

Keymed Bio (2162.HK)

2023 Interim Results Investor Presentation Deck

2023 August

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KeyMed Biosciences

CHAPTER 1

Keymed 2023 Company Highlights



Keymed Bio 2023 H1 Highlights & Latest Updates

Core Pipelines: CM310/ CM326/ CMG901/ CM313/ CM338

- **CM310 (IL-4R α) (**BTD*):** We have completed the data unblinding and preliminary statistical analyses of Phase III study for moderate-to-severe AD in adults by March 2023, and both of the co-primary endpoints were achieved successfully; the patient enrollment of Phase III clinical trial for CRSwNP has been completed in May 2023; Plan to initiate the Phase III trial for the treatment of Seasonal Allergic Rhinitis (SAR) in 2023 H2; Phase II/ III pivotal study for Asthma has been initiated in 2023 Q1 (led by CSPC)
- **CM326 (TSLP):** Phase II for moderate-to-severe AD in adults is ongoing, patient enrollment was completed in June 2023; Phase Ib/IIa for CRSwNP is ongoing, patient enrollment was completed in Feb 2023; Phase II for Asthma has been initiated in March 2023 (led by CSPC)
- **CMG901 (CLDN 18.2 ADC) (**BTD/ Fast Track/ Orphan Drug*):** Feb 2023, we announced a global exclusive license agreement with AstraZeneca for CMG901. Under the license agreement, AstraZeneca will be responsible for the R&D, manufacture and commercialization of CMG901 globally. KYM Biosciences has already received the upfront payment of \$63 million on transaction closing by the end of March 2023, and will receive additional development and sales-related milestone payments of up to \$1.1 billion as well as tiered royalties up to low double-digits. Phase I dose-escalation data was published in 2023 ASCO GI, preliminary efficacy results demonstrated that in the 8 Claudin 18.2-positive gastric/GEJ cancer patients receiving CMG901, ORR and DCR were 75.0% and 100%
- **CM313 (CD38):** Phase I data for the treatment of RRMM was released in 2023 EHA, Among the 29 out of 31 RRMM patients who had at least one post-baseline efficacy assessment, **ORR was 34.5%**; At a median follow-up of 6 months , **the mPFS for the 29 RRMM patients was 132 days**, the mOS was not reached yet; **Phase Ib/IIa for the treatment of SLE is ongoing**
- **CM338 (MASP-2):** Initiated the Phase II trial for the treatment of IgAN in Feb 2023

Other Assets: CM355/ CM350/ CM336/ CM369

- CM355 (CD20xCD3) / CM350 (GPC3xCD3)/ CM336 (BCMAxCD3): Phase I/II trials ongoing
- CM369 (CCR8): FPI in Feb 2023, co-develop with InnoCare

Keymed Bio 2023 H1 Highlights & Latest Updates

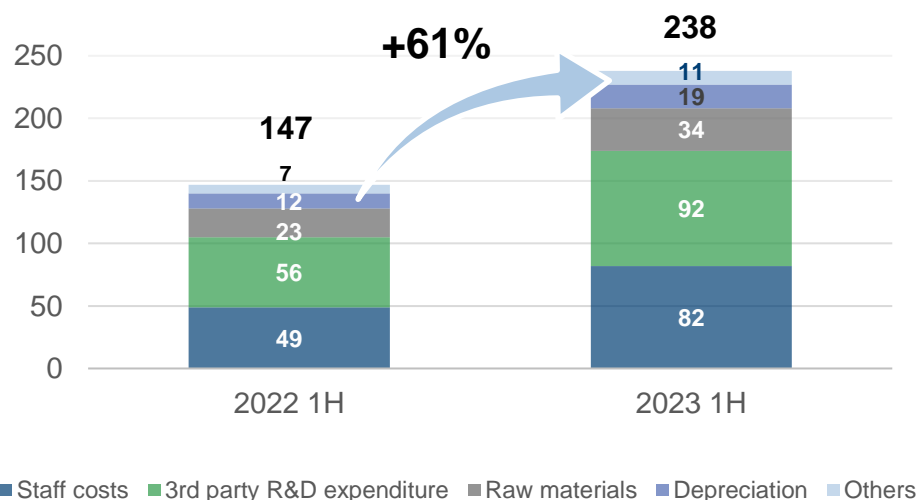
Expand Infrastructure & Talent Team

- By the mid of June 2023, the number of employees has been **reached 750**, among which clinical development staffs **over 250**, CMC staffs **over 340**. Besides Chengdu, we are operating our offices in Shanghai, Beijing, Wuhan, Guangzhou, Nanjing, etc.
- By the mid of 2023, commercial-scale in Chengdu can provide **18,600 L of manufacturing capacity in total**

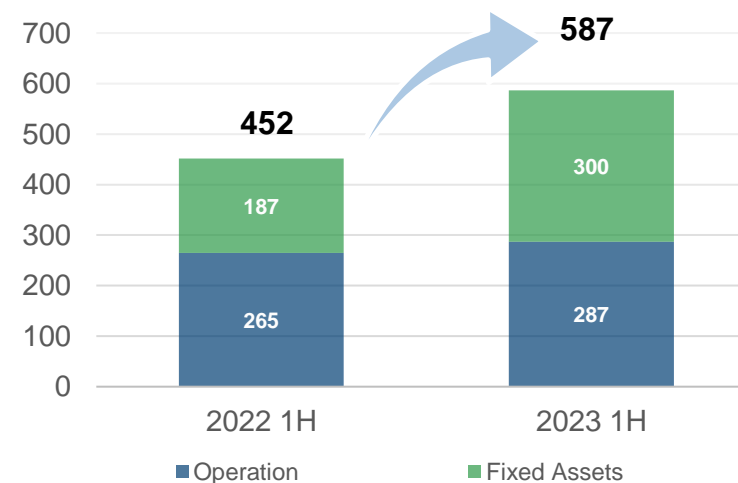
Financial Data & Capital Market Performance

