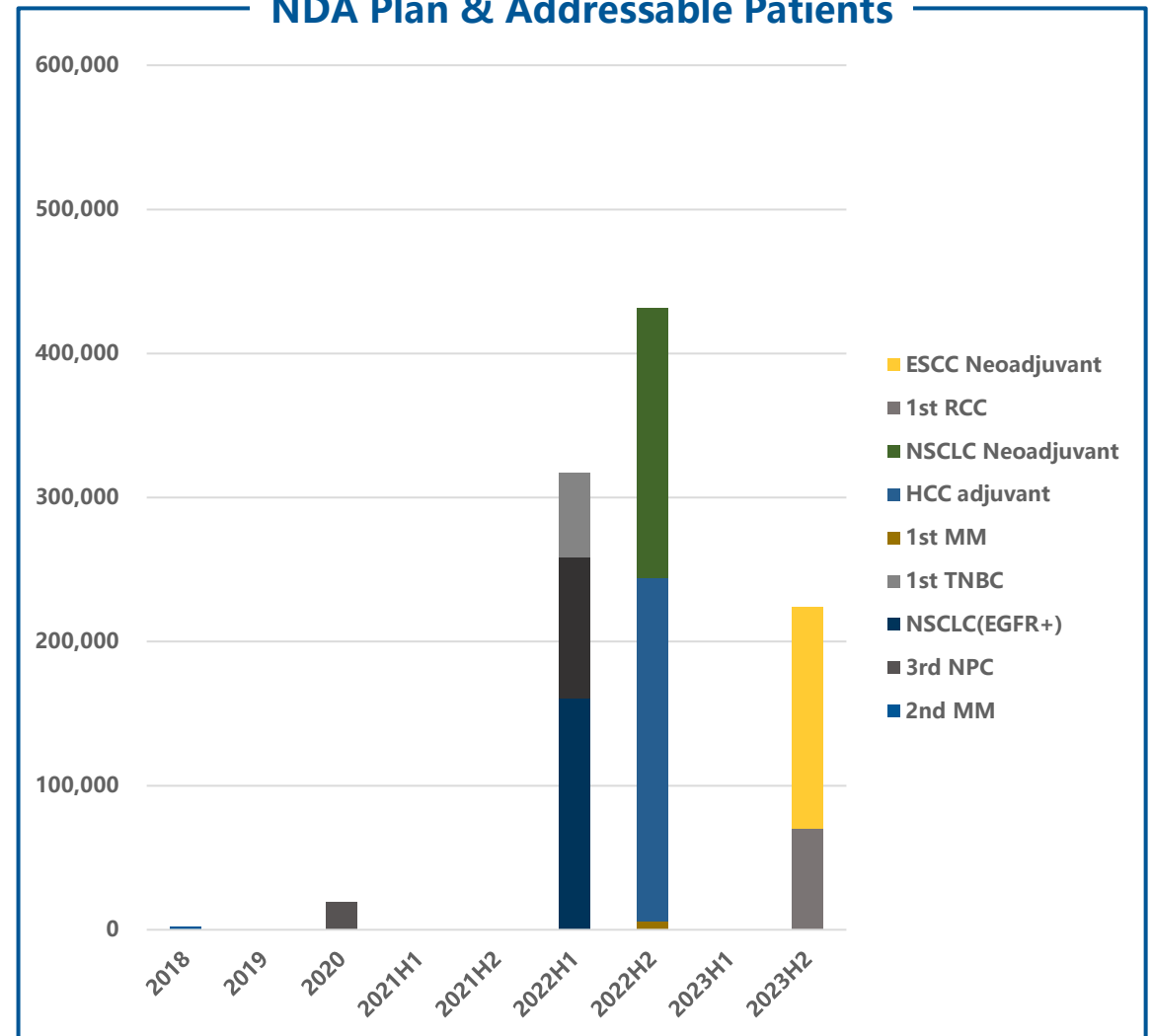
≥ Second Line

Toripalimab NDA Plan & Addressable Patients in China

Toripalimab NDA Plan & Addressable Patients



Toripalimab Leading Indications NDA Plan & Addressable Patients



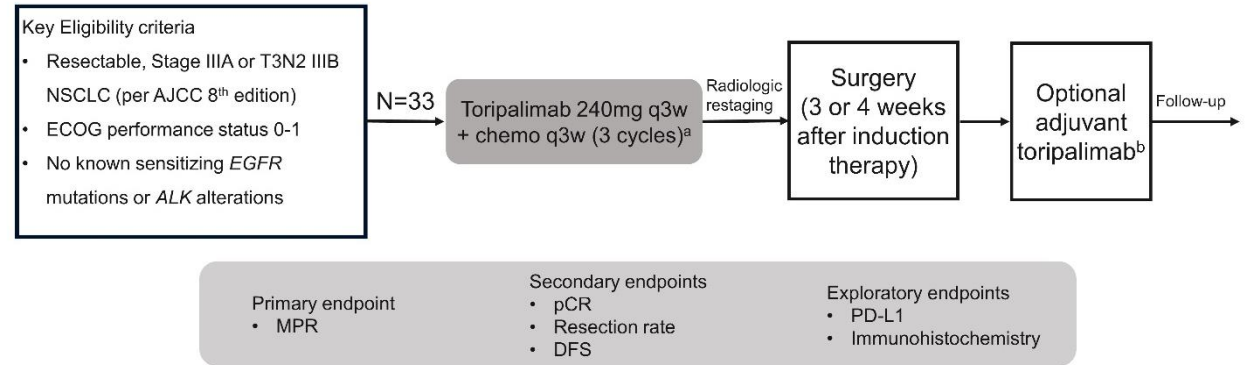
1. Resource: Internal forecast

ASCO #8541: Neoadjuvant Toripalimab + Chemotherapy in NSCLC

Background

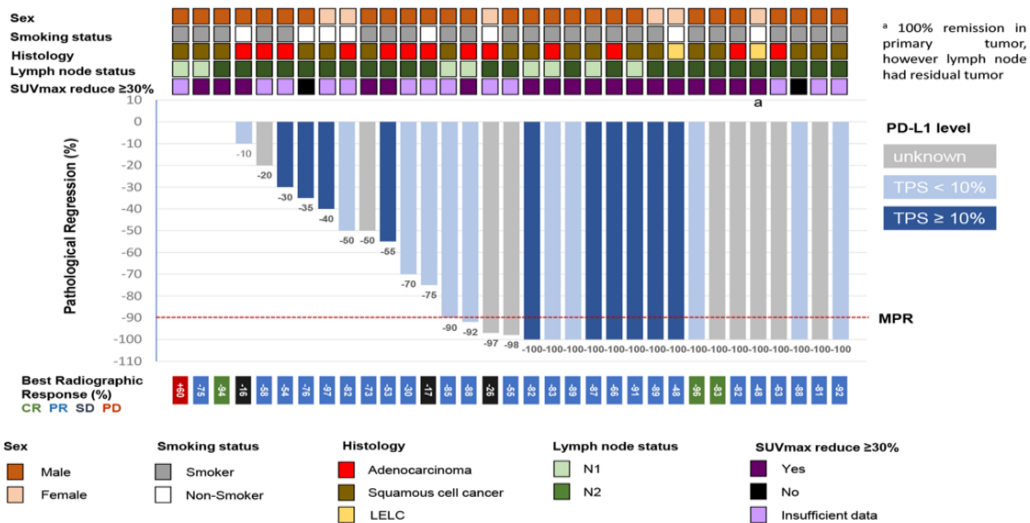
- Previous trials of neoadjuvant chemotherapy or chemoradiation following surgical resection is recommended in resectable stage III NSCLC, but these treatments provide modest survival benefits to patients with stage III NSCLC
- Neo TAP01 is a phase II trial evaluating toripalimab + chemotherapy as neoadjuvant treatment for resectable stage III NSCLC

Study Design



Database lock: April 15, 2021. The mean follow-up duration was 6.67 months.

