

A detailed 3D molecular model of a protein structure, rendered in shades of blue and cyan. The structure is complex, with multiple globular domains and flexible loops. The background is a soft, out-of-focus blue gradient. A white diagonal line cuts across the bottom right corner of the slide.

2019 Annual Result Presentation

*Shanghai Junshi Biosciences Co., Ltd.**

Mar 2020



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1 Business

Overview

Financial Highlights: FY 2019



Total Revenue

775 M

- Sales revenue of Toripalimab reached RMB **774** million during the Reporting Period
- Gross profit margin of sales was **88.3%**



R&D Expenses

946 M

- Key clinical trials are progressing
- More co-development in R&D and license-in expanding to small molecule drugs and ADC



Selling & Distribution Expenses

320 M

- Mainly due to the launch and commercialization of Toripalimab



Comprehensive Expense

741 M

- Mainly benefiting from the contribution of Toripalimab sales, but offset by the increase in R&D expenses and administrative expenses



Net Cash from Financing Activities

594 M

- Principally attributable to net cash from the exercise of over-allotment option of H shares amounting RMB404 million



Net Cash Used in Investing Activities

952 M

- Mainly due to Lingang Production Base's construction
- Pipeline was expanded through equity investment

Business Highlights: FY 2019

Product Commercialization



- Sales revenue reached RMB **774** million during the Reporting Period
- The NDA application for UBP1211 was accepted by NMPA

Pipeline Expansion



- Developed a product pipeline comprising **21** drugs candidates which covers monoclonal antibodies, fusion proteins, ADCs, and small molecule drugs

Clinical Trials



- **14** pivotal registered clinical trials being conducted , including: UC, NPC, melanoma, NSCLC, SCLC, TNBC, EC, HCC, RCC and GC

IND Application



- The IND application for JS004 was approved in China and the U. S.
- The IND application for JS005 was approved

Production Bases



- The technology upgrade of Wujiang Production Base was completed
- Lingang Production Base obtained the Drug Production License and started trial production

STAR Market



- The application for the A Share Listing was accepted
- On March 30 2020, the Listing Committee of the SSE reviewed the Company's application for listing

The Lightning-fast Expansion

The total revenue has shown an explosive growth, which increased by **82885.97%** and reached RMB775 million .



The fermentation capacity rose from 1,500L to 33,000L, a **22-fold** increase



The Pivotal registered clinical trials increased from 4 to 14, realizing “**1-digit** growth”.



The total number of employees increased by **136%**, from 600 to 1421



Our pipeline was expanded from 13 drugs to 21, an increase of **8** drugs



Proposed A Share Listing on STAR Market

2019

2020

The proposal was passed at the 12th Meeting of the Second Session of the Board of Directors

The resolution was approved at the 2018 Annual General Meeting, the 2019 First Class Meeting of Domestic Shareholders and the 2019 First Class Meeting of H Shareholders

The application for the A Share Listing was submitted and accepted

The company replied to the SSE's first round of enquiry



STAR 科创板
MARKET

Mar.

Jun.

Sep.

Dec.

Internal decision-making

Application preparation

Review Stage

Jan. –Feb.
The company received and replied to the SSE's second round of enquiry

Mar.
Approved for proposed A Share Listing

to be continued



In 2019, the company launched the process of an initial public offering and listing of A shares on the STAR Market, which has made stable advances, under the guidance of the board of directors. The listing will further improve the company's cash flow and enhance our financial strength

Our Robust Pipeline

Disease Areas	Candidates	Targets	Indications	Pre Clinical	Phase I	Phase II	Phase III	NDA	Origins		
Oncology	JS001 (Toripalimab)	PD-1	melanoma, mucosal melanoma, NPC, UC, NSCLC, SCLC, TNBC, EC, HCC, RCC and GC	NDA approved on 17 December 2018						In House	
	JS003	PD-L1	Solid tumors	IND approved in August 2018						In House	
	JS004	BTLA	Melanoma, lung cancer, lymphoma	IND approved on 18 April 2019						In House	
	JS006	TIGIT	Solid tumors							In House	
	JS007	CTLA-4	Lung cancer, melanoma							In House	
	JS009	(Undisclosed)	(Undisclosed)							In House	
	JS011	(Undisclosed)	(Undisclosed)							In House	
	JS012	(Undisclosed)	(Undisclosed)							In House	
	JS101	Pan-CDK	Breast cancer	IND approved in November 2018						In House	
	JS104	Pan-CDK	Breast cancer	In licensing in February 2019						Co-development	
	JS105	PI3K-α	Breast cancer, kidney cancer, Hodgkin's lymphoma	In licensing in February 2019						Co-development	
	Metabolic	JS501	VEGF	Colon cancer, non-small cell lung cancer	In licensing in June 2019						50% Rights in-licensing
JS014		IL-21	Solid tumors	In licensing in June 2019						Co-development	
JS108		TROP2	TNBC, SCLC, pancreatic cancer	IND accepted in November 2019						Co-development	
JS002		PCSK9	Hyperlipidemia							In House	
JS008		(Undisclosed)	(Undisclosed)							In House	
JS005		IL17A	Psoriasis	IND approved in August 2019						In House	
Auto-immunity		UBP1211	TNF-α	Rheumatoid arthritis, psoriatic arthritis, psoriasis	NDA accepted in November 2019						Biosimilar
		UBP1213	BlyS	Systemic lupus erythematosus	IND approved in November 2016						Co-development
		JS010	(Undisclosed)	(Undisclosed)							In House
Infectious disease		JS016	S protein	COVID-19							Co-development