- 2023 1H R&D Expenses: RMB 250 million (+52% YoY) ; Adjusted total comprehensive profit: RMB 64 million (+148% YoY)**
- As of June 30, 2023, the Company held **cash (including Bank wealth management products) of nearly RMB 3 billion**, and revenue amounted to **RMB 327 million** for the six months ended June 30, 2023, **mainly representing collaboration income from AstraZeneca** in respect of granting the relevant license

Research & Development (Excluding share based payment)



Cash Outflow of Operation and Fixed Assets



(UNIT: RMB million)

Diversified Pipeline Targeting Innovative Biological Therapies in the Autoimmune and Oncology Therapeutic Areas

Research areas	Drug Candidate	Target (Modality)	Focused Indications	Lead Identification	Pre-Clinical	IND	Ph-I	Ph-II	Ph-III	Partner	Commercial Rights		
Autoimmune	CM310 ★	IL-4Ra (mAb)	Moderate-to-severe AD--Adults	BTD granted by CDE								Global	
			Moderate-to-severe AD--Children & Adolescents									Global	
			CRSwNP									Global	
			Moderate-to-severe eosinophilic asthma									石药集团 CSPC	Global ex mainland China
			AR									Global	
	CM326 +	TSLP (mAb)	Moderate-to-severe AD									Global	
			CRSwNP									Global	
			Moderate-to-severe asthma									石药集团 CSPC	Global ex mainland China
			COPD									石药集团 CSPC	Global ex mainland China
	CM338	MASP-2 (mAb)	IgA nephropathy									Global	
Oncology	CMG901 +	Claudin 18.2 (ADC)	Gastric and Other Solid tumors	FTD & ODD granted by FDA		BTD granted by CDE					AstraZeneca		
	CM313	CD38 (mAb)	RRMM, lymphoma and other hematological malignancies									Global	
			SLE									Global	
	CM355	CD20xCD3 (Bispecific)	Lymphoma									INNOCARE	Global
	CM336	BCMAxCD3 (Bispecific)	RRMM									Global	
	CM350	GPC3xCD3 (Bispecific)	Solid tumors									Global	
	CM369	CCR8 (mAb)	Tumors									INNOCARE	Global

★ Core Product + Key Product

Abbreviations:

AD = atopic dermatitis; ADC = antibody drug conjugate; CRS = chronic rhinosinusitis; CRSwNP = chronic rhinosinusitis with nasal polyposis; COPD = chronic obstructive pulmonary disease; GEJ = gastroesophageal junction; mAb = monoclonal antibody; AR = allergic rhinitis; MM = multiple myeloma; PH = Phase; RRMM = relapsed or refractory multiple myeloma

Keymed Biosciences at a Glance



We are a biotechnology company with multiple clinical-stage assets, each of them being the leading contender within its respective competitive landscape



Internally-developed Pipeline

Consistently and successfully take on underserved and challenging disease areas

- **9** in clinical-stage development, each being among **first three** domestically-developed for its target or in its class to have obtained IND approval in China and/or the U.S
- Core and key assets: **CM310** (IL-4R α), **CM326** (TSLP), **CMG901** (Claudin18.2 ADC), **CM313** (CD38), **CM338** (MASP-2)

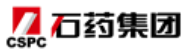


Fully-integrated R&D platform

- Innovative **antibody discovery** platform
- Proprietary **novel T cell engager (nTCE) bispecific antibody** platform
- **Bio-evaluation** platform
- **High-throughput screening** platform



Worldwide Collaboration



Out-licensed **CM310 & CM326's** asthma, COPD and other **respiratory diseases indications**

Jointly promote the R&D of novel drugs for **neurodegenerative diseases**



R&D, manufacture and commercialization of **CMG901** globally



Co-develop, manufacture and commercialize **CM355** (CD20xCD3) & **CM369** (CCR8)



Management team with rich industry experience and scientific expertise



Manufacturing Capacity

cGMP Compliant Manufacturing

- **~ 3-year** successful track record of supplying antibody drug candidates for various preclinical and clinical studies
- Chengdu:
 - A capacity of **1,600 L** was built in **2019**
 - **An additional 16,000L** of manufacturing capacity commenced operation in **2022**
 - A capacity of **1,000 L** was expanded in **2023**

Efficiently Promote Drug R&D and Commercialization

Autoimmune

Promote the pivotal study and the commercialization of CM310 at a fastest pace

★ CM310 (IL-4R α) --- BTD for AD

CM310 (AD) :We completed the Phase III trial data unblinding and preliminary statistical analyses by March 2023, and both of the co-primary endpoints were achieved successfully, plan to submit the BLA application in 2023; IND approval from FDA

CM310 (CRSwNP) : Completed Phase III patient enrollment by May 2023 and plan to submit the BLA application in 2024

CM310 (Asthma): **Initiated Phase II/III pivotal study**, led by CSPC

CM310 (SAR): Plan to initiate Phase III in 2023 H2

★ CM326 (TSLP)

CM326 (AD): Phase II clinical trial in adult with moderate-to-severe AD patients is ongoing, patient enrollment completed by June 2023

CM326 (CRSwNP): Phase Ib/IIa clinical trial ongoing, patient enrollment completed by Feb 2023

CM326 (Asthma): Phase II has been initiated, led by CSPC

★ CM338 (MASP-2)

CM338 (IgAN): **Phase II trial in IgAN is ongoing**

★ CM313 (CD38)

CM313 (SLE): Phase Ib/IIa trial is ongoing

Oncology

★ CMG901 (CLDN18.2 ADC) with AstraZeneca

*In Feb 2023, We announced **a global exclusive license agreement with AstraZeneca** for CMG901, **63 million USD upfront payment has been received by the end of March 2023**

***Multiple registrational (Phases 2 and 3) trials planned**

The latest data from the Phase Ia dose-escalation trial was presented at 2023 ASCO GI;

