



# RemeGen

## JP Morgan Healthcare Conference

San Francisco, January 15, 2025



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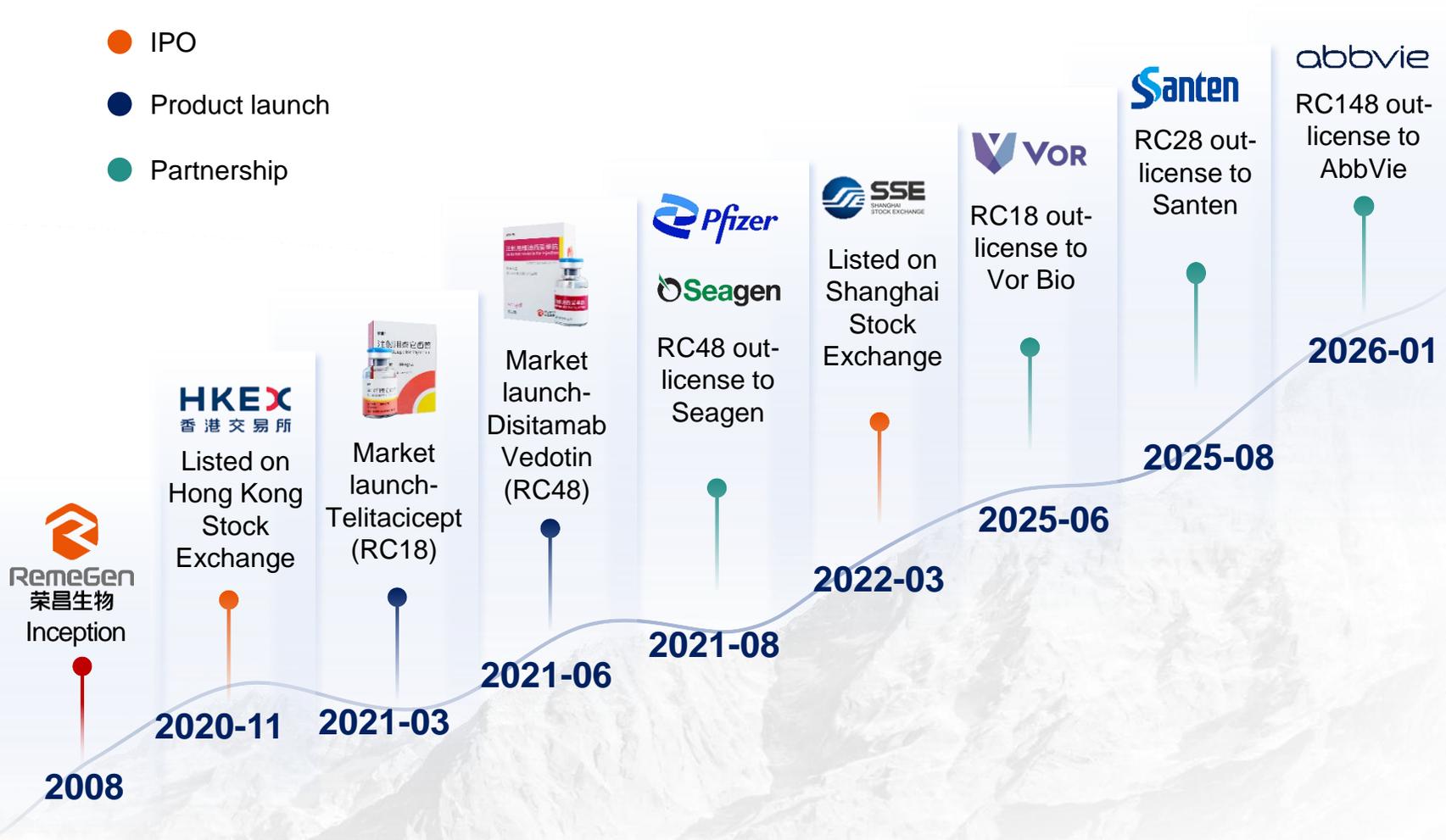
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# A Fully Integrated Biopharma with Stellar Track Record

## Company Milestone and Collaborations

- IPO
- Product launch
- Partnership



**4** Phase III clinical trials initiated in 2025

**7** Indications granted BTD by HAs

**10+** Indications approved or under BLA review

**70+** Completed or ongoing clinical trials

**7000+** Patients treated in clinical trials

# Highlights of Key Accomplishments in 2025

## Business Development

**Telitacicept (RC18)**  
Licensing Deal with Vor Bio



**RC28-E**  
Licensing Deal with Santen



## Data & Publication

### Telitacicept (RC18)

- **gMG:**
- 24-wk Data-AAN 
- OLE 48-wk Data-AANEM 
- **SjD:** LBA Poster Presentation-ACR 
- **IgAN:** LBA Oral Presentation-ASN 
- **SLE:** NEJM Publication 

### Disitamab Vedotin (RC48)

- **RC48-C016: Ph3 study in 1L UC**
- Oral Presentation-ESMO Presidential Symposium 
- NEJM Publication 
- **RC48-C027: Ph2/3 study in 1L GC**  
LBA Oral Presentation-ASCO 
- **RC48-C017: Ph2 study in neoadjuvant MIBC**  
Oral Presentation-ASCO GU 

## Regulatory Milestones

### Telitacicept (RC18)

- Marketing Approval for gMG (China)
- BLA Submission for SjD
- BLA Submission for IgAN

### Disitamab Vedotin (RC48)

- Marketing Approval for HER2+ BC with liver metastasis
- BLA Submission for HER2 low BC
- BLA Submission for 1L UC

### RC148

- CDE Approval for Ph3 1L NSCLC study
- CDE Approval for Ph3 2L NSCLC study
- FDA Approval for Ph3 2L NSCLC study

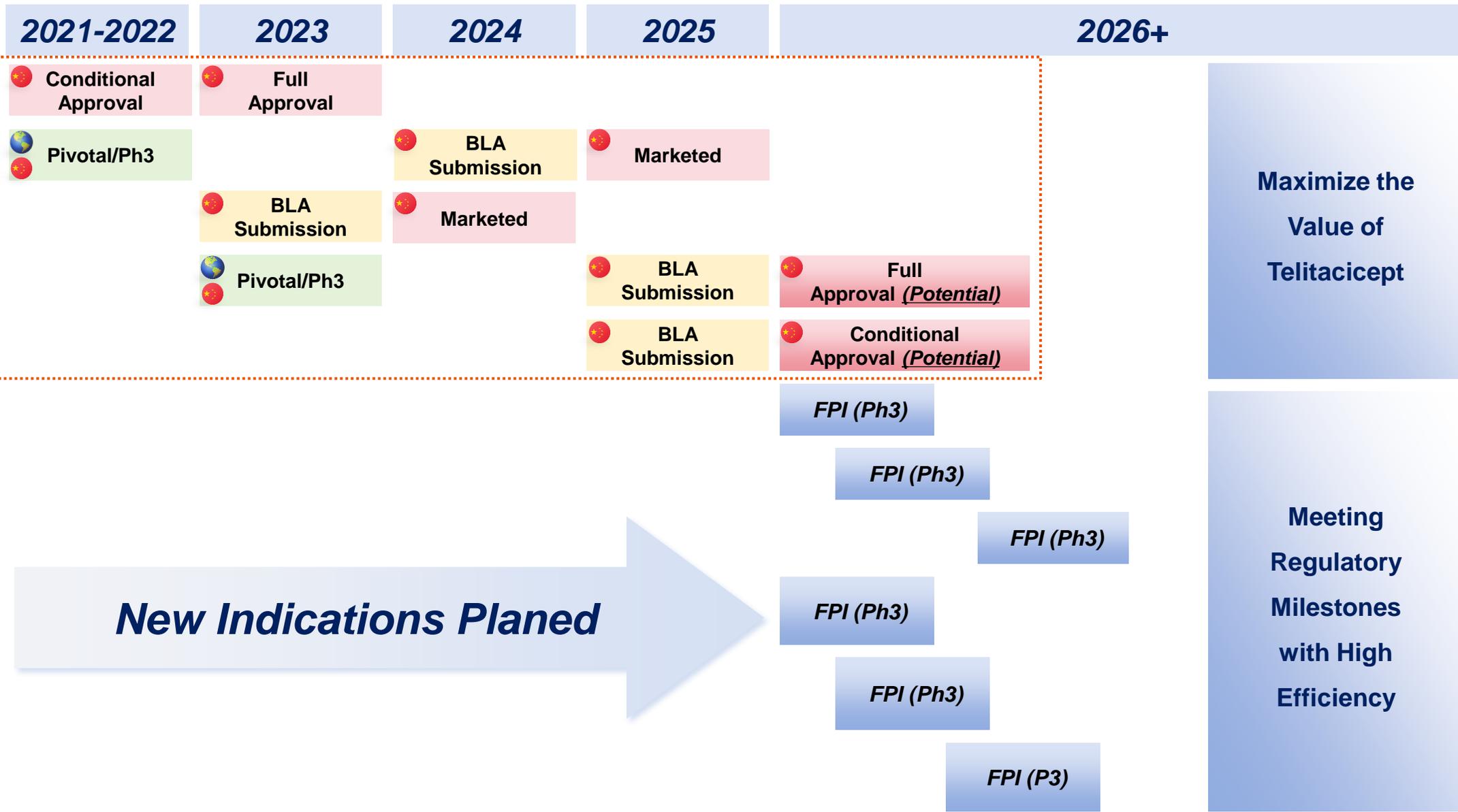
### RC28-E

BLA Submission for DME

### RC278

IND Approval+FPI

# Telitacicept – Maximizing Commercial Potential in Autoimmune Diseases



**Maximize the Value of Telitacicept**

**Meeting Regulatory Milestones with High Efficiency**

***New Indications Planed*** →

# Telitacicept – Substantial Value from Next Wave of New Indications

## Unmet Medical Needs

*Autoimmune Encephalitis*  
**300,000**



*Membranous Nephritis*  
**2,300,000**



*Pediatric SLE*  
**130,000**



*Pediatric IgAN*  
**500,000**



*CTD-ILD*  
**180,000**



*Ocular Myasthenia Gravis*  
**90,000**



\*Sources: DRG database & HCP interviews

\*Prevalent cases in China

## Large Potential Market



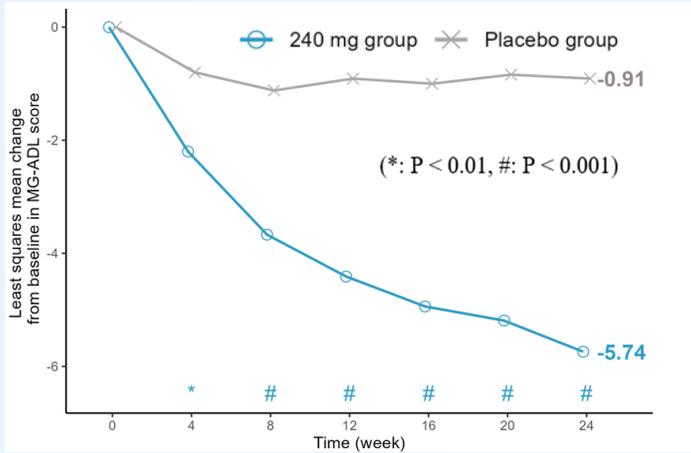
\*Sources: RemeGen metanalysis and estimates