■ Macromolecule
■ Small Molecule

2 Commercialized-stage product and related clinical development

Toripalimab Registration Pivotal Trials & Results

Adjuvant/Neo Adjuvant

HCC Adjuvant
JUPITOR04 PIII
Mono vs Placebo

NSCLC Neo Adjuvant
JUPITOR09 PIII
Mono vs Placebo

First Line

NSCLC EGFR(-)
JUPITOR03 PIII
Combo vs chemo

NSCLC EGFR(+)
JUPITOR07 PIII
Combo vs chemo

TNBC
JUPITOR05 PIII
Combo vs albumin-bound paclitaxel

SCLC
JUPITOR08 PIII
Combo vs chemo

RCC
JUPITOR12 PIII
Combo with Axitinib vs Sunitinib

Melanoma
JUPITOR01 PIII
Mono vs Dacarbazine

NPC
JUPITOR02 PIII
Combo vs chemo

EC
JUPITOR06 PIII
Combo vs TP

HCC
JUPITOR10 PIII
Combo with Avastin vs Sorafenib

≥ 2nd Line

Melanoma
POLARIS01 PII
Mono single arm

NPC
POLARIS02 PII
Mono single arm

UC
POLARIS03 PII
Mono single arm

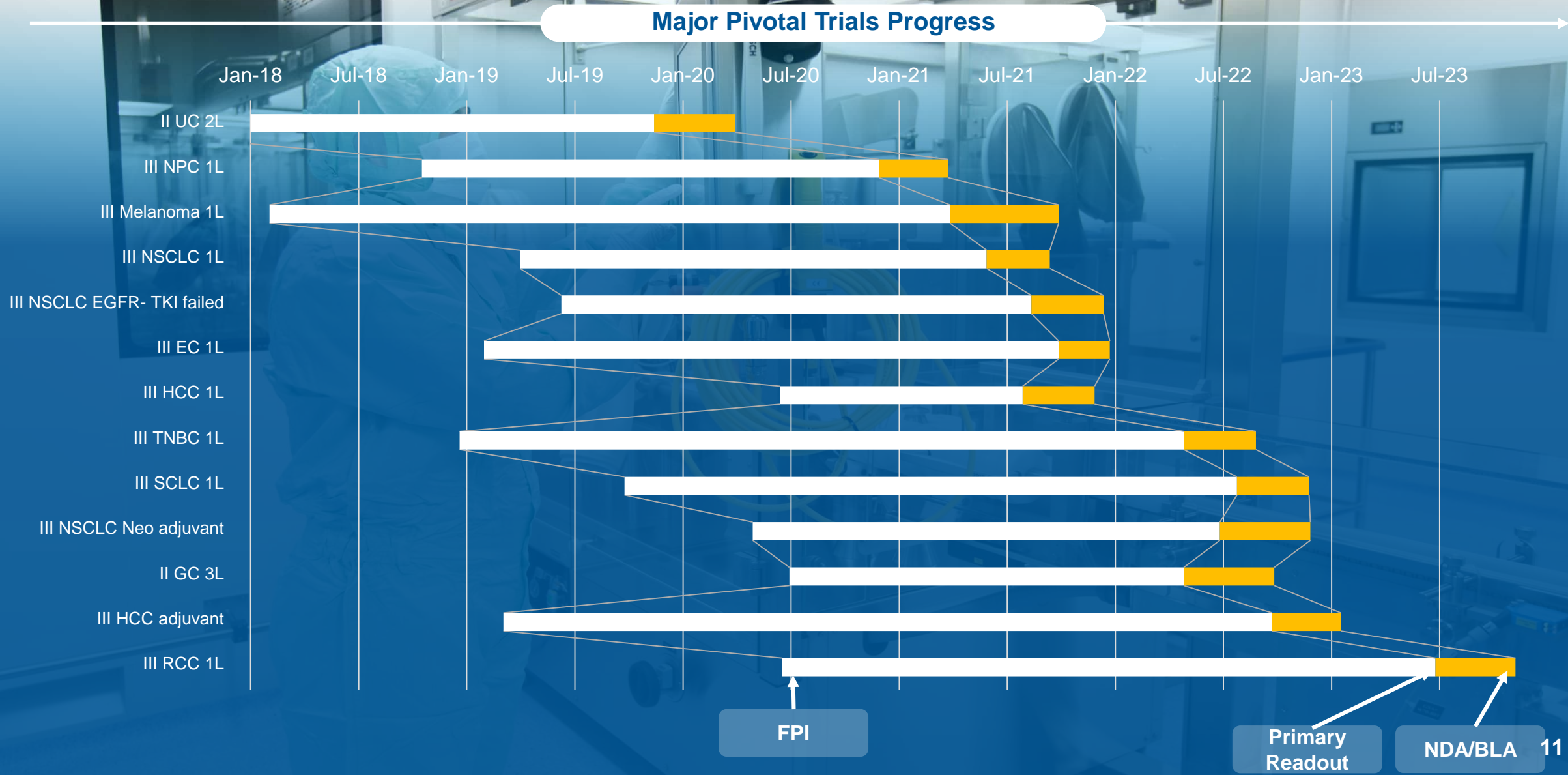
GC
POLARIS04 PII
Mono single arm



The clinical results of major registration pivotal trials

Indication	Advanced or metastatic urothelial carcinoma (Phase II)	Refractory or metastatic Nasopharyngeal carcinoma (Phase II)	Non-small cell lung carcinoma (with failing EGFR-TKI treatment, Phase II)	Advanced esophageal squamous cell carcinoma (Phase II)
ORR	25.7%	25.5%	50%	18.6%
DCR	45.9%	47.1%	87.5%	47.5%
N	148	165	40	59
Note	Clinical results after the completion of enrollment	Interim results for pivotal clinical trial	/	/

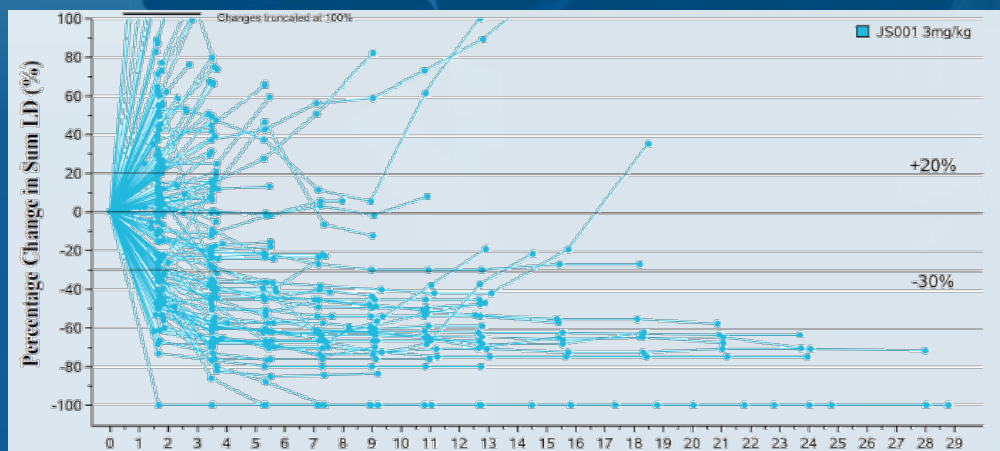
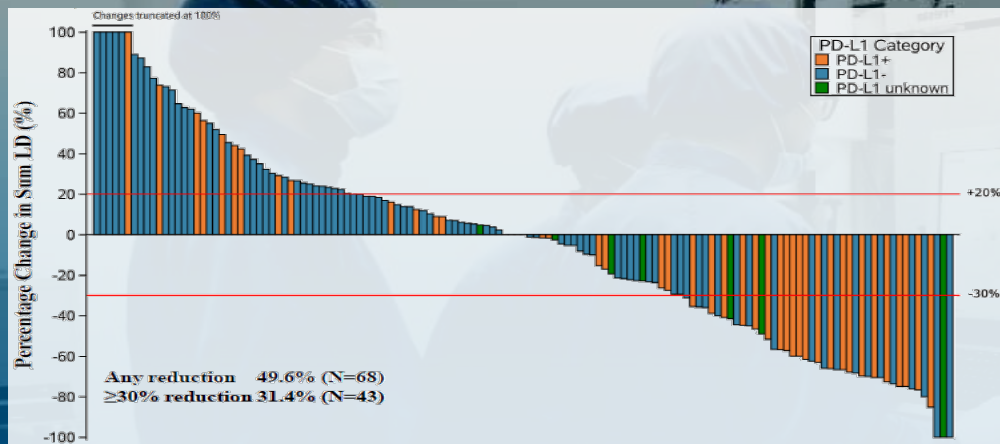
Timeline of Toripalimab Registration Pivotal Trials