CMG901 has been granted the **Orphan-drug Designation & Fast Track Designation** from FDA, along with **BTB** from CDE

★ CM313 (CD38)

CM313 (RRMM): The latest data of Phase I has been published at 2023 EHA (Data as of October 10, 2022)

★ CM355 (CD20xCD3)

Phase I/II trial is ongoing

★ CM336 (BCMAxCD3)

Phase I/II trial is ongoing

★ CM350 (GPC3xCD3)

Phase I/II trial is ongoing

★ CM369 (CCR8)

First Dosing in Feb 2023, Phase I trial is ongoing

Synergistic Cooperation, Advancing Our Business Efficiency

Promoting Our Collaborations at a Productive Pace Globally



- **【AstraZeneca】** In Feb 2023, We announced a global exclusive license agreement with AstraZeneca for **CMG901**. Under the license agreement, AstraZeneca will be responsible for the R&D, manufacture and commercialization of CMG901 globally
- With multiple registrational (Phases 2 and 3) trials planned with AstraZeneca, 63 million USD upfront payment has been received by the end of March 2023



- **【CSPC】** To develop and commercialize **CM310** for the treatment of moderate-to-severe asthma, COPD and other respiratory diseases in Chinese Mainland, **moderate-to-severe Asthma in Phase II/ III pivotal study**
- **【CSPC】** To develop and commercialize **CM326** for the treatment of moderate and severe asthma, COPD and other respiratory diseases in Chinese Mainland
- **【CSPC】** To jointly promote the R&D of novel drugs for **neurodegenerative diseases**



- **【INNOCARE】** Co-develop **CM369 (CCR8)**, FPI in Feb 2023
- **【INNOCARE】** Co-develop **CM355 (CD20*CD3)**, Phase I/II trial ongoing

Top-notch Management Team, Outstanding Industry Reputation



Bo Chen, Ph.D.
*Chairman
Executive Director,
Chief Executive Officer*



Changyu Wang, Ph.D.
*Executive Director,
Senior Vice President
Preclinical Evaluation and Translational Medicine*



Gang Xu, Ph.D.
*Executive Director,
Senior Vice President
Drug Discovery*



Qian Jia, Ph.D.
*Senior Vice President
CMC and Regulatory Affairs*



Yanrong Zhang
*Chief Financial Officer
Joint Company Secretary*



Joy Yan, M.D., Ph.D.
*Chief Medical Officer
Clinical Development*

16,000L Facility Put into Operation, Competitive Cost-efficiency

We have consistently and successfully manufactured antibodies in-house for preclinical and clinical studies

New Commercial-scale Manufacturing Facility

Commercial production base – Phase I construction

- We are building a new manufacturing facility on a parcel of land with approximately **113 Mu**
- The first phase of commercial-scale facility is designed to install **three production lines with 8*2,000 L bioreactors**, and is expected to provide **16,000 L** of manufacturing capacity
- The first phase of the commercial-scale facility has been completed and put into operation by the end of 2022, and has now been fully put into operation; Further **increase the ration of domestic substitution**, to effectively reduce the production costs



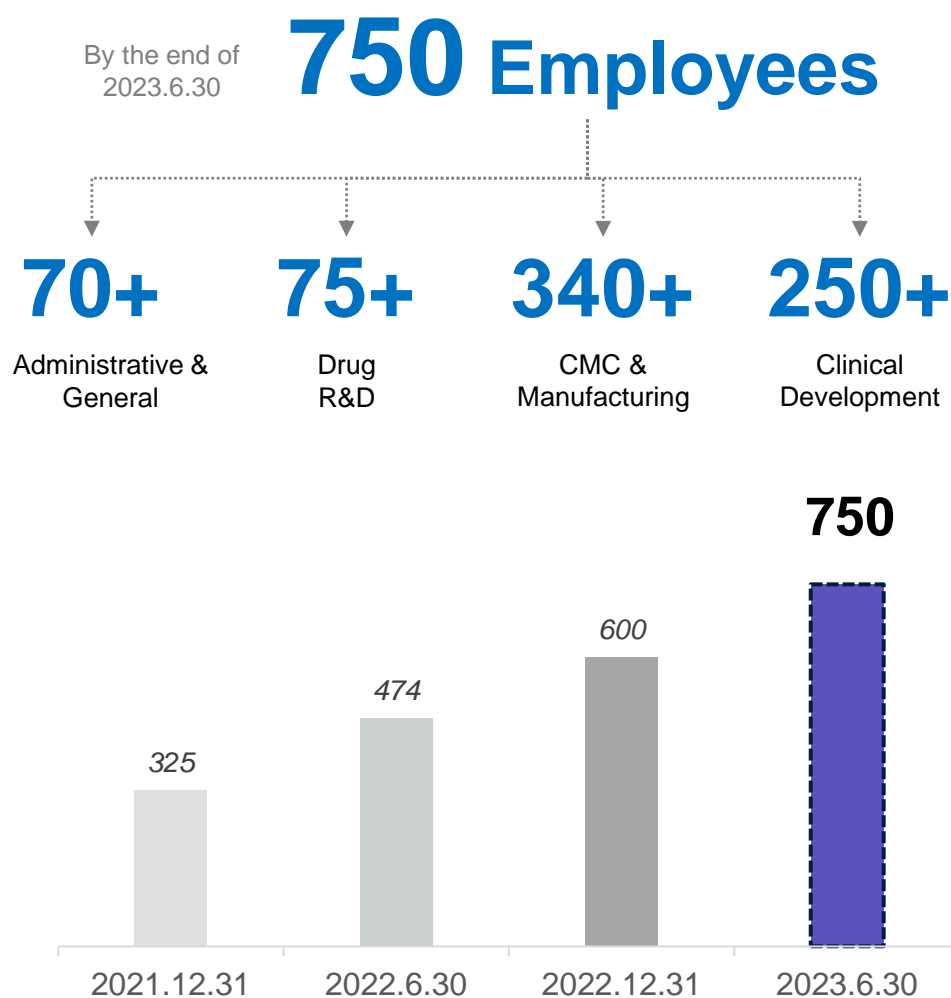
Our Chengdu facility is equipped with **three 200 L and two 1,000 L bioreactors**,
With **one vial filling line** and **one pre-filled syringe filling line**.

