RemeGen
荣昌生物

RemeGen
2025 Q3 Report

October, 2025

Disclaimer

The documents, opinions and materials presented in this presentation (the “Document”) have been prepared by RemeGen Co., Ltd. (the “Company”) for use in presentations by the Company and does not constitute a recommendation regarding the securities of the Company. You fully understand that the Document is being made available on a confidential basis and subject to the following provisions. The contents of this Document have not been reviewed by any regulatory authority in any jurisdiction. The distribution of this Document in certain jurisdictions may be restricted by law, and the recipients into whose possession this Document comes should inform themselves about, and observe such restrictions. By accessing this Document, you are agreeing (i) that you have read and agree to comply with the contents of this notice and disclaimer and (ii) to maintain absolute confidentiality regarding the information disclosed in this Document.

This Document has not been independently verified and is not intended to form the basis of any investment decision. It does not constitute an offer or invitation to sell, or any solicitation of any offer to subscribe for or purchase any securities in any jurisdiction in which the making of such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction or would not otherwise be in compliance with the laws and regulations of such jurisdiction, and nothing contained herein shall form the basis of any investment decision, contract or commitment whatsoever. This Document contains no information or material which may result in it being deemed (1) to be an advertisement, invitation or document containing an advertisement or invitation falling within the meaning of section 103 of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (the “Securities and Futures Ordinance”) or (2) in Hong Kong to have effected an offer to the public without compliance with the laws of Hong Kong or being able to invoke any exemption available under the laws of Hong Kong, and is subject to material change without notice.

The securities of the Company have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the “U.S. Securities Act”), or under the laws of any state of the United States. This Document does not constitute or form a part of any offer or solicitation to purchase or subscribe for securities in the United States and is not for distribution and may not be distributed, directly or indirectly, in or into the United States (including its territories and possessions, any state of the United States and the District of Columbia). The securities of the Company will not be offered or sold in the United States except pursuant to an exemption from, or in a transaction not subject to the registration requirements of the U.S. Securities Act. There will be no public offer of the Company’s securities in the United States.

This Document and the information contained herein as well as information presented orally or otherwise are strictly confidential and must be treated as such. Neither the information contained in this Document nor any copy hereof may be, directly or indirectly, taken or transmitted into or distributed in the United States, Canada, Australia, Japan, PRC, Hong Kong or any other jurisdiction which prohibits the same except in compliance with applicable securities laws. Any failure to comply with this restriction may constitute a violation of U.S. or other jurisdiction's securities laws. Upon request, the recipient will promptly return this Document and any other written information made available in the presentation, without retaining any copies.

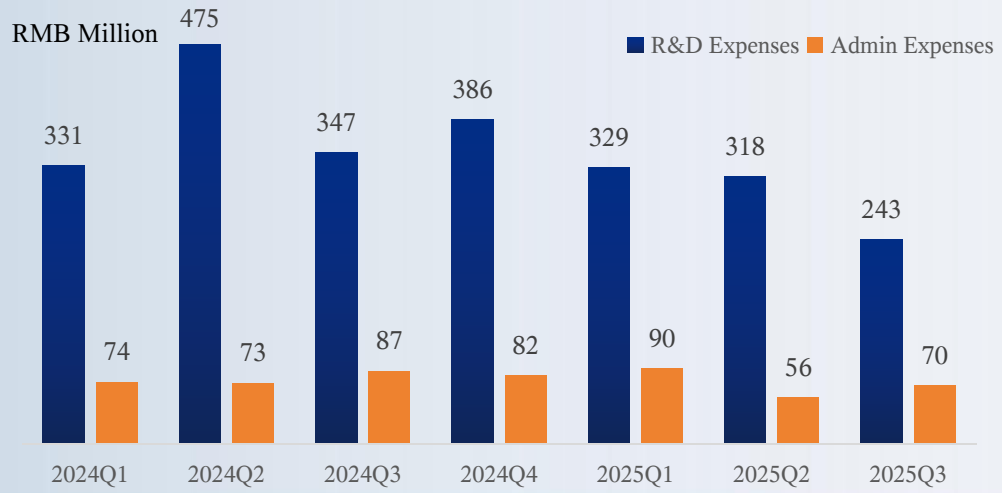
This Document does not purport to be comprehensive or to contain all the information that a recipient may need in order to evaluate the Group. No representation, warranty or undertaking, express or implied, is given and, so far as is permitted by law, no responsibility or liability is accepted by any person (for the avoidance of doubt, including but not limited to, the Company and its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing), with respect to the accuracy, reliability, correctness, fairness or completeness of this Document or its contents. The information communicated in this presentation contains certain statements that are or may be forward looking. These statements typically contain words such as "will", "expects", “intends”, “plans to” and "anticipates" and words of similar import. These forward-looking statements reflects the current view of the Company with respect to future events are based on a number of assumptions about the Company’s operations and factors beyond the Company’s control and are subject to significant risks and uncertainties, and, accordingly, actual results may differ materially from these forward-looking statements. In particular, but without limitation, no representation or warranty is given as to the achievement or reasonableness of, and no reliance should be placed on, any assumptions, projections, targets, estimates, forecasts or any forward-looking statements contained in this Document. Each of the Company and its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing assumes no obligation to update or otherwise revise these forward-looking statements for new information, events or circumstances that occur subsequent to such dates. None of the Company and any of its affiliates, controlling persons, directors, officers, partners, employees, agents, representatives or advisers of any of the foregoing shall have any liability (in negligence or otherwise) in respect of the use of, or reliance upon, the information contained herein by you or any person to whom the information herein is disclosed.

In furnishing this Document, the Company and its affiliates undertake no obligation to provide any additional information or to update this Document or any additional information or to correct any inaccuracies which may become apparent.