\*Expected by 2040

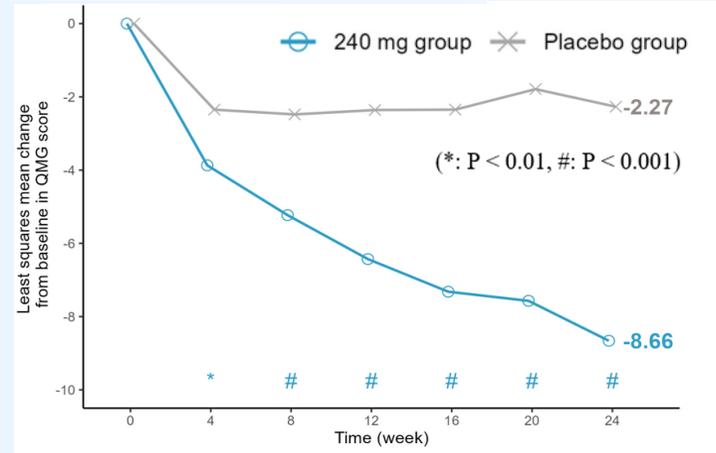
# Telitacicept – Phase III Data for Generalized Myasthenia Gravis (gMG)

Significant Change in MG-ADL (difference: -4.83) and QMG Scores (difference: -6.39) from Baseline for Telitacicept compared with Placebo at Week 24.

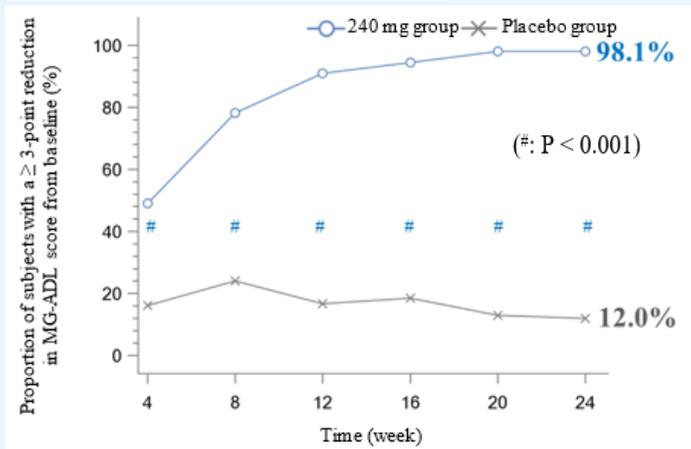
**A** Mean Change in MG-ADL Score over 24 weeks



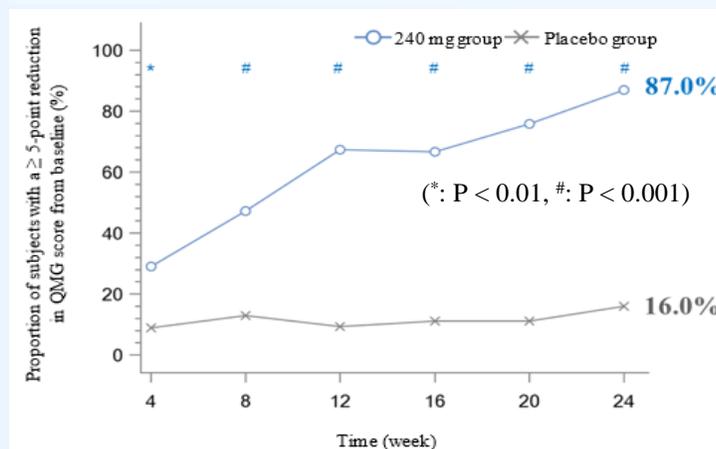
**B** Mean Change in QMG Score over 24 weeks



**C** Proportion of patients with a  $\geq 3$  point reduction in MG-ADL score from baseline over 24 weeks



**D** Proportion of patients with a  $\geq 5$  point reduction in QMG score from baseline over 24 weeks



Selected for *Oral Presentation at AAN 2025 and AANEM 2025*, Telitacicept showed best-in-class efficacy in Ph3 trial for gMG.

## Phase 3 Clinical Trial in China Enrolled 114 patients

- Telitacicept 240mg: 57 patients
- Placebo: 57 patients

## Results of a Phase 3 Study-48 weeks

Efficacy Results of the 24-week open-label extension (OLE) period: At Week 48, in patients who continued on telitacicept vs. those who switched from placebo, change from baseline in MG-ADL and QMG was -7.5 vs. -6.3 and -9.8 vs. -9.3, respectively.

# Telitacicept – Phase III Data for Sjögren’s Disease (SjD)

Selected as *Late-Breaking Poster at ACR 2025*, Telitacicept demonstrated clinically meaningful efficacy in Ph3 trial for SjD.

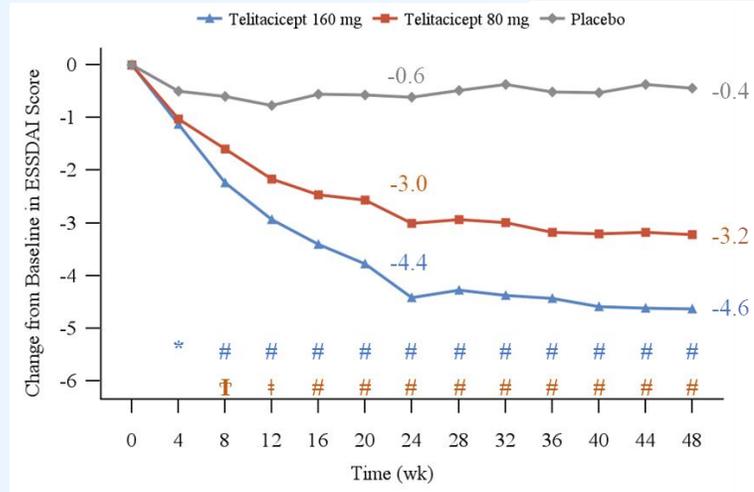
## Phase 3 Clinical Trial in China Enrolled 381 patients

- Telitacicept 160mg: 127 patients
- Telitacicept 80mg: 127 patients
- Placebo: 127 patients

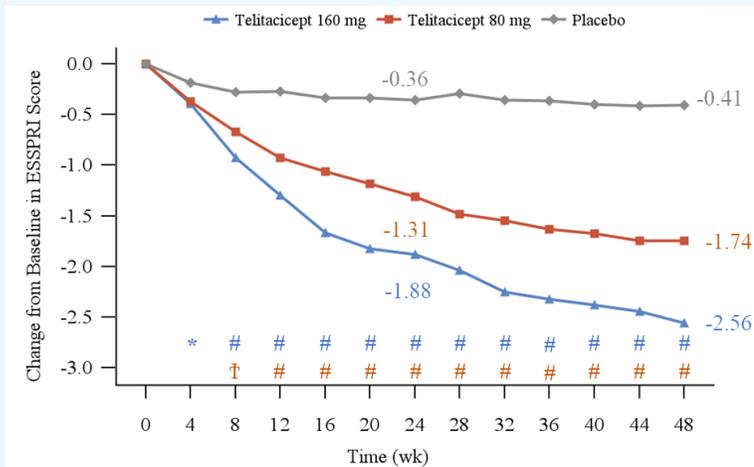
The primary efficacy endpoint is the change from baseline in ESSDAI score at Week 24.

Statistically significant decrease in ESSDAI score from baseline at Week 24 was observed in Telitacicept 160 mg arm (LS Mean change: -4.4 vs -0.6,  $p < 0.0001$ ) and in Telitacicept 80 mg arm (LS Mean change: -3.0 vs -0.6,  $p < 0.0001$ ) as compared with placebo.

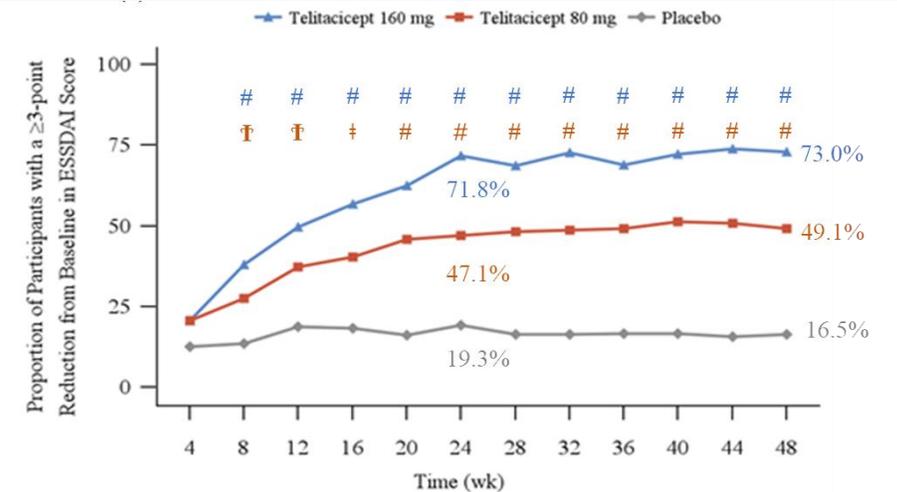
**A** Change from baseline in ESSDAI score over 48 weeks



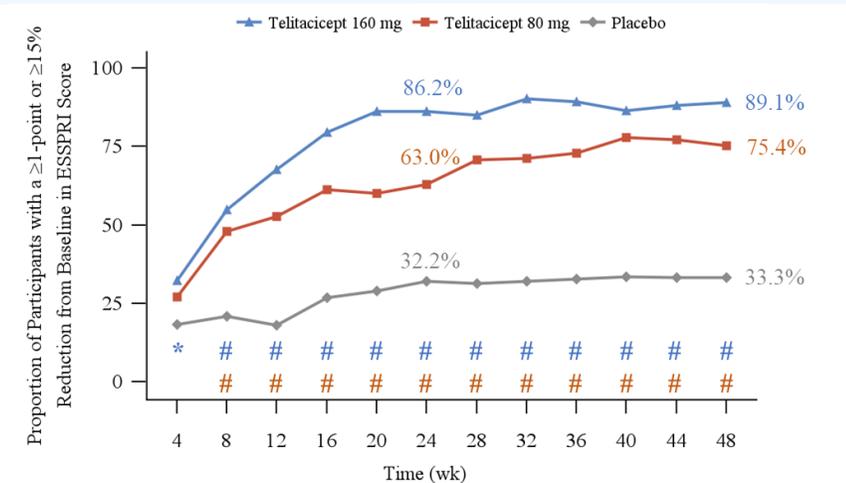
**C** Change from baseline in ESSPRI score over 48 weeks