Our site is designed to comply with the cGMP requirements of NMPA and FDA



Recruit Talents to Meet the Growing Demand for the Development

We have built a stable core team and continuously recruit talents to match the Company's growing demand for R&D, clinical trial, manufacture, operation and commercialization



★ In addition to the headquarters in Chengdu, we have opened offices in Shanghai, Beijing, Wuhan, Guangzhou, Nanjing and other cities



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CHAPTER 2

Pipeline Progress



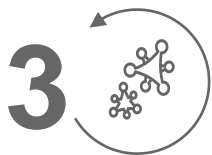
Investment Highlights



1 Integrated biotechnology company that has consistently developed **innovative antibody therapies**, targeting some large underserved medical needs in the **autoimmune and oncology therapeutic areas**



2 A differentiated **autoimmune** portfolio led by an **IL-4R α** antibody drug targeting a wide spectrum of allergic patients. Leading product **CM310 (IL-4R α)** has entered into **pivotal study stage**



3 An oncology portfolio comprising multi-modality antibody therapies, highlighted by a **Claudin 18.2 ADC (CMG901)** and multiple **bispecific antibodies** developed on our proprietary **nTCE platform**



4 Fully-integrated in-house capabilities that well position our drug candidates for **cost-effective development and manufacturing**


1 Integrated biotechnology company, consistently developed innovative antibody therapies, targeting some large underserved medical needs in the autoimmune and oncology therapeutic areas





Fully-integrated platform encompassing all of the key functions in the biologic drug development



Industry-leading R&D Engine

 **Consistently and cost-effectively** translate science into medicine in a timely manner

 Pipeline consists of **9** drug candidates in clinical stage

 Each being among the **first three domestically-developed** for its target or in its class to have obtained IND approval in China and/or the U.S.



Proprietary Platforms

Innovative antibody discovery platform


- ✓ Discovery and optimization of drug candidates with high bioactivity and specificity
- ✓ **Discovered 6 antibodies and advanced them to clinical development stage:**
 - CM310 (IL-4R α antibody)
 - CM326 (TSLP antibody)
 - CM313 (CD38 antibody)
 - CM338 (MASP-2 antibody)
 - CM369 (CCR8 antibody)
 - CMG901 (Claudin 18.2 ADC)

Proprietary nTCE bispecific antibody platform

- ✓ Specializes in the design and engineering of bispecific antibodies
- ✓ **Generated 3 clinical stage bispecific antibody drug candidates with enhanced T-cell mediated tumor killing and minimized cytokine release syndrome:**
 - CM355 (CD20xCD3 bispecific)
 - CM336 (BCMAxCD3 bispecific)
 - CM350 (GPC3xCD3 bispecific)



Manufacturing Capacities

 Manufacturing facility in Chengdu is equipped with bioreactors with a **total capacity of 2,600L**

 **Additional 16,000 L** of manufacturing capacity debut by 2022

2 A Differentiated Autoimmune Portfolio Led by an IL-4R α Antibody Drug Targeting a Wide Spectrum of Allergic Patients

Growth Drivers of Allergic Diseases

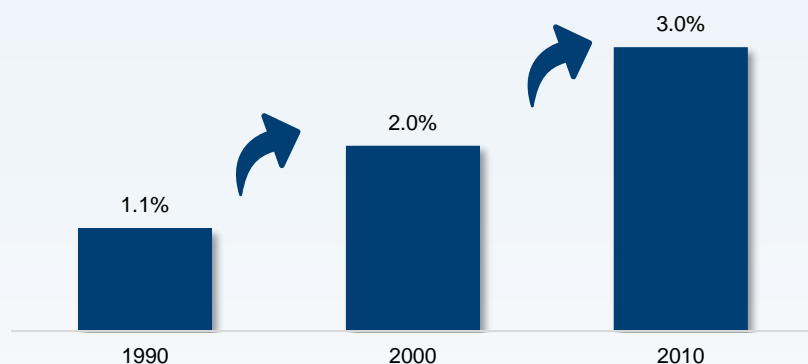


Increase in
Urbanization

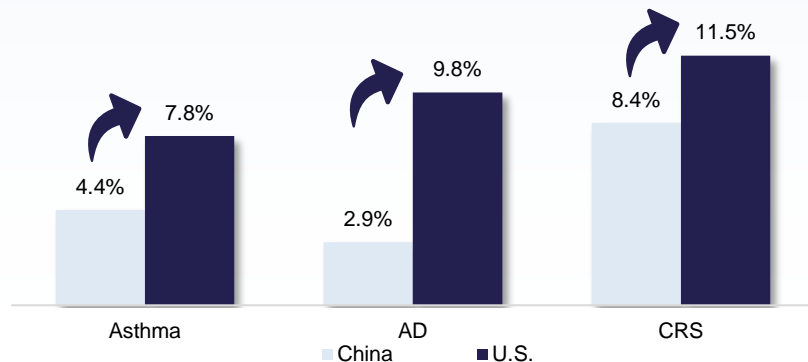


Improvement of
Hygiene Condition

Growing Asthma Prevalence in China¹



Allergic Diseases Prevalence – China vs. U.S.²



Source: Frost & Sullivan
Notes: 1. Children/Adolescents prevalence
2. Prevalence in adults as of 2019

Treatment Paradigm Evolution

Traditional Options

Glucocorticoids

Antihistamines

Significant Unmet Clinical Needs



Limited Efficacy



Severe Adverse Events

New Treatment Solutions

Biologic Therapies

- ✓ Widely used and studied for **a wide spectrum of allergic diseases**
- ✓ **High efficacy and excellent safety**