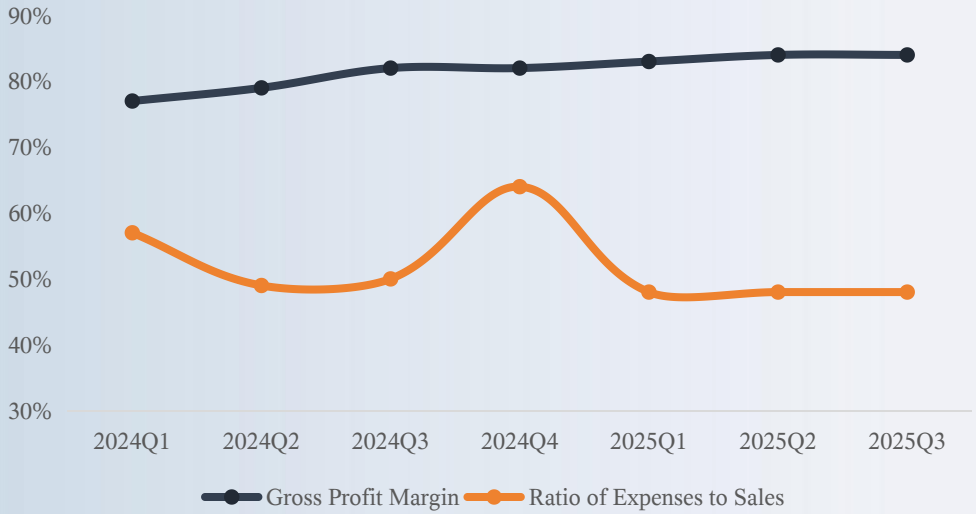
Key Financial Summary

Strong Revenue Growth

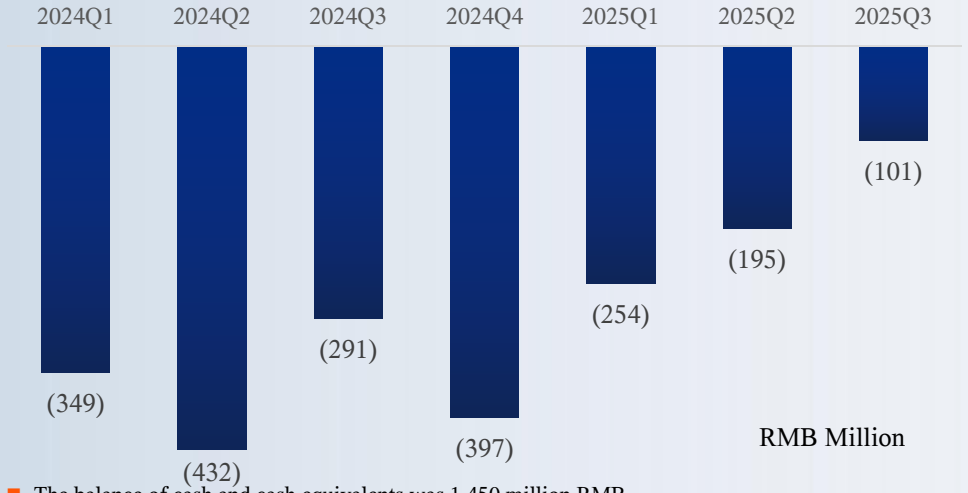
Costs Under Control



Improved Commercialization Efficiency



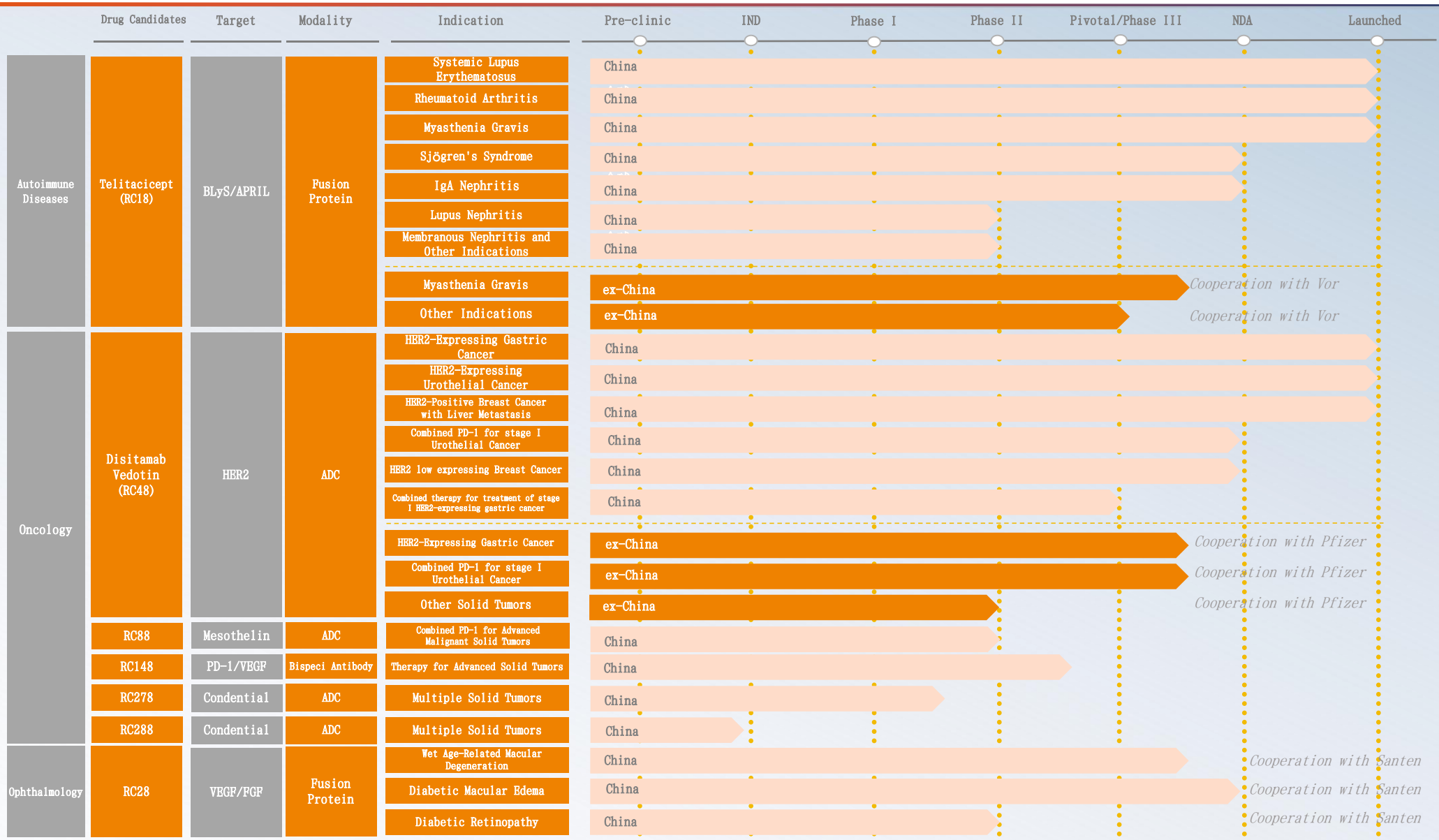
Consistent Loss Reduction



The balance of cash and cash equivalents was 1,450 million RMB.

RemeGen 荣昌生物

Ongoing Clinical Trials



Telitacicept - Maximize Commercial Potential

3
Approved Indications for Marketing

2
BLA Filing

2+
Indications in Phase 3 Trials

8+
Indications in Planning/Initiating

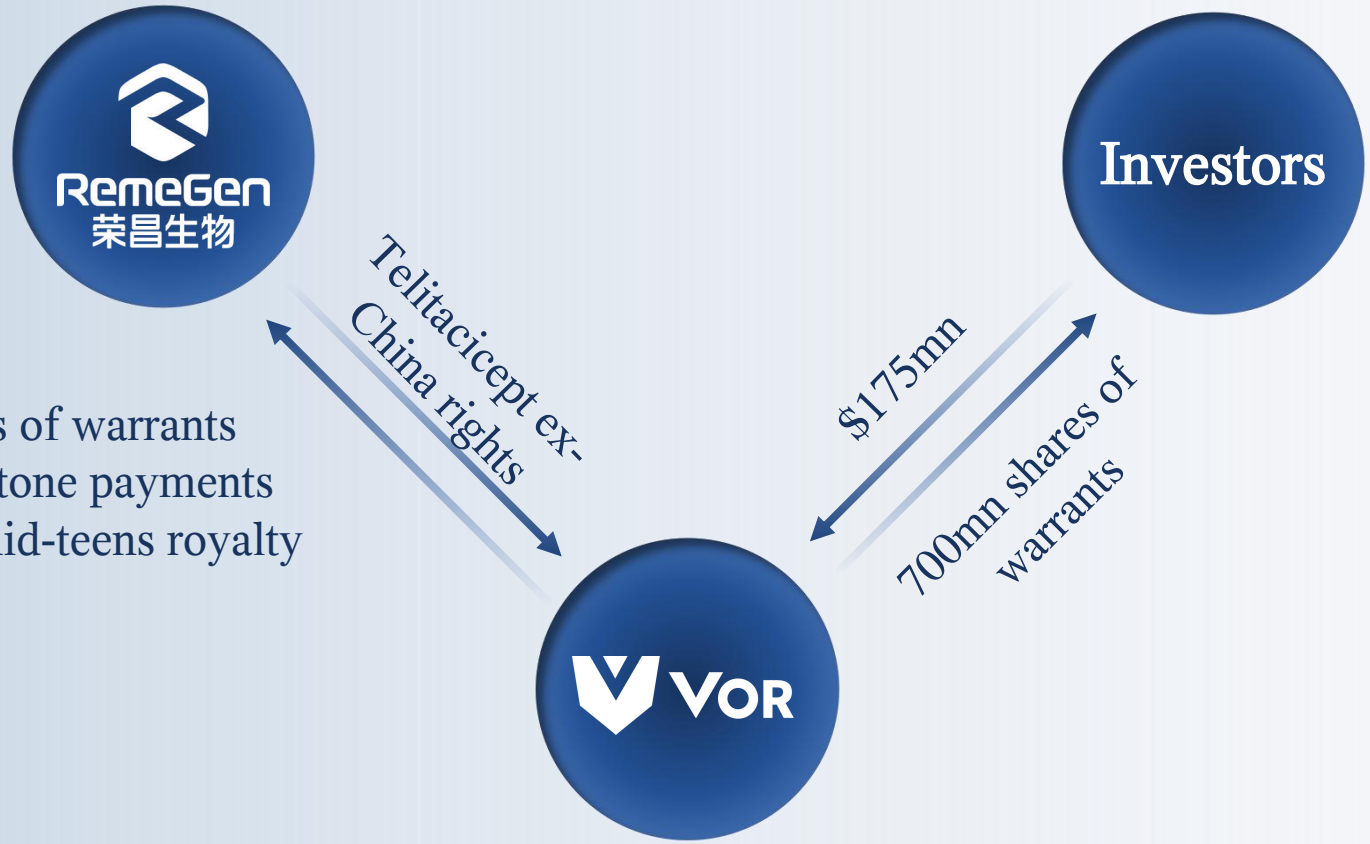
LAUNCHED	*Pivotal/Phase 3*	*Potential New Indications*	
Systemic Lupus Erythematosus	Systemic Lupus Erythematosus*	Lupus Nephritis	CTD-ILD
Rheumatoid Arthritis	Myasthenia Gravis	Membranous Nephritis	Idiopathic Thrombocytopenic Purpura
Myasthenia Gravis	*China BLA Filed*	IgG4-Related Disease	Ocular Myasthenia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

*Global Phase 3 Ready

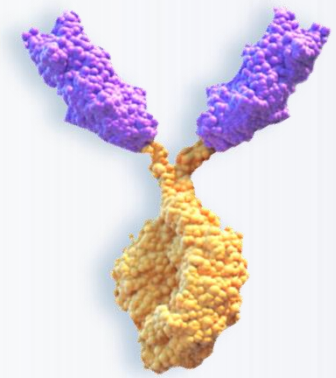
Telitacicept – Substantial Global Opportunity

PRINCIPAL TERMS OF THE LICENSE AGREEMENT with VOR BIO

- $45mn+320mn shares of warrants
- Up to US$4,1B milestone payments
- High single digit to mid-teens royalty on product sales



Commercialization – Telitacicept 泰爱®



- First-in-class BLyS/APRIL dual-targeting drug
- Approved for SLE, MG and RA in China

- ~900 member rheumatology focused sales team
- Listed in 1000+ hospital procurement list

- New indications (IgAN,SS, and etc) to provide sustained growth driver in the coming years
- Aim to become a leading therapy in treating B-cell-mediated autoimmune diseases

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 3 Clinical Trial in China

<u>Enrolled 114 patients</u>

- Telitacicept: 57 patients
- Placebo: 57 patients

Efficacy Data of Phase 3 Trial

Telitacicept 24 weeks:

- ✓ MG-ADL score improvement ≥ 3 reached 98.1%
- ✓ QMG score improvement ≥ 5 reached 87%

Telitacicept 48 weeks:
MG-ADL score continued to decline to -7.5 points

Key Milestones

China Phase 3 Study met primary endpoint Q3 2024

China BLA filing Q4 2024

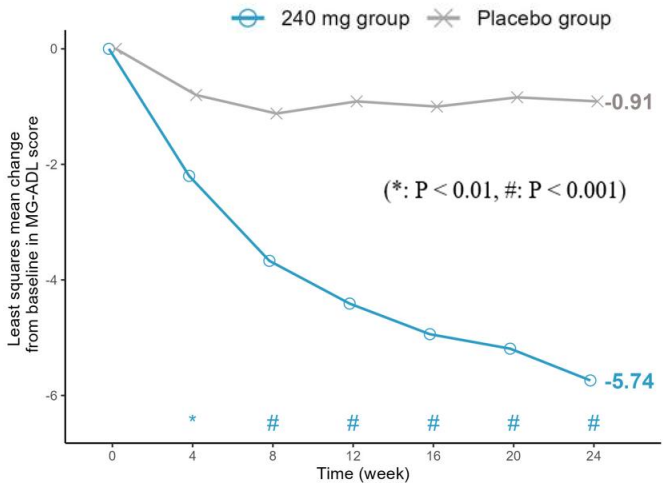
China BLA Approval Q2 2025

MG: Results of a Phase 3 Study-24 weeks

Efficacy Endpoints: Significant Change in MG-ADL (difference: -4.83) and QMG Scores (difference: -6.39) from Baseline for Telitacicept compared with Placebo

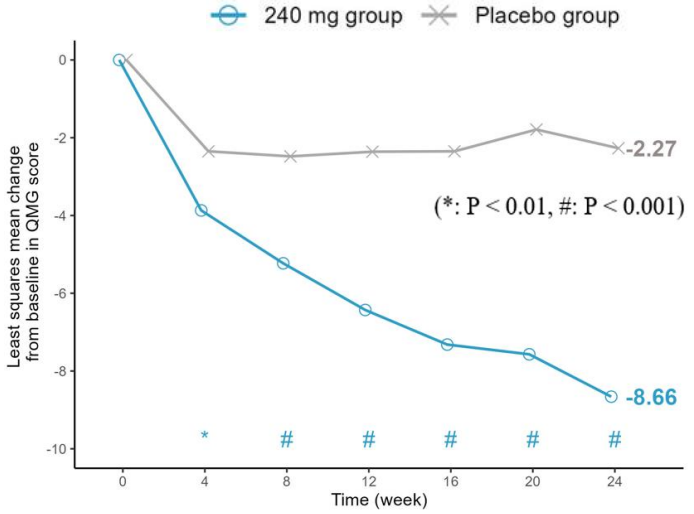
A

Mean Change in MG-ADL Score†



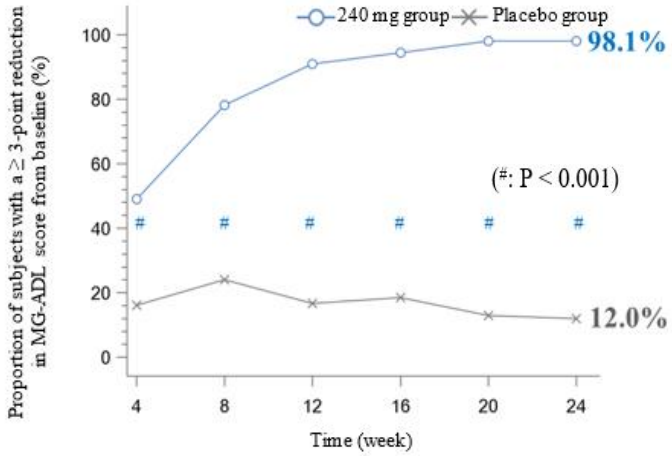
B

Mean Change in QMG Score†



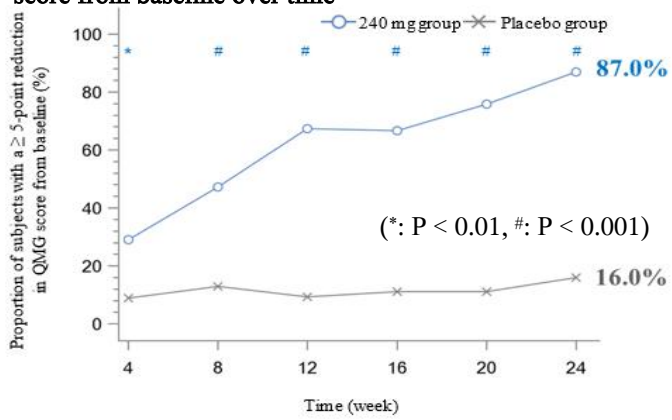
C

Proportion of patients with a ≥ 3 point reduction in MG-ADL score from baseline over time