**B** Proportion of patients with a  $\geq 3$ -point reduction in ESSDAI score



**D** Proportion of patients with a  $\geq 1$  point or 15% reduction in ESSPRI score



# Telitacicept – Phase III Data for IgA Nephropathy (IgAN)

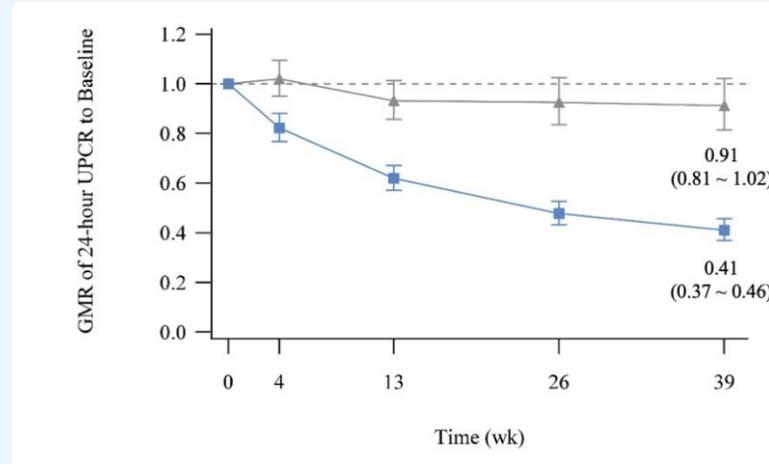
Selected as *Late-Breaking Oral Presentation at ASN 2025*, Telitacicept achieved primary endpoint of reducing proteinuria in stage A of Ph3 trial for IgAN.

## Phase 3 Clinical Trial in China (TELIGAN) Enrolled 318 patients

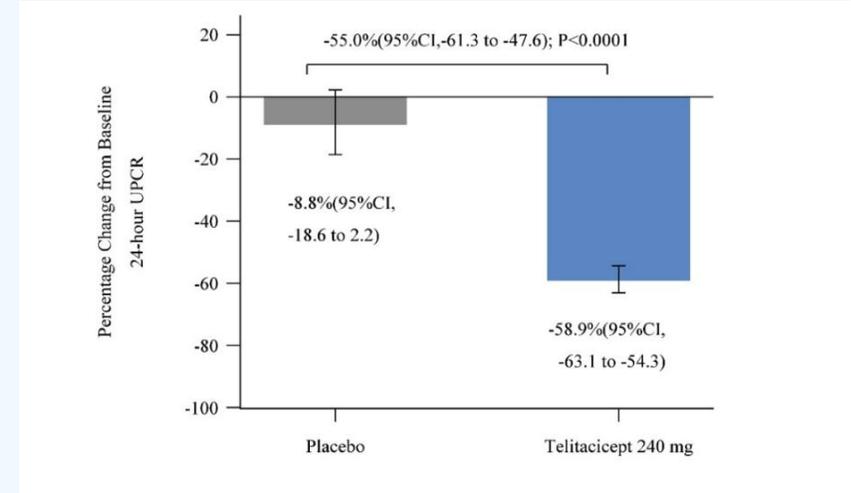
- Telitacicept 240mg: 159 patients
- Placebo: 159 patients

Telitacicept resulted in a 55.0% reduction (95% CI, -61.3% to -47.6%;  $p < 0.0001$ ) in 24-hour UPCR based on placebo-adjusted GMR at Week 39.

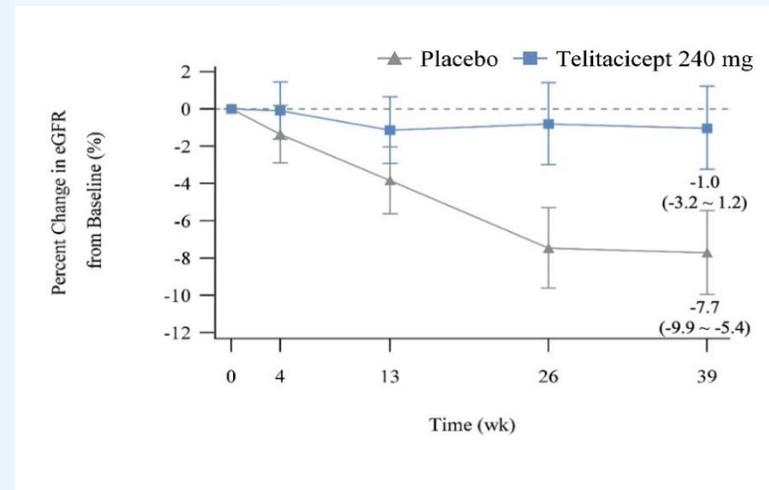
**A** Geometric mean ratio (GMR) of 24h UPCR relative to baseline over 39 weeks



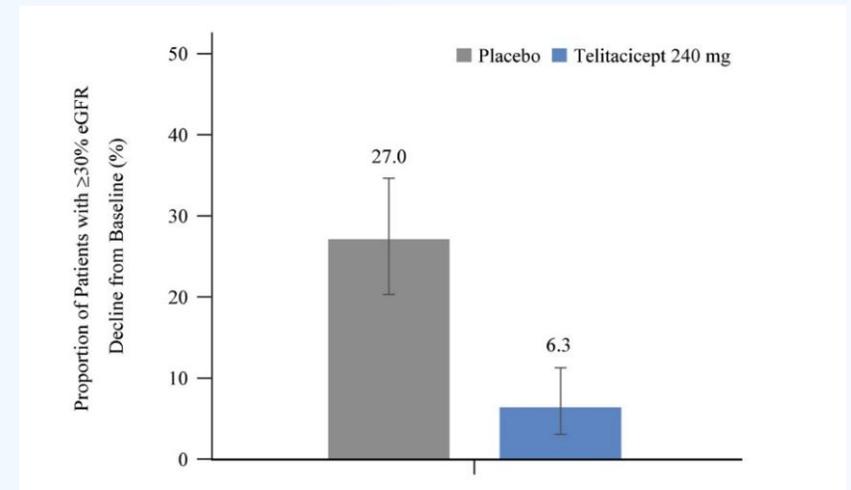
**B** GMR change from baseline of 24h UPCR at Week 39



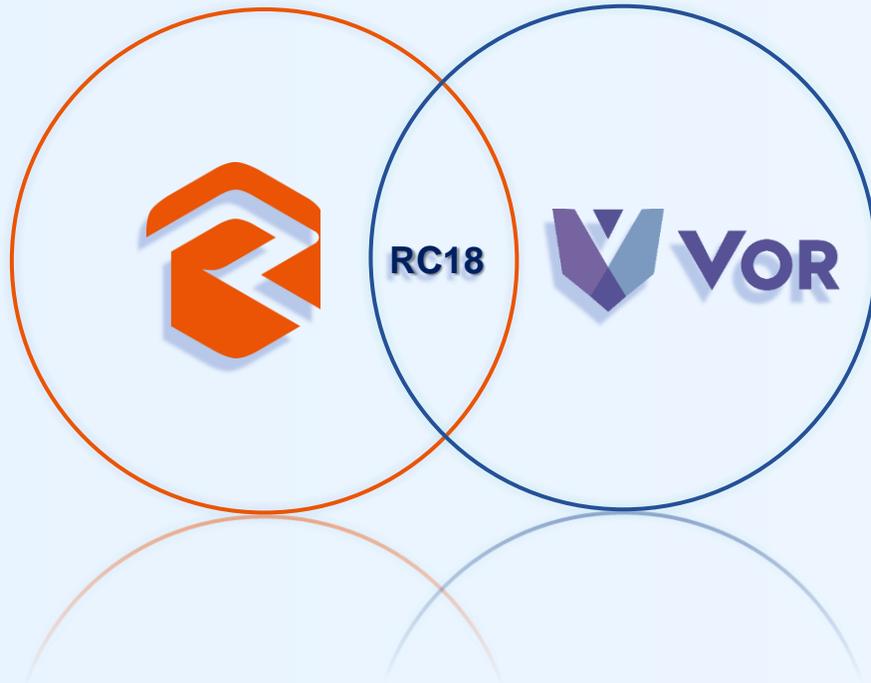
**C** GMR change from baseline of eGFR over 39 weeks



**D** Proportion of patients with  $\geq 30\%$  eGFR decline at Week 39



# Telitacicept – Global Expansion Underway with VOR



- \$45mn upfront
- 20+% stake in Vor through warrants
- Up to US\$4,1B milestone payments
- High single digit to mid-teens royalty on product sales

Indications	Preclinival	Phase 1	Phase 2	Phase 3	Marketing Approval	Milestones
Generalized Myasthenia Gravis (gMG)	Progressing through Phase 2			Phase 3		Topline Data in 1H27
Sjögren's Disease (SjD)	Progressing through Phase 2			Phase 3 Ready		Global Phase 3 Trial to be Initiated

# Key Oncology Trials Ongoing/Being Initiated in China

	On market	BLA	Ph3	Ph2
NSCLC			1L sqNSCLC RC148 + Chemo  2L NSCLC RC148 + Docetaxel	1L NSCLC RC148 + Chemo  2L NSCLC RC148 + Docetaxel  2L NSCLC (Plan) RC278
Gastric Cancer	r/m HER2+ GC RC48		1L HER2 positive mGC RC48 + PD-1 + trastuzumab  1L HER2 low mGC RC48 + PD-1 + chemo	1L mGC RC48 combo  GC Perioperative RC48 + PD-1 ± chemo  1L/2L CLDN18.2+ RC118 + PD-1
Urothelial Cancer	r/m HER2+ UC RC48	1L HER2+ r/m UC RC48 + PD-1	HER2+ NMIBC (Plan) RC48 + BCG	MIBC Perioperative RC48 + PD-1
Breast Cancer	r/m HER2+ BC RC48	2L HER2 low BC RC48 mono		HER2+ BC neoadj RC48 + PD-1  HER2 low TNBC RC148 + RC48
Colorectal Cancer			1L Ph2/3 CRC RC148 + Chemo	2/3L CRC (Plan) RC278

