RemeGen
荣昌生物

RemeGen
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A Solid Foundation Drive Innovation and Profitability

2 Commercialized drugs

Well established team delivering product potential

- ***Telitacicept (RC18)*** *- FIC Blys-April fusion protein drug*
- ***Disitamab vedotin (RC48)*** *- First domestic HER-2 ADC launched in China, ex-China rights out-licensed to* ***Pfizer***

30+ Clinical trials ongoing

Immunology and oncology focused pipeline

- ***30+*** *clinical trials ongoing including*
- ***6*** *proprietary new molecules in clinical stage*
- ***30*** *pre-IND stage projects*

3300+ Employees

Fully integrated biopharma

- ***1000+*** *R&D*
- ***1400+*** *commercialization*
- ***500+*** *manufacturing*

Commercialization Yielding Fruits

Strong revenue growth with improving efficiency

70K+

Liters of biologic manufacturing facility

State-of-the-art infrastructure in Yantai

Self owned R&D center and manufacture facility

Key Highlights in the Past Year and Future Expectations

Accomplishments in 2024

Approval for Marketing
RC18 RA in China

BLA Submission
RC18 MG
RC48 HER2+ BC with liver metastasis

Catalysts in 2025

Approval for Marketing
RC18 MG in China
RC48 HER2+ BC with liver metastasis

BLA Submission
RC18 IgAN
RC18 pSS
RC28 DME
RC48 1L UC
RC48 HER2 low BC

Telitacicept - Maximize Commercial Potential

2
Approved Indications for Marketing

1
Indication in BLA Review

5+
Indications in Phase 3 Trials

8+
Indications in Planning/Initiating

LAUNCHED	*Pivotal/Phase 3*	*New Indications*	
Systemic Lupus Erythematosus	*Systemic Lupus Erythematosus	Lupus Nephritis	CTD-ILD
Rheumatoid Arthritis	Myasthenia Gravis	Membranous Nephritis	Idiopathic Thrombocytopenic Purpura
	*Sjogren's Syndrome	IgG4-Related Disease	Ocular Myasthenia Gravis
BLA	*IgA Nephropathy	Pediatric Systemic Lupus Erythematosus	Autoimmune Hepatitis
Myasthenia Gravis	Neuromyelitis Optica Spectrum Disorder		

*Global Phase 3 Ready

Telitacicept - First BLyS/APRIL Dual-Targeting Drug for SLE

SLE Market Size

8.55 million patients in global

1.10 million patients in China

$14.3 billion
Market size expected in 2030 (Global)

Source: Frost & Sullivan

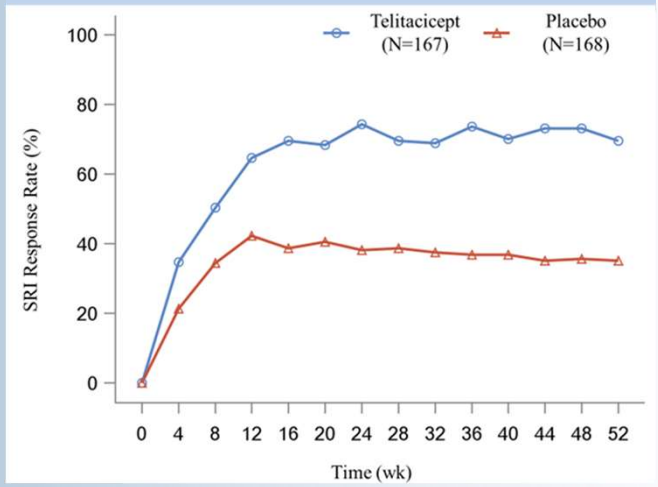
Clinical Results

Phase 3 Clinical Trial in China

335 patients

- Telitacicept: 167
- Placebo: 168

Efficacy Data of Phase 3 Study
(SRI-4 response)



Note: Missing data was inputted as non responder in SRI-4

Key Milestones

Conditional approval in China in 2021

Full Approval in China 2023

Robust sale growth (80+% increase 2024 3Q Vs. 2023 3Q)

Telitacicept for Rheumatoid Arthritis (RA)

RA Market Size

45.0 million patients in global

6.4 million patients in China

$65.7 billion
Market size expected in 2030 (Global)

Source: Frost & Sullivan

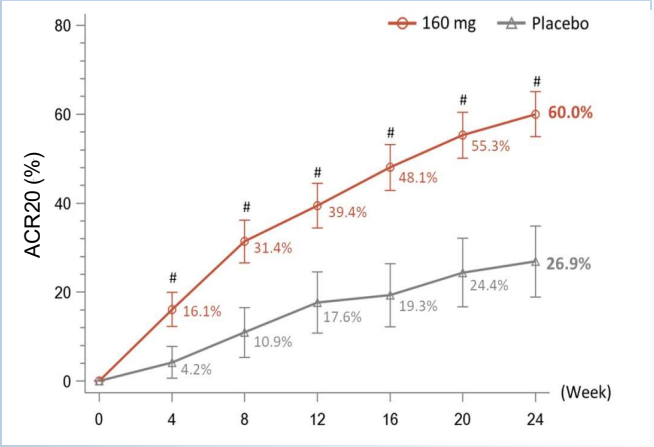
Clinical Results

Phase 3 Clinical Trial in China

479 patients

- Telitacicept: 360 patients
- Placebo: 119 patients

Efficacy Data of Phase 3 Study



Key Milestones

China Phase 3 Study met primary end point Q2 2023

China BLA filing Q3 2023

China BLA Approval Q3 2024

Telitacicept for Myasthenia Gravis (MG)