D

Proportion of patients with a ≥ 5 point reduction in QMG score from baseline over time



MG: Results of a Phase 3 Study-24 weeks

Safety Results

Infection-associated AEs occurring in >5% of subjects

	Telitacicept (N=57)		Placebo (N=57)	
	n (%)	Events	n (%)	Events
Infections and infestations	26 (45.6)	46	34 (59.6)	50
Upper respiratory tract infection	12 (21.1)	17	20 (35.1)	24
Urinary tract infection	9 (15.8)	11	6 (10.5)	6
Pneumonia	1 (1.8)	1	6 (10.5)	6
Respiratory tract infection	1 (1.8)	1	2 (3.5)	2
Influenza	0 (0)	0	3 (5.3)	3

Serious AEs

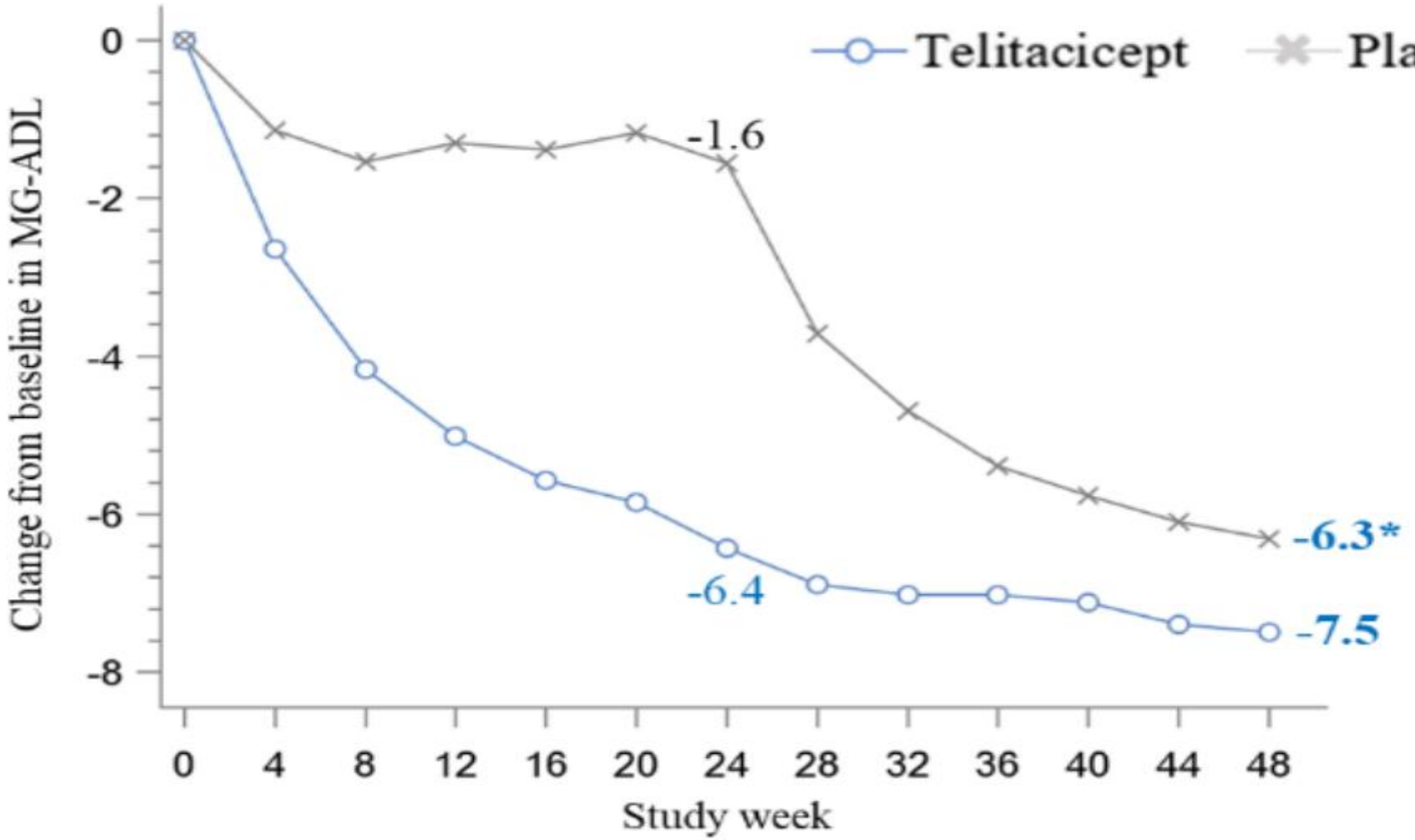
	Telitacicept (N=57)		Placebo (N=57)	
	n (%)	Events	n (%)	Events
Serious AEs	4 (7.0)	4	6 (10.5)	7
Pneumonia	1 (1.8)	1	4 (7.0)	4
COVID-19 pneumonia	1 (1.8)	1	0 (0)	0
Influenza	0 (0)	0	1 (1.8)	1
Upper respiratory tract infection	0 (0)	0	1 (1.8)	1
Open fracture	0 (0)	0	1 (1.8)	1
Pneumonitis	1 (1.8)	1	0 (0)	0
Accidental death	1 (1.8)	1	0 (0)	0

- Injection site reactions were reported in 14.0% of the telitacicept group and 1.8% of the placebo group

Safety conclusion: Telitacicept demonstrated a safety profile consistent with data from clinical trials in systemic lupus erythematosus, rheumatoid arthritis, progressive systemic sclerosis and IgA neuropathy, and post-marketing data

MG: Results of a Phase 3 Study-48 weeks

Efficacy Endpoints: After 24 weeks significant change in MG-ADL (difference: -4.83) , after 48 weeks the MG-ADL score continued to decline to -7.5 points