IgE Antibody



Approved by the FDA as the first biologic for allergies in 2003

IL Family



Dupilumab (IL-4R α) has been approved for AD, Asthma, and CRSwNP

Small Molecular Targeted Therapies

JAK Inhibitor



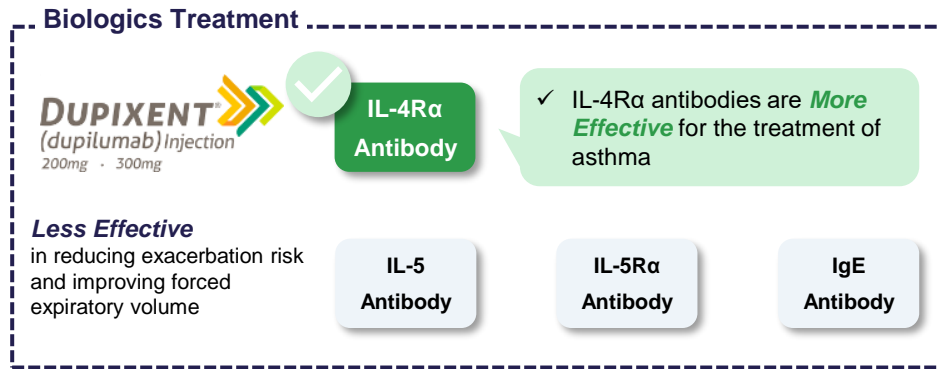
■ **Less tolerated in children with allergic diseases**

2 IL-4R α -Targeted Medication Market Overview

IL-4R α Antibodies as More Effective Biologic Drugs

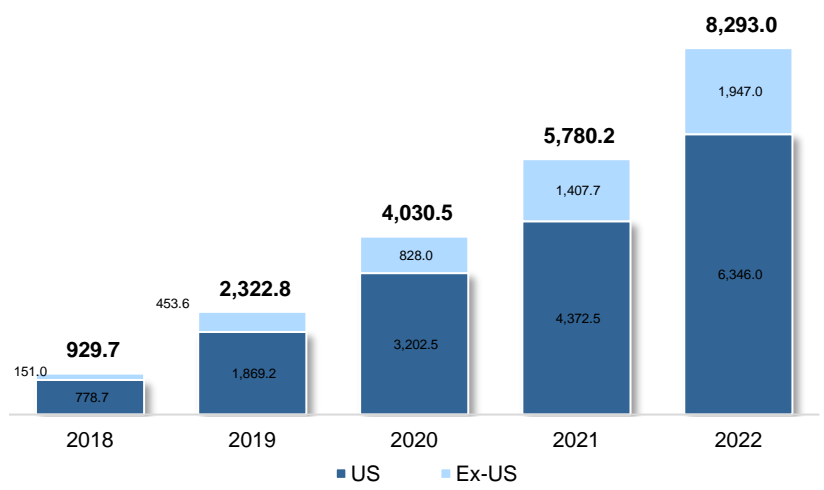


Allergic Diseases (Asthma)



Sales and IP Rights of Dupixent

Unit: Million Euro



District	Compound	Regulatory Exclusivity
United States	<ul style="list-style-type: none"> 2027.10 2031.03 with PTE 	2029.03
European Union	<ul style="list-style-type: none"> 2029.10 2032.09 with SPC¹ 	2027.09
Japan	<ul style="list-style-type: none"> 2029.10 2034.05 with PTE² 	2026.01

Source: Frost & Sullivan and Sanofi Annual Report
Notes: 1.SPC: Supplementary Protection Certificate; 2.PTE: Patent Term Extension

2

CM310 - Most Advanced Domestically-developed IL-4R α Antibody Candidate in China

Significant market potential



The first and only marketed IL-4R α antibody and the only approved biologic targeting IL-4R α in China

- **Large market potential:**
 - Launched in 2017, Dupixent has achieved **annual sales of more than 8.2 billion Euro globally in 2022**
- **Multiple indications:**
 - Besides the indications approved, Dupixent is currently being evaluated in several other new indications

Favorable clinical trials results

- CM310 is a humanized, highly potent antagonist antibody against IL-4R, being developed for treating a wide range of type II allergic diseases (including moderate-to-severe AD, moderate-to-severe eosinophilic asthma, CRSwNP) and potentially COPD



Efficacy

- **Phase IIb in patients with moderate-to-severe AD:**

	CM310 High dose	CM310 Low dose	Dupilumab ₂
EASI-75 response (treatment group ¹)	73.1%	70.6%	57.3%
EASI-75 response (placebo group)	18.2%		14.5%



Efficacy

- **Phase II in patients with CRSwNP:**

	NPS change from baseline	NCS change from baseline
CM310 treatment group	2.23	1.23
Placebo group	0.19	0.30

