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2024 H1 Results Presentation

August, 2024

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CATALOG

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03 COMMERCIALIZATION

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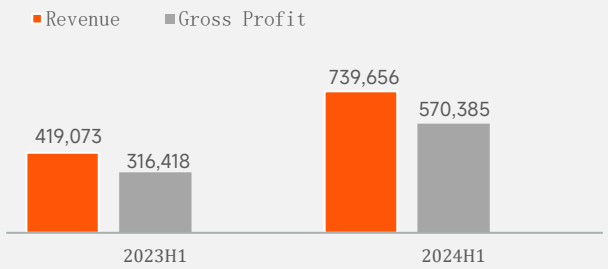
01

FINANCIAL SUMMARY

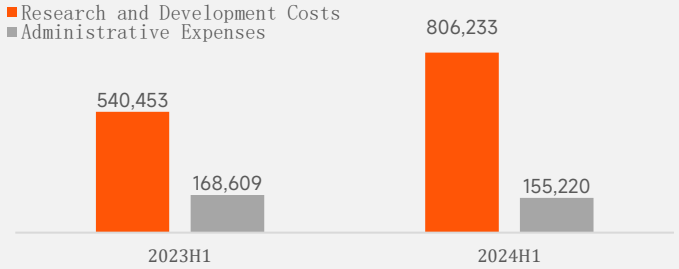
Key Financial Summary (2024Q1)

Revenue (RMB 000)



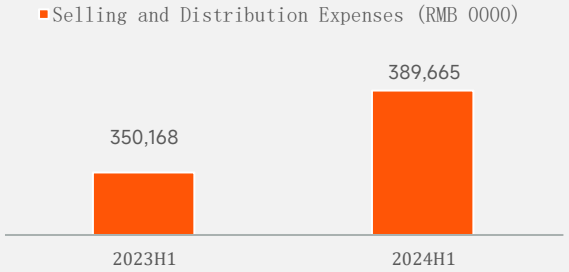
- Increase in sales revenue was mainly attributable to year-on-year growth in sales of the two commercialized products.

R&D and Admin Expenses (RMB 000)



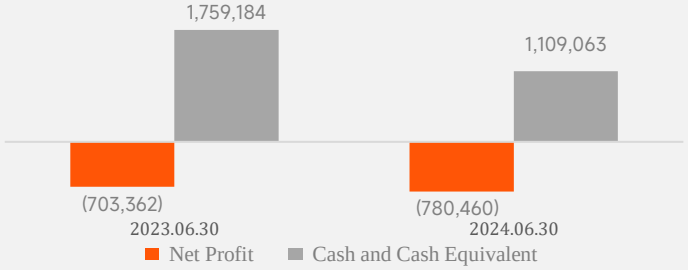
- Increase in R&D costs is mainly due to the continuous development of clinical trials and the increased number of R&D employees.

Selling and Distribution Expenses (RMB 000)



- Increase in selling and distribution expenses is mainly due to the continuous increase in the marketing of commercialized products

Cash Balance(RMB 000)



- Decrease in cash balance is mainly due to the operating activities and investing activities.

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02

CLINICAL DEVELOPMENT

Product Pipeline Across Three Therapeutic Areas

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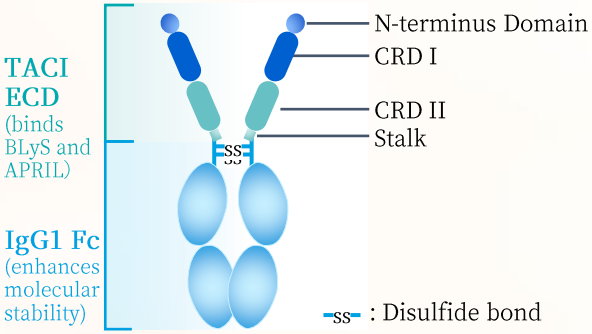
Development Status by Region

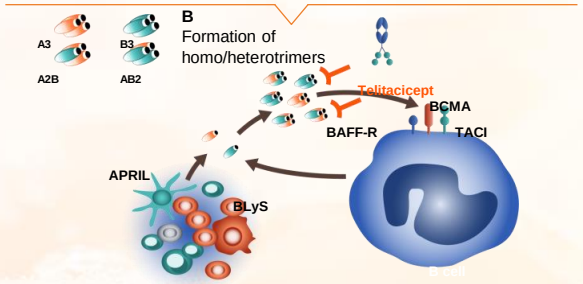
	Drug Candidates	Target	Modality	Pre-clinic.	IND	Ph I	Ph II	Pivotal/Ph III	BLA	Launched
Autoimmune Diseases	Telitacicept (RC18)	BLyS/APRIL	Fusion protein	China						
				Global						
Oncology	Disitamab Vedotin (RC48)	HER2	ADC	China						
				Global				*Collaboration with Seagen/Pfizer*		
	RC88	Mesothelin	ADC	China						
	RC148	PD-1/VEGF	Bispecific antibody	China						
	RC198	IL-15/IL-15Rα	Fusion protein	China						
	RC248	DR5	ADC	China						
	RC248	DR5	ADC	China						
Ophthalmology	RC28	VEGF/FGF	Fusion protein	China						