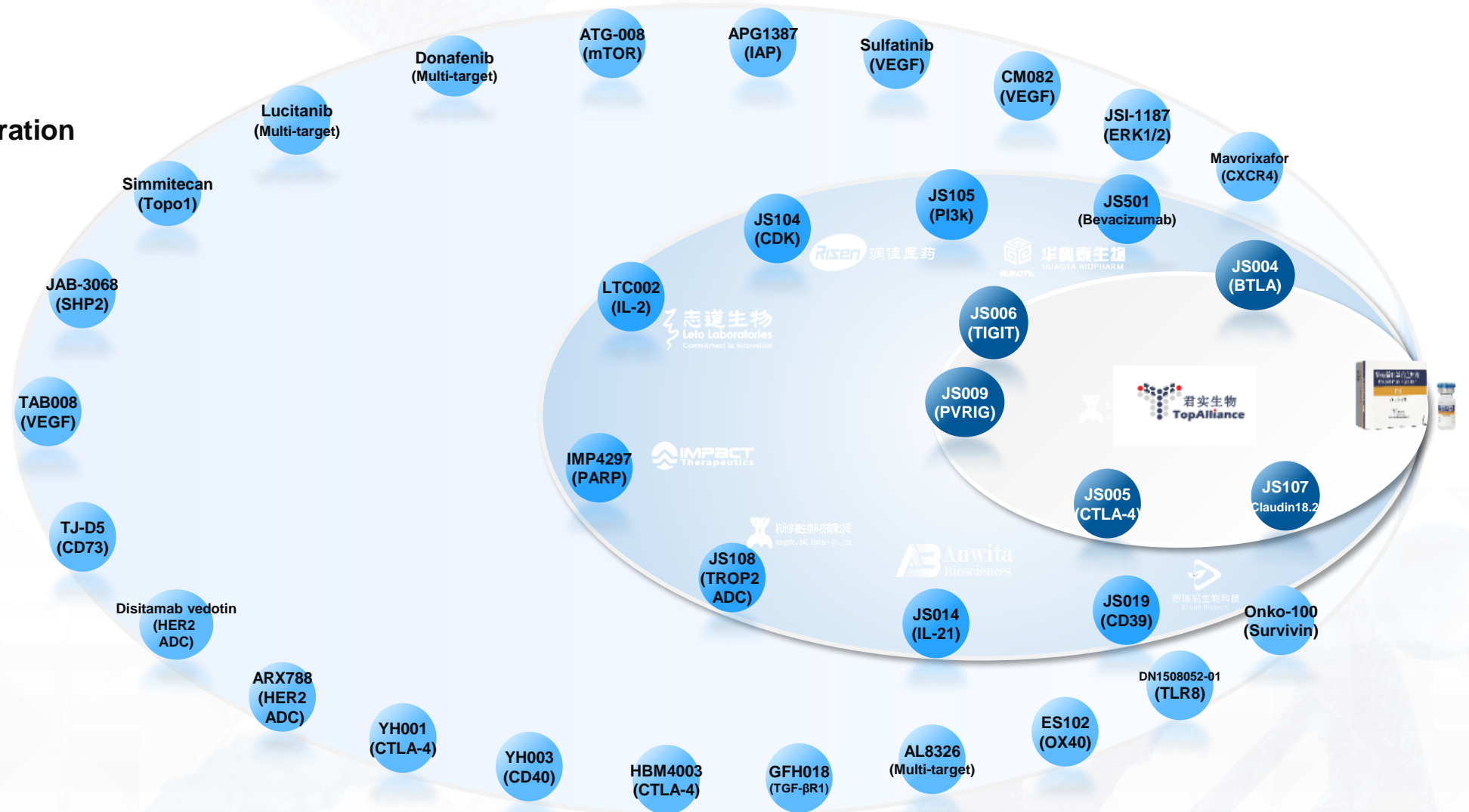
Summary



- R0 resection in 96.7% patients
- **MPR rate were 66.7% , pCR rates were 45.5%**
- The most common grade 3 TRAEs was anemia (2, 6.1%)
- Neo TAP01 is the second study and **the first** in the Asian population to show the benefits of neoadjuvant immunotherapy with chemotherapy for resectable stage III NSCLC

Well-Structured PD-1 Combo Solution

- In-house
- Co-development
- Clinical trial collaboration

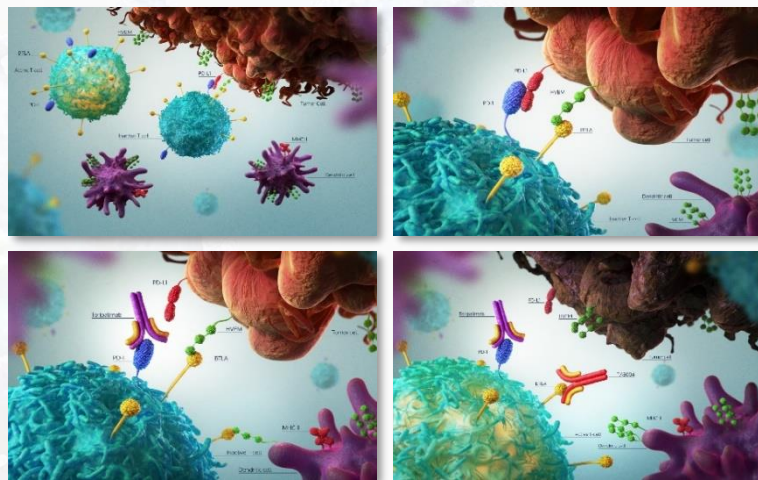


PART5: New Targets, New Molecules and New Platforms

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

JS004/TAB004: the World's First-in-human Anti-BTLA Monoclonal Antibody

JS004/TAB004 binds to BTLA receptor and blocks negative signaling, promoting antigen-specific T cell response and working synergistically with toripalimab