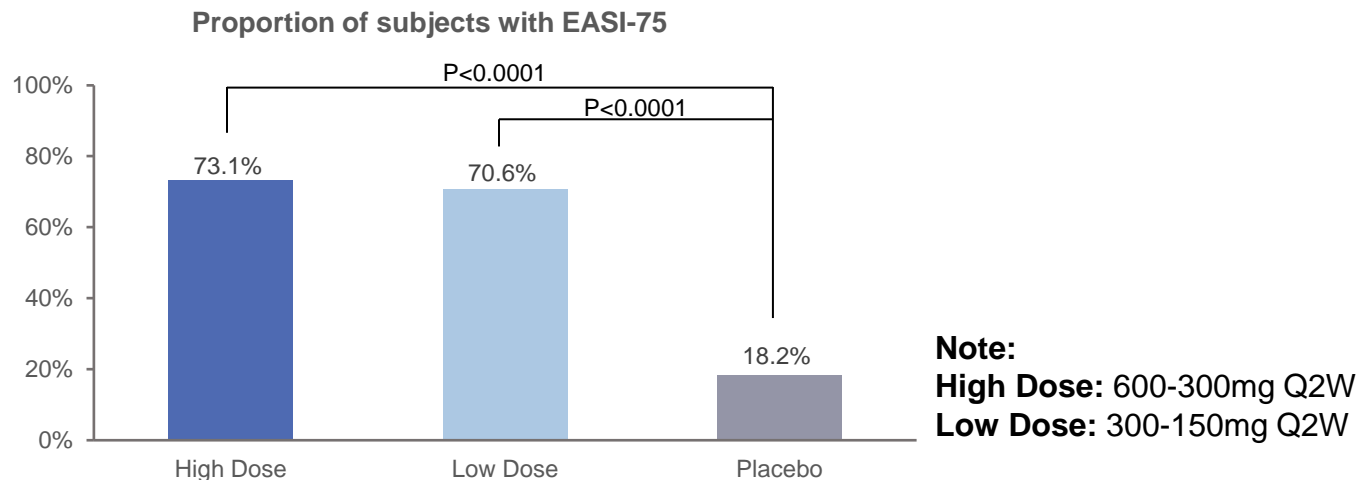
- **CM310 exhibited good safety and favorable PK and PD properties in humans, and TRAEs associated with CM310 were generally mild to moderate in nature**

Future plan

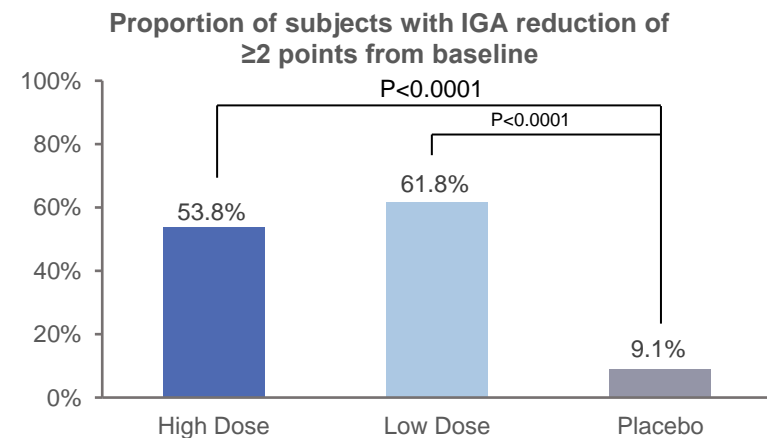
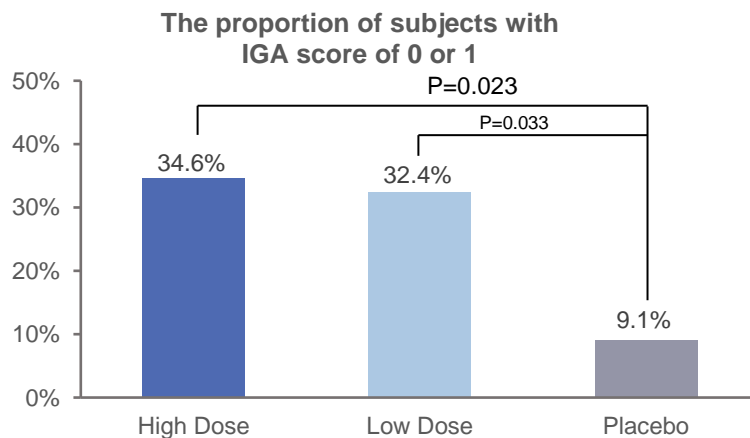
- **Phase III trial** to evaluate the efficacy in moderate-to-severe adult AD patients is ongoing;
- Completed the **Phase III AD trial** data unblinding and preliminary statistical analyses by March 2023, **both co-primary endpoints were achieved successfully**
- **Phase III trial** to evaluate the efficacy in patients with CRSwNP is ongoing, **Phase II data has been published on eClinical (IF: 15.1) in June, 2023**
- **Collaboration with CSPC:** Has initiated **a Phase II/III clinical trial** for moderate-to-severe asthma (2023 Q1)
- IND approval for the treatment of AR (Allergic Rhinitis), plan to initiate the pivotal study in 2023 H2; IND approval for the treatment of AD from FDA

2 CM310 - Encouraging Clinical Efficacy in Phase IIb Clinical Trials, Potential BIC

Primary Endpoint: The proportions of subjects with EASI-75 in high and low dose groups were significantly superior to that in the placebo group

