

Junshi Biosciences

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O1Company
Overview





2012-2022: In China, For Global

Commercialized Products

1 has achieved global commercialization, 1 has been submitted in the US, UK and EU

Toripalimab(TUOYI[®], JS001)

- 6 approved indications in China
- FDA BLA and EMA MAA accepted, MHRA MAA submitted
- ODD, BTD, FTD, PRD granted by the FDA
- Academic achievements: WCLC, ESMO, ASCO

Adalimumab(JUNMAIKANG[®], UBP1211)

- 1st prescription issued in May
- Up to now, 8 indications approved in China

Etesevimab(JS016)

- the 1st Chinese-developed COVID mAb to participate in the global fight against the pandemic
- EUA authorized in 15+ countries and regions in 2021

52+ Drug Candidates in Pipeline

>100 company-led clinical studies, covering nearly 10,000 patients in >10 countries and regions worldwide

Business Development

International strategic operations

VV116(Oral Nucleoside Drug)

- International multi-center Ph3 clinical studies ongoing
- The domestic clinical study of VV116 Versus Paxlovid reached primary and secondary endpoints
- Relevant results published in the NEJM
- Approved in Uzbekistan

Tifcemalimab(TAB004/JS004)^{FIH}

- Entered the dose expansion stage in Phase Ib/II
- Clinical results published at the ASCO, ASH

IND Approved in the US and China

7 drug candidates including TAB009, JS105, JS110

Coherus

- Cooperation for toripalimab in the US and Canada
- Exercise the option program TAB006/JS006

Hikma

Cooperation for toripalimab in the MENA

Financial Performance

- Operating Income Q1-Q3 2022: ¥1,218 mn
- R&D Expenses Q1-Q3 2022: ¥1,636 mn
- Raised ¥3.7 B from Issuance of A Shares in Dec
- A Shares included in the CSI 500 Index and the SSE 180 Index
- ė.

R&D Pipeline Covering a Wide Variety of Therapeutic Areas



Pre-Clinical			Phase 1			Phase 2	Phase 3	Approved
JS011 Undisclosed Tumors	JS120 IDH1 Tumors	JS209 CD112R+TIGIT Tumors	JS001sc PD-1 Tumors	JS015 DKK1 Tumors	JS112 Aurora A SCLC	Tifcemalimab BTLA Lung cancer, Melanoma, etc	JS109 PARP Ovarian cancer	Toripalimab PD-1 Tumors
JS013 CD93 Tumors	JS121 SHP2 Tumors	JS211 PD-L1+Undisclosed Tumors	JS003 PD-L1 Tumors	JS019 CD39 Tumors	JS113 EGFR 4th Gen NSCLC	JS005 IL-17A Psoriatic, spondylitis	Bevacizumab VEGF NSCLC	Adalimumab TNF-α Rheumatoid Arthritis, etc
JS018 IL-2 Tumors	JS122 FGFR2 Tumors	JS008 Undisclosed	JS006(TAB006) TIGIT Tumors	JS101 Pan-CDK Breast cancer, etc.	JS116 KRAS Tumors		Ongericimab PCSK9 Hyperlipidemia	Etesevimab* S protein COVID-19
JS104 Pan-CDK Breast cancer, etc	JS123 ATR Tumors	JS401 Undisclosed (RNAi) Metabolic diseases	JS007 CTLA-4 Lung cancer, melanoma	JS105 PI3K-α Breast cancer, renal cell cancer	JS201 PD-1+TGF-β Tumors		JT001(VV116) RdRp COVID-19	
JS114 Nectin4 ADC Tumors	JS205 EGFR+cMet Tumors	JS010 CGRP Migraine	JS009(TAB009) CD112R/PVRIG Tumors	JS107 Claudin18.2 ADC Gastrointestinal cancer	JS203 CD3+CD20 Tumors			
JS115 BCMA ADC Multiple myeloma	JS206 IL2+PD-1 Tumors	JT003(VV993) 3CLpro COVID-19	JS012 Claudin 18.2 Gastric cancer	JS108 TROP2 ADC TNBC	JS103 Uricase Hyperuricacidemia		Oncology	Metabolism Neuroscience
	JS207 PD-1+VEGF Tumors	JT109 Vaccine ZIKA Virus	JS014 IL-21 Tumors	JS110 XPO1 Multiple myeloma, etc	UBP1213sc BLyS Systemic lupus erythematosus	+	Infectious Disease	Approved
				JS111 EGFR exon 20 NSCLC	JS026 S protein COVID-19	' • Re	JunTop Biosciences	Pipeline cv Use Authorization