Clinical Progress of Telitacicept (RC18)

Schematic Diagram of Molecular Structure

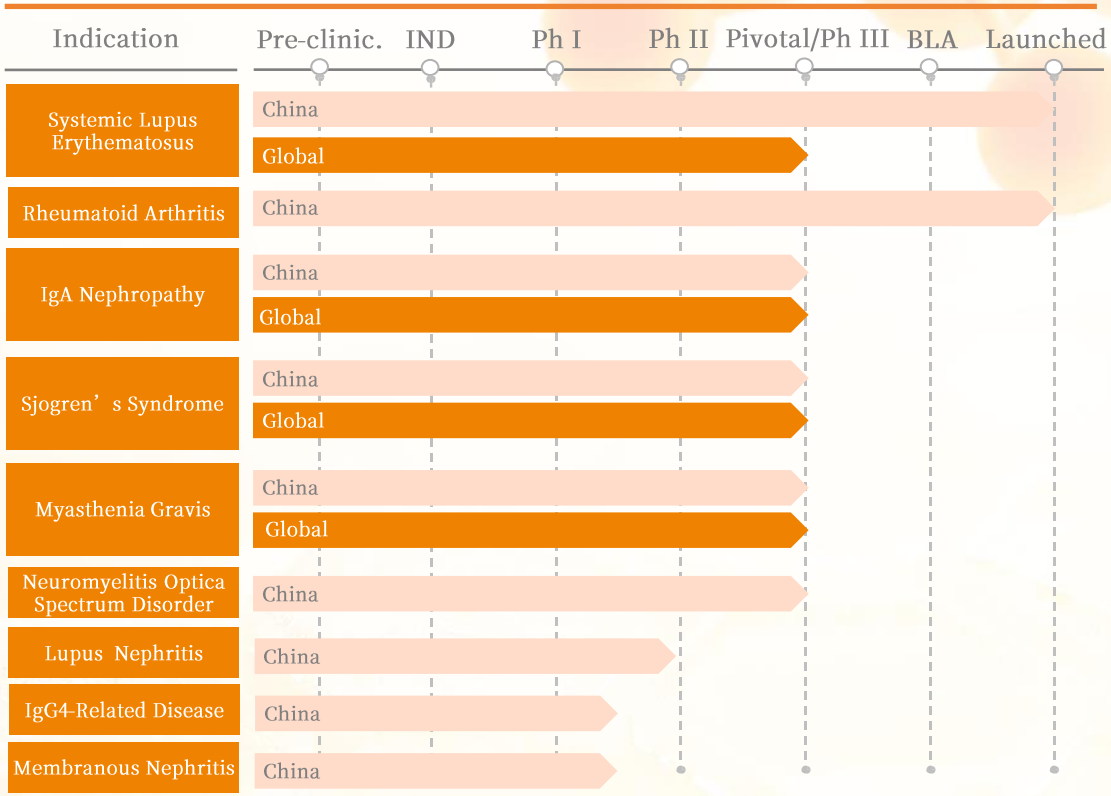


Dual-targeting Mechanism of Action



	B-cell surface binding sites		
	BAFF-R	BCMA	TACI
BLyS	++	++	+++
APRIL	–	++	++

Development Status by Region



Telitacicept - Clinical Progress in China（SLE）

SLE（China）

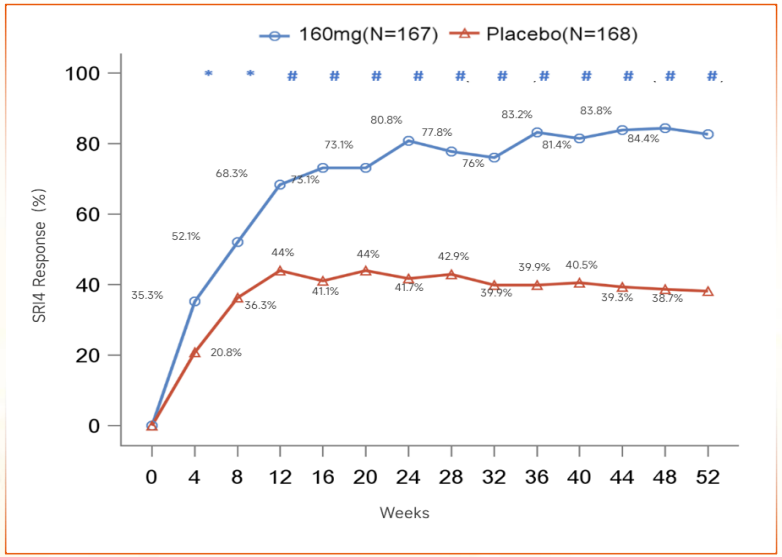
Launched in China

Phase III Clinical Trial

Enrolled 335 patients

- Telitacicept 160mg: 167
- Placebo: 168

Efficacy Data of Phase III Study



Telitacicept - Clinical Progress in China （RA）

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RA（China）

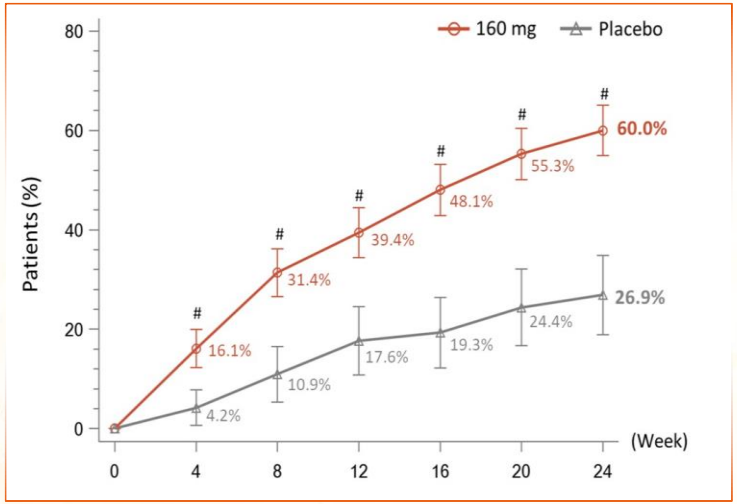