MG Market Size

1.20 million patients in global

0.22 million patients in China

$7.24 billion
Market size expected in 2030 (Global)

Source: Frost & Sullivan

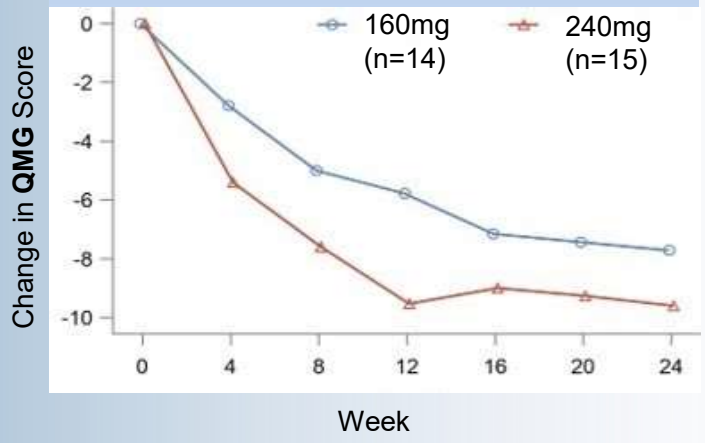
Clinical Results

Phase 2 Clinical Trial in China

Enrolled 29 patients

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

Efficacy Data of Phase 2 Trial



Key Milestones

China Phase 3 Study met primary endpoint Q3 2024

China BLA filing Q4 2024

Potential China BLA Approval Q2 2025

Telitacicept for IgA Nephropathy (IgAN)

IgAN Market Size

10.2 million patients in global

2.37 million patients in China

$2.50 billion
Market size expected in 2030 (Global)

Source: Frost & Sullivan

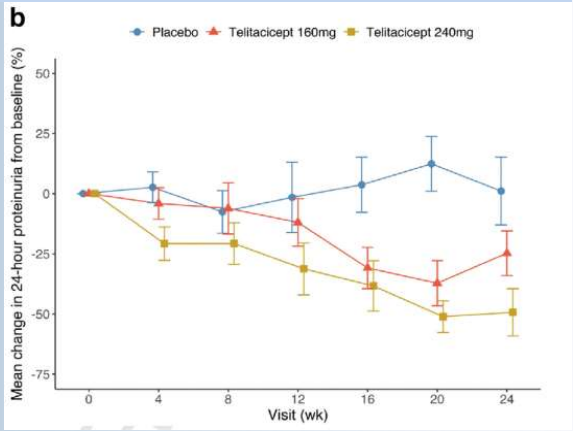
Clinical Results

Phase 2 Clinical Trial in China

Enrolled 44 patients

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

Efficacy Data of Phase 2 Trial



Key Milestones

China Phase 3 Study LPI Q2 2024

9M Data readout 1H 2025

Potential BLA filing 1H 2025

Telitacicept for Primary Sjogrens Syndrome (pSS)

pSS Market Size

4.28 million patients in global

0.65 million patients in China

$6.1 billion
Market size expected in 2030 (Global)