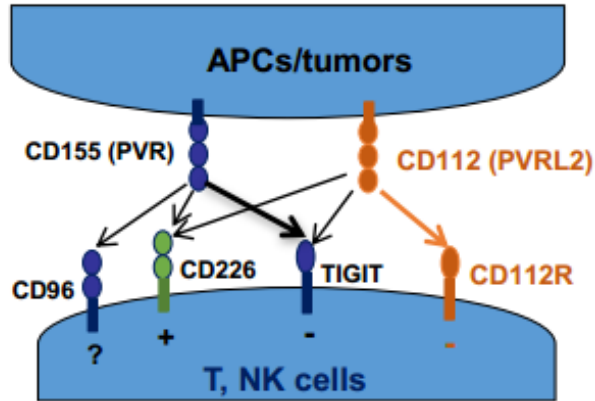
Prevalence

Indications	China	Northern American	Europe	Others
Lung	883,100	328,224	582,924	810,543
Lymphoma	283,604	305,299	467,338	769,359
HNSCC	191,524	182,911	432,734	1,019,093
NPC	186,908	7,756	17,323	170,520
TNBC	139,010	118,911	213,812	307,339
Melanoma	22,281	368,049	517,196	185,292

Source : WHO 2020

Region	Study	Ongoing Clinical Trial	Indication	Design	N	2020 Q4	2021 Q1	2021 Q2	2021 Q3
US	TAB004	1	Advanced Solid Malignancies and Lymphoma	Dose Escalation and Expansion TAB004 Monotherapy	~500	Complete dose escalation			
				Dose Escalation and Expansion TAB004+ Toripalimab Combination				Start dose escalation	
China	JS004	5	Advanced Solid Malignancies (Including: Melanoma, HNSCC, NPC, LC) and Lymphoma	Dose Escalation and Expansion TAB004 Monotherapy	~632	Complete dose escalation			
				Dose Escalation and Expansion TAB004+ Toripalimab Combination				Start dose escalation	

New Immune Checkpoint Inhibitor: JS009/TAB009 Anti-CD112R Monoclonal Antibody



CD112R: A new immune checkpoint pathway discovered by Junshi from the origin

- **CD112R(PVRIG), an inhibitory immune checkpoint**
- Treatment of T cells with anti-CD112R in combination with PD-1 or TIGIT inhibitors further increased T cell activation and improved the efficacy of clinical treatment

Comparable Transactions

	Drug	Date	Licensor	Licensee/ Collaborator	Details
SRF813	CD112R mAb	2020.12	Surface Oncology	GSK	\$815 million total potential value have rights to develop and commercialize SRF813
COM701	CD112R mAb	2018.10	Compugen	BMS	BMS makes a \$12 million equity investment in Compugen enter into a clinical trial collaboration to evaluate COM701 in combination with nivolumab in patients with advanced solid tumors

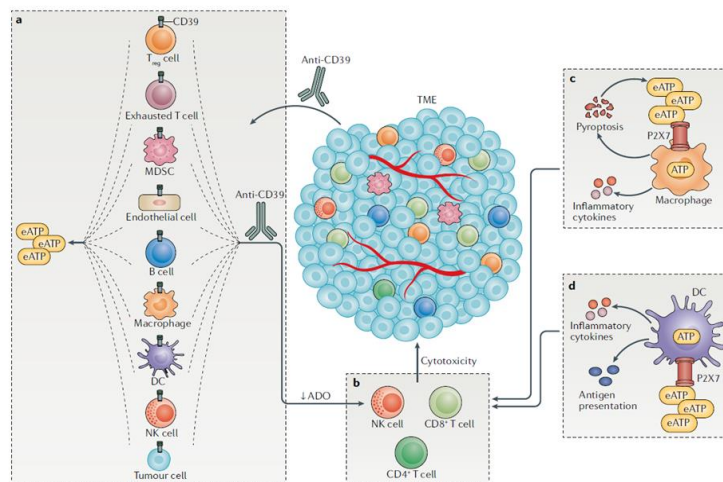
Prevalence

Indications	China	Northern American	Europe	Others
Colorectum	1,416,426	554,680	1,536,168	1,746,061
Lung	883,100	328,224	582,924	810,543
Oesophagus	347,912	26,160	64,061	228,255
Cervixuteri	297,278	47,675	172,721	977,537
Lymphoma	283,604	305,299	467,338	769,359
Brain, central nervous system	214,529	85,937	197,846	338,840
TNBC	139,010	118,911	213,812	307,339

Source : WHO 2020

JS019 — Anti-CD39 Monoclonal Antibody with Special MoA

□ In October 2021, the IND application for the JS019 has been accepted by the NMPA