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

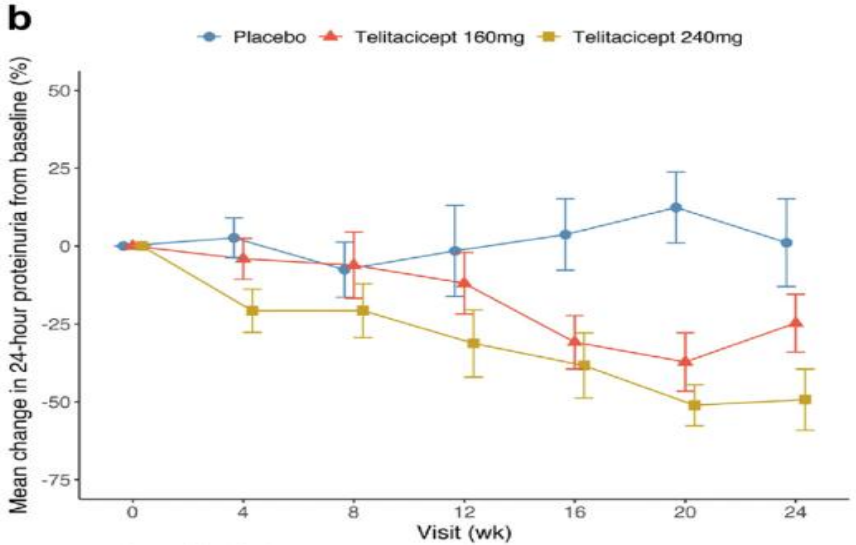
Clinical Results

Phase 2 Clinical Trial in China

<u>Enrolled 44 patients</u>

- 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
2H 2025

Potential BLA filing
2H 2025

Telitacicept for 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

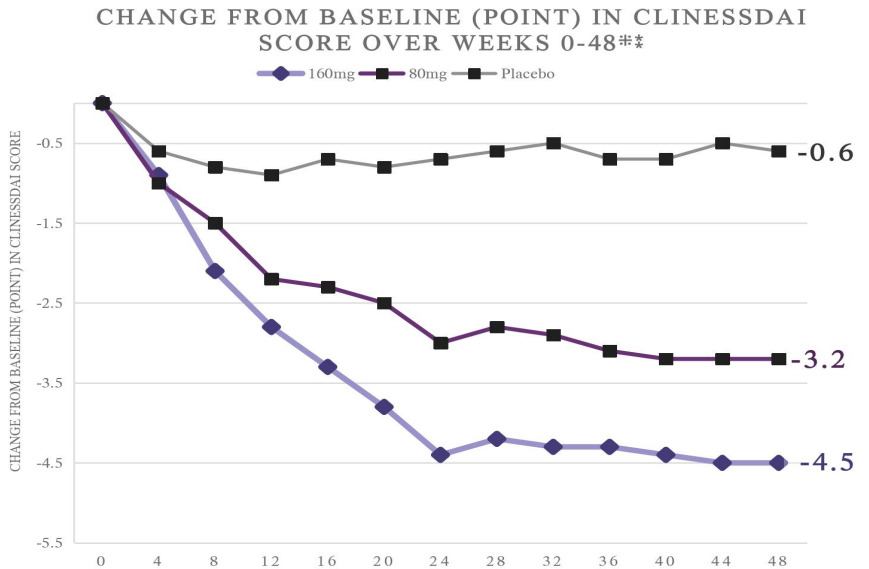
Clinical Results

Phase 3 Clinical Trial in China

<u>Enrolled 381 patients</u>

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

Efficacy Data of Phase 3 Trial



Key Milestones

China Phase 3 Study
LPI Q2 2024

Data readout
2H 2025

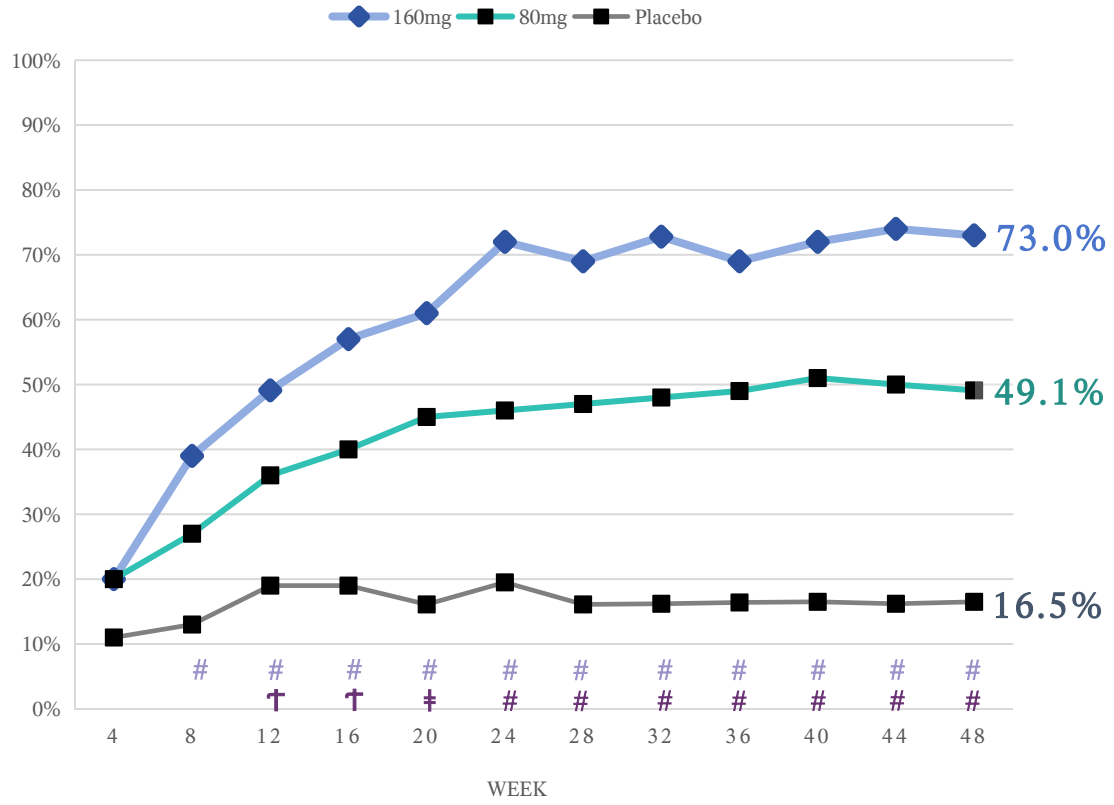
Potential BLA filing
2H 2025

SS: Results of a Phase 3 Study

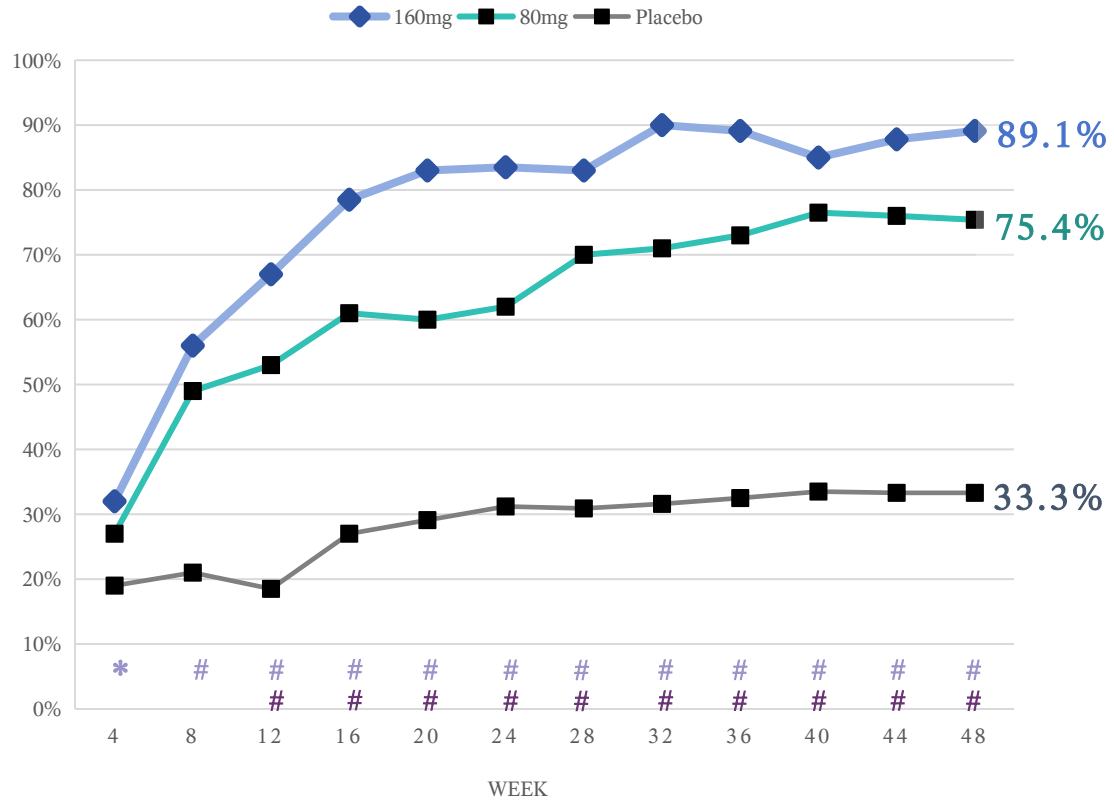
Telitacicept Is Driving Broad, Early Symptom Relief in SS

Nearly 90% of patients report improvement as physicians confirm disease control in 3 out of 4 patients

PROPORTION OF PARTICIPANTS WITH ≥ 3-POINT REDUCTION FROM BASELINE IN ESSDAI SCORE OVER TIME*‡



PROPORTION OF PARTICIPANTS WITH ≥ 1-POINT OR ≥ 15% REDUCTION FROM BASELINE IN ESSPRI SCORE OVER TIME*‡



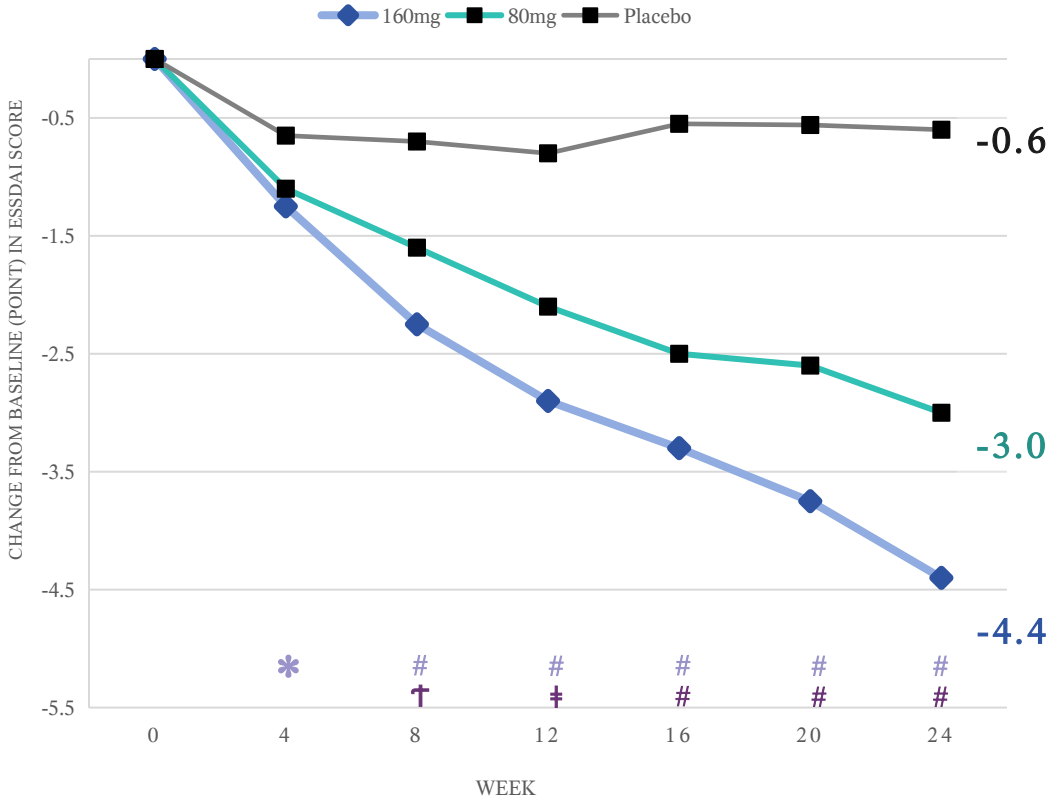
(* P<0.05, † P<0.01, ‡ P<0.001, # P<0.0001)

SS: Results of a Phase 3 Study

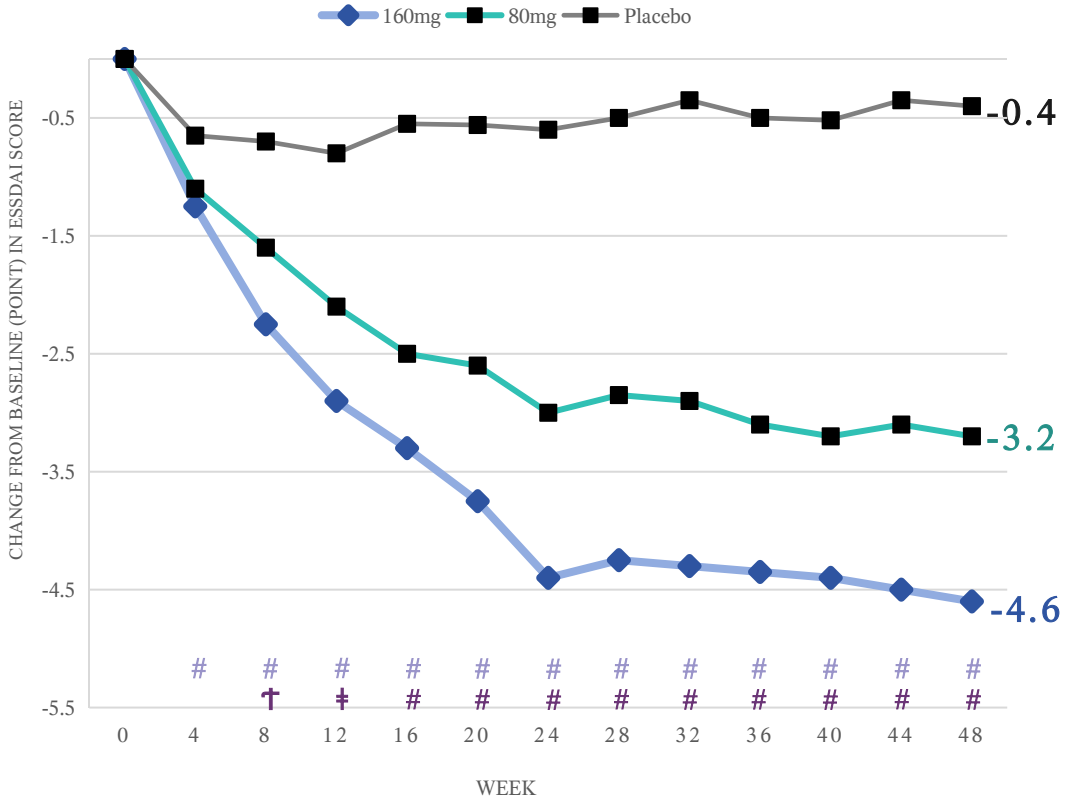
Deep, Consistent ESSDAI Reduction Through 48 Weeks