Launched in China in July, 2024

Phase III Clinical Trial

Enrolled **479** patients

- Telitacicept 160mg: 360 patients
- Placebo: 119 patients

Efficacy Data of Phase III Study



Telitacicept - Clinical Progress in China （IgAN）

IgAN (China)

Enrollment completed for the phase III study

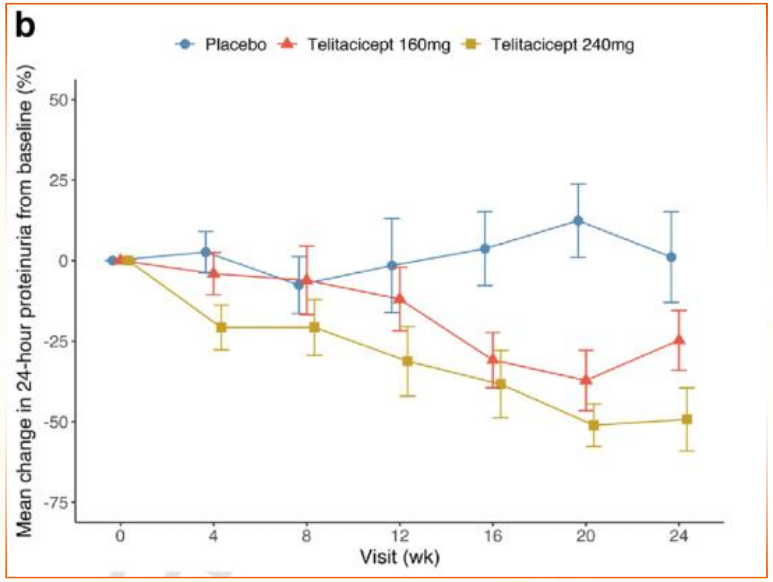
Phase II Trial

Enrolled **44** patients

- Telitacicept 160mg: 16 patients
- Telitacicept 240mg: 14 patients
- Placebo： 14 patients

KIDNEY WEEK 2021
San Diego, CA | Nov. 4-7

Efficacy Data of Phase II Trial



Telitacicept - Clinical Progress in China （MG）

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MG (China)