RC48
RC148
RC278
RC118

# RC48 – Phase III Data in 1<sup>st</sup> Line Urothelial Cancer

Data presented at ESMO 2025 and simultaneously published in NEJM

BLA approval expected in 2026 Q2

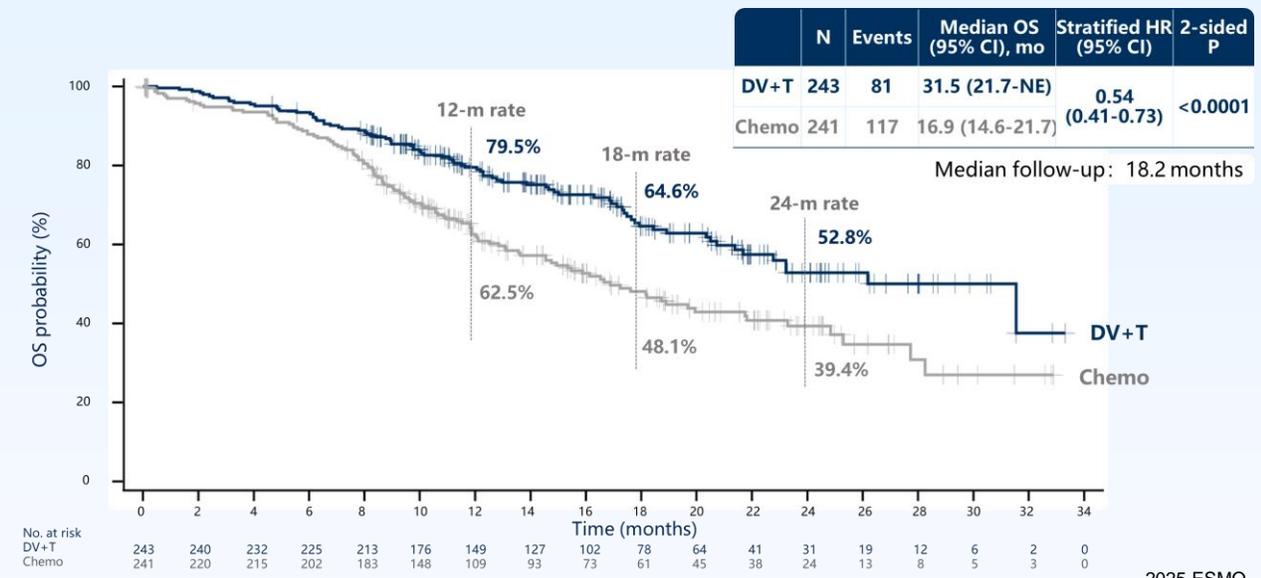
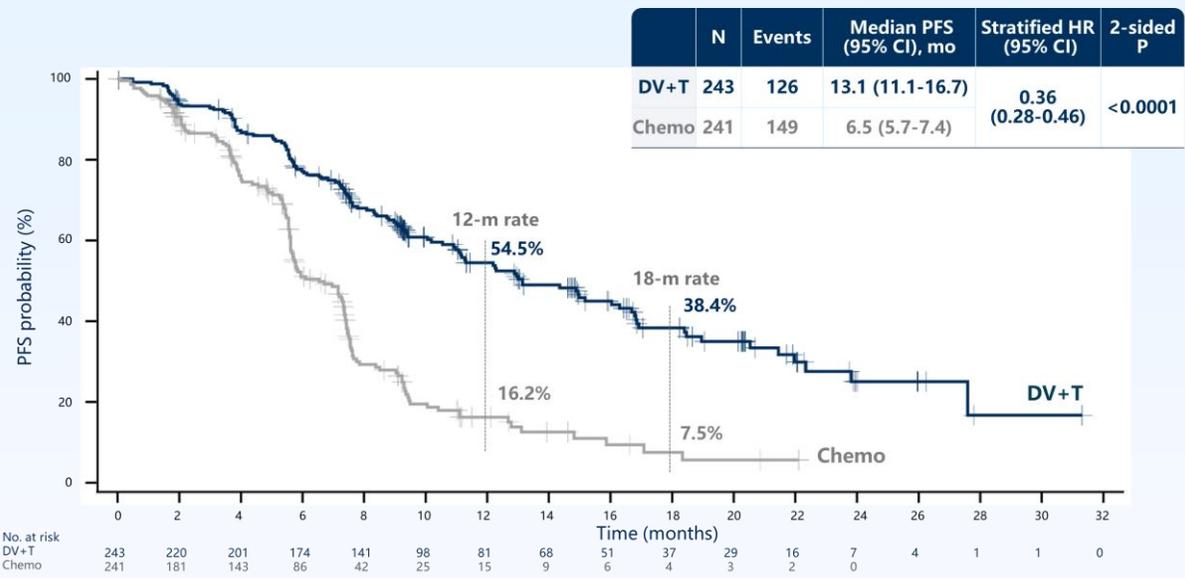
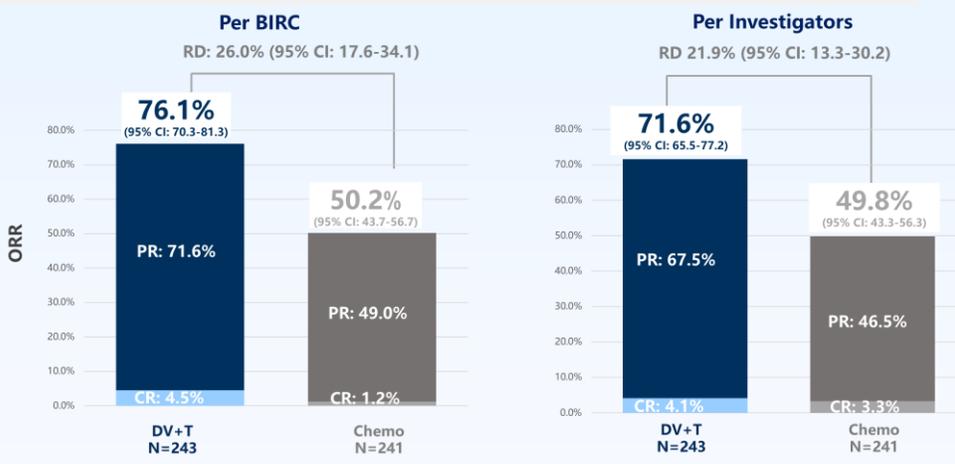
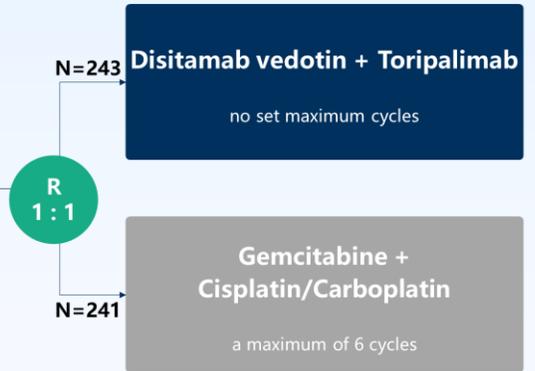
BERLIN 2025 ESMO congress

**Disitamab vedotin (DV) plus toripalimab (T) versus chemotherapy (C) in first-line (1L) locally advanced or metastatic urothelial carcinoma (la/mUC) with HER2-expression**

ORIGINAL ARTICLE

Disitamab Vedotin plus Toripalimab in HER2-Expressing Advanced Urothelial Cancer

- Key Inclusion criteria**
- No prior systemic treatment for unresectable locally advanced or metastatic UC
  - Central lab-confirmed HER2 IHC 1+, 2+, or 3+
  - Measurable disease per RECIST v1.1
  - Eligible for cisplatin or carboplatin
  - ECOG PS 0 or 1



# RC48 – Phase II Data in 1<sup>st</sup> Line Gastric Cancer

Data presented at ASCO 2025

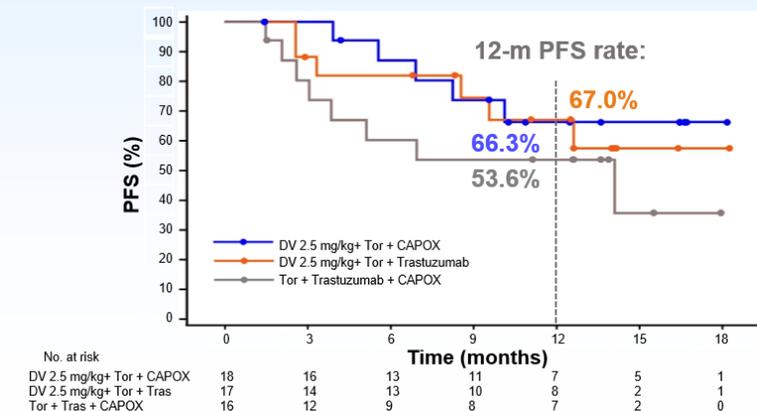
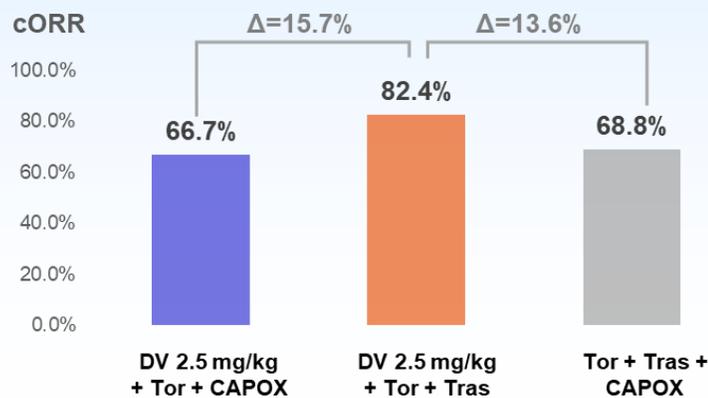
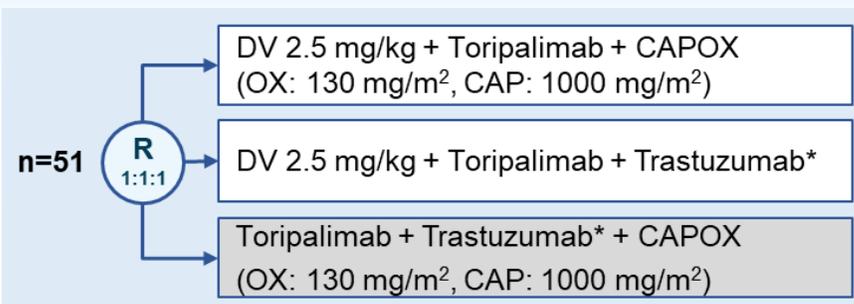
RC48 combo demonstrated promising efficacy in 1L GC HER2+ patients