Source: Frost & Sullivan

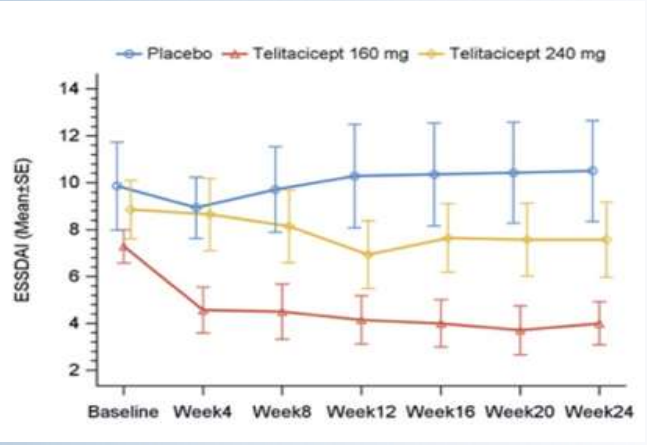
Clinical Results

Phase 2 Clinical Trial in China

Enrolled 42 patients

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

Efficacy Data of Phase 2 Trial



Key Milestones

China Phase 3 Study LPI Q2 2024

Data readout 1H 2025

Potential BLA filing 2H 2025

Key Oncology Trials Ongoing/Initiating

	Urothelial Cancer	Gastric Cancer	Breast Cancer	Ovarian Cancer	NSCLC
Early stage (Perioperative)	**Ph2 NMIBC** RC48 mono IVE **Ph2 MIBC** Perioperative RC48 + PD-1	**Ph2 GC** Perioperative RC48 + PD-1 ± chemo	**Ph2 HER2 low TNBC** RC48+PD-1+combo **Ph2 HER+ BC** RC48+Pertuzumab±PD-1		
1L	**Ph3 r/m UC** RC48 + PD-1 **Ph3 r/m UC** RC48 + PD-1	**Ph3 HER2+ mGC** RC48 + PD-1 + trastuzumab **Ph3 HER2 low mGC** RC48 + PD-1 + chemo **Ph2 mGC (HER2+ and Low)** RC48 + PD-1 + chemo/ trastuzumab **Ph2 CLDN18.2+ mGC** RC118 + RC148 / PD-1 + chemo	**Ph2 HER2 low TNBC** RC148+RC48		**Ph2 NSCLC** RC148 + chemo **Ph2 NSCLC** RC108 + Furmonertinib
2L	**Ph2 Pivotal r/m UC** RC48 + PD-1	**Ph2 CLDN18.2+ mGC** RC118 + RC148 / PD-1 **Ph2 HER2+ mGC** RC148 + RC48 **Ph2 HER2 Ex GC** RC48 + Tucatinib	**Ph3 HER2+ BC** RC48 mono **Ph3 Her2 low BC** RC48 mono **Ph2 HER2 Ex BC** RC48 + Tucatinib	**Ph2 PROC** RC148 + RC88 **Ph2 PROC** RC88 +PD-1	**Ph2 NSCLC** RC148 + Docetaxel **Ph2 NSCLC** RC148+RC88 **Ph2 NSCLC** RC88 +PD-1 **Ph2 NSCLC** RC108 + Furmonertinib **Ph1 DR5+ NSCLC** RC248 mono

RC48
RC88
RC108
RC118
RC148
RC248

Global studies, conducted by Pfizer

Clinical Strategy of Oncology Pipeline

Focus on solid tumors | ***Develop innovative drugs*** | ***Drive therapeutic transformation***

1

Expand indications for approved drug

- UC 1L: RC48-C016
- GC 1L: RC48-C039/C040
- BC 2L+ with liver metastasis: RC48-C006
- HR+/HER2-low: RC48-C012
- TNBC 1L: RC48-C036

2

Explore druggability for new targets

- MSLN-RC88
- cMET-RC108
- CLDN18.2-RC118
- BsAb-RC148
- DR5-RC248

3

Explore new treatment combinations

- ADC+PD-1

RC48+Toripalimab in C016/C017

- ADC+TKI

RC108+Furmonertinib in RC108 C001

- ADC+Chemo

RC48+CAPOX/trastuzumab +Toripalimab in C027/C039/C040

- BsAb combination

RC148+RC48/RC148+RC88/RC148+RC118

4

Develop next-generation technology platform

- New payload
- New linker technology
- Next-Generation ADC and BsAb platform

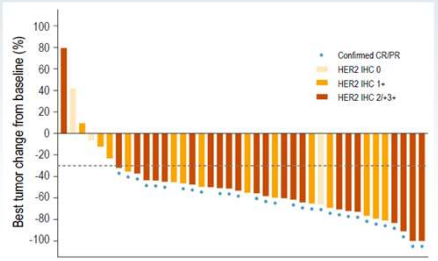
Expand Indications for RC48: Urothelial Cancer (UC)

1

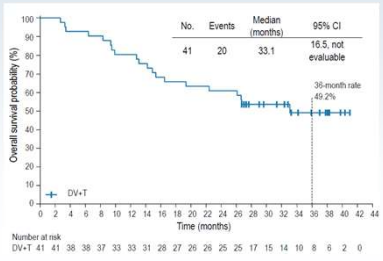
RC48-C014

1L/2L mUC POC study (RC48+Toripalimab)

Confirmed ORR was 75.0%



Median OS was 33.1m



ESMO 2024

RC48-C017

Perioperative POC study (RC48+Toripalimab)

pCR rate was 61.3%

Table 2. Pathologic Response

	Evaluable Patients N=31	Historical NAC [2] GC	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	-	-

ASCO 2024

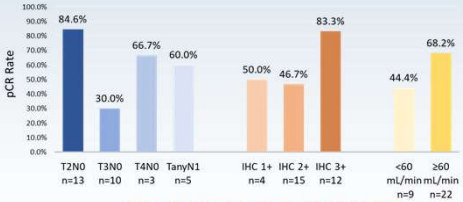


Figure 2. Subgroup Analysis for pCR Rate

RC48-C016

1L mUC Ph3 design

Key eligibility criteria

- Unresectable la/m UC
- HER2 IHC 1+，2+，3+

Stratified by

- Cisplatin eligibility
- Organ metastasis or not

R 1:1

N=452

Arm A: RC48 2mg/kg Q2W + Toripalimab 3mg/kg Q2w

Arm B: Gemcitabine Q3W + Cisplatin Q3W, For up to 6 cycles

Primary endpoints

- PFS (per IRC)
- OS

Estimated data readout: 1H 2025

Expand Indications for RC48: Gastric Cancer (GC)