Phase III clinical trial reached primary endpoints in August, 2024

Phase II Trial

Enrolled 29 patients

- Telitacicept 160mg: 14 patients
- Telitacicept 240mg: 15 patients

CDE：Breakthrough Therapy Designation

Efficacy Data of Phase II Trial

160mg，n=14	240mg，n=15
QMG：-7.7	QMG：-9.6

Telitacicept - Clinical Progress in China （PSS）

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pSS（China）

Enrollment completed for the phase III study

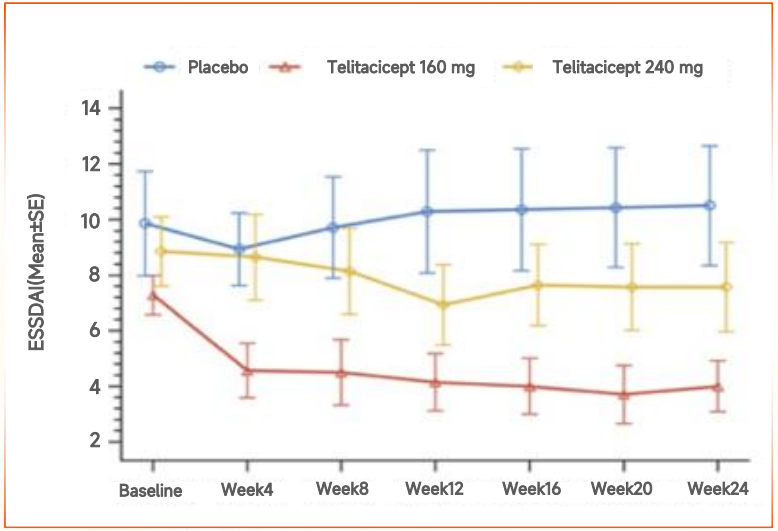
Phase II Trial

Enrolled 42 patients

- Telitacicept 160mg: 14 patients
- Telitacicept 240mg: 14 patients
- Placebo: 14 patients

British Society for Rheumatology

Efficacy Data of Phase II Trial



Telitacicept - Global Clinical Trials

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Telitacicept

Pushing forward registrational trials for SLE and other indications.

SLE

Global Phase III ongoing; plan to further accelerate the process.

MG

Obtained orphan drug and fast-track designations in the US.
Phase III first-patient-in.

IgA Nephritis

Reached consensus with FDA for the Phase III study

pSS

FDA granted the phase III IND, and fast track designation.

Telitacicept – New Indications for Domestic and Global Markets

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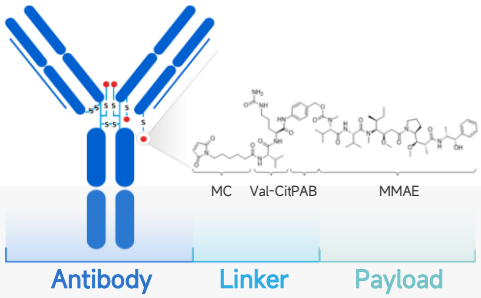
Aim to become

Leading drug for B-cell mediated auto-immune disease

- 2021 SLE（China） — Launched
- 2024 RA（China） — NDA
- 2025 MG（China） — Ph III
- pSS（China） — Ph III
- IGAN（China） — Ph III
- MG（Global） — Ph III
- 2030 SLE（Global） — Ph III

Clinical Progress of Disitamab Vedotin（RC48）



UC

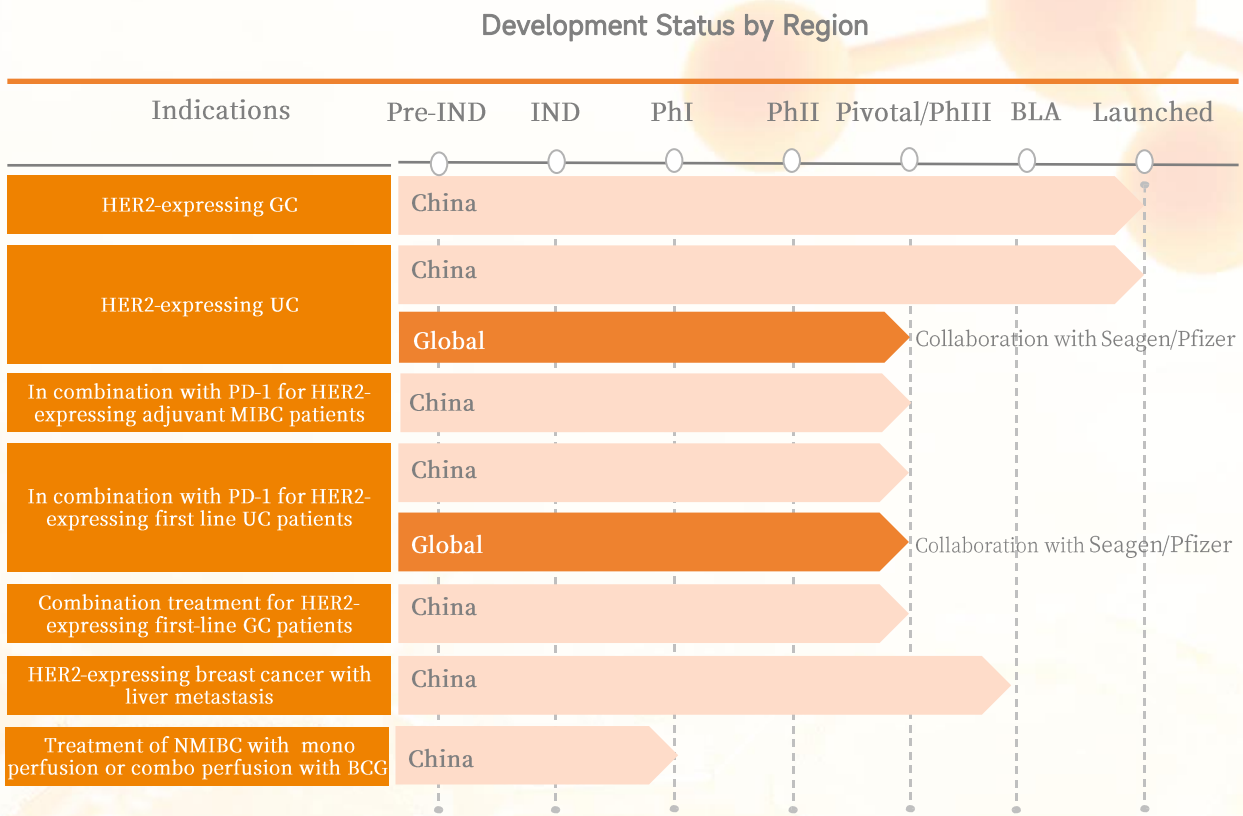
- Maintain the leading position in the UC indication;
- Continue to move into earlier line of treatments including first line, neoadjuvant and NMIBC settings;
- Enrollment completed in Phase III clinical trial of disitamab vedotin in combination with PD-1 for the treatment of advanced stage I urothelial cancer in China.