7x greater improvement means fewer active symptoms and broader systemic relief for patients

CHANGE FROM BASELINE (POINT) IN ESSDAI SCORE OVER WEEKS 0-24*



CHANGE FROM BASELINE (POINT) IN ESSDAI SCORE OVER WEEKS 0-48‡



(* $P<0.05$, † $P<0.01$, ‡ $P<0.001$, # $P<0.0001$)

SS: Results of a Phase 3 Study

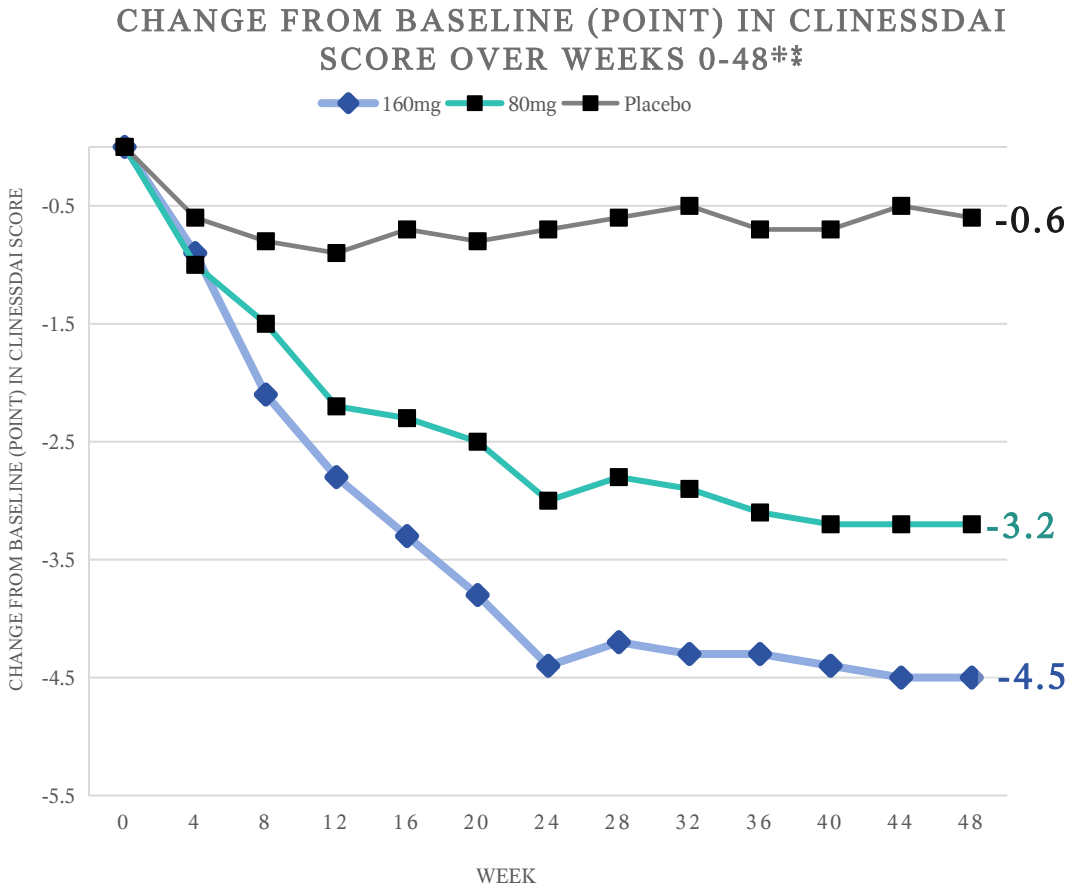
Deep, Consistent ClinESSDAI Reduction Through 48 Weeks

Sustained improvement in clinical benefit beyond serologic change

ESSDAI and ClinESSDAI remain nearly identical at week 48

-4.6 vs -4.5

ClinESSDAI excludes biological domain (IgG, complement), representing a more sensitive measure of pure clinical disease activity



SS: Results of a Phase 3 Study

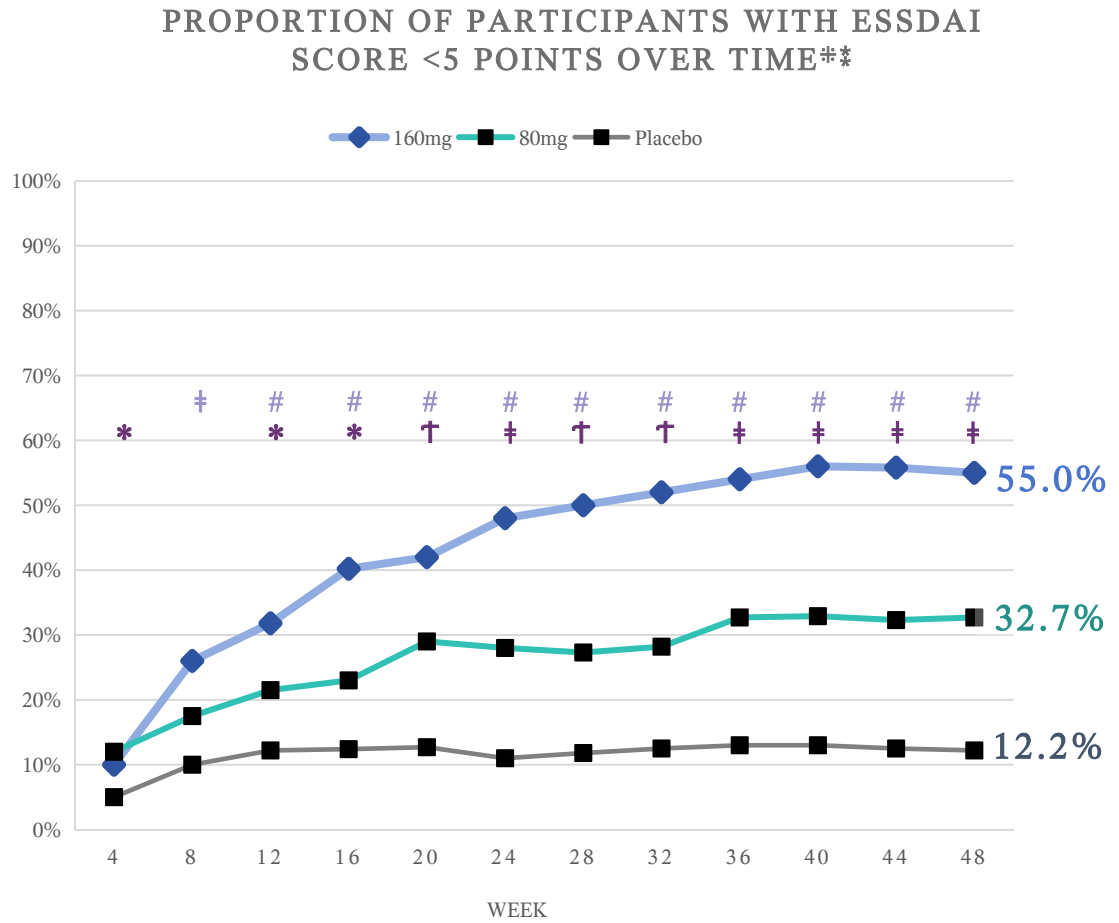
More Than Half of Patients Achieved Low Disease Activity

Nearly 5x more patients on 160mg vs placebo achieved this threshold

Low Disease Activity (ESSDAI <5) Represents Minimal Systemic Involvement

55% vs 12%

Consistent improvement sustained through 48 weeks, indicating durable immune stabilization



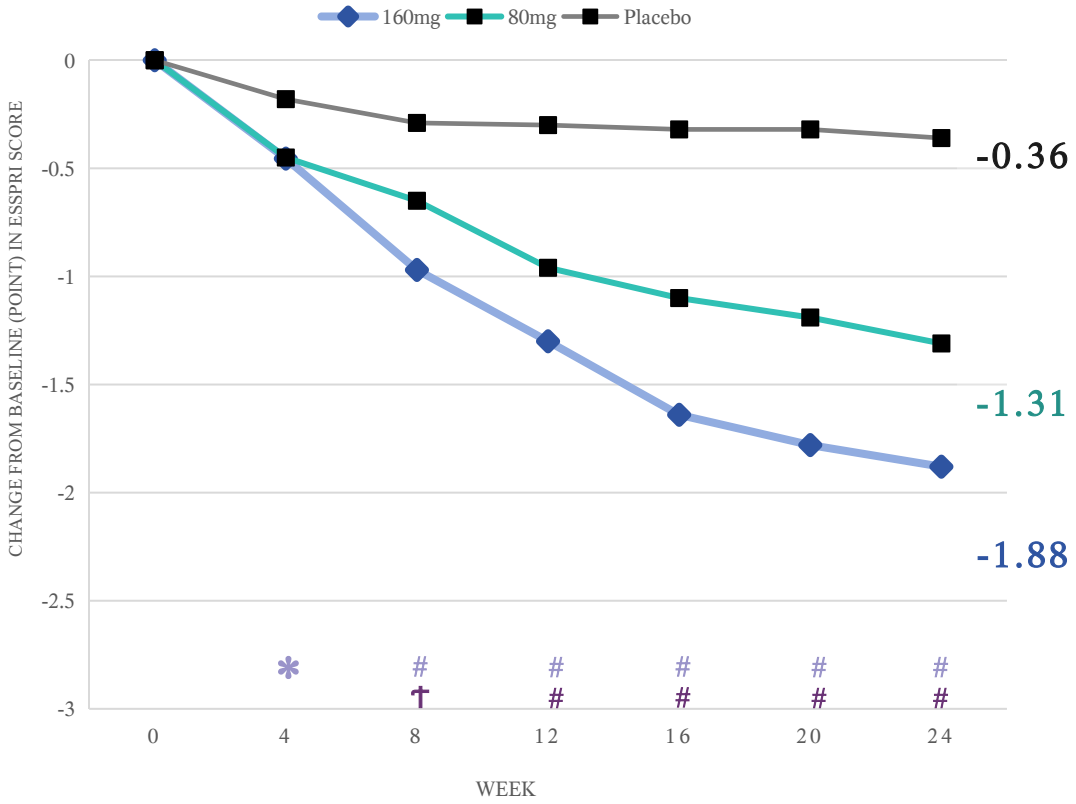
(* $P<0.05$, † $P<0.01$, ‡ $P<0.001$, # $P<0.0001$)