02 Respond



VV116(JT001): Promising 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.
- International multi-center Phase 3 clinical studies are ongoing.





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

Positive preclinical results

- **A high barrier to drug resistance**, which means it is effective against WT and various variants (e.g. Alpha, Beta, Delta, Omicron)
- Excellent in vitro efficacy
- High oral bioavailability (80% and 90% in rats and dogs)
- Significantly reduces the viral RNA copies and infectious virus titers in the lungs
- The results of in vitro bacterial reverse mutation test and chromosome aberration test are negative and there is no genetic toxicity

<u>nature</u> > <u>cell research</u> > <u>letter to the editor</u> > 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 ⁽²⁾, H. Eric Xu ⁽²⁾ & Jingshan Shen ⁽²⁾

Cell Research (2021) Cite this article

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

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

VV116(JT001): Positive Results of Completed Clinical Trials



Positive Three Phase I Clinical Study Results

- VV116 has shown satisfactory safety and tolerability. None of the three studies reported death, serious adverse events, grade three or higher adverse events, or adverse events leading to suspension or discontinuation of treatment. All adverse events were recovered without treatment or intervention. Compared with previously reported data for similar drugs, VV116 has a lower risk of hepatotoxicity.
- VV116 shows good pharmacokinetic characteristics.

Adverse events, n (%)	200 mg (n = 9)	400 mg (n = 9)	600 mg (n = 9)	Total VV116 (n = 27)	Placebo (n = 9)
Overall	3 (33.3)	5 (55.6)	6 (66.7)	14 (51.9)	5 (55.6)
VV116/placebo related	3 (33.3)	5 (55.6)	6 (66.7)	14 (51.9)	5 (55.6)
Severity					
Grade 1	3 (33.3)	5 (55.6)	6 (66.7)	14 (51.9)	4 (44.4)
Grade 2	0	0	0	0	1 (11.1)
Grade 3	0	0	0	0	0
Grade 4	0	0	0	0	0
Grade 5	0	0	0	0	0

MAD研究中的不良事件



First Clinical Study of China's Antiviral Oral Drug Against Omicron

- In all participants enrolled, the SARS-CoV-2 nucleic acid shedding time was **9.92 days** in the VV116 group (*VS. 11.13 days in the control group*).
- Time from the first day of VV116 treatment to the first day for the negative nucleic acid testing is **3.52 days**.
- The SARS-CoV-2 nucleic acid shedding time for participants who took the experimental treatment within 5 days from the first positive test result in the VV116 group is **8.56 days** (VS. 11.13 days in the control group)
- For safety profile, no serious adverse events were reported in both groups.

1、Safety, tolerability, and pharmacokinetics of VV116, an oral nucleoside analog against SARS-CoV-2, in Chinese healthy subjects

2. Shen Y, Ai J, Lin N, Zhang H, Li Y, Wang H, Wang S, Wang Z, Li T, Sun F, Fan Ž, Li L, Lu Y, Meng X, Xiao H, Hu H, Ling Y, Li F, Li H, Xi C, Gu L, Zhang W, Fan X. An Open, Prospective Cohort Study of VV116 in Chinese Participants Infected with SARS-CoV-2 Omicron Variants. Emerg Microbes Infect. 2022 May 17:1-22. doi: 10.1080/22221751.2022.2078230. Epub ahead of print. PMID: 35579892.