GC

Continue to push forward earlier line treatment studies in the GC field

BC

- Continue to push forward the earlier line treatment studies as well as HER2-low-expressing studies in the BC area.
- Phase III clinical trial of disitamab vedotin for the treatment of HER2-positive advanced breast cancer patients with liver metastasis achieved positive results



Data Continues to Support Disitamab Vedotin Leadership Position in Urothelial Cancer

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2024 ASCO ANNUAL MEETING

Clinical Data of Neoadjuvant Treatment with RC48 plus Toripalimab in muscle Invasive Bladder Cancer Patients with HER2 Expression.

Baseline Characteristics

- From May 2022 to Jan 2024, 47 eligible patients were enrolled.
- Patients demographics and baseline characteristics are shown in **Table 1.**

Table 1. Demographics and Baseline Characteristics

Characteristics	Patients enrolled N=47
Median age (range), years	64.0 (30, 82)
Male, n (%)	34 (72.3)
Histology, n (%)	
Pure urothelial carcinoma (UC)	36 (76.6)
UC with other differentiation or variants	11 (23.4)
Squamous differentiation	3 (6.4)
Glandular differentiation	2 (4.3)
Micropapillary features	2 (4.3)
Clear cell	1 (2.1)
Sarcomatoid	1 (2.1)
Others (with 2 types variants)	2 (4.3)
ECOG performance status, n (%)	
0	25 (53.2)
1	22 (46.8)
Baseline cTNM stage, n (%)	
cT2N0M0	19 (40.4)
cT3N0M0	14 (29.8)
cT4N0M0	6 (12.8)
cT2-4aN1M0	8 (17.0)
HER2 expression, n (%)	
IHC 1+	5 (10.6)
IHC 2+	27 (57.4)
IHC 3+	15 (31.9)
Creatine clearance, n (%)	
<60 mL/min	12 (25.5)
>=60 mL/min	35 (74.5)

Efficacy

- As of data cut-off date (15-Apr-2024), a total of 31 patients evaluable for efficacy underwent RC.

Table 2. Pathologic Response

	Evaluable Patients N=31	Historical NAC [2] GC	Historical NAC [2] ddMVAC
pCR (ypT0N0), n (%)	**19 (61.3)**	25.1%	35.2%
95% CI	42.2, 78.2	-	-
pPR (<ypT2, and N0), n (%)	**23 (74.2)**	46.5%	57.2%
95% CI	55.4, 88.1	-	-

NAC: neoadjuvant chemotherapy; GC: gemcitabine and cisplatin; dd-MVAC: dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin.

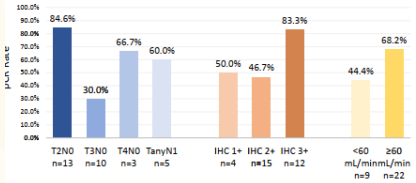

Figure 2. Subgroup Analysis for pCR Rate

Safety

- Treatment-related adverse events (TRAEs) were defined as treatment emergent adverse event related with either DV or toripalimab.
- Grade 3-4 TRAEs were reported in 14.9% of patients.

  Including gamma-glutamyltransferase increased, neutrophil count decreased, white blood cell count decreased, platelet count decreased, blood creatine phosphokinase increased, blood bilirubin increased, hepatic function abnormal, anaemia.
- No deaths occurred during the neoadjuvant stage.
- No surgery was cancelled due to TRAEs.

Table 3. Treatment Related Adverse Events

TRAEs in ≥ 20% of patients	N=47 Any Grade	N=47 Grade 3-4
Alopecia	18 (38.3)	0
Alanine aminotransferase increased	14 (29.8)	0
Aspartate aminotransferase increased	14 (29.8)	0
Rash	10 (21.3)	0
Peripheral sensory neuropathy	10 (21.3)	0

- No grade 3~5 DV-related peripheral neuropathy occurred.