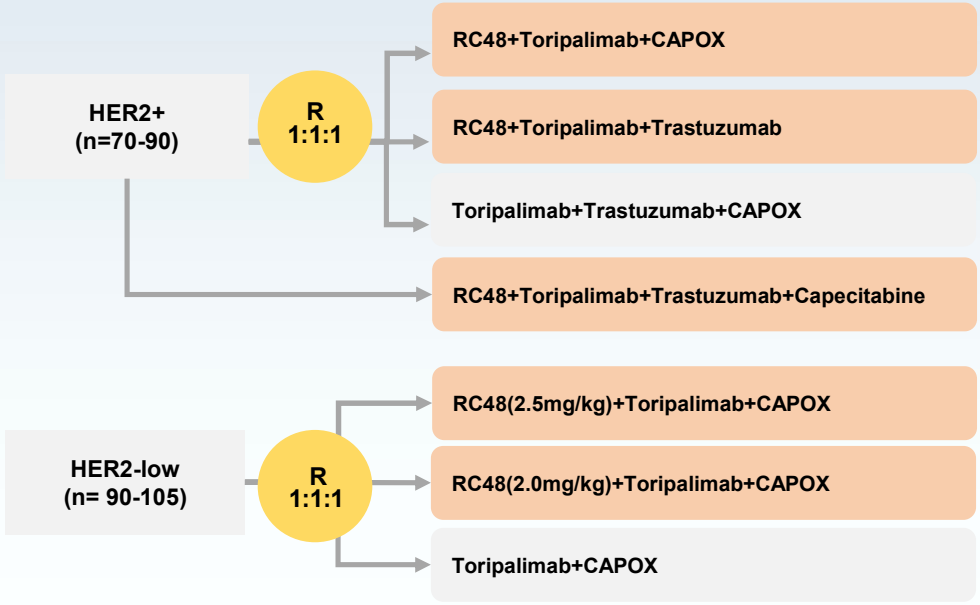
1

RC48-C027

1L la/m GC/GEJ POC study

Key eligible criteria:

- Locally advanced or metastatic gastric cancer (including gastroesophageal junction cancer)
- HER2 Expression:
  - ✓ HER2+: IHC3+ or IHC2+/FISH+
  - ✓ HER2-low: IHC2+/FISH-or IHC1+



RC48-C039

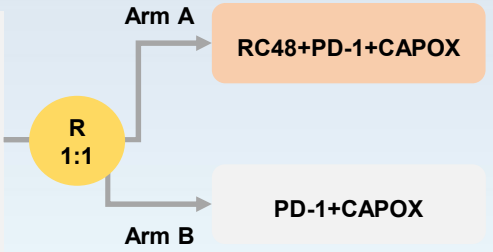
Phase 3 trial design of 1st line in HER2 expression GC/GEJ patients is currently under discussion with CDE

Key eligible criteria

- la/m GC/GEJ
- HER2 IHC 1+, 2+/FISH-

Stratified by

- HER2 status
- PD-L1 expression



Primary endpoints
- PFS (per IRC)

Key secondary endpoint
- OS

Expand Indications for RC48: Breast Cancer (BC)

1

RC48-C006

2L+ HER2+ BC with liver metastasis

Key eligible criteria
- BC w/ liver metastasis
- HER2 IHC 3+, 2+/FISH+

Stratified by
- Prior lines of chemo (≤1 vs. 2)
- Lung metastasis (yes or no)

R 1:1

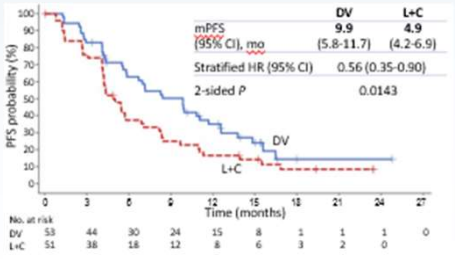
N=53 → RC48(2.0mg/kg), Q2W → Permitted to crossover

N=51 → L+C, Q3w

Primary endpoints
- PFS (per IRC)

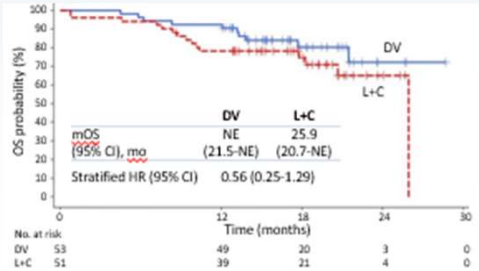
RC48 vs L+C

mPFS 9.9 vs 4.9 months, HR: 0.56



RC48 vs L+C

mOS NE vs 25.9 months, HR:0.56



SABCS 2024

RC48-C012

2L+ HER2-low BC Ph3 design

Key eligible criteria
- Unresectable Ia/m BC
- HER2 IHC 2+/FISH-
- HR positive or negative