VV116(JT001): 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 III 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.



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

VV116 versus Paxlovid achieved noninferiority in the "time to sustained clinical recovery" in the FAS population (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.

VV116(JT001): 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 (N = 384)	Paxlovid (N = 387)		
Any adverse event	259 (67.4%)	299 (77.3%)		
Adverse event with maximum grade of ≥3	10 (2.6%)	22 (5.7%)		
Serious adverse event	1 (0.3%)	2 (0.5%)		

VV116 showed fewer safety concerns than Paxlovid

VV116(JT001): International Multi-Center Ph3 Clinical Studies Ongoing 書案生物

At present, a number of phase III clinical studies for COVID-19 patients have been completed or are in progress as planned, including several international multi-center phase III clinical studies of VV116 on different populations globally.

JT001-010

01

- Mild to moderate COVID-19 patients at high risk for progression to severe COVID-19 including death
- Multi-center, observer-blinded, randomized, phase III study of VV116 versus Paxlovid
- Reached primary endpoint and secondary endpoints, results published in NEJM

02

JT001-015

- Mild to moderate COVID-19 patients with or without high risk
- Multi-center, double-blind, randomized, placebo-controlled phase III clinical study

03

JT001-004

- Mild to moderate COVID-19 patients with high risk of progression
- International, multi-center, doubleblind, randomized, placebo-controlled phase III clinical study



03 Immuno-Oncology Backbone



Toripalimab has demonstrated a compelling clinical profile in studies across multiple tumor types





- The clinically meaningful results of Toripalimab in treatments for patients with **ESCC**, **NPC** were published in internationally recognized journals and presented at global meetings.
- Submitted commercialization applications to the US, UK and EU



Pursue more commercial opportunities worldwide

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Out-licensed in **22** countries/regions

Collaborate with Coherus in the United States 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

Toripalimab Pivotal Clinical Trials Strategy





Postoperative Adjuvant/Perioperative

First Line

≥ Second Line

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

- The data from the China National Central Cancer Registry¹ shows that, **56.5% of the cancer patients were diagnosed at stage II or III** (when 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.

Stage distribution for Top 5 cancers in China



Postoperative Adjuvant/Perioperative Pipeline of Toripalimab in China







04 Next Generation of Immunotherapy





Tifcemalimab (TAB004/JS004): the World's First-in-human Anti-BTLA mAb Against Tumor



- 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 Signaling*
- 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)
- **TAB004/JS004** is the world's first-in-human anti-tumor recombinant humanized anti-BTLA monoclonal antibody specific to BTLA independently developed by Junshi Biosciences
- The combination of TAB004/JS004 and Toripalimab is a promising antitumor treatment strategy, which is expected to increase patients' response to immunotherapy and expand the range of potential beneficiaries
- The IND application was approved by the FDA and the NMPA in April 2019 and January 2020, respectively

Tifcemalimab (TAB004/JS004): Clinical Trial Progress in China and Overseas

- TAB004/JS004 has completed the dose-escalation stage in Phase Ia and entered the dose expansion stage in Phase Ib/II
- The combination clinical trials of TAB004/JS004 and Toripalimab are underway
- Conduct further clinical studies on the safety and efficacy of TAB004/JS004 against multiple types of tumors (relapsed/refractory lymphoma, melanoma, squamous cell carcinoma of the head and neck, NPC, lung cancer, etc.) in China and the United States

19

Region	Study	Ongoing Clinical Trial	Treatment	Indication
US	TAB004	1	TAB004 Mono TAB004+Toripalimab	Dose Escalation and Expansion in Melanoma, Lymphoma, NSCLC, RCC/UCC, Other
China	JS004	c	JS004 Mono	Dose Escalation and Expansion Advanced Solid Malignancies
			JS004 Mono JS004+Toripalimab	Dose Escalation and Expansion Relapsed/Refractory Lymphoma
			6	JS004 Mono JS004+Toripalimab
		J3004		JS004 Mono JS004+Toripalimab
			JS004+Toripalimab	HCC, CC, CRC, EC/GC
			JS004+Toripalimab	Safety Run-In and Expansion NSCLC, ES-SCLC