JS019 CD39
Tumor microenvironment regulation

Prevalence

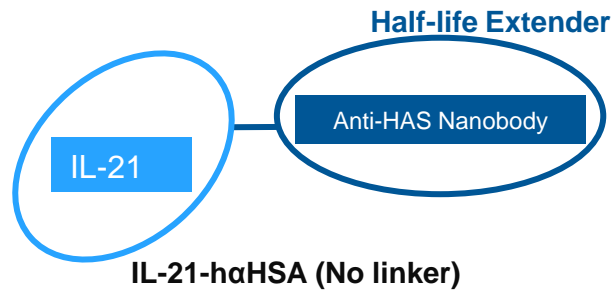
Indications	China	Northern American	Europe	Others
Lung	883,100	328,224	582,924	810,543
Stomach	688,588	50,387	213,013	853,980
Thyroid	733,227	243,888	325,708	682,104
Lymphoma	283,604	305,299	467,338	769,359
Kidney	187,205	236,359	405,983	378,000
Ovary	149,686	80,532	190,105	402,992
Pancreas	95,527	49,358	103,072	132,001

Source : WHO 2020

Comparable Transactions

	Drug	Date	Licensors	Licensee	Details
IPH5201	CD39 mAb	2018.10	Innate	AstraZeneca	\$50 million upfront + milestones + royalties have rights to develop and commercialize IPH5201
TJD5	CD73 mAb	2020.03	I-Mab	Kalbe Genexine Biologics	\$340 million total potential value have rights to develop and commercialize two product candidates, including TJD5
CB-708	CD73 small molecule inhibitor	2021.05	Calithera Biosciences	Antengene	\$255 million total potential value have rights to develop and commercialize CB-708

JS014 — the World's First Long-acting IL-21



JS014, a re-engineered IL-21 with improved pharmacological properties, enters the clinical stage

- Significantly increased half-life and exposure
- Improved stability and developability
- Single agent antitumor activity & synergistic with other therapeutic antibodies
- **In September 2021, the IND application for the JS014 has been approved by the NMPA**

Comparable Transactions

	Data	Licensor /Acquiree	Licensee /Acquirer	Details
NKTR-214	2018.02	Nektar	BMS	\$ 1.85 billion upfront + \$ 1.78 billion in milestones have global rights of NKTR-214 Nektar: BMS=65%: 35%
THOR-707	2019.12	Synthorx	Sanofi	\$2.5 billion total deal value Synthorx's lead product candidate THOR-707 and other earlier-stage cytokine programs

Prevalence

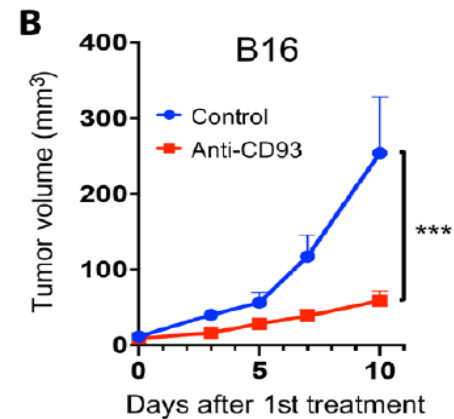
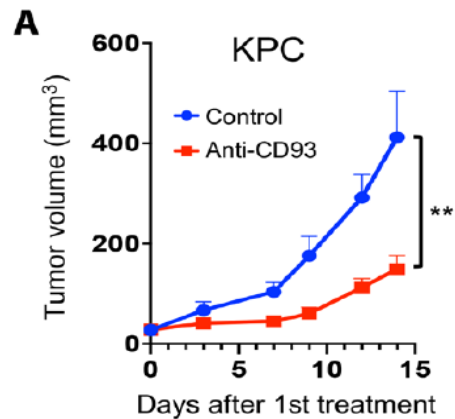
Indications	China	Northern American	Europe	Others
Lung	883,100	328,224	582,924	810,543
Lymphoma	283,604	305,299	467,338	769,359
Bladder	235,393	300,556	655,264	529,412
Brain, central nervous system	214,529	85,937	197,846	338,840
Kidney	187,205	236,359	405,983	378,000
TNBC	139,010	118,911	213,812	307,339
Melanoma	22,281	368,049	517,196	185,292

Source : WHO 2020

CD93 — New Emerging Target in Cancer Immunotherapy

- CD93 is one of the top genes in a previously reported human primary tumor angiogenesis gene signature, and CD93 overexpression in tumor vasculatures has been observed in many solid tumors, including pancreas cancer, kidney cancer, head and neck cancer, and colon cancer.
- Blockade of the CD93 pathway normalizes tumor vasculature to facilitate drug delivery and immunotherapy.