R 1:1

N=377 → RC48 2.0mg/kg

N=377 → TPC (paclitaxel/docetaxel/ vinorelbine/capecitabine)

Primary endpoints
- PFS (per IRC)

RC48-C036

1L HR-/HER2-low BC Ph2 design

Key eligible criteria
- Ia/m BC
- HER2 IHC 1+, 2+/FISH-
- HR negative

R 1:1

N=20-30 → RC48+RC148

N=20-30 → PD-L1 -: Albumin-bound paclitaxel
PD-L1 +: Toripalimab+Albumin-bound paclitaxel

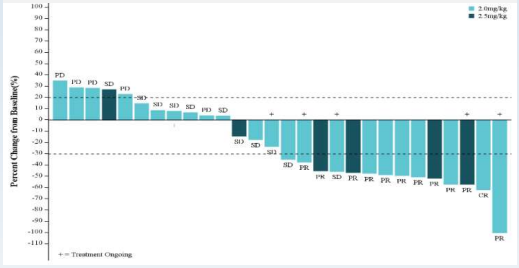
Primary endpoints
- PFS (per IRC)

Explore Druggability for New Targets: MSLN / c-MET / CLDN18.2

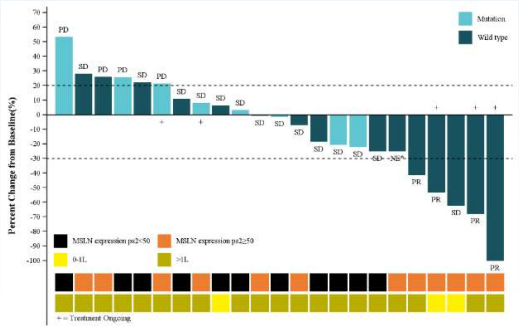
RC88 (MSLN)

- *RC88 is a first-in-class, ADC targeting MSLN with MMAE as payload. More than 70% of RC88 contains DAR of 4.*
- *FDA has granted RC88 FTD in PROC in Jan 2024.*

Efficacy in patients with OC
ORR 45.2% / cORR 41.9%



EGFR/ALK wildtype w/ MSLN PS2*>50
ORR 41.7%



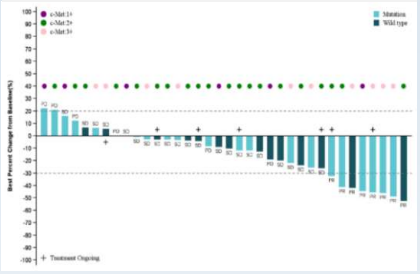
*PS2: percentage of tumor cells staining at moderate/strong intensity (IHC 2+ or high)

ASCO 2024

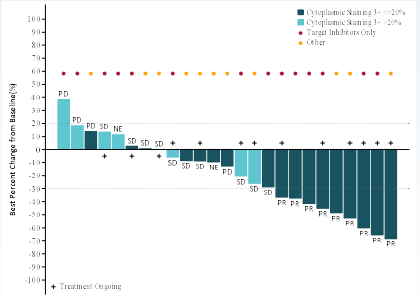
RC108 (c-MET)

- *RC108 is an ADC targeting c-MET with MMAE as payload.*

EGFRm + c-MET high expression**
RC108 mono ORR 30%



EGFRm + c-MET high expression**
RC108 + Furmonertinib ORR 50%

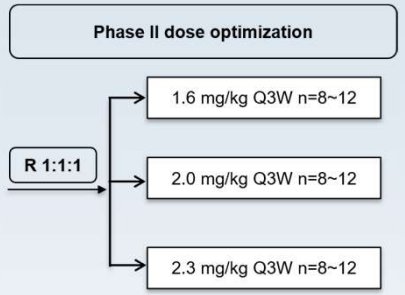


**c-MET high expression: IHC1+ with cytoplasmic 3+ ≤20%

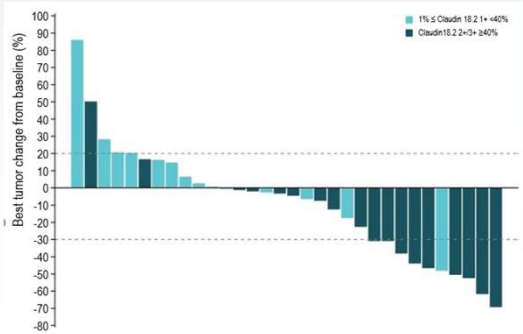
- *A randomized, controlled, open-Label Phase III clinical study (comparing RC108+Furmonertinib vs. Furmonertinib in patients with EGFR+/MET overexpression) is currently being planned.*

RC118 (CLDN18.2)

- *RC118 is an ADC targeting CLDN18.2 with MMAE as payload*
- *RC118 monotherapy exhibited promising ORR in heavily pretreated CLDN18.2 positive GC patients.*



2.0 mg/kg ORR:54.5%
All patients ORR:44.4%

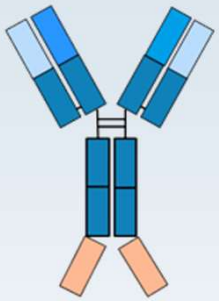


- *The Phase 2 study of R118 combined with PD-1 or RC148 is currently being enrolled and has initially seen good efficacy.*