Toripalimab in Urothelial Carcinoma

POLARIS-03: Full data analysis

Full Data Analysis



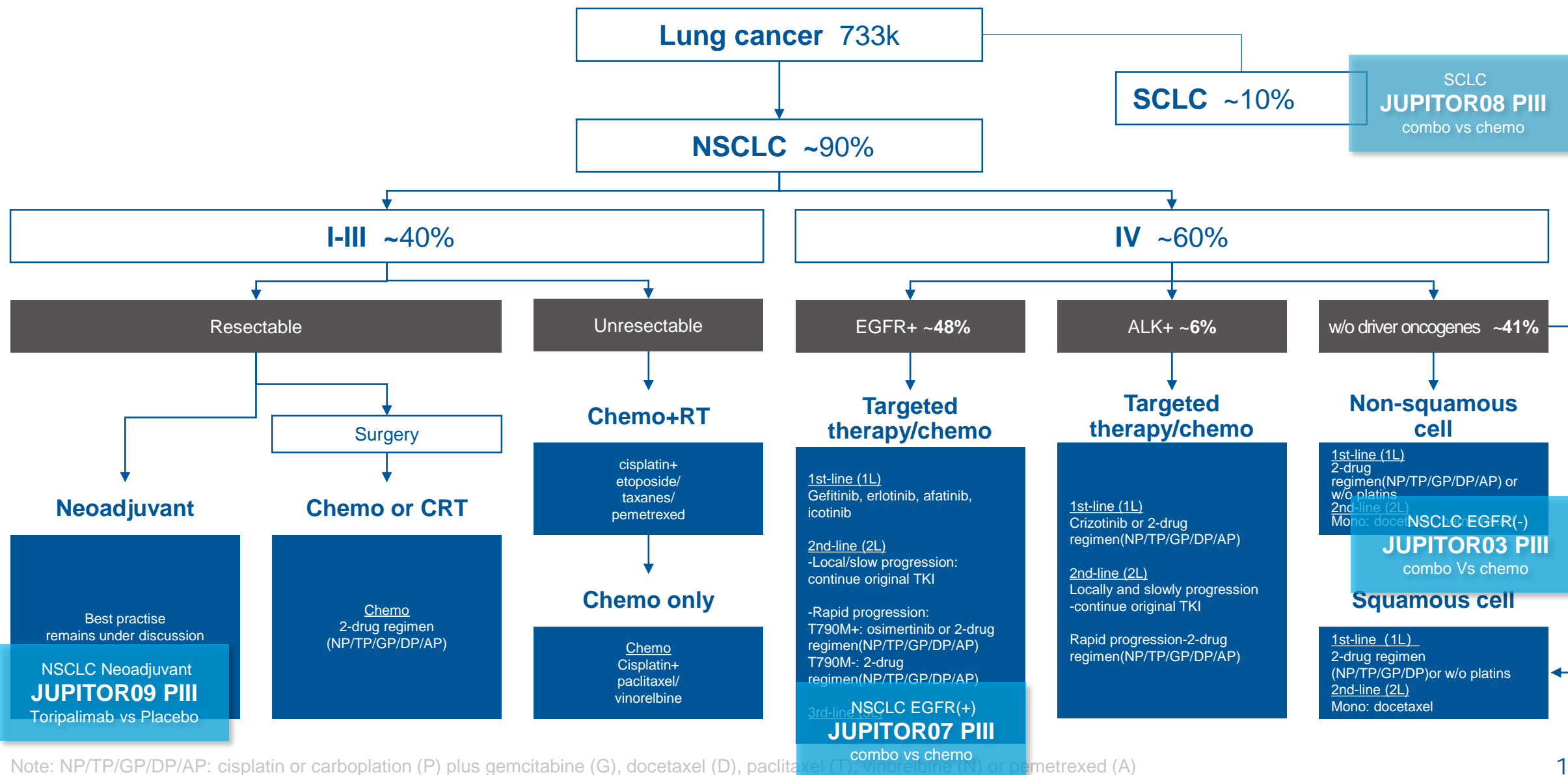
Biomarker: Subgroup Evaluation

Group	n/N	ORR and 95% CI
Subgroups (FAS population N=148)		
Age (years)	≤65	20/92 21.7 (13.8, 31.6)
	≥65	18/56 32.1 (20.3, 46.0)
Gender	Male	23/98 23.5 (15.5, 33.1)
	Female	15/50 30.0 (17.9, 44.6)
ECOG at baseline	0	17/56 30.8 (19.8, 38.0)
	1	21/82 25.6 (16.6, 36.4)
Site of primary tumor	Upper urinary tract	18/70 25.7 (16.0, 37.6)
	Lower urinary tract	19/76 25.0 (15.8, 36.3)
	Other	1/1 100.0 (2.5, 100.0)
	Unknown	0/1 NE (NE, NE)
Site of metastasis	Lymph node only	9/19 47.4 (24.4, 71.1)
	Visceral	29/129 22.5 (16.6, 30.7)
Last treatment line prior to enrollment	1 st line	31/115 27.0 (19.1, 36.0)
	2 nd line and beyond	7/33 21.2 (9.0, 38.9)
Prior systemic treatment with platinum	Yes	36/140 25.7 (18.7, 33.8)
	No	2/8 25.0 (3.2, 62.5)
Time since last systemic treatment	<3 months	20/90 22.2 (14.1, 32.2)
	≥3 months	18/56 32.1 (20.3, 46.0)
	Unknown	0/2 NE (NE, NE)
PD-L1 expression	Positive	10/46 41.3 (27.0, 56.8)
	Negative	16/95 16.8 (9.9, 25.0)
	Unknown	3/2 42.9 (0.9, 81.6)
Post-treatment ADA	Positive	3/10 30.0 (6.7, 65.2)
	Negative	35/126 27.8 (20.2, 36.5)
	Unknown	0/12 NE (NE, NE)

- As of 1/6/2020, among the FAS population (n=148), 2 CR, 36 PR and 30 SD were observed
- The ORR was 25.7%, and DCR was 45.9%
- The median time to response was 1.8 months, median PFS was 1.9 months, and the median DOR was 15.7 months. The median OS was 20.8 months although the OS data was not mature

- Tumor PD-L1 expression by JS311 IHC staining
- JS311 had similar performance with 22C3 and SP263, while having stronger staining positivity than SP142
- PD-L1 positive patients (n=46) had significant better ORR than PD-L1 negative patients (n=95), 41.3% versus 16.8%

The Company's Layout in Lung Cancer



Note: NP/TP/GP/DP/AP: cisplatin or carboplatin (P) plus gemcitabine (G), docetaxel (D), paclitaxel (T), vinorelbine (V) or pemetrexed (A)
Source: CSCO (Chinese Society of Clinical Oncology), Goldman Sachs Global Investment Research, Internal Estimation

EGFR+ Advanced NSCLC Patients Failed to Prior EGFR TKI Therapies



INTERNATIONAL
ASSOCIATION
FOR THE STUDY
OF LUNG CANCER
Conquering Thoracic Cancers Worldwide



A Phase II, multicenter, open-label, single-arm study for pts with EGFR activating mutations who have failed prior EGFR-TKI therapies without T790M mutation or failed Osimertinib treatment.



As of 7/25/2019, among all 40 patients, 20 confirmed partial responses and 15 stable disease were observed for a **50.0% ORR** (95% CI, 33.8% to 66.2%) and an **87.5% DCR** (95% CI, 73.2% to 95.8%).