Anti-CD93 inhibits tumor growth



Prevalence

Indications	China	Northern American	Europe	Others
Colorectum	1,416,426	554,680	1,536,168	1,746,061
Head and neck	212,805	203,234	480,815	1,132,326
Kidney	187,205	236,359	405,983	378,000
Pancreas	95,527	49,358	103,072	132,001

Source : WHO 2020

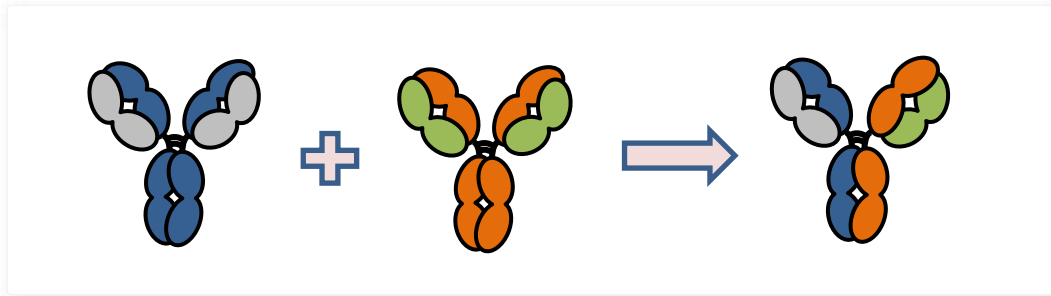
Deploy Bispecific Antibodies

Mature mAb platform technology: Develop mAb against different targets based on mature mAb platform technology and develop BsMAb with multiple MoA

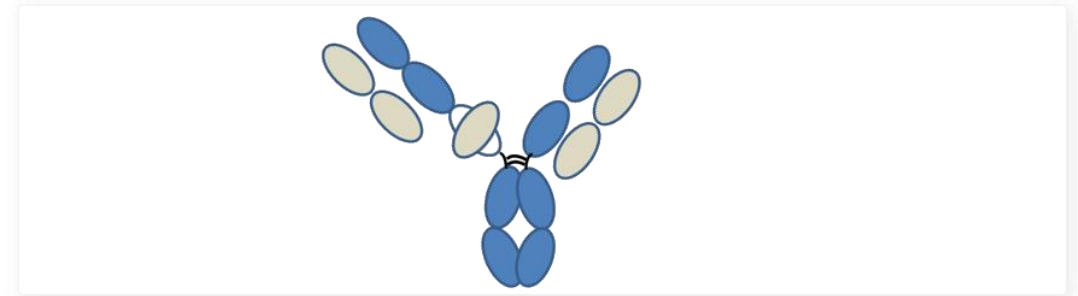
Comprehensive evaluation system: Form a comprehensive set of BsMAb evaluation systems for different MoA, which can evaluate BsMAb with multiple MoA

Multiple Formats of BsMAb

- In vitro recombinant “1+1” platform technology



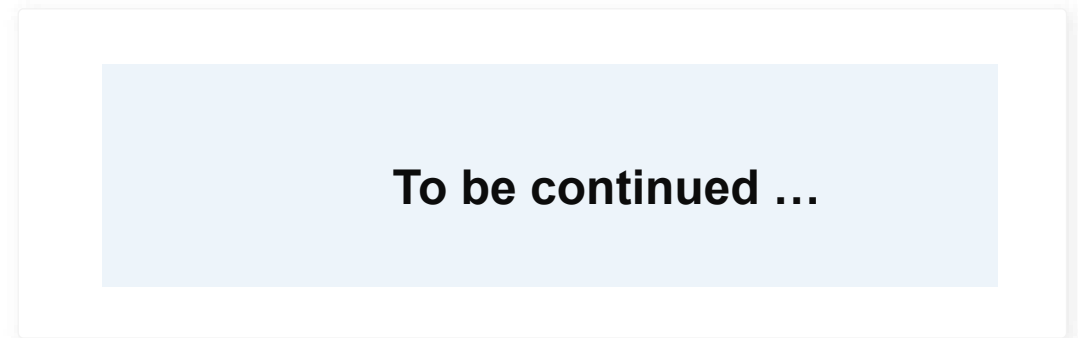
- ScFv-based “2+1” asymmetric platform technology



- ScFv-based “2+2” symmetric platform technology



- Other novel formats

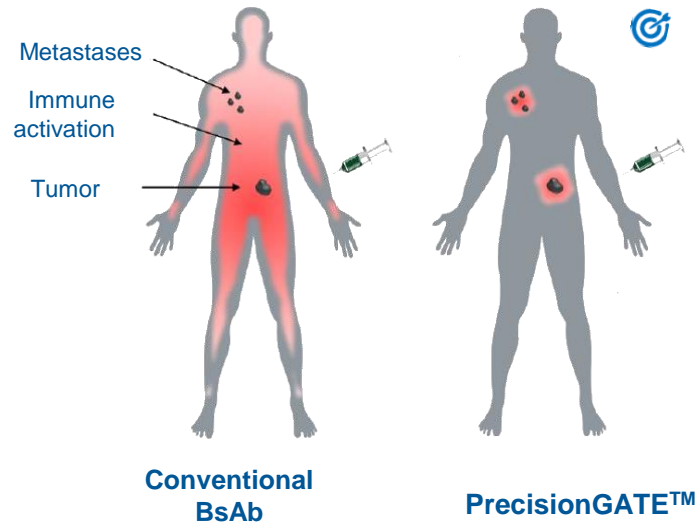


The Next-generation of T-cell Engaging Cancer Immunotherapies: PrecisionGATE™

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.