2025 ASCO ANNUAL MEETING

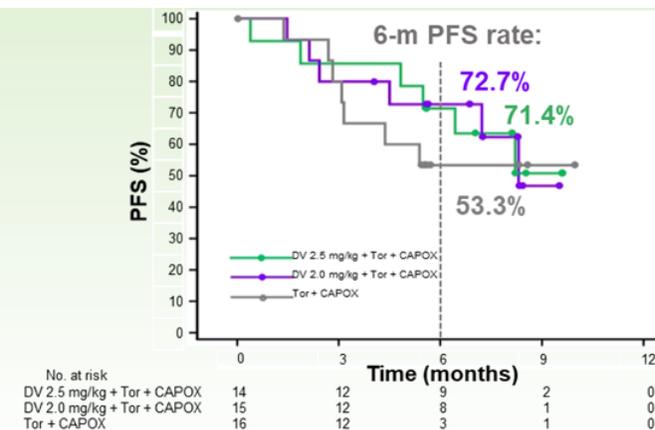
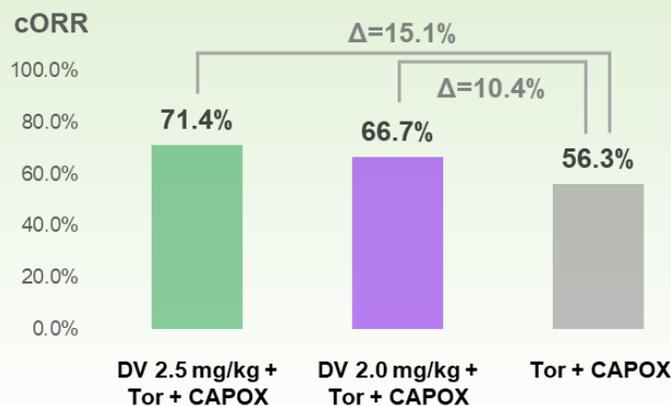
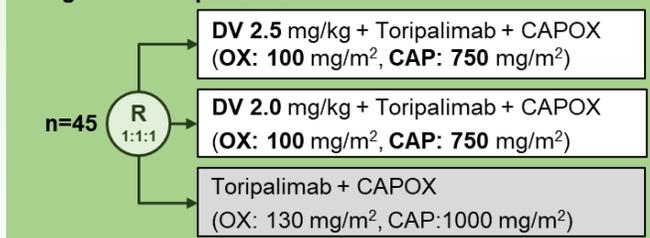
Disitamab vedotin (DV) plus toripalimab (Tor) and chemotherapy (C)/trastuzumab (Tra) as first-line (1L) treatment of patients (pts) with HER2-expressing locally advanced or metastatic (la/m) gastric cancer

## HER2-positive GC



## HER2-low GC

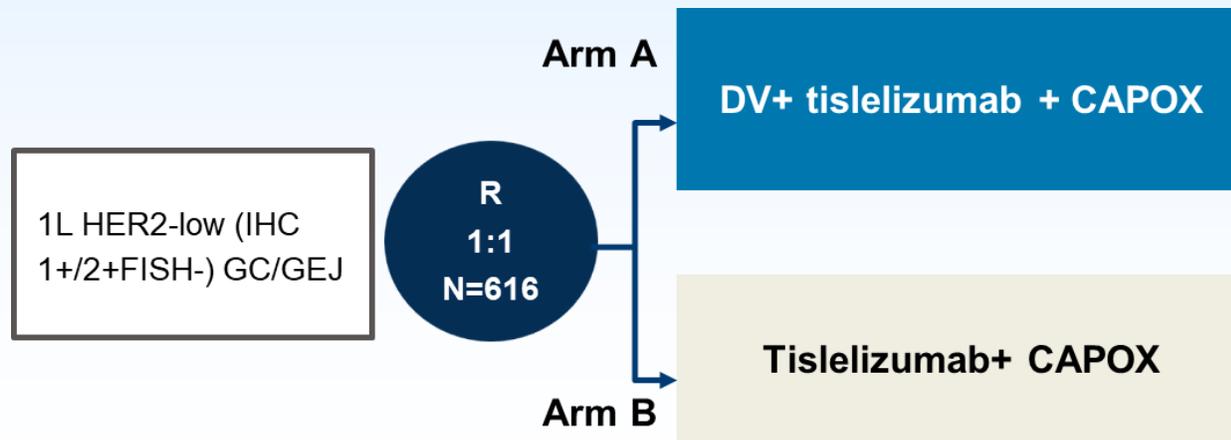
HER2-median/low-expressing cohort  
Stage 2: dose optimization



# RC48 – Two Phase III Trials in 1<sup>st</sup> Line Gastric Cancer Ongoing

## RC48-C039:

1L Ph3 study in  
HER2 low GC

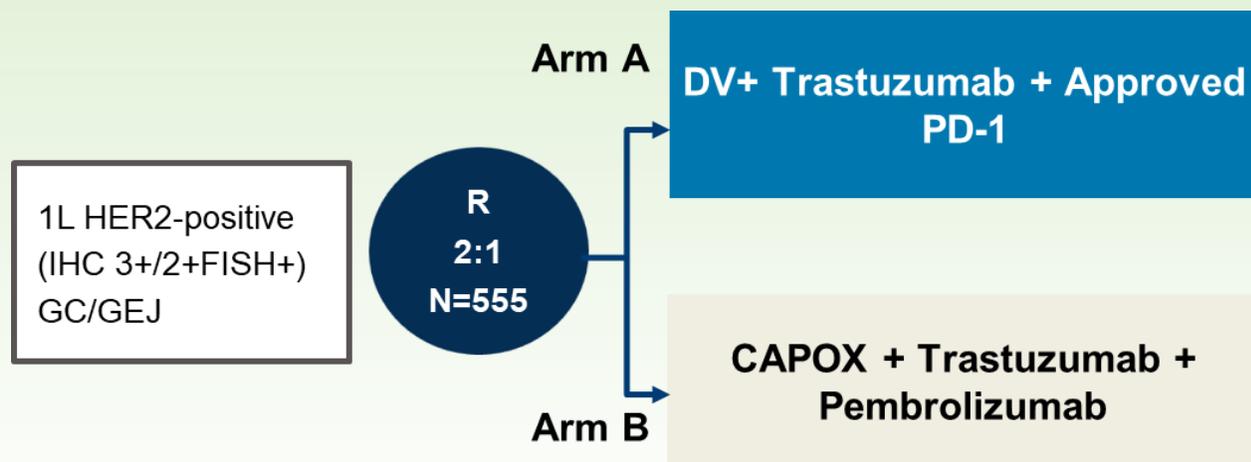


Primary endpoint  
PFS (per IRC)

Key secondary endpoint  
OS

## RC48-C040:

1L Ph3 study in  
HER2 positive GC

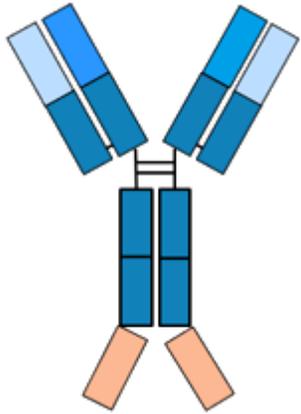


Primary endpoint  
PFS (per IRC)

Key secondary endpoint  
OS

# RC148 – Rapidly Advancing to Pivotal Studies

## RC148(PD-1/VEGF)



Anti-PD-1 antibody

Anti-VEGF nanobody

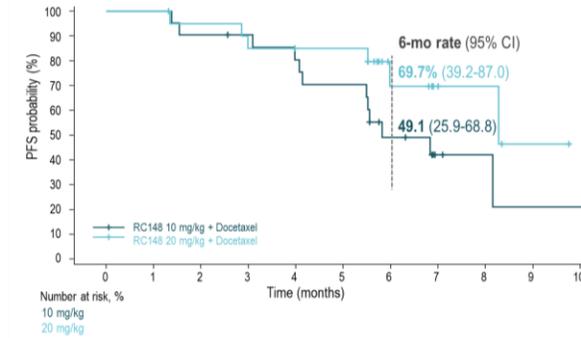
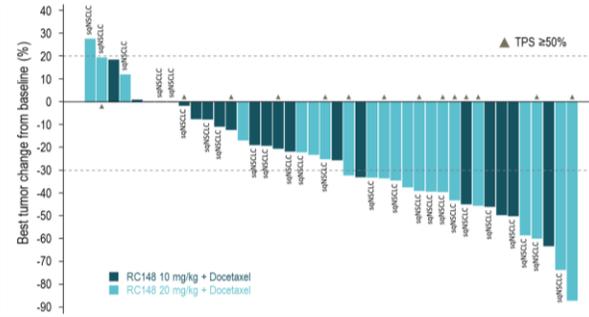
\*Design of RC148

## RC148 Clinical progress

### Green lights obtained for:

1. Ph3 for 1L sqNSCLC in combo with chemo from the CDE
2. Ph3 for 2L NSCLC in combo with chemo from the CDE with BTD status
3. Ph3 for 2L NSCLC in combo with chemo from the US FDA

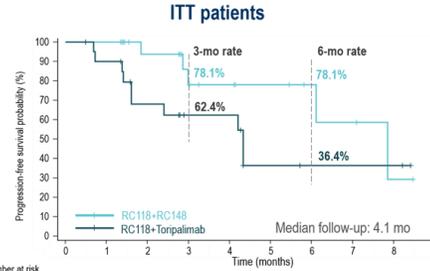
## Promising data from RC148 combo with ADC or chemo



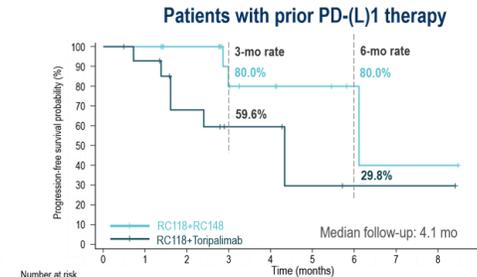
### RC148 + Docetaxel

- 20 mg/kg showed a higher cORR vs 10 mg/kg (66.7% vs 28.6%).
- 20 mg/kg showed a longer mPFS (median: 8.28 [95% CI: 5.98-NE] vs 5.82 [4.14-NE] m; HR: 0.445) compared with the 10 mg/kg.