TAB004/JS004(Tifcemalimab): Promising Clinical Data



ASCO 2022

#2643: Phase la 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 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 18 months)

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



- As of Oct 26, 2022, Among 25 evaluable patients receiving monotherapy, 1 PR (follicular lymphoma) and 7 SD were observed (Lugano 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

Novel Immune Checkpoint Inhibitors: Anti-CD112R & Anti-TIGIT



JEM Identification of CD112R as a novel checkpoint for human T cells Yuwen Zhu,¹ Alessandro Paniccia,¹ Alexander C. Schulick,¹ Wei Chen,^{1,3} Michelle R. Koenig,¹ Joshua T. Byers,¹ Sheng Yao,⁴ Shaun Bevers,² and Barish H. Edil¹ ¹⁰Department of Surgery and ¹⁰Department of Biochemistry and Molecular Genetics, Anschutz Medical Campus, University of Colorado, Aurora, CO 80045 ¹⁰Department of Hepatolilay and Phancreatic Surgery, Second Affiliated Hospital, Zhejiang University, 310027 Hangzhou, China ¹¹TepAlliance Biosciences, Inc., Roctwille, MD 20850 T cell immunoglobulin and ITIM domain (TIGIT) and CD226 emerge as a novel T cell cosignaling pathway in which CD226 and TIGIT serve as costimulatory and coinhibitory receptor - like proteins, as a new coinhibitory receptor for human T cells. C0112, Bis preferentially expressed on T cells and inhibits T cell receptor-mediated signals. We further identify that C0112, widely ex-

pressed on antigen-presenting cells and tumor cells, is the ligand for CD112R with high affinity. CD112R competes with CD226

to bind to CD112. Disrupting the CD112R-CD112 interaction enhances human T cell response. Our experiments identify

CD112R as a novel checkpoint for human T cells via interaction with CD112.

APC s/tumors CD155 (PVR) CD112 (PVRL2) CD96 CD226 TIGIT CD112R T, NK cells The TIGIT/CD226/CD96/CD112R axis

TAB009 (JS009)

- CD112R(PVRIG) is a new immune checkpoint pathway discovered by Junshi from the origin. 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.
- JS009 is a recombinant humanized anti-CD112R monoclonal antibody injection independently developed by Junshi Biosciences, mainly for the treatment of advanced malignant tumors.
- In April 2022, the IND application for the JS009 has been approved by the FDA.
- In August 2022, the IND application for the JS009 has been approved by the NMPA.

TAB006 (JS006)

- **TIGIT** is another immunosuppressive target of the PVR family. Its ligands include PVR and CD112, and its binding site for CD112 is different from that of CD112R.
- **JS006** is a specific anti-TIGIT monoclonal antibody injection developed independently by Junshi Biosciences, JS006 can specifically block the TIGIT-PVR inhibitory pathway and stimulate the activation of killing immune cell to secrete tumor-killing factors.
- In January 2021, the IND application for the JS006 has been approved by the NMPA. In February, the IND application for the JS006 has been approved by the FDA.
- In January 2022, Coherus has also initiated the process to exercise its option to license JS006 (TIGIT-targeted antibody), in the US and Canada.

JS009 + TAB006/JS006 + toripalimab can further increase T cell activation and improve the efficacy of clinical treatment

Other Potential Candidates...



JS013: Anti-CD93

- 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.
- JS013 has promising results in preclinical trials, the company will advance it to the clinical stage.

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

- JS014 is recombinant IL-21, a nanobody fusion protein of HSA, of which the halflife can be significantly prolonged through fusing anti HSA nanobodies.
- Significantly increased half-life and exposure.
- Improved stability and developability.
- Single agent antitumor activity & synergistic with other therapeutic antibodies.
- In August 2021, the IND application for the JS014 has been approved by the NMPA.