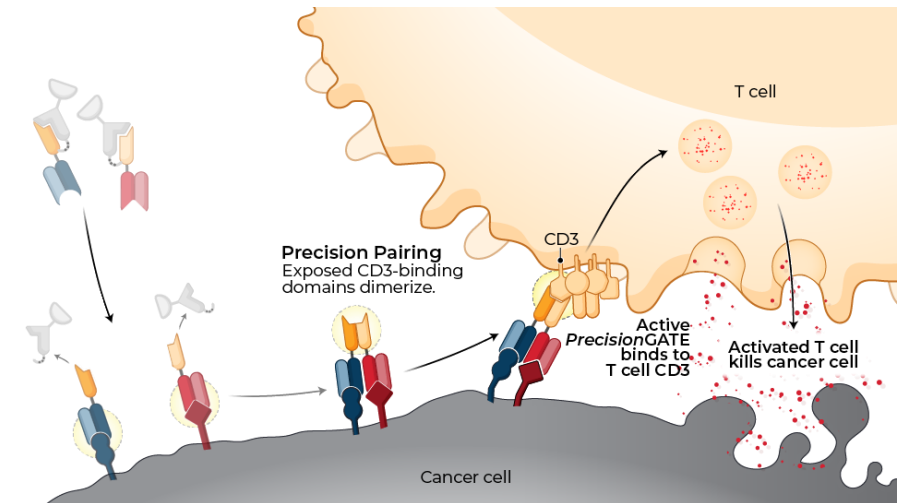
Background



Because 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



PrecisionGATE™ 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.

ADC-based Therapies

- Development strategy: improve the therapeutic index of traditional ADC through the innovation of antibodies, linkers and payloads, and explore new immunoconjugate complexes based on other mechanisms such as immune activation
 - Build an independent ADC R&D platform from early R&D to GMP production integration
-
- ✓ **Antibody:** Use the exploration and innovation of the aforementioned antibody platform to enhance the therapeutic effect of traditional ADC
 - ✓ **Explore technology:** Low-toxicity and high-efficiency ADC technology
 - ✓ **Evaluation system:** A comprehensive evaluation system: molecular design, transient expression and purification, drug efficacy evaluation in vivo and in vitro, toxicity prevention test, pharmacy evaluation, which can evaluate different MoA



- As the mRNA Technology Platform gradually matures, mRNA has progressed into a promising new class of medicine
- Immorna is an innovative drug research company that focuses on developing self-replicating and conventional mRNA-based therapeutics and vaccines
- Junshi and Immorna look forward to working together to develop more revolutionary therapeutics for patients worldwide through our mRNA Technology Platform with domestic intellectual property rights

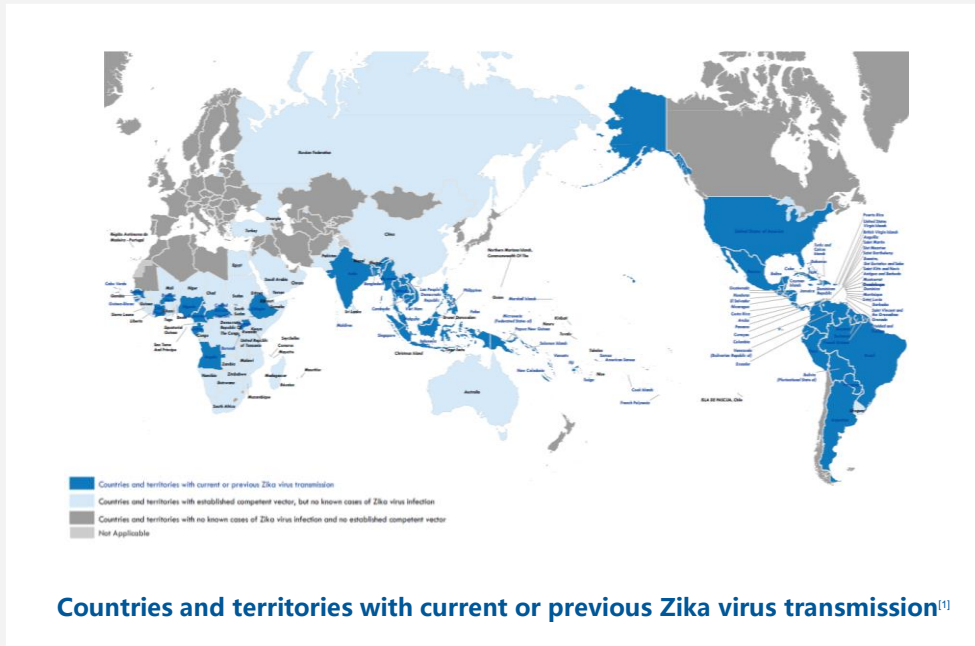
Junshi Biosciences Partners with Immorna to Develop mRNA-based Therapies