Table 4. DV-related Peripheral Neuropathy

	N=47 Any Grade	N=47 Grade 2
DV-related peripheral neuropathy	17 (36.2)	1 (2.1)
Muscular weakness	1 (2.1)	0
Peripheral sensory neuropathy	9 (19.1)	0
Paraesthesia	5 (10.6)	1 (2.1)
Hypoaesthesia	3 (6.4)	0

Data First Time to Show Promising Potential of Disitamab Vedotin in Cervical Cancer

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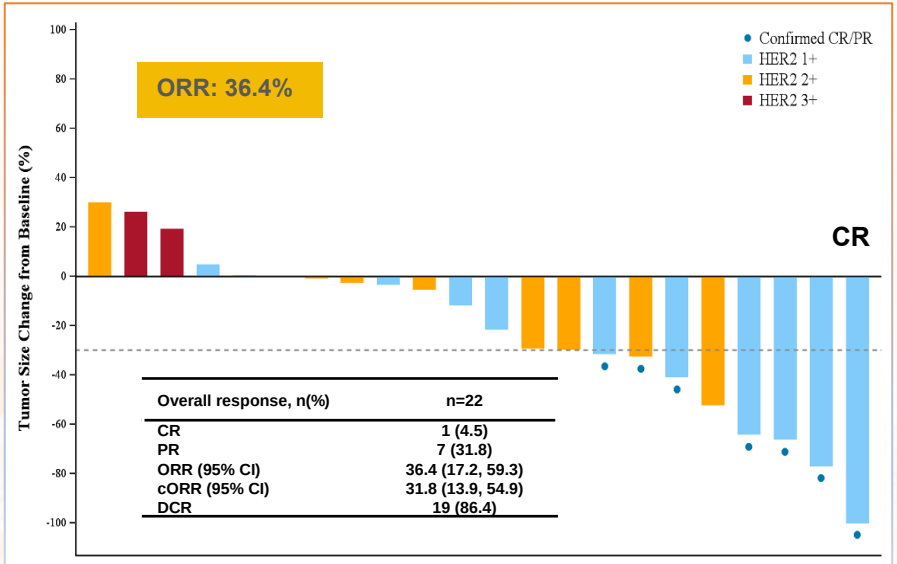
ESGO European Society of Gynaecological Oncology

25th European Congress on Gynaecological Oncology

March 7-10, 2024 | Barcelona, Spain

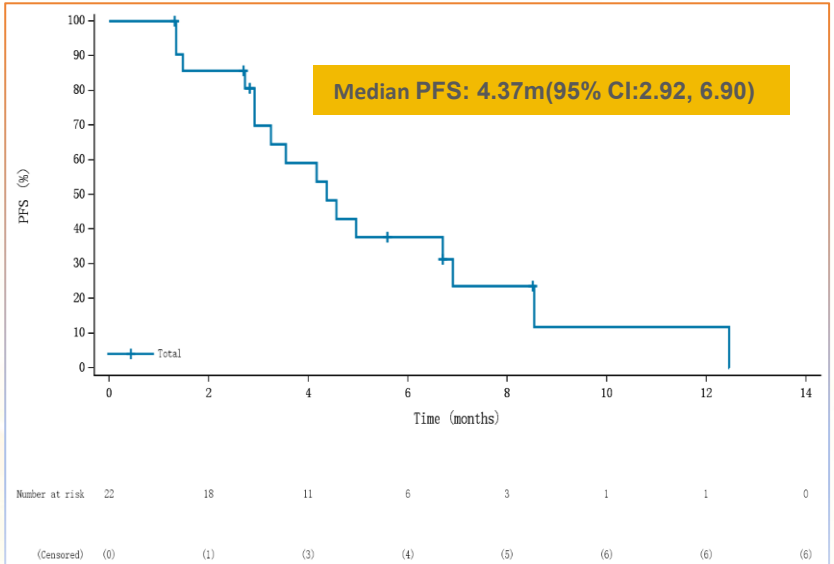
Clinical data of RC48 for HER2-expressing CC patients

Target Lesion Change from Baseline



Overall response, n(%)	n=22
CR	1 (4.5)
PR	7 (31.8)
ORR (95% CI)	36.4 (17.2, 59.3)
cORR (95% CI)	31.8 (13.9, 54.9)
DCR	19 (86.4)

PFS



*Based on literature, historical PFS was 2.1-5.0m.