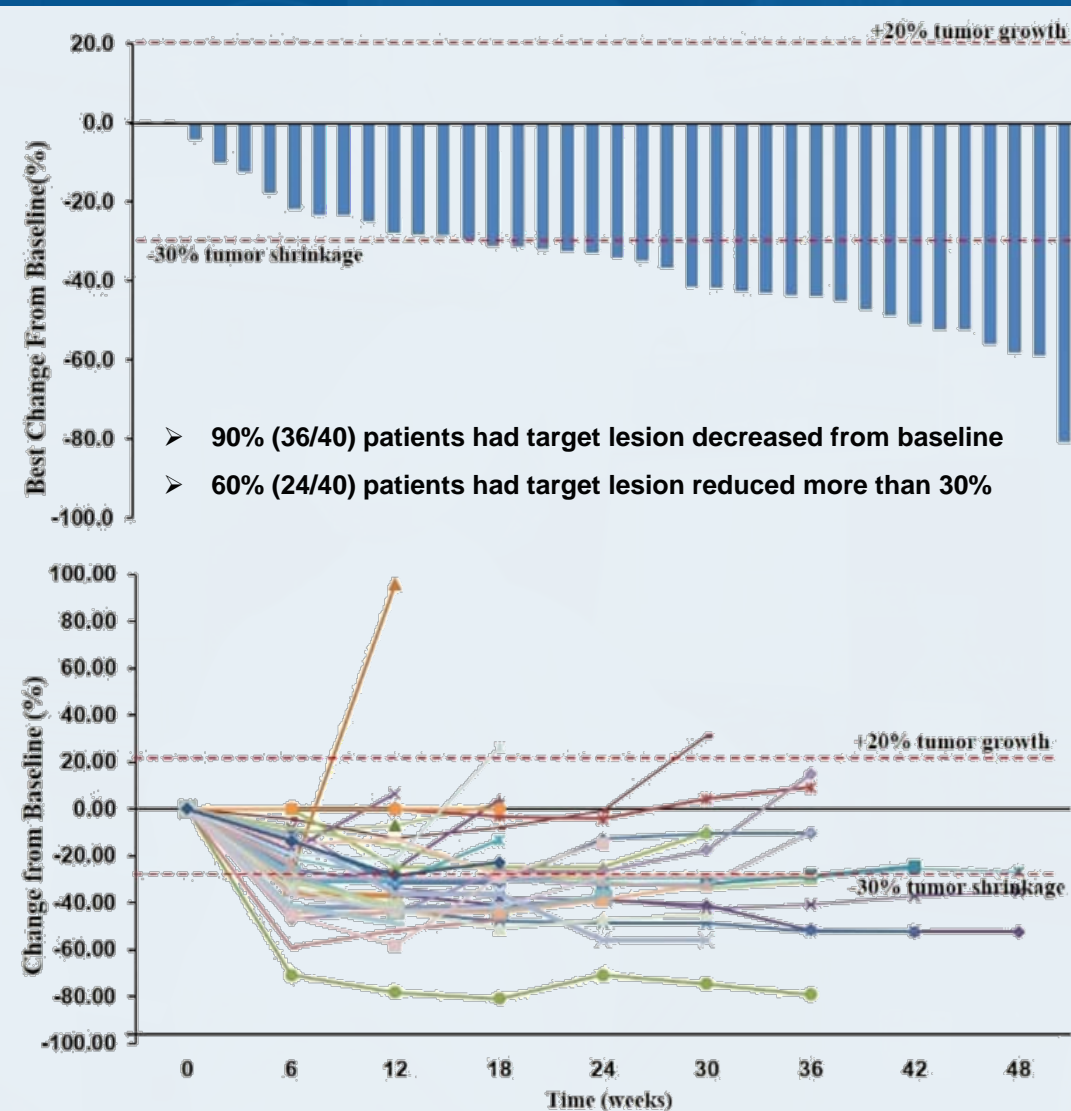
Median PFS was 7.0 months, while median DOR was 7.0 months.



PD-L1+ patients ORR 60.0%, mPFS 8.3 months versus PD-L1- patients ORR 38.9%, mPFS 5.7 months



EGFR L858R ORR 58.9%, mPFS 7.1 months versus Exon 19 deletion ORR 43.5%, mPFS 5.1 months



Academic Achievements



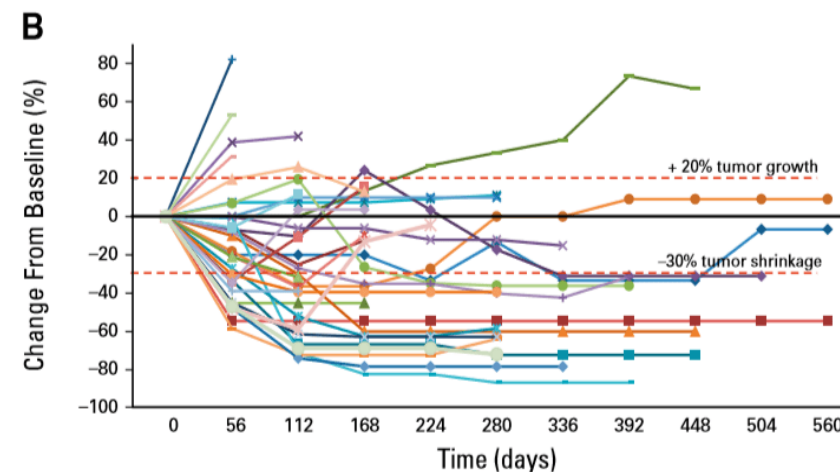
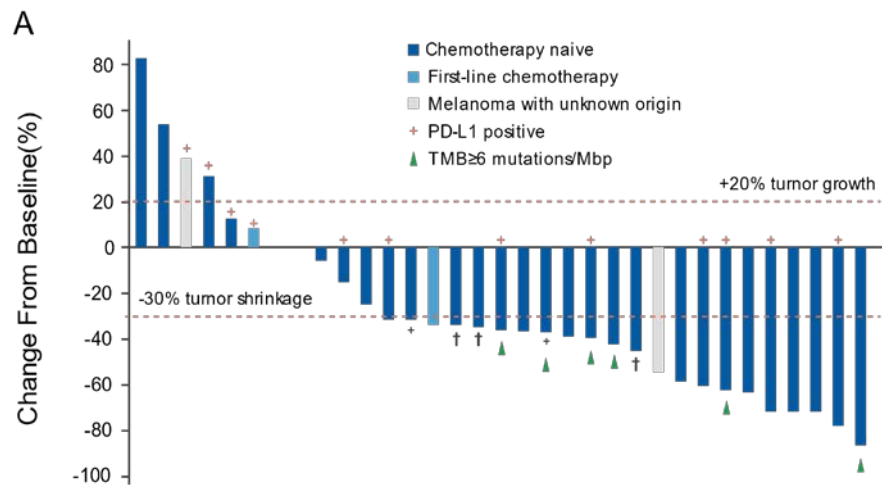
In addition to the outstanding performance in top academic journals, Toripalimab also shone in a series of authoritative academic conferences

Axitinib-Toripalimab Combination Therapy for Mucosal Melanoma

On August 12 2019, the research results on Toripalimab in combination with axitinib in the treatment of advanced mucosal melanoma (NCT03086174) was published in the Journal of Clinical Oncology

The combination therapy was granted the orphan-drug designation by the FDA

Long-lasting efficacy of the combination therapy
 ORR 48.3%, DCR 86.2%



“Axitinib in Combination With Toripalimab , a Humanized Immunoglobulin G4 Monoclonal Antibody Against Programmed Cell Death-1, in Patients With Metastatic Mucosal Melanoma: An Open-Label Phase IB Trial.”

Sheng X, et al. J Clin Oncol. 2019 Aug 12;JCO1900210. doi: 10.1200/JCO.19.00210.

Toripalimab in Gastric Cancer

ORIGINAL ARTICLE

Safety, efficacy and tumor mutational burden as a biomarker of overall survival benefit in chemo-refractory gastric cancer treated with toripalimab, a PD-1 antibody in phase Ib/II clinical trial NCT02915432

F. Wang^{1†}, X. L. Wei^{1†}, F. H. Wang^{1†}, N. Xu², L. Shen³, G. H. Dai⁴, X. L. Yuan⁵, Y. Chen⁶, S. J. Yang⁷, J. H. Shi⁸, X. C. Hu^{9,10}, X. Y. Lin¹¹, Q. Y. Zhang¹², J. F. Feng¹³, Y. Ba¹⁴, Y. P. Liu¹⁵, W. Li¹⁶, Y. Q. Shu¹⁷, Y. Jiang¹⁸, Q. Li¹⁹, J. W. Wang²⁰, H. Wu²¹, H. Feng²¹, S. Yao²¹ & R. H. Xu^{1*}