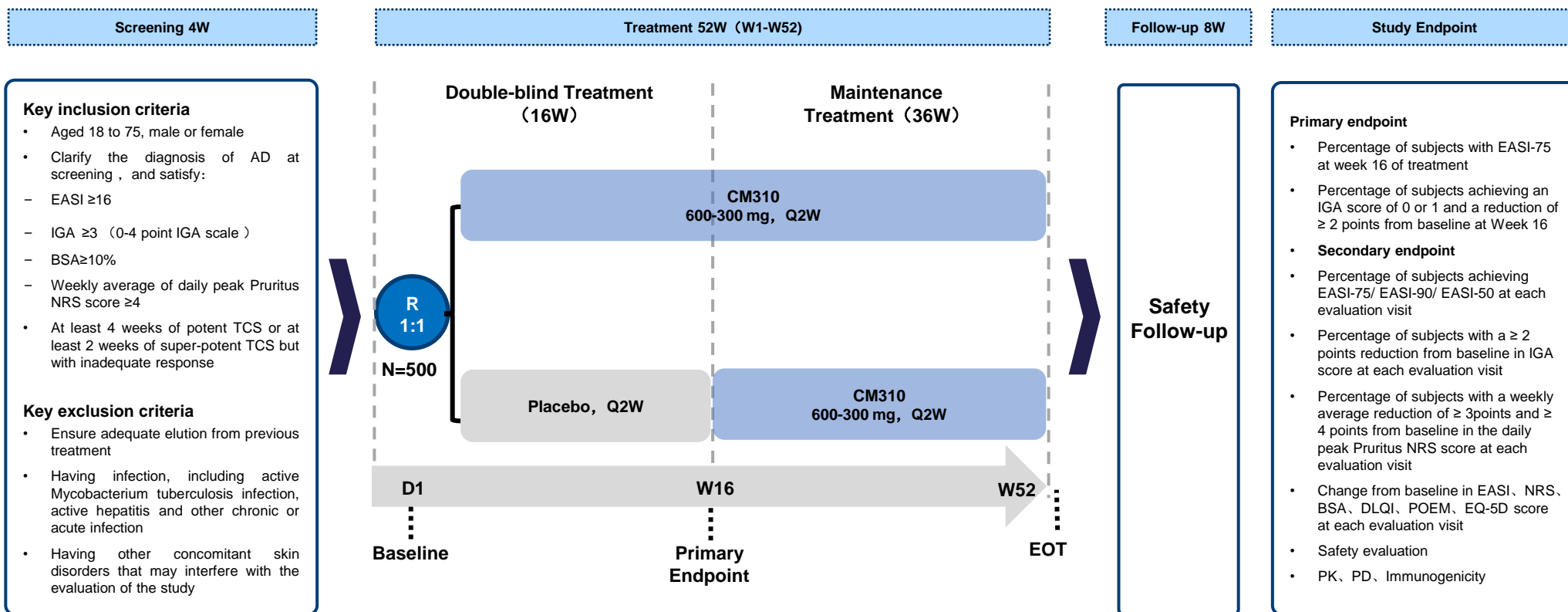


Secondary Endpoints: In term of the proportion of subjects with IGA score of 0 or 1 and the proportion of subjects with IGA reduction of ≥ 2 points from baseline, the treatment groups are also significantly superior to the placebo group



2 CM310 - AD Phase III Clinical Study Design

A Randomized, Double-blind, Placebo-Controlled Phase III Clinical Study
to Evaluate the Efficacy and Safety of CM310 Recombinant Human Monoclonal Antibody Injection in Subjects with Moderate-to-Severe Atopic Dermatitis



EASI: Eczema Area and Severity Index

EASI-50/75/90: $\geq 50\%/75\%/90\%$ improvement from baseline in EASI

IGA: Investigator Global Assessment

BSA: Body surface area

SC: Subcutaneous injection

NRS: Numerical Rating Scale

DLQI: Dermatology Life Quality Index

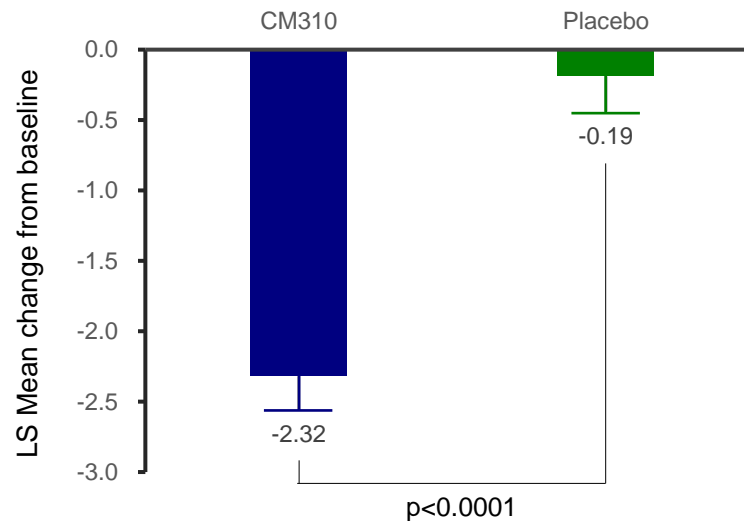
POEM: Patient Oriented Eczema Measure

EQ-5D: Europe Five Dimensions Questionnaire

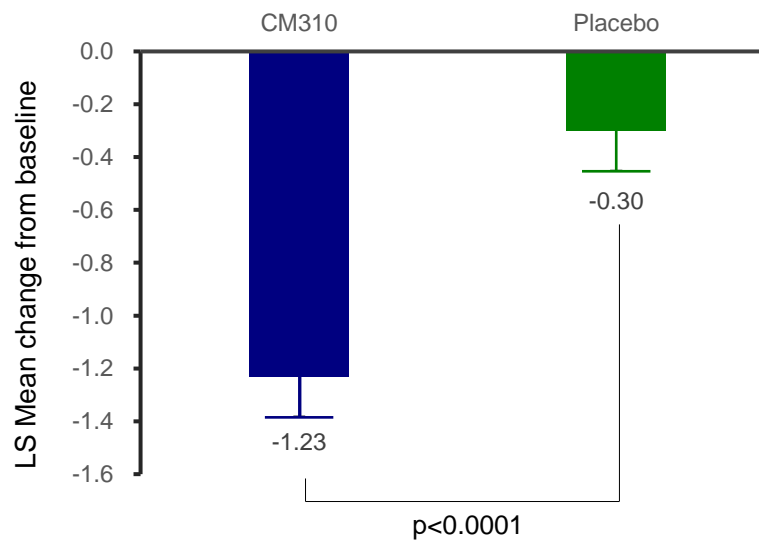
600-300mg Q2W: 600 mg (first dose) -300 mg (subsequent doses)

2 CM310 - Phase II for CRSwNP Meets Co-Primary Endpoints

Change from baseline in nasal polyp score at Week 16 (Based on MMRM model)



Change from baseline in nasal congestion score at Week 16 (Based on MMRM model)