SS: Results of a Phase 3 Study

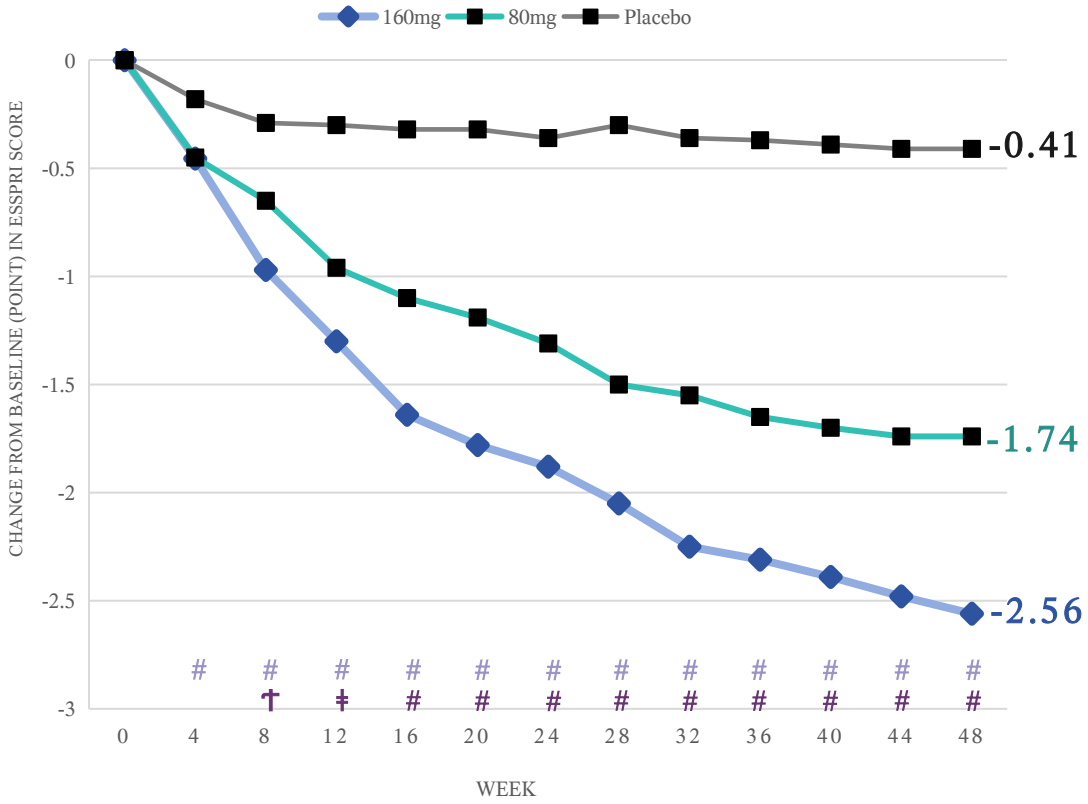
Sustained Improvement in ESSPRI Through 48 Weeks

Reduction in patient-reported fatigue, pain, and dryness by ~2.6 points at one year

CHANGE FROM BASELINE (POINT) IN ESSPRI SCORE OVER WEEKS 0-24*



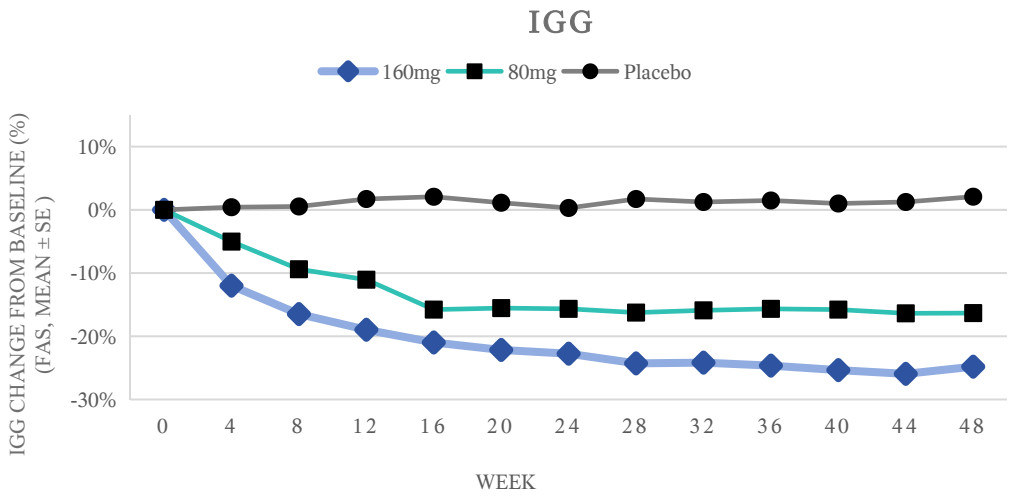
CHANGE FROM BASELINE (POINT) IN ESSPRI SCORE OVER WEEKS 0-48‡

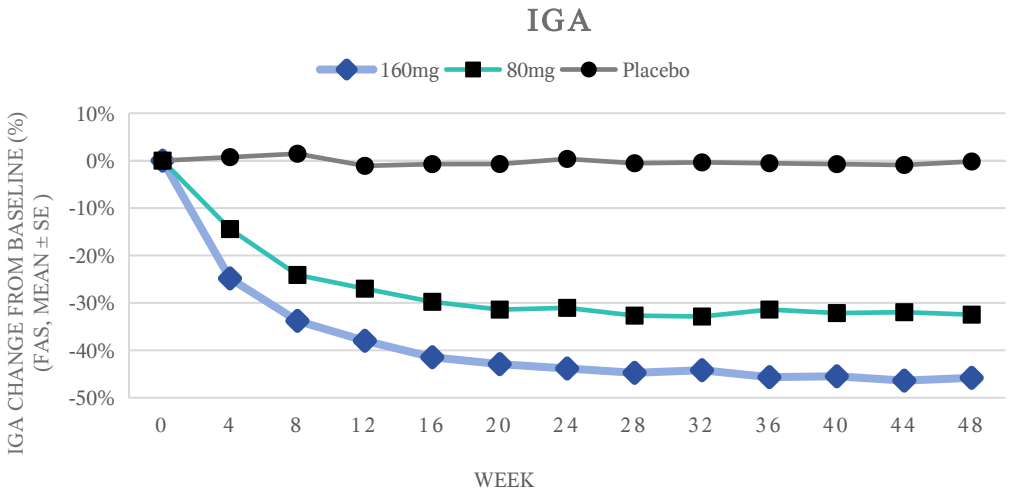


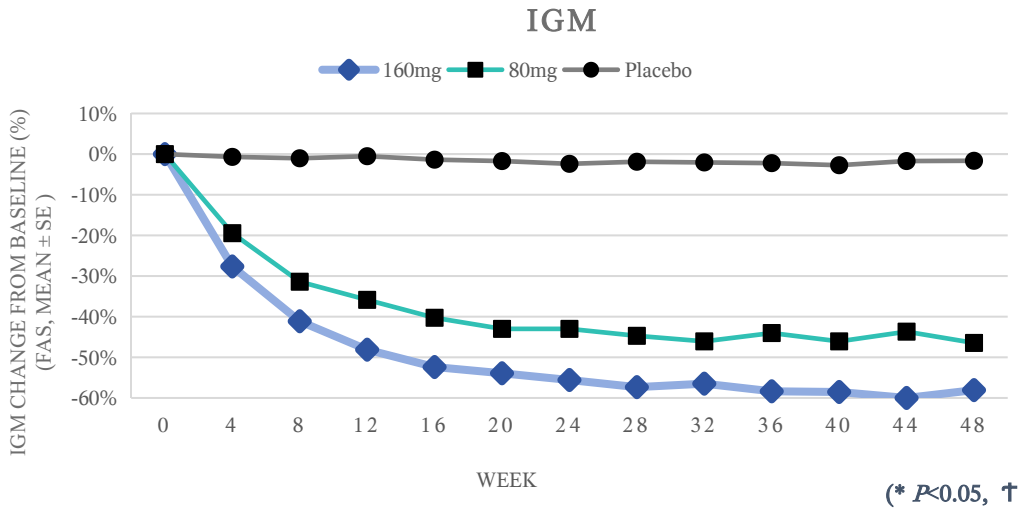
(* $P<0.05$, † $P<0.01$, ‡ $P<0.001$, # $P<0.0001$)

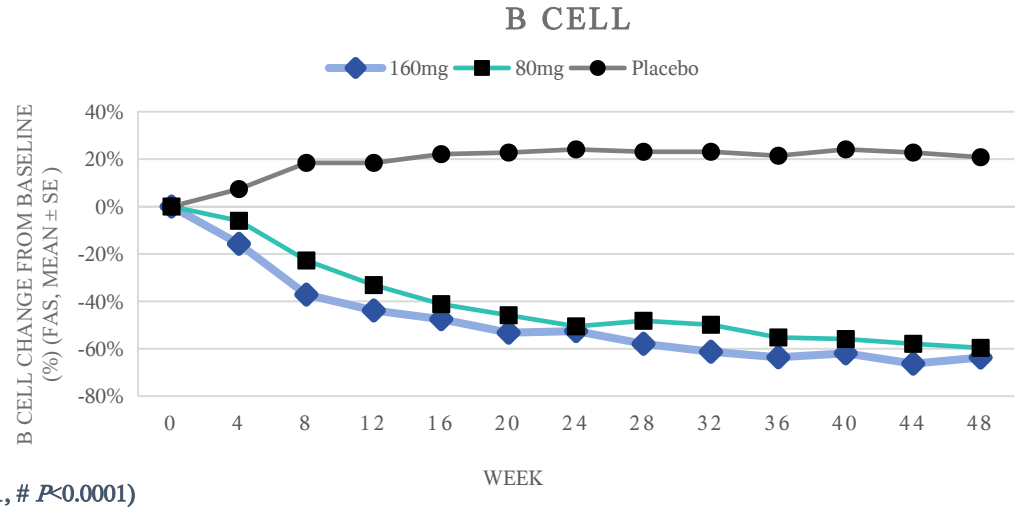
SS: Results of a Phase 3 Study

Consistent Reduction in IgG, IgA, IgM, and B Cells









(* $P<0.05$, † $P<0.01$, ‡ $P<0.001$, # $P<0.0001$)

SS: Results of a Phase 3 Study

Safety Profile

	Telitacicept 160mg (N=127)	Telitacicept 80 mg (N=126)	Placebo Group (N=127)
TEAE, n(%)	122 (96.1)	119 (94.4)	112 (88.2)
TRAE, n(%)	107 (84.3)	106 (84.1)	74 (58.3)
TESAE, n(%)	11 (8.7)	14 (11.1)	10 (7.9)
TRSAE, n(%)	2 (1.6)	5 (4.0)	4 (3.1)
Severe TEAE, n(%)	3 (2.4)	5 (4.0)	3 (2.4)
Severe TRAE, n(%)	0	1 (0.8)	1 (0.8)
Death, n(%)	0(0)	0(0)	0(0)
Common TEAE (incidence ≥ 10% in any group)			
Upper respiratory tract infections, n(%)	80 (63.0)	85 (67.5)	74 (58.3)
Urinary tract infection, n(%)	8 (6.3)	15 (11.9)	7 (5.5)
Cough, n(%)	11 (8.7)	14 (11.1)	8 (6.3)
Hepatic function abnormal, n(%)	7 (5.5)	16 (12.7)	7 (5.5)
Injection site reaction, n(%)	53 (41.7)	51 (40.5)	5 (3.9)
Pyrexia, n(%)	4 (3.1)	14 (11.1)	4 (3.1)

Consistent with data from clinical trials in SLE, RA, gMG, and post-marketing data

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
- HR+/HER2-low: RC48-C012
- TNBC 1L: RC48-C036

2

Explore druggability for new targets

- BsAb-RC148
- MSLN-RC88
- cMET-RC108
- CLDN18.2-RC118
- RC278

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

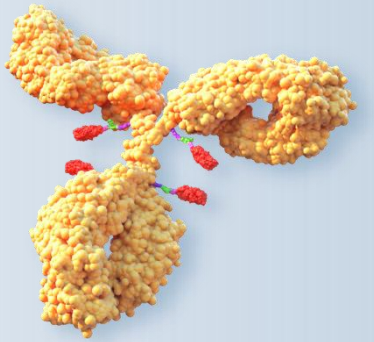
- New payload
- New linker technology
- Next-Generation ADC and BsAb platform

Commercialization - Disitamab Vedotin 爱地希®

- The first domestic ADC drug approved in China
- Approved in 2L(+) UC and GC patients

- ~500 member oncology focused sales team
- Listed in 1000+ hospital procurement list

- Solidifying a leading position in HER-2 expressing urothelial cancer patients
- Multiple ongoing trials to expand the target patient pool



Phase III RC48-C016 Study Results

Background

- HER2-targeted antibody-drug conjugate monotherapy has demonstrated efficacy in the post-chemotherapy setting for HER2-positive UC and is approved in both China (disitamab vedotin) and the USA (T-DXd).