¹State Key Laboratory of Oncology in South China, Department of Medical Oncology, Sun Yat-sen University Cancer Center, Collaborative Innovation Center for Cancer Medicine, Guangzhou; ²Department of Medical Oncology, The First Affiliated Hospital, School of Medicine, Zhejiang University, Hangzhou; ³Laboratory of Carcinogenesis & Translational Research for the Ministry of National Education, Department of GI Oncology, Peking University School of Oncology, Beijing Cancer Hospital & Institute, Beijing; ⁴Department of Medical Oncology, Chinese PLA General Hospital & Chinese PLA Medical Academy, Beijing; ⁵Department of Oncology, Tongji Hospital, Huazhong University of Science and Technology, Wuhan; ⁶The State Key Laboratory of Biotechnology, Department of Abdominal Cancer, West China Medical School, Cancer Center, West China Hospital, Sichuan University, Chengdu; ⁷Department of Internal Medicine, Affiliated Cancer Hospital of Zhengzhou University, Henan Cancer Hospital, Zhengzhou; ⁸Department of Medical Oncology, Linyi Cancer Hospital, Linyi; ⁹Department of Medical Oncology, Fudan University Shanghai Cancer Center, Shanghai; ¹⁰Department of Oncology, Shanghai Medical College, Fudan University, Shanghai; ¹¹Department of Medical Oncology, Fujian Medical University Union Hospital, Fuzhou; ¹²Department of Medical Oncology, Harbin Medical University Cancer Hospital, Harbin; ¹³Department of Oncology, Nanjing Medical University Affiliated Cancer Hospital, Jiangsu Cancer Hospital, Jiangsu Institute of Cancer Research, Nanjing; ¹⁴Department of Gastrointestinal Oncology, Tianjin Cancer Hospital, Tianjin; ¹⁵Department of Medical Oncology, The First Hospital of China Medical University, Shenyang; ¹⁶Department of Medical Oncology, The First Hospital of Jin University, Changchun; ¹⁷Department of Oncology, Jiangsu Provincial Hospital, Nanjing; ¹⁸Digestive Medical Oncology, Cancer Hospital of Shantou University Medical College, Shantou; ¹⁹Department of Medical Oncology, Shanghai General Hospital, Shanghai; ²⁰Jiao Tong University School of Medicine, Shanghai; ²¹State Key Laboratory of Oncology in South China, Department of Ultrasonography, Sun Yat-sen University Cancer Center, Collaborative Innovation Center for Cancer Medicine, Guangzhou; ²²Shanghai Junshi Biosciences Co., Ltd, Shanghai, China

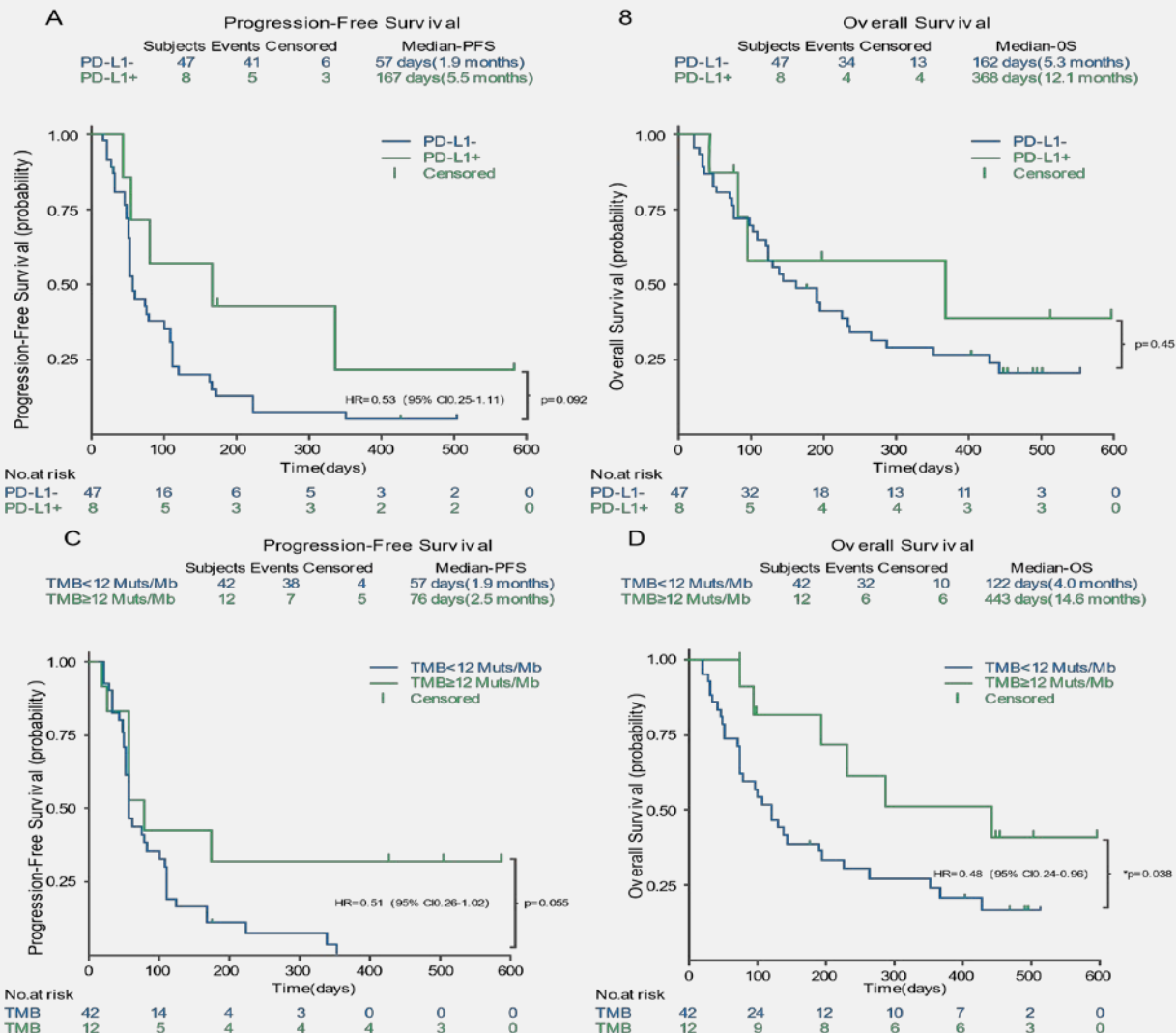
*Correspondence to: Prof. Rui Hua Xu, State Key Laboratory of Oncology in South China, Department of Medical Oncology, Sun Yat-sen University Cancer Center, Collaborative Innovation Center for Cancer Medicine, 651 Dong Feng Road East, Guangzhou 510060, Guangdong, China. Tel: +86-20-8734-3468; E-mail: xurh@sysucc.org.cn

[†]These authors contributed equally to this study.

Background: High tumor mutational burden (TMB-H) is correlated with enhanced objective response rate (ORR) and progression-free survival (PFS) for certain cancers receiving immunotherapy. This study aimed to investigate the safety and efficacy of toripalimab, a humanized programmed death-1 (PD-1) antibody, in advanced gastric cancer (AGC), and the predictive survival benefit of TMB and PD-L1.

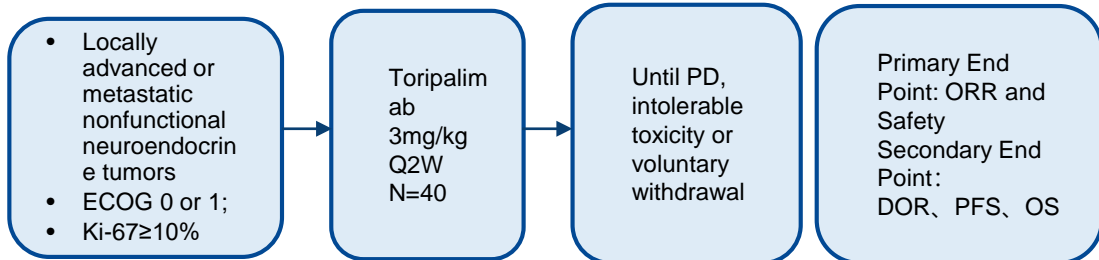
Patients and methods: We reported on the AGC cohort of phase Ib/II trial evaluating the safety and activity of toripalimab in patients with AGC, oesophageal squamous cell carcinoma, nasopharyngeal carcinoma and head and neck squamous cell carcinoma. In cohort 1, 58 chemo-refractory AGC patients received toripalimab (3 mg/kg d1, Q2W) as a monotherapy. In cohort 2, 18 chemotherapy-naïve AGC patients received toripalimab (360 mg d1, Q3W) with oxaliplatin 130 mg/m² qd, d1, capecitabine 1000 mg/m² b.i.d., d1-d14, Q3W as first-line treatment. Primary end point was ORR. Biomarkers such as PD-L1 and TMB were evaluated for correlation with clinical efficacy.