Disitamab Vedotin （RC48）Global Clinical Progress

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Pivotal Study for Second-line UC Patients

Cohort 1 —— HER2 positive
Cohort 2 —— HER2-low-expressing
Cohort 3 —— Combination with PD-1

Treatment for Second-line UC Patients（Seagen /Pfizer ）

Enrollment ongoing

Phase III Study of First-line UC Patients

Treatment group —— DV + Keytruda
Control group —— Chemotherapy + Keytruda
Planned —— 700 patients

Combination with Keytruda for first-line UC Patients （Seagen /Pfizer ）

Enrollment ongoing

Clinical Progress of Other Molecules

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Status（Clinical Sites Indicated on Status Bar）

	Drug Candidates	Target	Modality	Indication	Status
Oncology	RC88	Mesothelin	ADC	In combination with PD-1 for advanced malignant solid tumors	China
				Ovarian Cancer, Carcinoma Tubae and Primary Peritoneal Cancer	China
	RC148	PD -1/VEGF	Bispecific-Antibody	Multiple solid tumors	China
				In combination with ADC for Multiple solid tumors	China
	RC198	IL-15/ IL-15Rα	Fusion Protein	Multiple solid tumors	China
	RC248	DR5	ADC	Multiple solid tumors	China
	RC278	Confidential	ADC	Multiple solid tumors	China
Ophthalmology	RC28	VEGF/FGF	Fusion Protein	Wet-AMD	China
				DME	China
				DR	China

Pre-IND | IND | Ph I | Ph II | Pivotal/Ph III | BLA | Launched

Data to Show RC88's First-in-Class Potential Position in Ovarian Cancer

2024 ASCO ANNUAL MEETING

Clinical Data of RC88 in Patients with Ovarian Cancer

Efficacy

1. OC Efficacy

- As of cut-off date (22-Mar-2024), a total of 31 efficacy-evaluable patients in 2.0mg/kg group that received 2-4 lines of therapies.
- Among the above pts, ORR and confirmed ORR (cORR) were 45.2% (14/31, 95%CI 27.3, 64.0) and 41.9% (13/31, 95%CI 24.5, 60.9), respectively.
- The median DoR was 8.02 mo (95%CI 2.83 8.54). The median OS was not yet mature and will be reported later (**Figure 3, 4**).

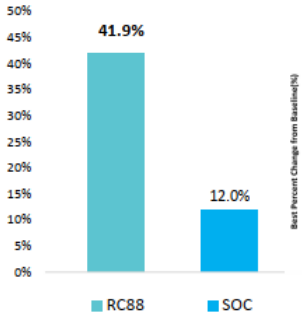

Figure 3 ORR Comparison of OC and SOC[3] (Standard of Care: Chemotherapy)

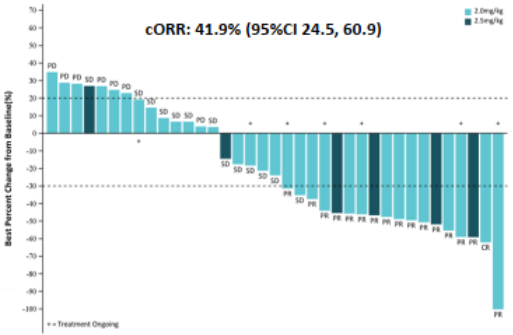

Figure 4 Target Lesion Change from Baseline of OC

Safety

- TRAEs are summarized in **Table 3** and **Table 4**. No RC88-related deaths occurred in the 2.0mg/kg group.
- The safety profile was better in 2.0mg/kg than 2.5mg/kg, therefore 2.0mg/kg was chosen as RP2D in further studies in China.

Table 3 Overview of TRAEs

Categories, n(%)	Dose Expansion (N=150)		Total (N=170)
	2.0mg/kg (N = 93)	2.5mg/kg (N = 57)	
TRAEs	88 (94.6)	55 (96.5)	163 (95.9)
TRAEs ≥ Grade 3	28 (30.1)	20 (35.1)	58 (34.1)
Treatment related SAE	10 (10.8)	11 (19.3)	22 (12.9)
TRAEs leading to treatment discontinuation	3 (3.2)	2 (3.5)	7 (4.1)
TRAEs leading to death	0	1 (1.8)	2 (1.1)

Table 4 Overview of Most Common TRAEs with Incidence ≥20%

Most common TRAEs (≥20%, PT), n(%)	Total (N = 170)	
	Any grade	≥ Grade 3
White blood cell count decreased	79 (46.5)	15 (8.8)
Neutrophil count decreased	75 (44.1)	38 (22.4)
Anaemia	65 (38.2)	7 (4.1)
Nausea	56 (32.9)	1 (0.6)
Aspartate aminotransferase increased	53 (31.2)	1 (0.6)
Alanine aminotransferase increased	47 (27.6)	0
Decreased appetite	47 (27.6)	1 (0.6)
Weight decreased	44 (25.9)	0
Asthenia	39 (22.9)	2 (1.2)
Vomiting	39 (22.9)	1 (0.6)

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03

COMMERCIALIZATION

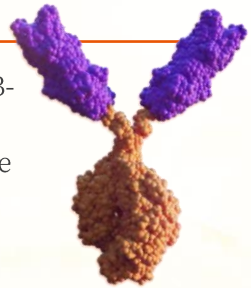
Commercialization - Telitacicept（泰爱®）

泰爱®

- Successfully included in the NRDL
- Recruited about 800 experienced sales members
- Listed in over 900 top-grade hospitals in core prefecture-level or above cities
- Covered over 26,000 targeted physicians

As the global first-in-class BLyS/APRIL dual-targeting recombinant TACI-Fc fusion protein drug, Telitacicept has achieved remarkable clinical results in SLE, and has the potential to become the **best-in-class** drug for lupus in the world.