ESMO 2024

Explore Druggability for New Targets: RC148 (PD-1/VEGF)

RC148(PD-1/VEGF)



Anti-PD-1 antibody

Anti-VEGF nanobody

RC148
(PD-1 x VEGF BsAb)

Design of RC148

- Symmetrical structure, 2+2 format,
- MW about 170 kDa
- Fc function silent
- Preferred CMC/manufacturability

RC148 Clinical studies completed or on going

Dose escalation and expansion/optimization

Phase1 study

- Dose escalation and expansion in solid tumor
- Combo with Docetaxel in NSCLC

Ph1 data supported dose optimization and selection.

POC study in NSCLC

Phase 2 study

- Combo with chemo in 1L NSCLC
- Combo with chemo in 2L AGA+ NSCLC

Ph2 data to support pivotal study in NSCLC.

Combo with ADCs

Phase 1b studies

- Combo with RC118 in GC
- Combo with RC88 in PROC
- Combo with RC48 in GC and BC

Ph2 data served as POC to support potential pivotal studies for combo therapy.

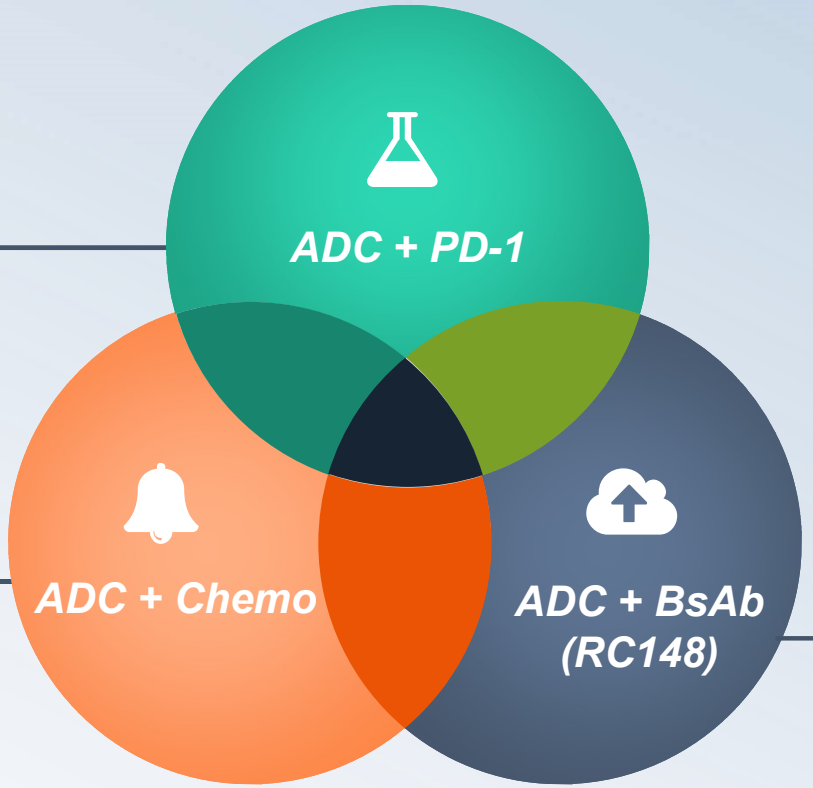
Explore New Treatment Combinations

ADC + PD-1

RC48+Toripalimab in C016/C017

ADC + Chemo

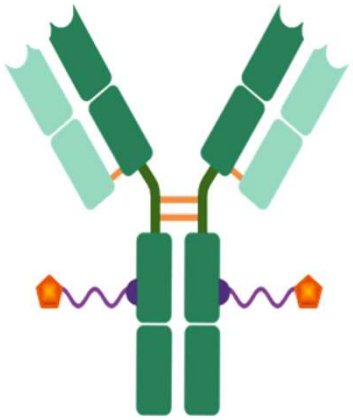
RC48+CAPOX/trastuzumab +PD-1antibody in C027/C039/C040



ADC + BsAb (RC148)

RC148+RC48/RC148+RC88/RC148+RC118…

Develop Next-generation Technology Platform



Payload development:
- Topoisomerase I inhibitor
- Non-cytotoxic payloads

Linker development:
- Bivalent linkers

Site specific conjugation :
- PY-thiol bridging
- Glycan-conjugation
- Cys-engineered thiomAb

Novel technology to enhance ADC safety and efficacy

NEW IND in 1H 2025: RC278

An ADC presenting FIC/BIC potential

Target：
A novel tumor associated antigen

Antibody：
A humanized mAb

Linker-Payload ：
A Topo1 based payload with a cleavable linker

Conjugation：
Site-specific, DAR=8

Progress in Ophthalmology Product (RC28)

RC28-E is a novel dual decoy receptor Fc-fusion protein that can potentially block vascular endothelial growth factor (VEGF) and fibroblast growth factor-2 (FGF-2) simultaneously