2025 ESMO IO



	Events, n (%)	Median PFS, mo (95% CI)	HR (95% CI)
RC118+RC148	5 (23.8)	7.9 (3.0, NE)	0.43 (0.15, 1.27)
RC118+Toripalimab	10 (47.6)	4.3 (1.6, NE)	



	Events, n (%)	Median PFS, mo (95% CI)	HR (95% CI)
RC118+RC148	3 (18.8)	6.1 (2.9, NE)	0.32 (0.08, 1.27)
RC118+Toripalimab	7 (46.7)	4.3 (1.6, NE)	

### RC148 + RC118 vs RC118 + PD-1

- ITT patients: ORR 57.1% vs 33.3%; mPFS 7.9 vs 4.3 m (HR 0.43)
- Patients with prior PD-(L)1 therapy: ORR 62.5% vs 20.0%; mPFS: 6.1 vs 4.3 months (HR 0.32)

2025 ESMO IO

## Best in class data in 1L NSCLC

- As of Dec 2025, RC148 plus platinum-based chemotherapy in 1L treatment of NSCLC demonstrated potentially best-in-class efficacy in ORR terms
- Favorable safety profile with no severe adverse events such as serious bleeding

# RC148 – Global Licensing Deal with AbbVie

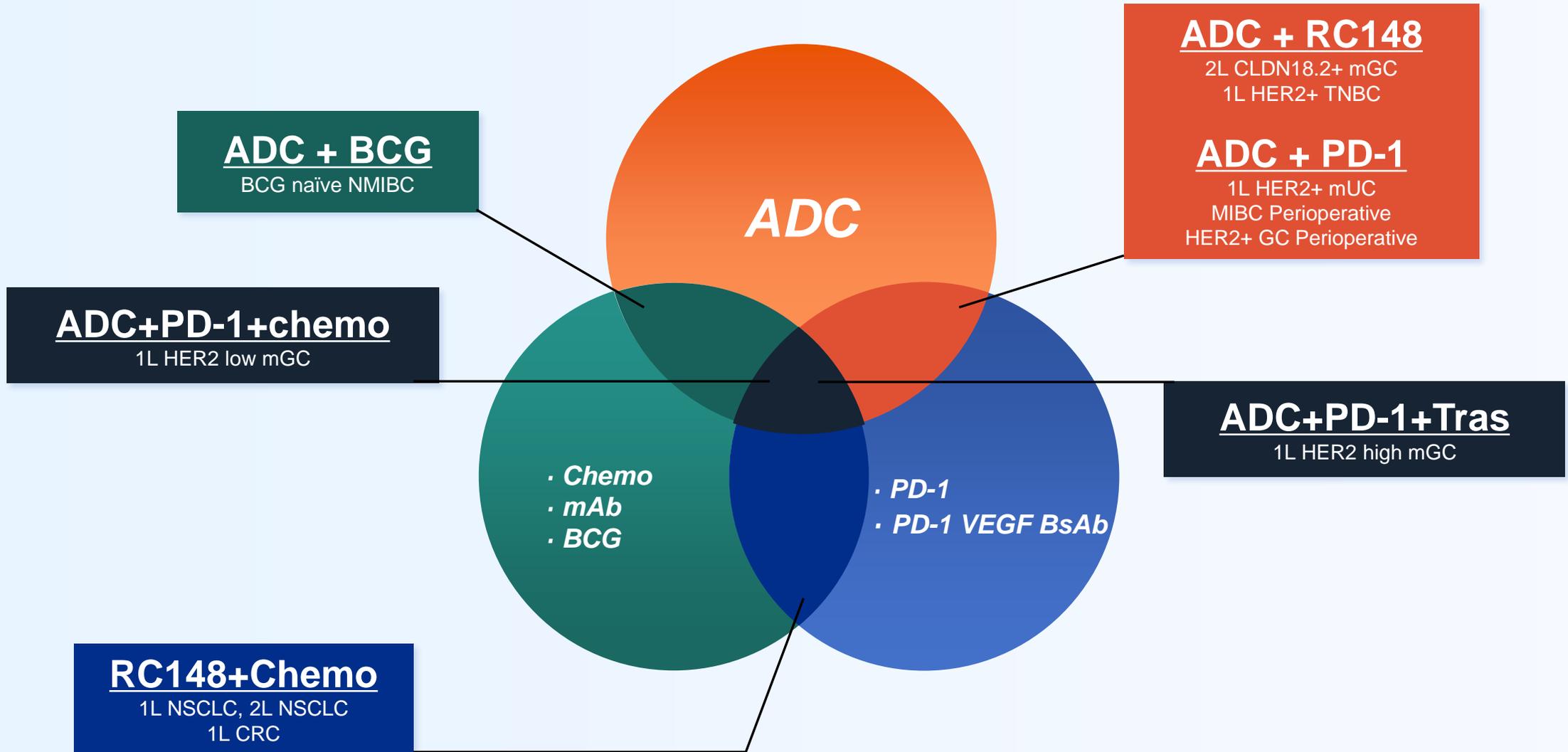


RemeGen  
荣昌生物

abbvie

- \$650mn upfront payment
- Up to \$4,95B development, regulatory, and commercialization milestone payments
- Double digit royalty on product sales

# Explore Treatment Combinations



# RC278 – A Rising Star ADC Molecule Targeting CDCP1

## RC278 (Ph I)

**Target:**  
CDCP1

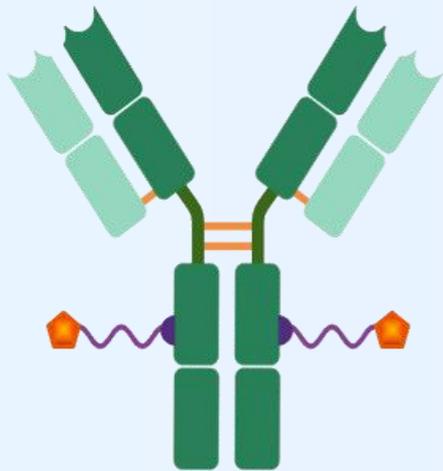
**Antibody:**  
A humanized mAb

**Linker-Payload:**  
A Top1i based payload with a cleavable linker

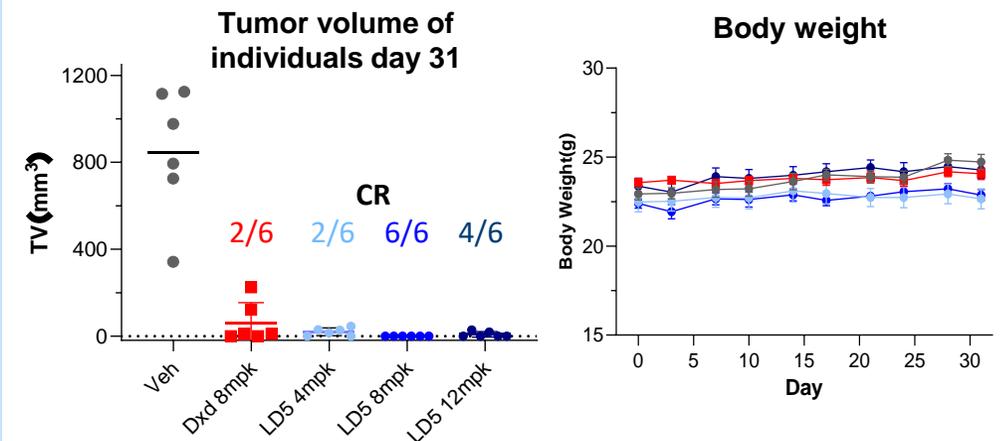
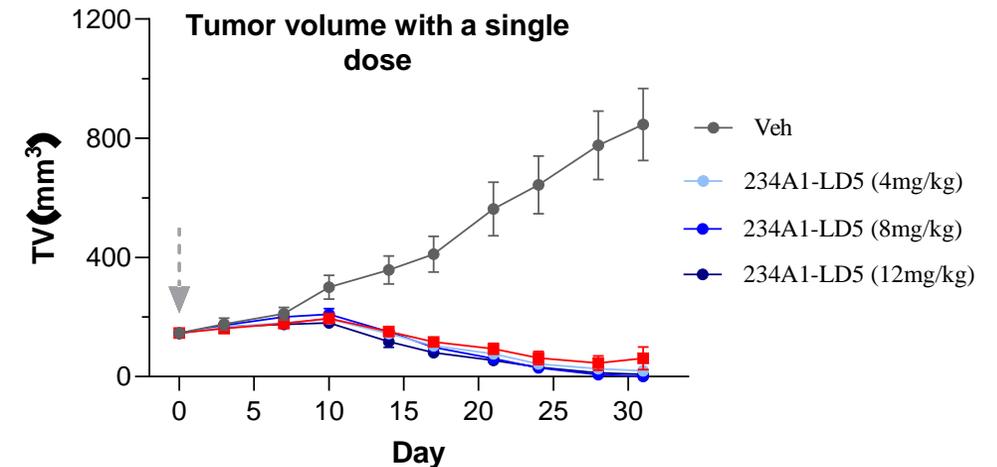
**Conjugation:**  
Site-specific, DAR=8

**Potential indication:**  
CRC, Lung, Breast, Prostate, Pancreas

**Development:**  
Ph1: Dose escalation and expansion  
CRC, Lung, Breast



**RC278 showed robust tumor regression  
In a CRC PDX model**

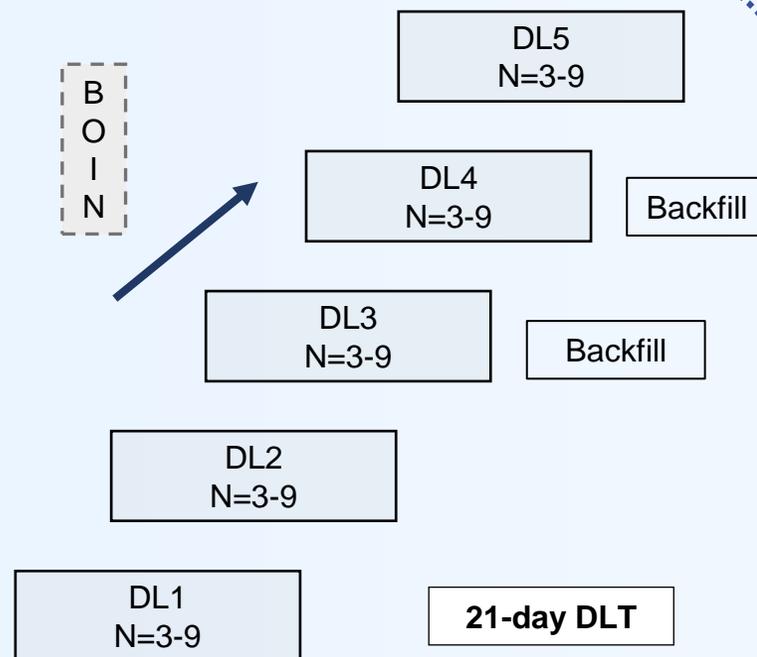


## Dose-Escalation

### Inclusion Criteria

- ✓ Locally advanced unresectable or metastatic solid tumor
- ✓ Disease progression after standard therapy or intolerance to standard therapy

**Focused on Potential indication:**  
CRC, NSCLC, SCLC, Breast cancer.



## Dose-Optimization (Mono)

NSCLC

(R)

Dose level 1  
n = 20-30

Dose level 2  
n = 20-30

CRC

(R)