• JS013 is in preclinical studies.



05 Other Modalities





A Broad Modalities Portfolio Across Therapeutic Areas

52+ Drug Candidates

6+ Modalities

Monoclonal antibodies; bispecific antibodies; fusion proteins; small molecules; ADC; nucleic acid based medicines; vaccines

5 Therapeutic areas

Oncology, Metabolism, Immunology, Infectious Disease, Neuroscience



In Mar 2022, the IND for the JS107 (Anti-Claudin18.2 ADC) has been approved by the NMPA

ADCs



Small molecule inhibitors for cancer therapy , targets cover PARP, Pi3K-α, XPO1

Small Molecules



JS203(CD20xCD3), JS205(EGFR×cMet), JS207(PD-1xVEGF) ...

BsAbs



Collaborate with to develop the next-generation of T-cell engaging cancer immunotherapies

MsAbs



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

JS401: The potentially first siRNA drug specific for this target in China

Nucleic Acid Drugs

•

Covering five therapeutic focus areas

Our Therapeutic Areas



Multiple Bispecific Antibody Programs



JS203 CD20 x CD3 Bispecific



JS205 EGFR × cMet Bispecific

- JS205 is a bsAb targeting EGFR and cMET with a common light chain.
- EGFR and cMET signaling pathway plays an important role in tumor development. EGFR×cMet bispecific antibody inhibits tumor growth through multiple mechanisms.
- JS205 is in preclinical studies.



JS207 PD-1 x VEGF Bispecific



- 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.

- JS203 is a recombinant humanized anti-CD20xCD3 bispecific antibody self-developed by the Company, mainly for the treatment of relapsed/refractory B-cell non-Hodgkin lymphoma.
- In July 2022, the IND application for the JS203 has been approved by the NMPA.



TwoGATE™: 3rd Generation T-cell Engager Platform









- 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 1st bispecific T-cell engager HER2 BiTE.
- The results from toxicity studies performed in cynomolgus monkeys display that, comparing with HER2 BiTE, TwoGATE™ molecules significantly reduce the risk for CRS.



Mixed Hyperlipidemia: JS401

- The potentially first siRNA drug specific for this target in China
- Long-term effectiveness for mixed hyperlipidemia
- Plan to submit an IND application in 2023

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



to the FIC molecule in RGA





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



06 Strong Candidates in Clinical Stage



Small Molecule Inhibitors for Cancer Therapy



Late-stage clinical product JS109

- Junshi and IMPACT entered into the JV Agreement for the R&D and commercialization of the drug.
- Senaparib (JS109) is a novel agent targeting PARP.
- The Company is conducting a Phase II pivotal study of JS109 monotherapy in treating advanced ovarian cancer patients with BRCA mutation, and a Phase III study of JS109 as the 1L maintenance treatment in platinum-sensitive advanced ovarian cancer patients. Enrollment has been completed in the Phase III study.
- In August 2022, the fixed-dose combination capsules of senaparib and temozolomide for the treatment of adult patients with SCLC was granted orphan-drug designation by the FDA.



 Senaparib(JS109) has been well-tolerated with significant anti-tumor activity in both Chinese and Australian patients

Other small molecule projects

Candidate	es Targets	Origins	Commercial Rights	Clinical Stage	
JS105	ΡΙ3Κ-α	50% Rights in-licensing	Global	Phase I in China and the U.S.	
JS110	XPO1	50% Rights in-licensing	Global	Phase I in China and the U.S.	
JS111	EGFR exon 20	50% Rights in-licensing	Global	Phase I in China	
JS112	Aurora A	50% Rights in-licensing	Global	Phase I in China	
JS113	EGFR 4th Gen	50% Rights in-licensing	Global	Phase I in China	

Treatments for Autoimmune and Metabolic Diseases

● ● ● ■ 日实生物 ■ ■ TopAlliance

JS005: Anti-IL-17A mAb

- Indications: psoriatic, spondylitis
- Origins: In-house, developed independently by Junshi
- Commercial Rights: Global
- Clinical Stage: Phase II in China
- Three Phase II clinical studies on moderate to severe psoriasis, ankylosing spondylitis and non-radiographic axial spondyloarthritis are in progress.