DME

8.8 *million patients (China)*

13.0 *billion RMB*

Market size expected in 2030 (China)

Source: Frost & Sullivan

Q1 2024

Completed enrollment for phase Ⅲ study (China)

H2 2025

BLA filing (China)

wAMD

4.9 *million patients (China)*

8.0 *billion RMB*

Market size expected in 2030 (China)

Source: Frost & Sullivan

Q4 2024

Completed enrollment for phase Ⅲ study (China)

H1 2026

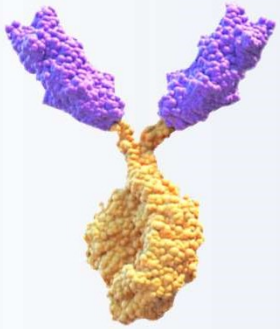
BLA filing (China)

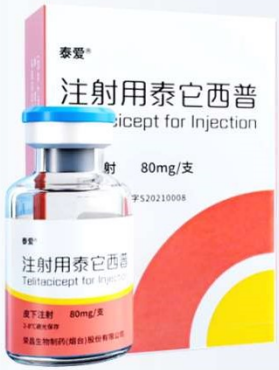
DR

2024

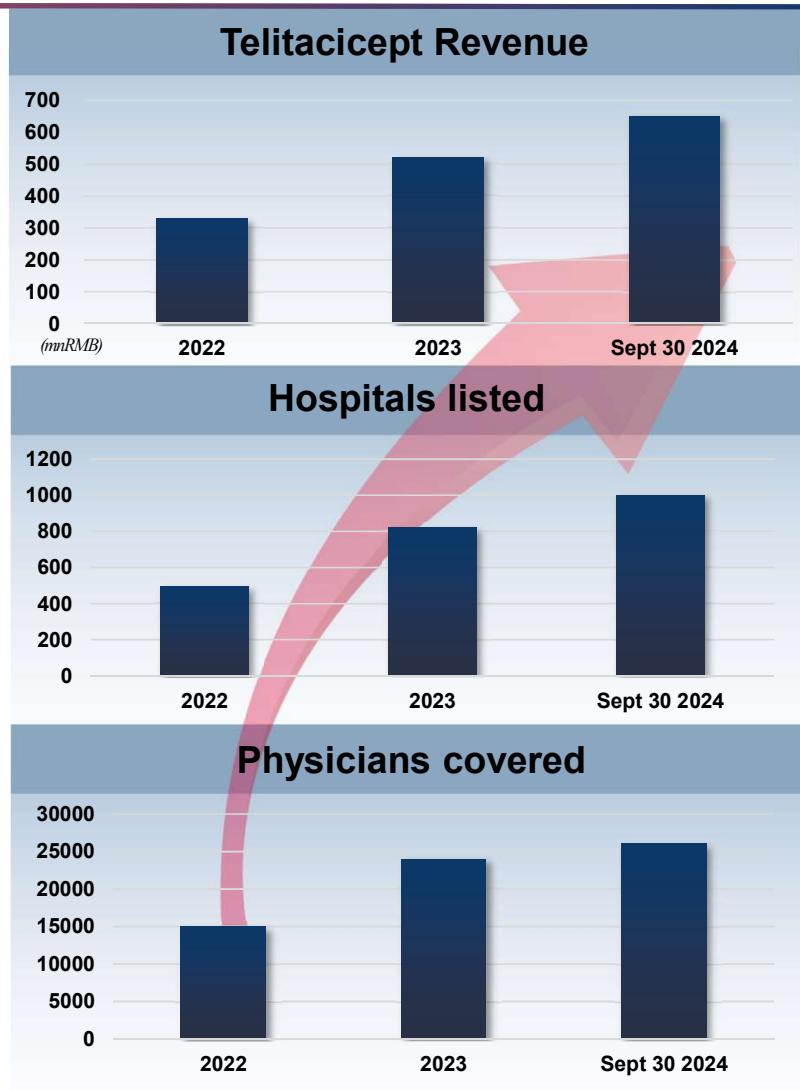
Phase Ⅱ study completed (China)