Results: In cohort 1, the ORR was 12.1% and the disease control rate (DCR) was 39.7%. Median PFS was 1.9 months and median OS was 4.8 months. The TMB-H group showed significant superior OS than the TMB-L group [14.6 versus 4.0 months, HR = 0.48 (95% CI 0.24-0.96), *P* = 0.038], while PD-L1 overexpression did not correlate with significant survival benefit. A 77.6% of patients experienced at least one treatment-related adverse event (TRAE), and 22.4% of patients experienced a grade 3 or higher TRAE. In cohort 2, the ORR was 66.7% and the DCR was 88.9%. A 94.4% of patients experienced at least one TRAE and 38.9% of patients experienced grade 3 or higher TRAEs.



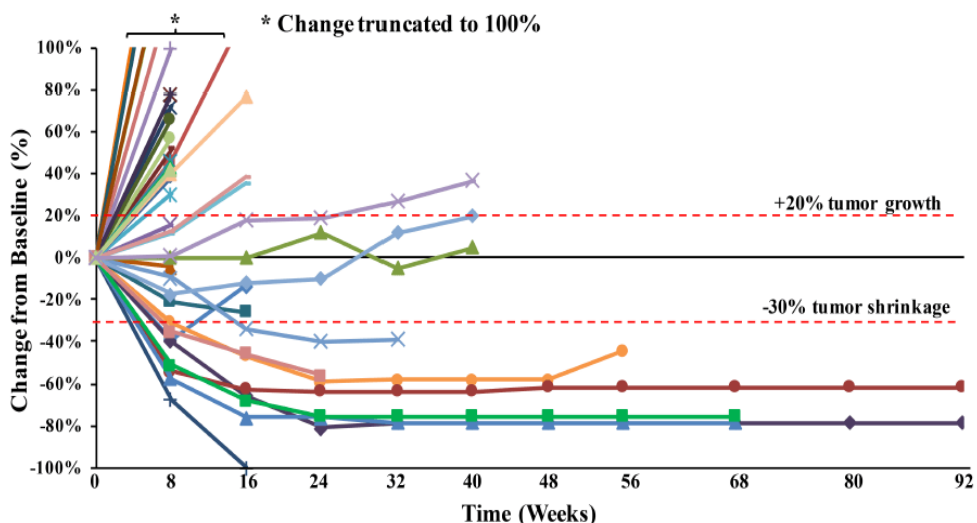
Toripalimab in Neuroendocrine Neoplasms

Experimental Design



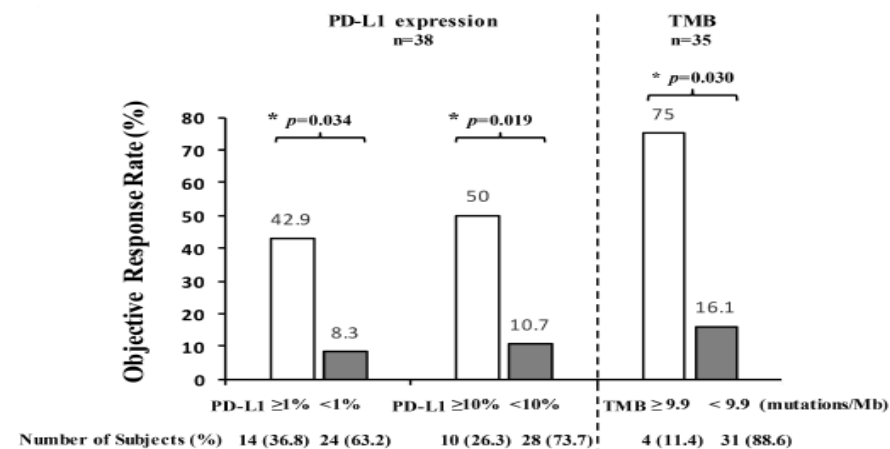
- NENs are a highly heterogeneous group of tumors. Patients with recurrent or metastatic neuroendocrine neoplasms (NENs) had a poor prognosis and few treatment options. Therefore, it remains an unmet medical need
- NCT03167853 is an open-label multi-center single arm phase Ib study evaluating the safety and efficacy of toripalimab in patients with recurrent or metastatic NENs.

Efficacy Analysis



- As of Aug 30, 2019, 8 PR and 6 SD were observed
- The ORR was 20%, DCR was 35%, median DOR was 15.2 months and the median PFS was 2.5 months

Biomarker: Subgroup Evaluation



- Patients with PD-L1 expression (≥10%) or high tumor mutational burden (TMB) had better ORR than PD-L1 <10% (50.0% vs 10.7%, p=0.019) and TMB low patients (75.0% vs 16.1%, p=0.03).

Commercialization

In 2019, our sales department had more than 340 personnel and 90% of them came from MNCs



Sales revenue of Toripalimab reached **RMB774.1 million**



Dealership was adopted to complement professional academic promotion

Strategic cooperation was established with several domestic companies including Sinopharm to build a nationwide sales network

The company promoted commercialization of Toripalimab with reference to product characteristics and positioning



In 2019, the company made continued efforts to assemble a productive marketing and commercialization team and developed a basic capacity to promote our innovative drugs based on commercialization, laying a solid foundation for the future marketing and sales of other drugs in development.

Other Core Products Development

2 JS002

a recombinant humanized anti-PCSK9 monoclonal antibody for injection independently developed by the Company for the treatment of cardiovascular diseases.

The Company is the first PRC company to obtain clinical trial approval for the target drug.

At present, the Phase II clinical trial has completed enrollment and is conducting follow-ups.

Based on the obtained clinical research data, JS002 shows sound safety and tolerability profile.

No serious adverse events (SAE) or any withdrawal due to adverse events (AE) are reported during the study. In terms of lowering LDL-C, JS002 shows a comparable lipid reduction and longer duration compared with products of the same target.

Currently, the Company is initiating preparations for Phase III clinical studies with larger patient population.

1 UBP1211

a recombinant humanized anti-TNF- α -monoclonal antibody injection, which targets autoimmune diseases such as rheumatoid arthritis, and is a biosimilar of Humira (adalimumab)

The Company has submitted a NDA application for UBP1211 to NMPA and it was accepted in November 2019

3 JS005

a recombinant humanized anti-IL-17A monoclonal antibody injection, which targets autoimmune diseases including psoriasis.

JS005 obtained the Drug Clinical Trial Notification from the NMPA in August 2019.