UBP1213sc: Anti-BLyS mAb

- Indications: systemic lupus erythematosus(SLE)
- Origins: In-house, developed independently by Junshi
- Commercial Rights: Global
- Clinical Stage: Phase I in China
- In November 2021, the IND application for UBP1213sc has been approved by the NMPA.

Ongericimab (JS002): Anti-PCSK9 mAb

- Indications: hyperlipidemia
- Origins: In-house, developed independently by Junshi
- Commercial Rights: Global
- Clinical Stage: Phase II/III in China
- A Phase II clinical study in patients with homozygous familial hypercholesterolemia (rare disease) has completed enrollment. Phase III clinical studies with larger patient population (including non-familial and heterozygous familial hypercholesterolemia) are ongoing.



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

Upcoming Commercial Launches





10+ NMEs **15+** Indications

The information provided does not purport to be comprehensive nor render any form of financial or other advice, nor give any guarantee of our future results or business development. Given their nature, we cannot assure that any outcome expressed above will be realized in whole or in part. The actual results of our R&D activities and business developments are subjected to internal risks and uncertainties.



07 Commercialization



TUOYI® Continuing Steady Commercial Execution





Product Sales

- TUOYI® achieved sales revenue of RMB515 million in the first three quarters of 2022.
- The sales revenue of TUOYI[®] in the first quarter of 2022 increased by **212%** as compared with the fourth quarter of 2021.
- Although affected by the pandemic from April to May, the sales revenue in the second quarter of 2022 still increased by **70%** compared with the first quarter.
- The sales revenue of TUOYI[®] in the third quarter of 2022 increased by 16% as compared with the second quarter of 2022, achieved three consecutive quarters of sequential growth.





Commercialization Team

- Complete the adjustment to the commercialization team and have a commercialization team of more than 1,100 people.
- Complete the establishment and restoration of the marketing regional team.
- Supplement the core market personnel.



Sales Staff

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. Fill the gaps in immunotherapy for patients with advanced NPC and non-selective patients with advanced UC in the NRDL

The **only** anti-PD-1 mAb used in the treatment of melanoma and NPC in the NRDL

Included in supplementary medical insurance, reducing the burden on patients The indications of TUOYI[®] that has been included in the NRDL were entitled to supplementary reimbursement under the NRDL in **113** provinces/cities

NRDL

1L treatment for NPC has entered the medical insurance catalogues in **20** provinces/cities, for which supplementary medical insurance could be obtained in **61** provinces/cities

More large indications of TUOYI[®] have entered the commercial approval stage

The prospective layout of multi-indication perioperative clinical research is showing a strong advantage

Promising competitiveness in commercialization

Three indications of

TUOYI[®] included in the





08 Future and Prospects



Future and Prospects

Anti-SARS-CoV-2 Drugs

Speed up commercialization of our anti-SARS-CoV-2 Drugs such as VV116, broaden the COVID-19 drugs pipeline and contribute to the world's anti-pandemic efforts with China innovation

Innovation

Accelerate clinical trials of TAB004/JS004, the world's first-in-human anti-BTLA mAb, in China and the United States, announce the readout of Phase I/II clinical data and expand the range of beneficiaries of immunotherapy through origin innovation

Internationalization

Promote marketing approval of TUOYI[®] in overseas market, establish the market position in the US, UK, EU, MENA and continue to expand the global commercialization network

Commercialization

With more indications of TUOYI[®] entering the commercial approval stage, the gradual realization of the prospective layout advantages of multi-indication perioperative clinical research and the upgrade of production capacity of commercial production batches, the domestic sales of TUOYI[®] would begin to enter a positive cycle

THANK YOU