Commercialization – Telitacicept 泰爱®

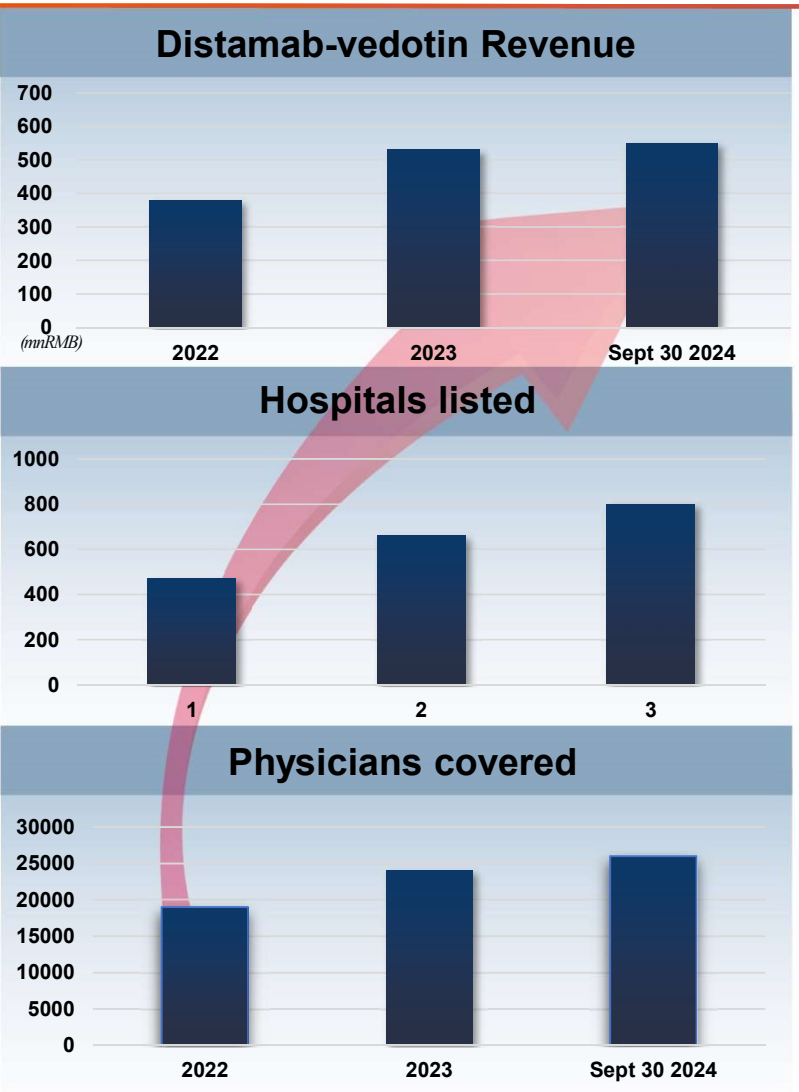




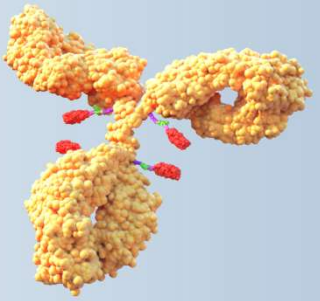
- First-in-class BLyS/APRIL dual-targeting drug
- Approved for SLE and RA in China
- ~800 member rheumatology focused sales team
- Listed in 1000+ hospital procurement list
- Covering 25,000+ targeted doctors
- New indications (MG,IgAN,pSS, and etc) to provide sustained growth driver in the coming years
- Aim to become a leading therapy in treating B-cell-mediated autoimmune diseases



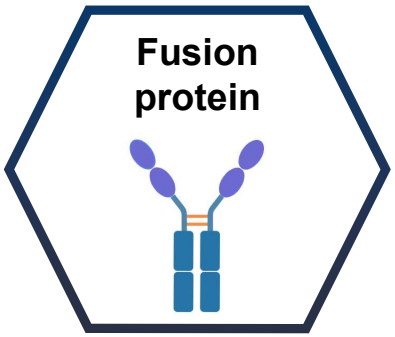
Commercialization - Disitamab Vedotin 爱地希®

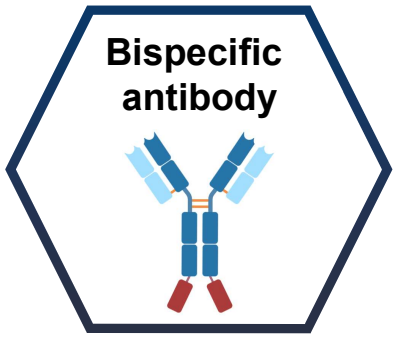


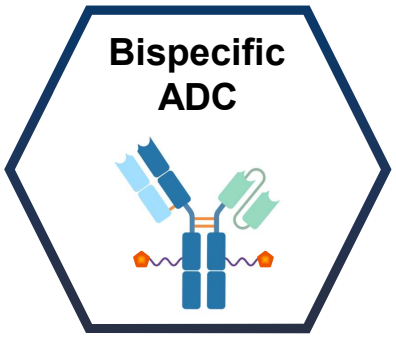
- The first domestic ADC drug approved in China
- Approved in 2L(+) UC and GC patients
- ~600 member oncology focused sales team
- Listed in 800+ hospital procurement list
- Covering 25,000+ targeted doctors
- Solidifying a leading position in HER-2 expressing urothelial cancer patients
- Multiple ongoing trials to expand the target patient pool



Cutting-edge Technology Platform for FIC and BIC Molecules







Target Discovery

Identify novel targets and bispecific pairs by AI driven multi-omics deep biology analysis

Antibody Discovery

Generate monoclonal antibodies and nanobodies by hybridoma and display platforms

Protein Engineering

Employ structure-based approach for humanization, affinity maturation and manufacturability design

ADC Technology

Develop novel payloads, site-specific conjugation, and next generation ADC platform

Four Technology Pillars To Enable Innovative Therapeutic Development

RemeGen
荣昌生物

THANK YOU