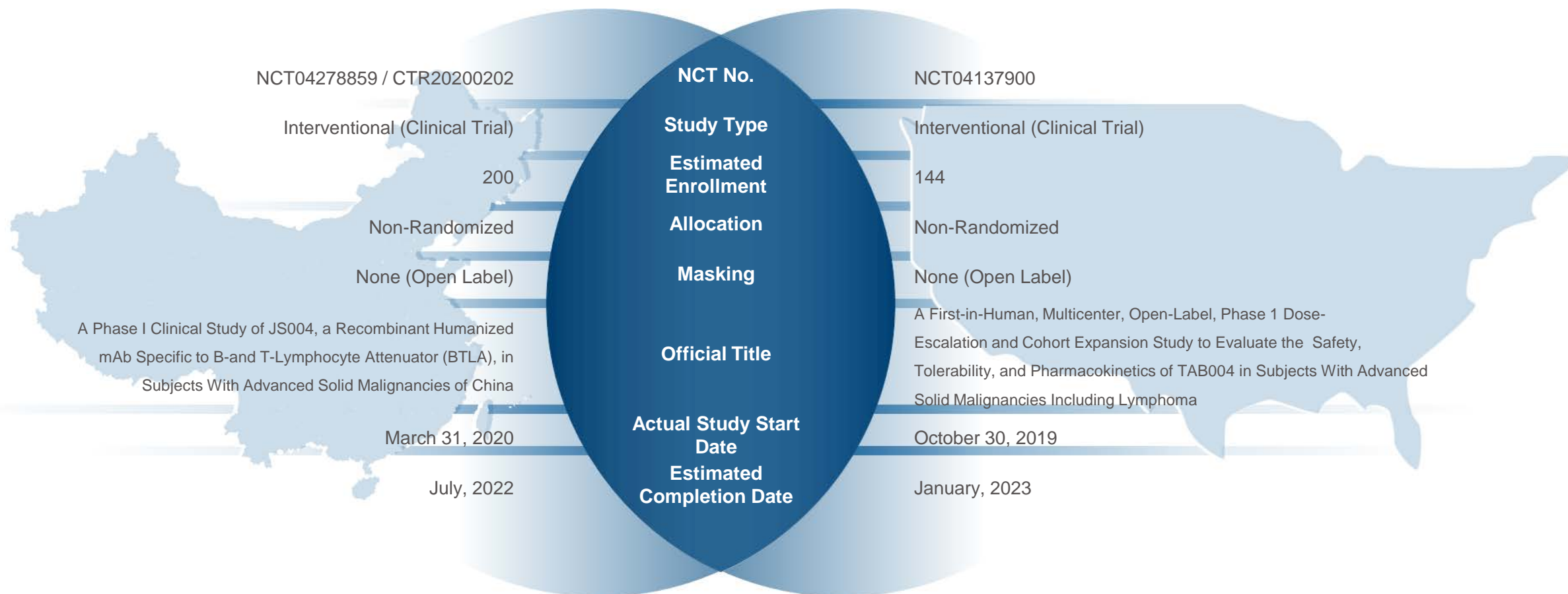
The amino acid sequence of JS005, especially the sequence of the CDR region (the region that binds to the target molecule) is different from the CDR sequences of similar monoclonal antibodies on the market and is a unique new structure.

In preclinical studies, JS005 has shown efficacy and safety comparable to those of marketed anti-IL-17 monoclonal antibodies.

The Phase I clinical trial of JS005 is expected to complete the first patient enrollment in the first half of 2020.

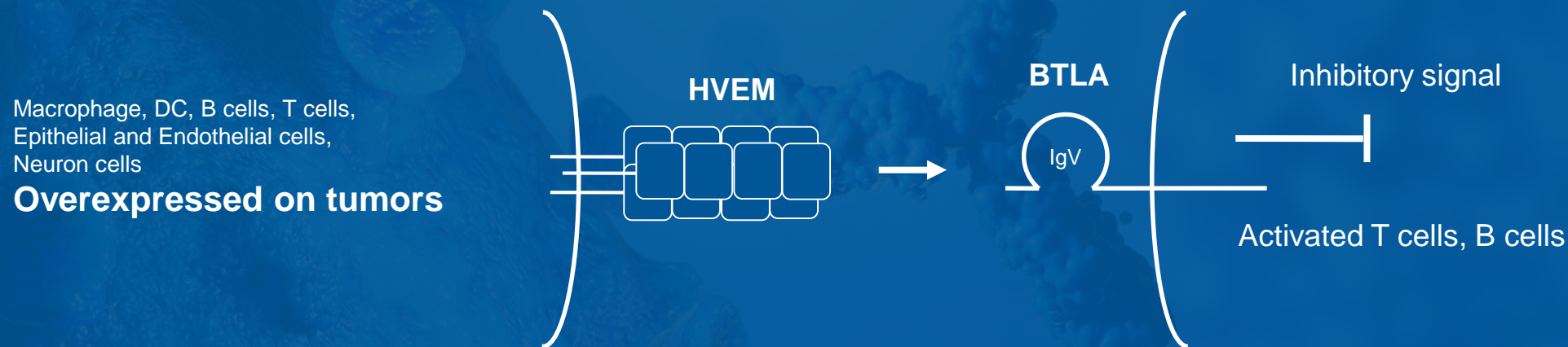
TAB004 first in Human anti-BTLA antibody for solid tumors

- In April 2019, TAB004/ JS004 was approved by the U.S. FDA for drug clinical trial, being the world's first anti-BTLA monoclonal antibody for injection approved for clinical trials
- In October 2019, the first patient has been dosed in the Phase I clinical study
- In January 2020, the IND application of TAB004/JS004 was approved by the NMPA



TAB004 first in Human anti-BTLA antibody for solid tumors

BTLA is a parallel checkpoint with PD-1 to regulate lymphocyte activation.



BTLA



PD-1 like molecule expressed on activated T and B cells



BTLA co-expresses with PD-1 on tumor specific T cells from human melanoma and non-small cell lung cancer patients



BTLA-deficient mice show enhanced T cell activation and have exacerbated disease in animal models of autoimmunity and inflammation (RA, SLE, EAE and Asthma)



BTLA blockade promotes antigen-specific T cell response and works synergistically with toripalimab (anti-PD-1)



HVEM overexpressed in tumors and suppressed T cell function through BTLA



The IND application was approved by FDA and NMPA in April 2019 and January 2020, respectively; no competitor compound in clinical stage

3 Other Business Development

Other Business Development

Enhance Pipeline through BD

Shanghai



Co-development for an Avastin biosimilar with Huaota Biosciences

- HOT-1010/JS501 is a recombinant humanised anti-VEGF monoclonal antibody injection, which has received clinical trial approval from NMPA and is in Phase I clinical trial.
- Selectively binds to human VEGF and blocks its biological activity, mainly used for the treatment of metastatic CRC and advanced, metastatic or recurrent NSCLC.

Suzhou



Co-development for two drug candidates with Risen pharma

- A pan-CDK inhibitor that can effectively inhibit the activity of a number of cyclin-dependent kinases, including CDK-1, CDK-2, CDK-4, CDK-6 and CDK-9.
- An oral α -specific PI3K inhibitor.

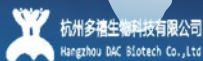
San Francisco



Co-development for a novel IL-21 fusion protein with Anwita

- IL-21 is an active cytokine to stimulate the activation of innate and adaptive immune cells, such as natural killer (NK) cells and cytotoxic T cells.
- AWT008 is Anwita's proprietary IL-21 fusion protein with a prolonged half-life and improved in vivo antitumor activities in animal models, and is intended for development as single agent or in combination with other therapeutic agents due to its proposed mechanism.
- Subscribe for 20% of its outstanding shares.