- An ORR of 76.3% and median PFS of 9.3 months were observed with DV plus toripalimab (a humanized anti-PD-1 monoclonal antibody) in patients with previously untreated or chemotherapy-refractory HER2-expressing (IHC 1+, 2+, or 3+) la/mUC based on the previous phase Ib/II RC48-C014 study.

- HER2 expression is highly prevalent in UC, with HER2 IHC ≥ 1+ accounting for up to 70% of UC.

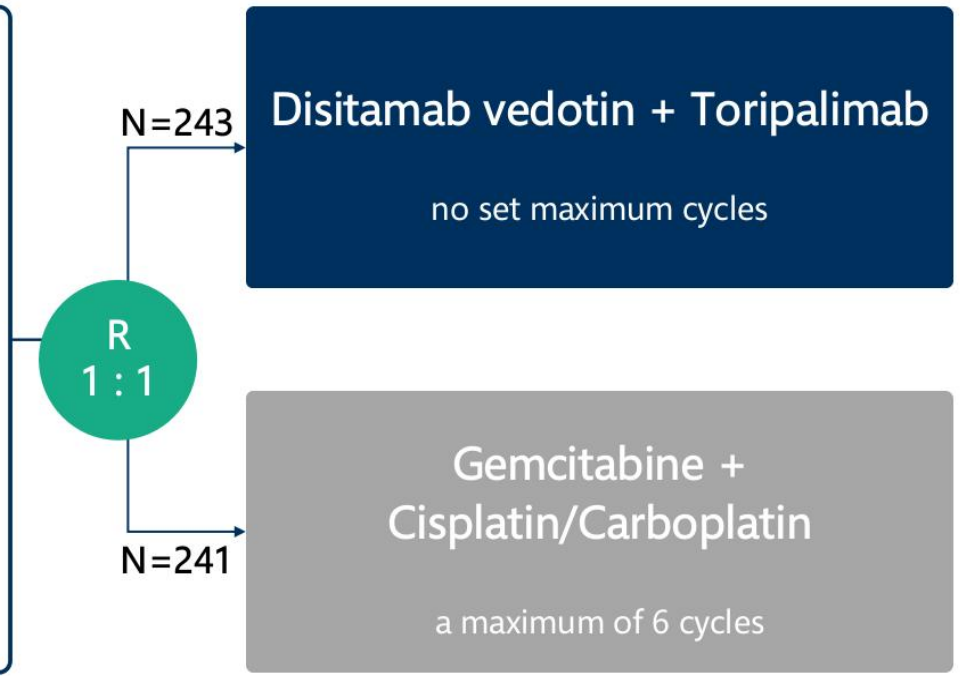
The RC48-C016, an open-label, multicenter, randomized phase 3 trial, was conducted to evaluate DV+T vs chemotherapy in the 1L treatment of patients with HER2-expressing la/mUC in China. We report the prespecified final PFS analysis and interim OS analysis.

Phase III RC48-C016 Study Results

C48-C016 Study Design (NCT05302284)

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 ciscplatin or carboplatin
- ECOG PS 0 or 1



Dual primary endpoints:

- PFS assessed by BIRC
- OS

Secondary endpoints:

- PFS assessed by investigators
- ORR (per RECIST v1.1), DCR, and DoR assessed by BIRC and investigators
- Safety
- QoL, PK, and immunogenics

Stratification factors

- Cisplatin-eligibility (eligible vs ineligible)
- HER2 expression status (1+ vs 2+/3+)
- Visceral metastases (present vs absent)

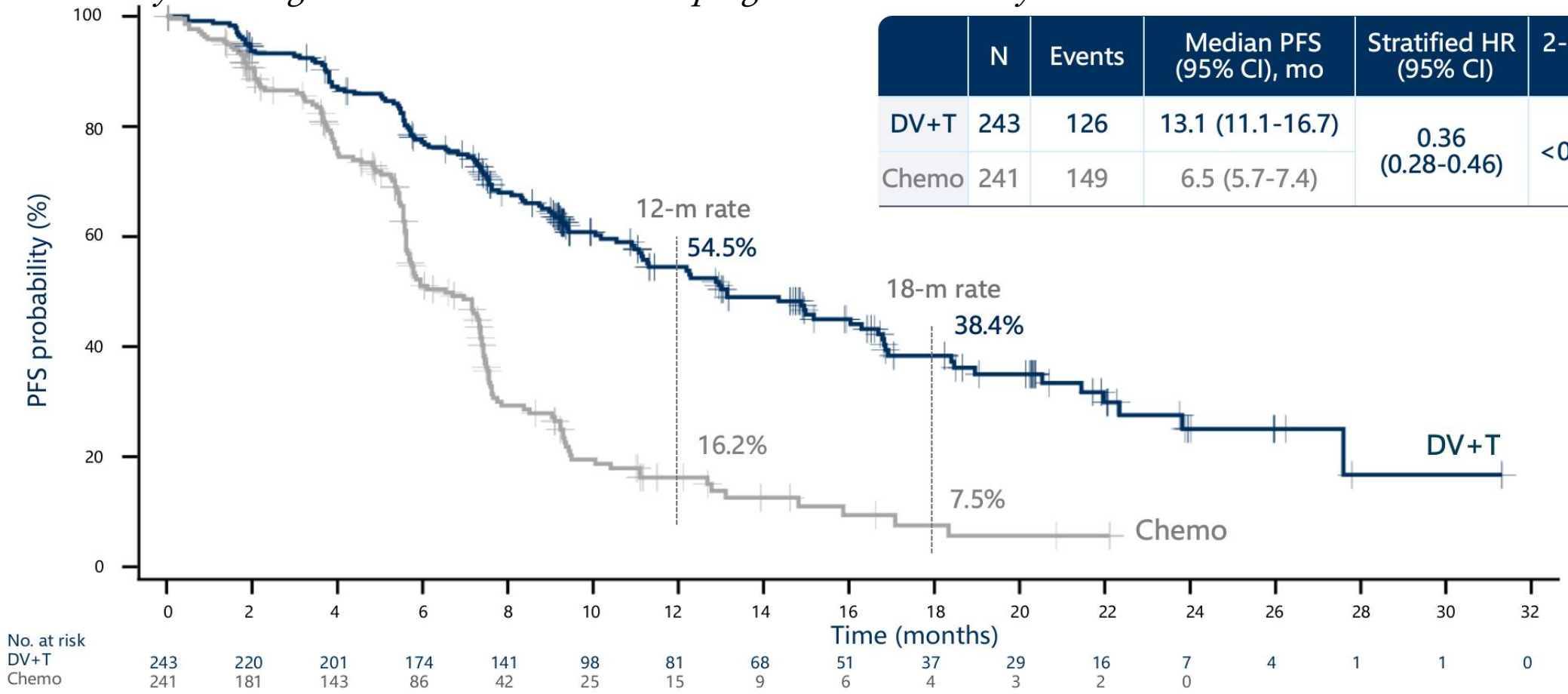
- Treatment continued until disease progression/death, intolerable toxicity, or consent withdrawal.
- In the Chemo group, assignment of cisplatin or carboplatin was protocol-defined. Chemo was administered for a maximum of 6 cycles.
- Statistical plan for analysis: the first analysis was planned to be performed after approximately 278 PFS (final) and 183 OS events (interim).

Phase III RC48-C016 Study Results

Progression-free Survival according to BIRC

Clinically meaningful reduction in the risk of progression or death by 64% with DV+T

	N	Events	Median PFS (95% CI), mo	Stratified HR (95% CI)	2-sided P
DV+T	243	126	13.1 (11.1-16.7)	0.36 (0.28-0.46)	<0.0001
Chemo	241	149	6.5 (5.7-7.4)		



- The investigator assessment (median: 12.3 vs 6.2 months; stratified HR: 0.36 [95% CI: 0.28-0.46]) was consistent with BIRC.