Dose level 1  
n = 20-30

Dose level 2  
n = 20-30

## Dose-Optimization (Combo)

# RC28 – Marching into Ophthalmology Market with A Strong Partner

*A novel dual decoy receptor Fc-fusion protein that can potentially block VEGF and FGF-2 simultaneously*

## **DME**

**Q3 2025**

BLA Submission  
(China)

**H2 2026**

Approval for  
Marketing(China)

## **wAMD**

**Q4 2025**

LPO  
Completed

**H2 2026**

BLA Submission  
(China)

## **DR**

**Q4 2025**

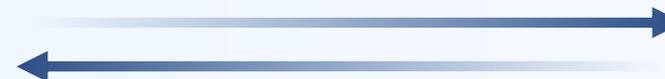
Pre-BLA Submission  
(China)

**H2 2026**

BLA Submission  
(China)

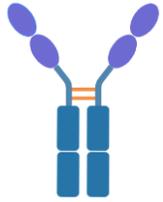
## PRINCIPAL TERMS OF THE LICENSE AGREEMENT with SANTEN CHINA

RC28-E rights in Greater China, South Korea, Thailand, Vietnam, Singapore, the Philippines, Indonesia and Malaysia

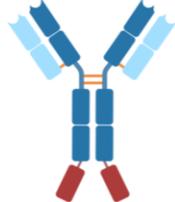


- RMB **250 million** upfront payment
- RMB **520 million** development and regulatory milestone
- RMB **525 million** sales milestone
- Tiered **royalties** on sales

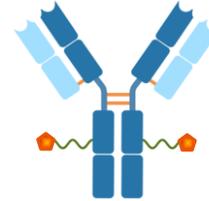
## Fusion protein



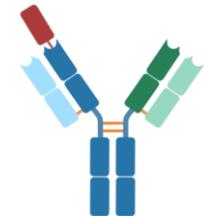
## Bispecific antibody



## ADC



## TCE/MCE



### Target Discovery

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

### Antibody Discovery

Generate monoclonal antibody and nanobody lead molecules by hybridoma and display platforms

### Protein Engineering

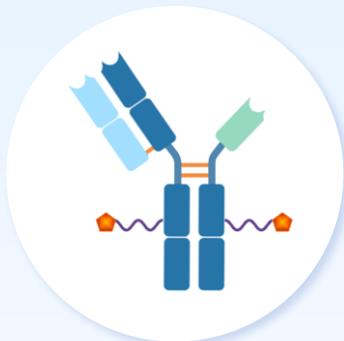
Deliver desired preclinical candidates (PCCs) and novel platforms via AI-guided and structure-based designs

### ADC Technology

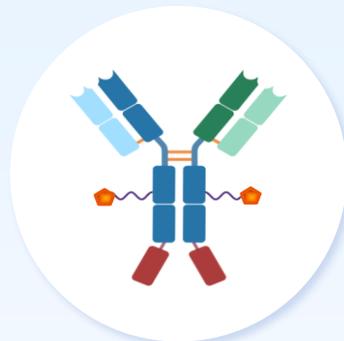
Develop novel payload, drug linker, site-specific conjugation methods to deliver ADC PCCs and next generation ADC platforms

# Emerging Discovery Pipeline Highlights

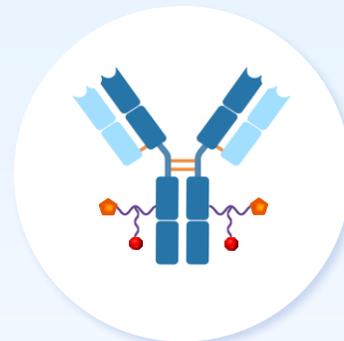
## Oncology



*BsADC  
IND Enabling*



*TsADC  
PCC Enabling*



*ADC dual payload  
PCC Enabling*

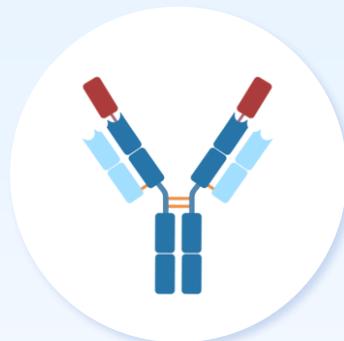


*Trispecific TCE  
PCC Enabling*

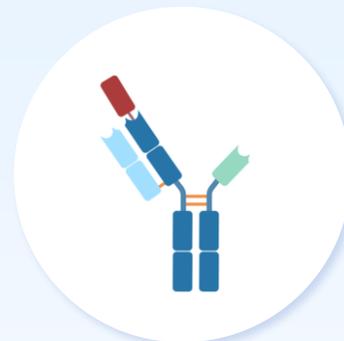
## Autoimmune



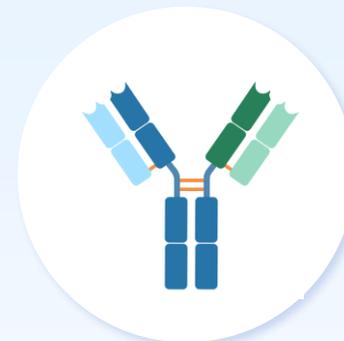
*Fusion Protein  
PCC Ready*



*BsAb  
PCC Enabling*



*TCE  
PCC Enabling*



*MCE  
PCC POC*

# RC288 – A Potential BIC Bispecific ADC for Prostate Cancer

## RC288

### Target:

Tumor associated antigens PSMA and B7H3

### Bispecific antibody:

via humanized mAb and VHH nanobody

### Linker-Payload :

A Top1i based payload with a bivalent cleavable linker

### Conjugation :

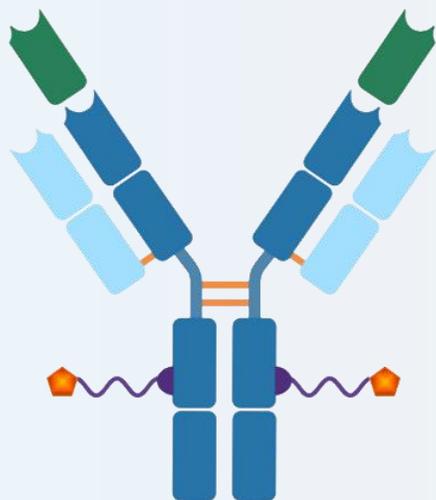
Site-specific, DAR=8

### Key indication :

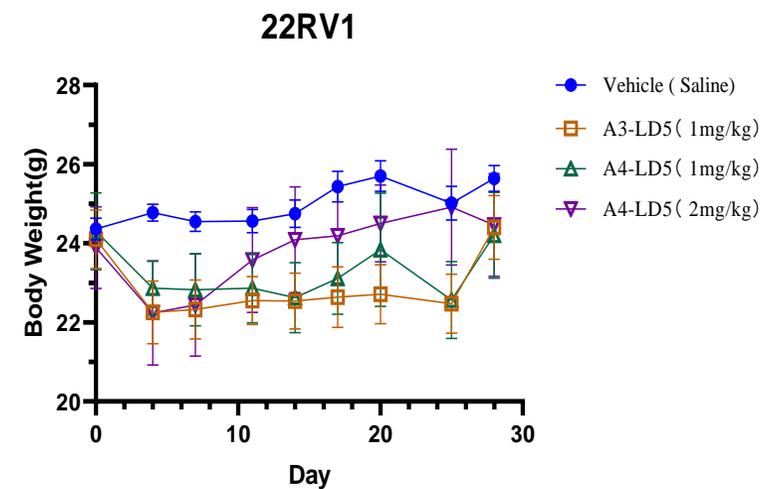
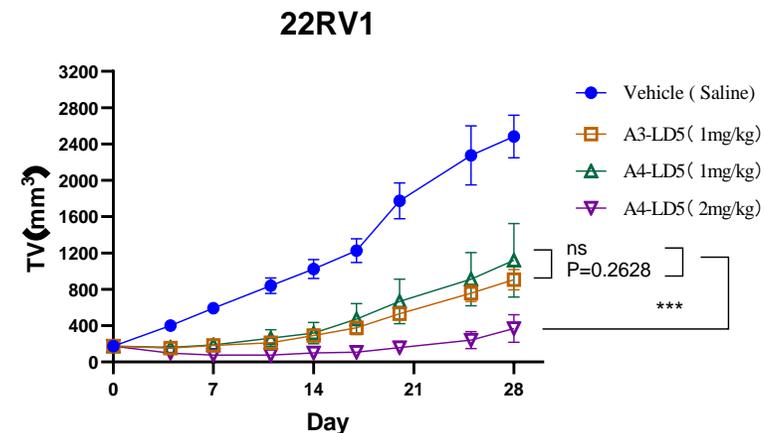
Prostate

### Development :

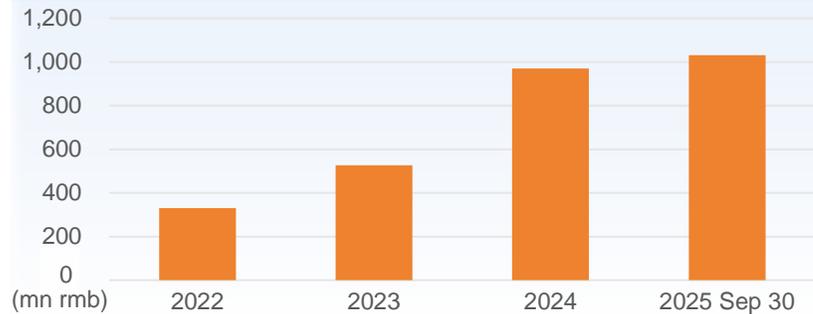
Ph1 planned for early 2026



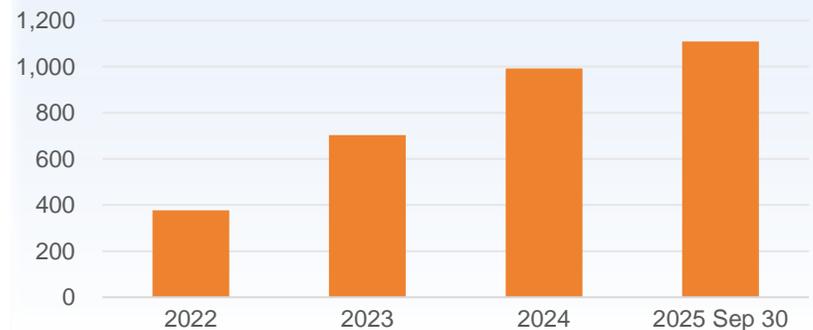
*RC288 demonstrated robust efficacy and good safety profile in preclinical models*