July 2021, Junshi announced that the company has established a joint venture with Immorna to develop and commercialize new drugs for the global market in the fields of cancer, infectious diseases, rare diseases, and other diseases, based on the mRNA technology and other technology platforms.



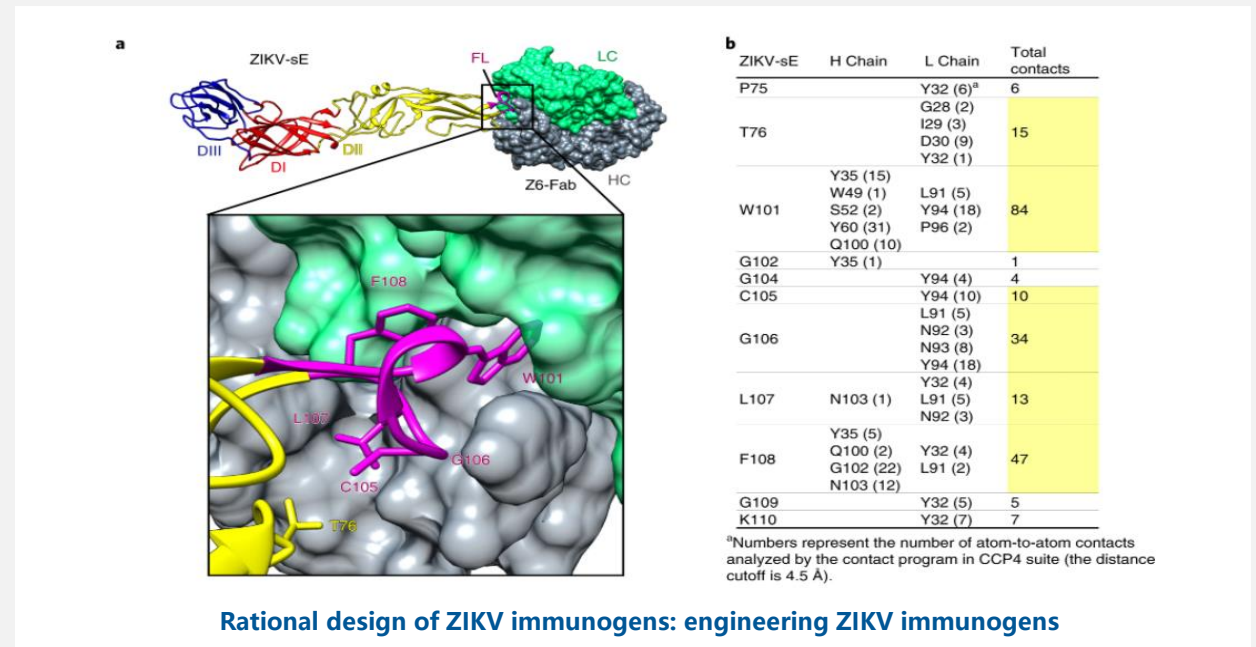
Collaborate with IMCAS Again: Novel ZIKV Vaccine

Junshi signs a collaboration agreement with the IMCAS to jointly develop ZIKV vaccine



- ZIKV is a mosquito-borne pathogen belonging to the genus Flavivirus. And WHO declared it a Public Health Emergency of International Concern in 2016. ZIKV epidemic spread to 86 countries worldwide.
- No vaccine is yet available for the prevention or treatment of ZIKV infection worldwide.

- The ZIKV vaccine jointly developed by Junshi and IMCAS is based on the research results from the team of professor Gao Fu, an academician at the Chinese Academy of Sciences.
- The team of professor Gao Fu proposed a new strategy for a protective ZIKV vaccine to eliminate ADE of DENV^[2] by the rational design of an improved ZIKV immunogens based on structural biology and the strategy will provide guide for the clinical use of the novel ZIKV vaccine.



1. https://www.who.int/health-topics/zika-virus-disease#tab=tab_1
 2. Dai, L., Xu, K., Li, J. et al. Protective Zika vaccines engineered to eliminate enhancement of dengue infection via immunodominance switch. Nat Immunol 22, 958–968 (2021).

Thank You