It has shown promising results in many B-cell-mediated autoimmune diseases（including IgAN、pSS、MG), and has the potential to become a **leading drug for treating a variety of B-cell-mediated autoimmune diseases.**



Commercialization - Disitamab Vedotin（爱地希®）

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爱地希®

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- Listed in over 700 top-grade hospitals in core prefecture-level or above cities
- Covered over 25,000 targeted physicians

It is the first innovative ADC drug approved in China, and it is also the only China originated ADC drug that got **breakthrough therapy designation** in both China and U.S.

Expecting a dominant position in the **UC area**

Potential to show certain advantages in earlier lines of HER2-low-expressing GC and BC patients

UPCOMING CATALYSTS in 2024

01

Telitacicept :

- ✓ China MG Phase III data readout and BLA submission
- ✓ Global SLE Phase III stage II first patient in.

02

Disitamab Vedotin :

- ✓ China HER2-expressing breast cancer with liver metastasis BLA submission
- ✓ Global RC48G001 (RC48+PD-1 in UC) results oral presentation on 2024 ESMO

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04

COMPANY OVERVIEW

Remegen in a Snapshot

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Dual-Listed Company

Main Board of HKEX (09995.HK)
Sci-Tech Innovation Board of SSE (688331.SH)

Three Technology Platforms

Antibody Discovery | ADC | Bispecific Antibody

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Two Commercialized Products

Telitacicept（First-in-Class）
Disitamab Vedotin（Best-in-Class in UC）

Three Therapeutic Areas

Autoimmunity | Oncology | Ophthalmology

Full-fledged Biopharma Company

Discovery | Clinical Development | Manufacturing| Commercialization

Superior Management Team with Strong Track Record

Weidong WANG

Co-Founder,
Chairman,
Executive Director

- Representative of China’s 13th National People’s Congress
- Founded and managed RC Pharma in 1992; 30 years of entrepreneurial, operational and managerial experience in the pharmaceutical sector
- Bachelor degree in pharmacy; visionary and deep understanding of the pharmaceutical industry

Dr. Jianmin FANG

Co-Founder,
CEO,
Executive Director

- Member of scientific expert committee of the National Scientific and Technological Major Project for “Major Drug Innovation”
- Over 20 years of experience in biopharma R&D
- Over 40 drug invention patents
- Strong corporate leadership and capabilities of organization and management

Dr. Ruyi HE

CSO,
Head of Clinical Research,
Executive Director

- Deputy Division Director at FDA
- Chief Scientist at CDE of the NMPA
- Involved in FDA guidance development in multiple therapeutic areas
- Plays a major role in global registration and international multi-center clinical trials

Proven Ability to Transform R&D into Commercialization

R&D Center

World-class drug discovery facilities for molecular discovery, process research, formulation development, quality control, and pilot production in Yantai, Shanghai and California, U.S.
Highly efficient clinical development team in China and the U.S.

Commercialization Facilities

Established a biologic drug production system complying to international GMP standards with a capacity of 42,000 liters, expanding to total production capacity of over 80,000 liters by 2025.

Commercialization Team

Telitacicept – about 800 member rheumatology focused sale team
Disitamab Vedotin – about 600 member oncology focused sale team

Global Presence

1、Headquartered in Yantai
Production, R&D, Clinical & Admin

2、South San Francisco
Early Stage Discovery

3、Shanghai R&D Centre
Early Stage Discovery

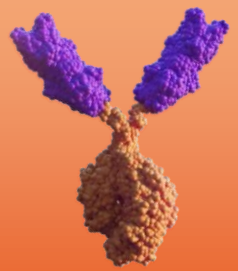
4、Beijing
Clinical & Registration

5、Rockville, Maryland
Global Clinical & Registration

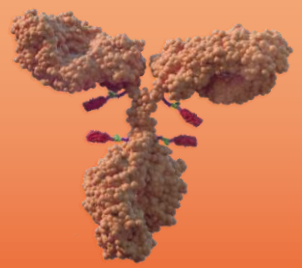
6、Australia
Clinical & Registration

7、Hong Kong
Capital Market Operation

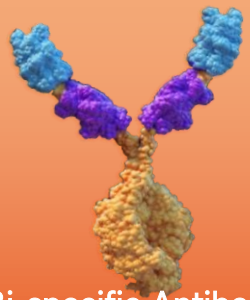
Three Core Technical Platforms



Antibody Discovery Platform



Antibody-drug Conjugate Platform



Bi-specific Antibody Platform

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Questions & Answers