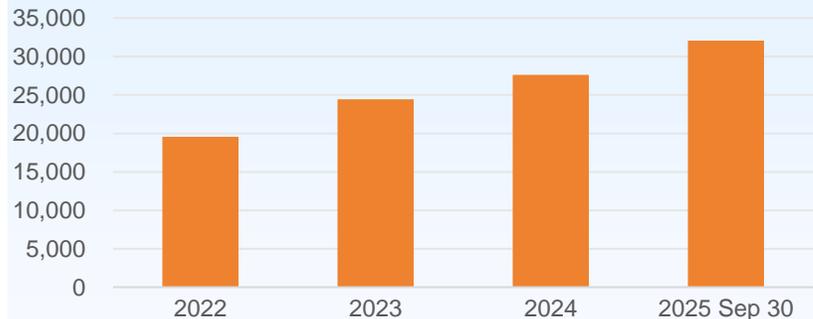
### Telitacicept Revenue



### Hospitals listed



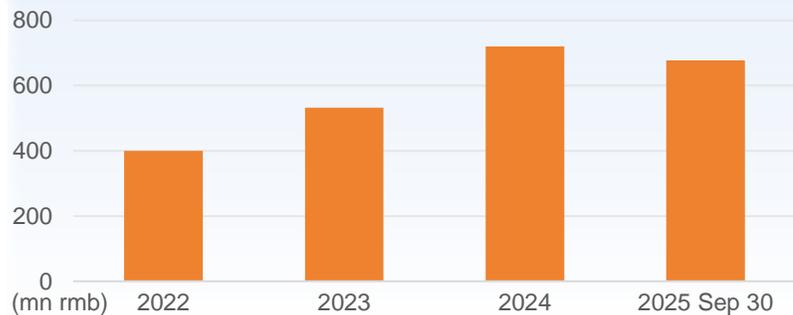
### Physicians covered



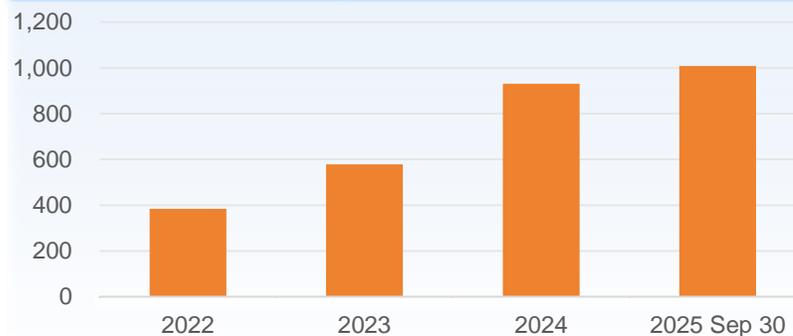
- First-in-class B<sub>LYS</sub>/APRIL dual-targeting drug
- Approved for SLE, MG and RA in China
- ~900 member rheumatology focused sales team
- Listed in 1000+ hospital procurement list
- Covered 32,000+ targeted doctors
- New indications (IgAN, SjD, and etc) to provide sustained growth driver in the coming years
- Aim to become a leading therapy in treating B-cell-mediated autoimmune diseases



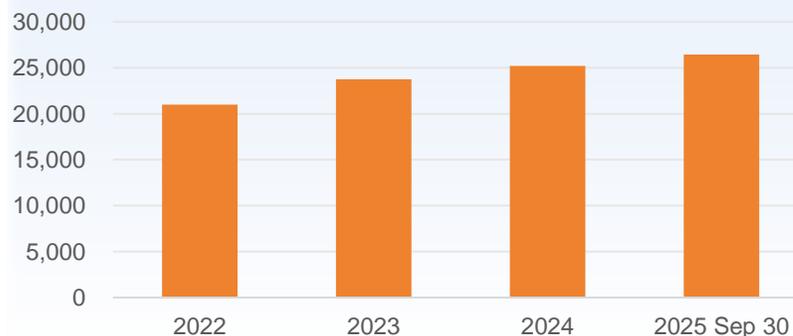
## Disitamab-Vedotin Revenue



## Hospitals listed



## Physicians covered



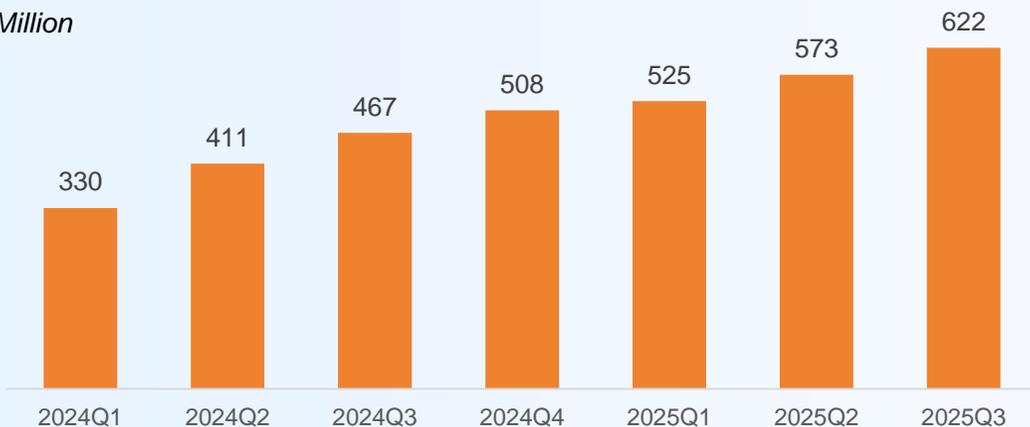
- The first domestic ADC drug approved in China
- Approved in 2L(+) UC, GC and BC patients
- ~600 member oncology focused sales team
- Listed in 1,000+ hospital procurement list
- Covered 26,000+ targeted doctors
- Solidifying a leading position in HER-2 expressing urothelial cancer patients
- Multiple ongoing trials to expand the target patient pool



# Key Financial Summary

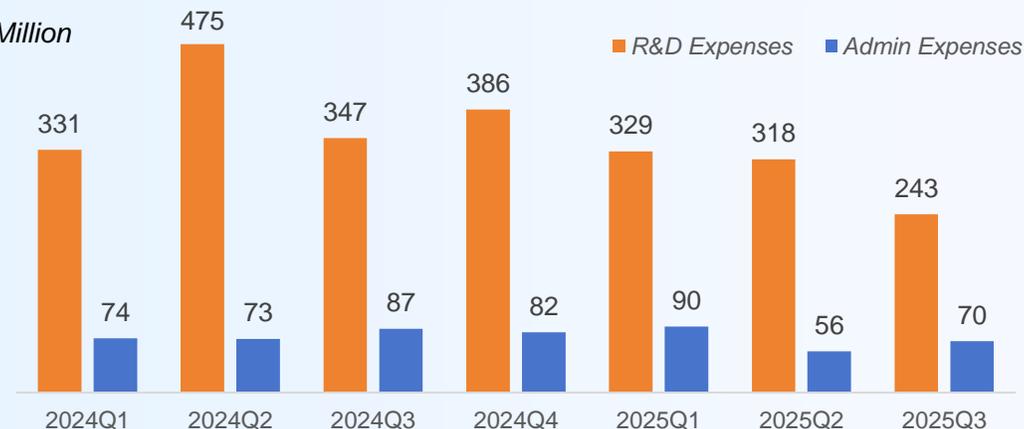
## Strong Revenue Growth

RMB Million

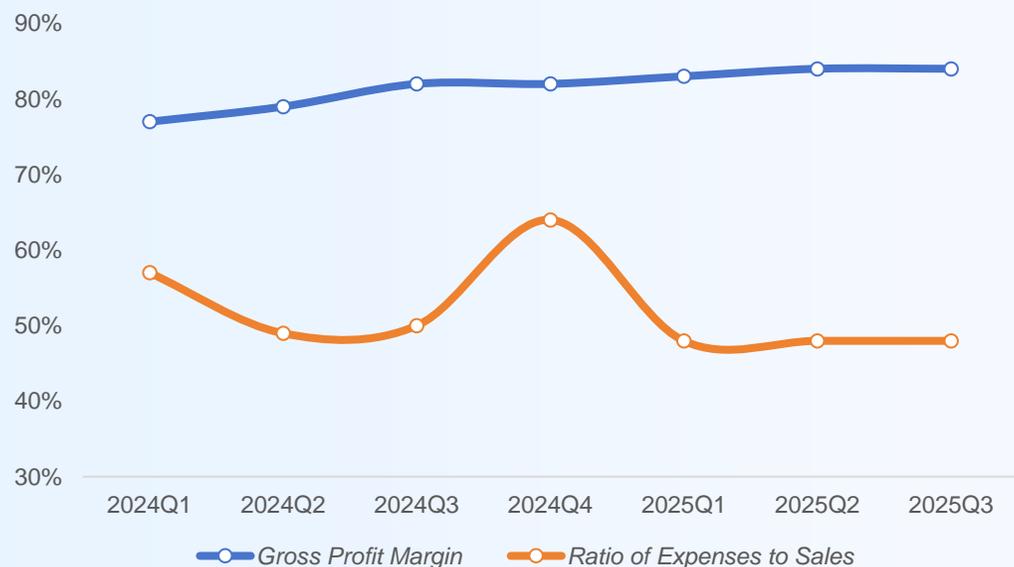


## Costs Under Control

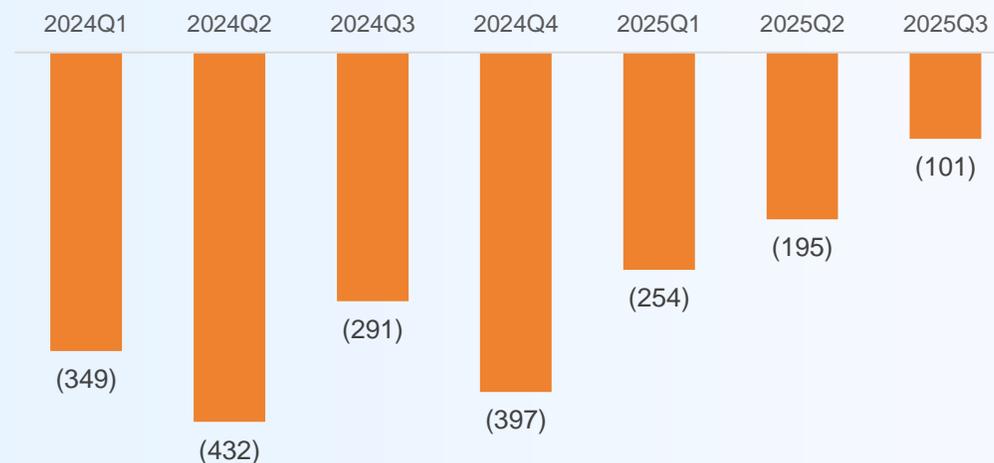
RMB Million



## Improved Commercialization Efficiency



## Consistent Loss Reduction



● The balance of cash and cash equivalents was 1,450 million RMB on 9/30/2025

RMB Million



RemeGen

荣昌生物