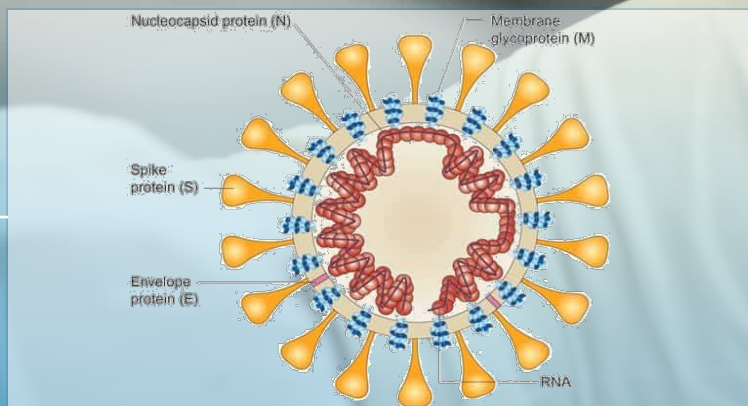
Hangzhou



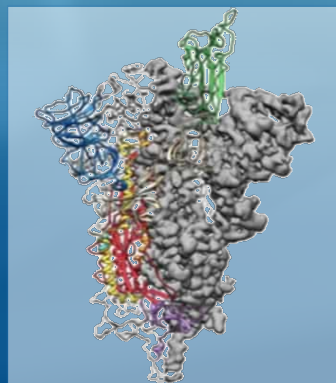
Co-development for an anti-Trop2 monoclonal antibody – Tub196 conjugate with DAC Biotech

- DAC-002/JS108 is an anti-Trop2 monoclonal antibody conjugated with an antitubulin Tubulysin B analog through a smart linker.
- Mainly used to treat solid tumors such as Trop2-positive TNBC, SCLC and PC. Currently, an application for clinical trials has been submitted to and has been accepted by NMPA.
- The Company currently holds approximately 4.5479% in the shares of DAC Biotech.

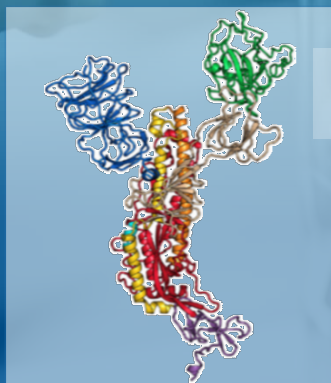
Development Strategy for Neutralizing Antibodies



Structure of Viral particle

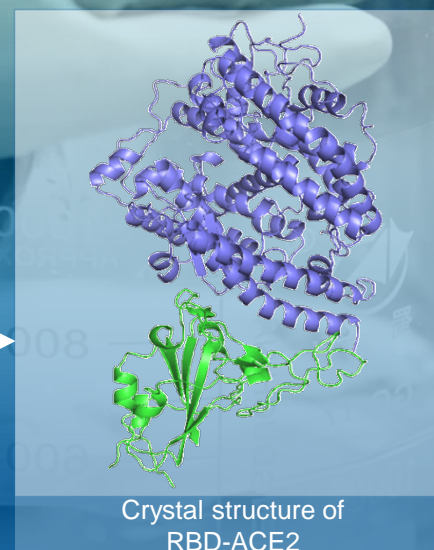


S protein trimer



S protein monomer

RBD domain



Crystal structure of RBD-ACE2

- ❑ The spike protein mediates receptor binding and membrane fusion

- ❑ The spike protein defines the range of the hosts and specificity of the virus.

- ❑ The spike protein can be transmitted between different hosts through gene recombination or mutation of the receptor binding domain (RBD), leading to a higher mortality rate.

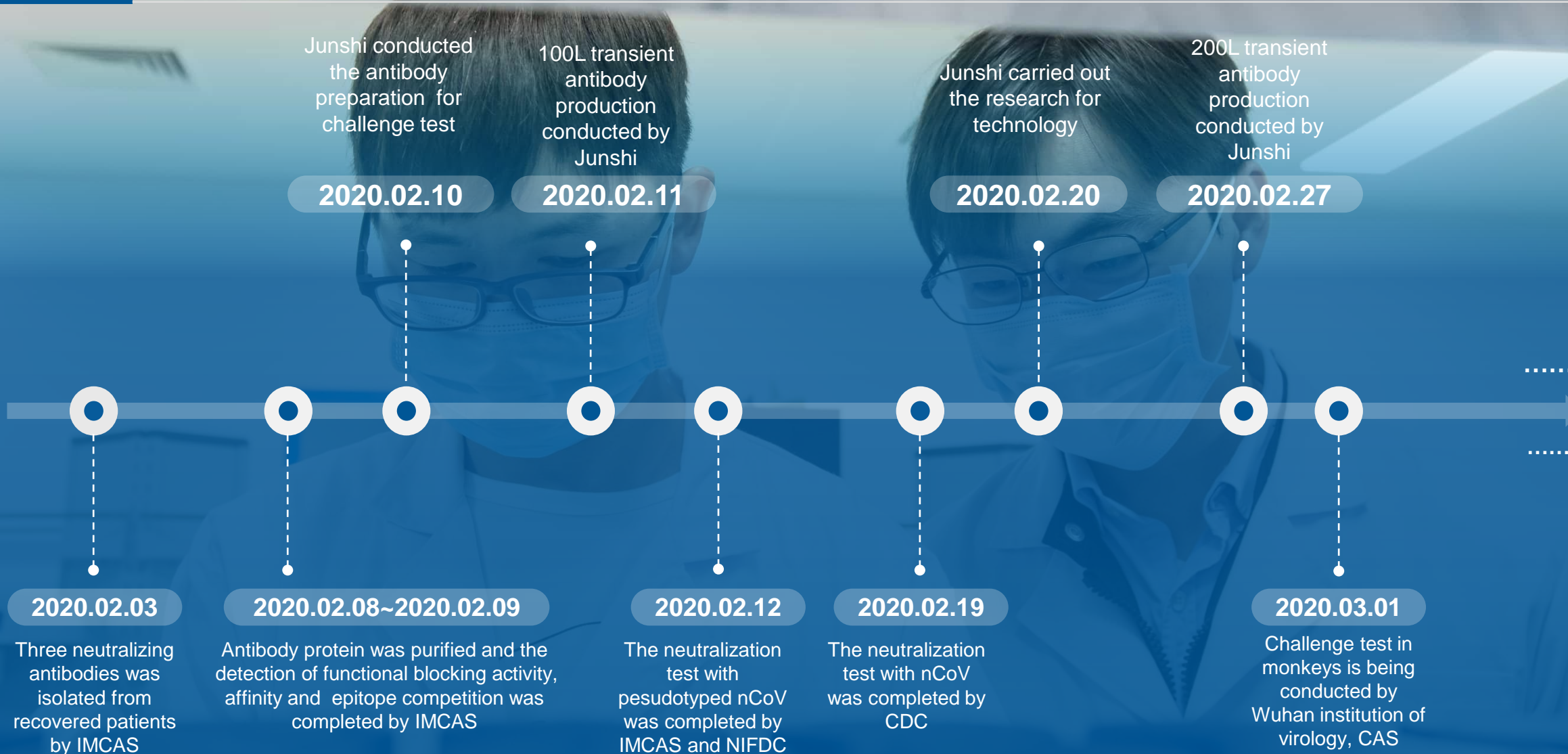
- ❑ The spike protein is the main component to bind with the neutralizing antibody.

- ❑ The spike protein is the key target for vaccine design.



The Blocking neutralizing antibody targeting the RBD of Spike protein may effectively neutralize virulence!

Research Process of Neutralizing Antibodies



4 Manufacturing Facilities

Our Production Base

Single-use bioprocessing platform for lower capital and operating costs, flexibility and sustainability



Suzhou Wujiang

Production Base

- Constructed in accordance with the **GMP Standard**
- Construction completed in 2016
- Commercial capacity was expanded from 3 × 500L to 6 × **500L** bioreactors

Shanghai Lingang

Production Base

- Currently under construction in accordance with **cGMP standard**
- 5 production lines with a total of **30,000L** fermentation capability
- Drug production license obtained



君实生物 TopAlliance Biosciences

Our Lingang Production Base



Advanced imported production, filling and detection equipment to ensure quality, safety and controllability



Cleanroom design based on high standards and production to be implemented strictly following cGMP as planned



Whole-process and intelligent data interactive system to realize real-time control



THANK YOU



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TopAlliance