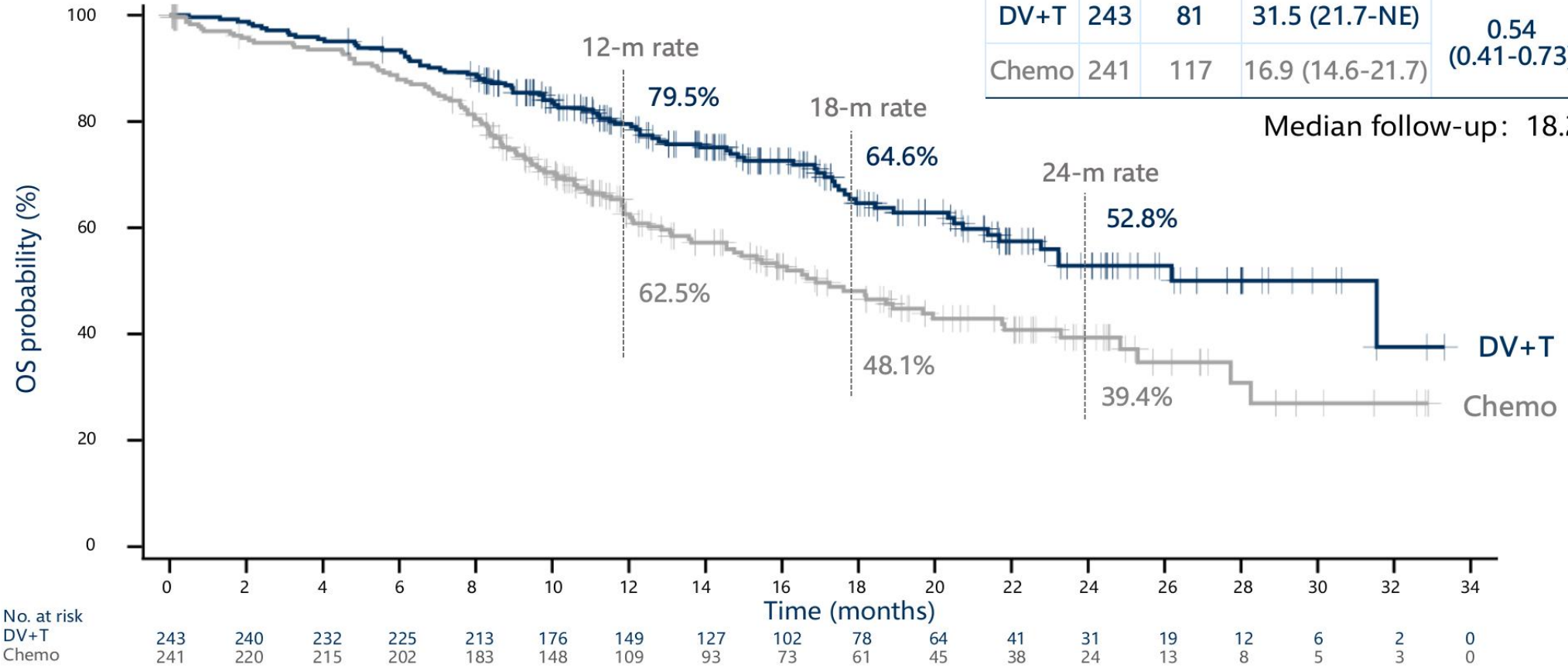
Phase III RC48-C016 Study Results

Overall Survival

Clinically meaningful reduction in the risk of death by 46% with DV+T

	N	Events	Median OS (95% CI), mo	Stratified HR (95% CI)	2-sided P
DV+T	243	81	31.5 (21.7-NE)	0.54 (0.41-0.73)	<0.0001
Chemo	241	117	16.9 (14.6-21.7)		

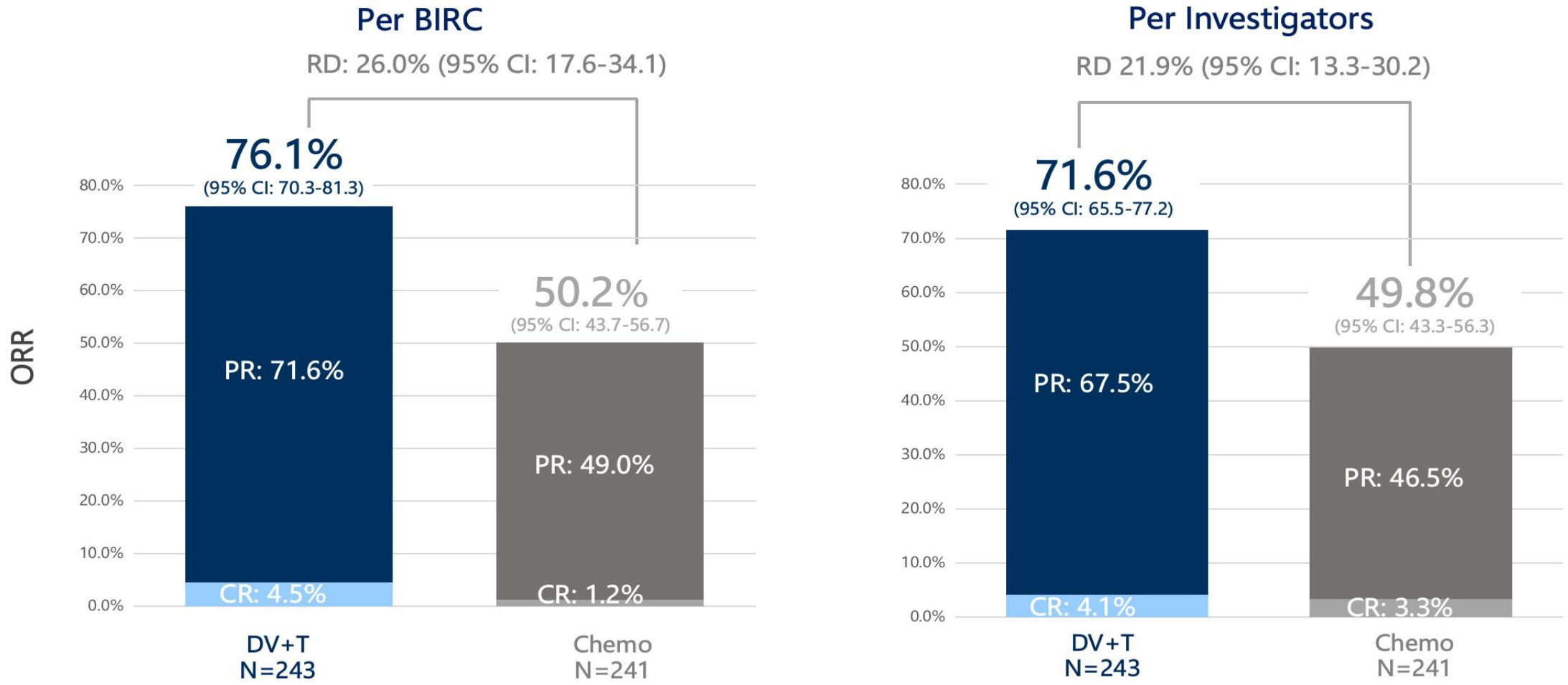
Median follow-up: 18.2 months



Phase III RC48-C016 Study Results

Tumor Response

Significant improvement in tumor response in patients with DV+T by BICR and investigators

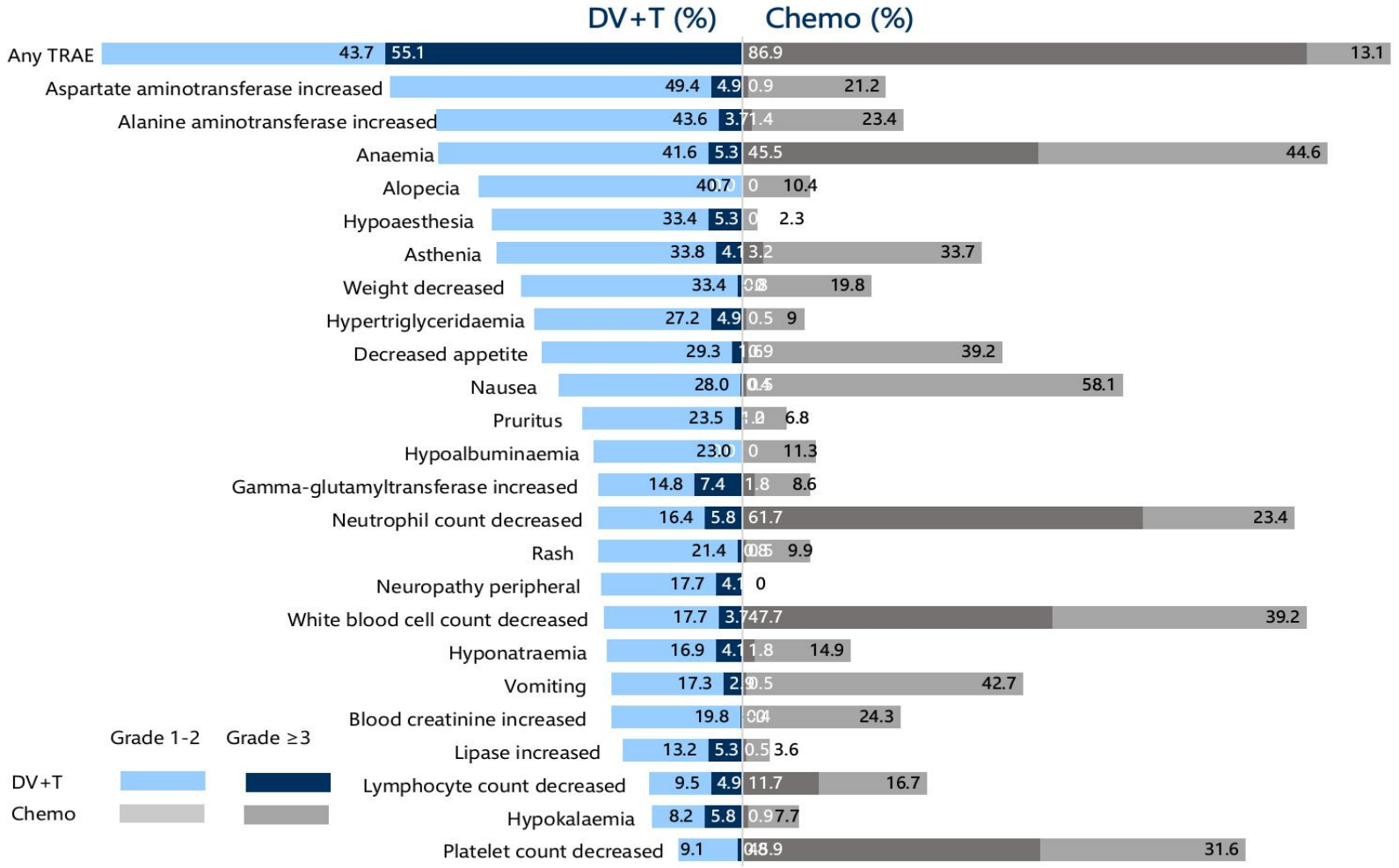


RD (rate difference) and it's corresponding 95%CI was calculated using a stratified Miettinen-Nurminen method. Abbreviations: CR, complete response; PR, partial response.

Phase III RC48-C016 Study Results

Safety Summary

Incidence of grade ≥3 TRAEs: 55.1% with DV+T vs 86.9% with chemo



n (%)	DV+T (N = 243)	Chemo (N = 222)*
Treatment-emergent adverse events (TEAEs)	243 (100)	222 (100)
Treatment-related adverse events (TRAEs)	240 (98.8)	222 (100)
Grade ≥3 TRAEs	134 (55.1)	193 (86.9)
Grade 3	107 (44.0)	93 (41.9)
Grade 4	24 (9.9)	97 (43.7)
Grade 5	3 (1.2)	3 (1.4)
Serious TRAEs	69 (28.4)	90 (40.5)
Immune-related adverse events		
Any grade	114 (46.9)	/
Grade ≥3	46 (18.9)	/
TRAE leading to discontinuation of any study treatment	30 (12.3)	23 (10.4)

*19 patients in the chemo group did not receive the assigned treatment after randomization and were excluded from safety analysis.

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)

License Agreement for RC28-E

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.

RemeGen 荣昌生物 → Santen

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

Upcoming Catalysts

Remainder of 2025

Data read-out:

- Telitacicept for IgAN – Interim China Phase III data (9 month UPCR)
- Telitacicept for pSS – China Phase III data
- Telitacicept for gMG - China Phase III 48 weeks data
- RC-148 early stage data

FY2026

- Potential China approval of Telitacicept for IgAN
- Potential China approval of Telitacicept for SS
- Potential China approval of RC48 in 1st line UC
- Potential China approval of RC 28 for DME
- BLA filing of RC28 for wAMD
- Data read-out from Telitacicept for IgAN China Phase III data (2 year full-data)
- Updates of RC148 clinical progress
- Updates of RC48 ex-China regulatory and clinical progress from Pfizer
- Updates of Telitacicept ex-China clinical progress

RemeGen
荣昌生物

THANK YOU