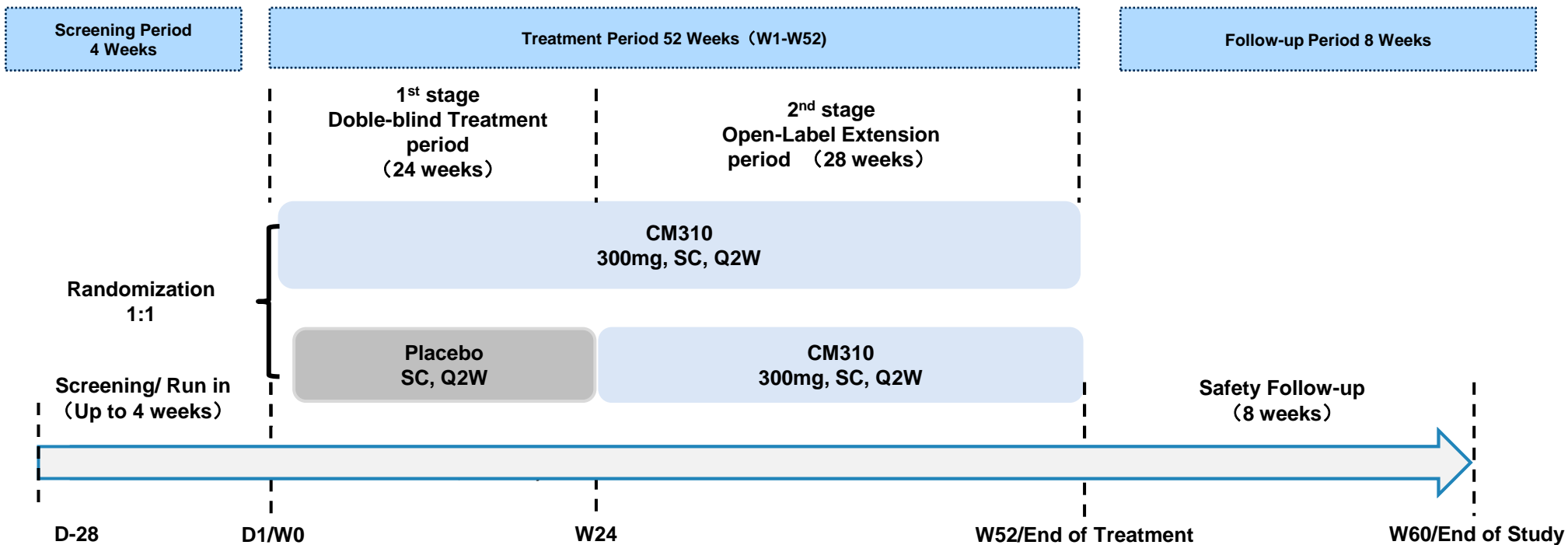


MMRM: Mixed model for repeated measures
 LS Mean: Least square mean

2 CM310 - CRSwNP Phase III Clinical Study Design

A Randomized, Double-blind, Placebo-controlled Phase III Study to Evaluate the Efficacy and Safety of CM310 Recombinant Humanized Monoclonal Antibody Injection in Patients with Chronic Rhinosinusitis with Nasal Polyps

Primary Endpoint	Change from baseline in nasal polyp score (NPS) at week 24, Change from baseline in nasal congestion score (NCS) at week 24
Study Design	<ul style="list-style-type: none"> • Randomized, double-blind, placebo-controlled • Double-blind treatment period , randomized 1:1 to CM310 or placebo (24 weeks) • Open-Label Extension period of CM310 (28 weeks) • Safety Follow-up period (8 weeks)
Sample Size	180 (1 st stage is double-blind, randomized treatment period)



2

CM326 - Most Advanced Domestically-developed TSLP Antibody Candidate in China

Potential drug for both eosinophil dependent and independent inflammatory diseases

Observed from **60% of moderate-to-severe asthma patients**



The efficacy of many existing biologic drugs is correlated with elevated eosinophil level



Amgen/AstraZeneca's Tezepelumab:

- Reduced asthma exacerbation rate regardless of the baseline blood eosinophil count
- May be effective for both type II-high and type II-low asthma



- CM326 is being developed for the treatment of moderate-to-severe asthma and potentially other allergic diseases



- **First TSLP antibody has been approved by FDA in Dec, 2021**

Favorable potency and safety in preclinical and phase 1 clinical studies



Pharmacology studies

- CM326 is **five times more potent** than Tezepelumab analog in the inhibition of TSLP-induced cell proliferation and activation



Toxicity studies

- A single dose of up to 550 mg/kg CM326 and Q2W dosing of up to 300 mg/kg CM326 were **both well tolerated** in monkeys



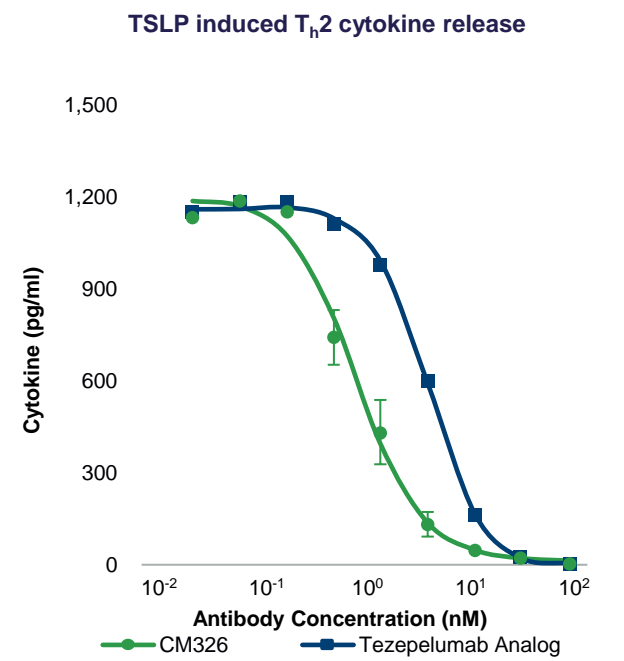
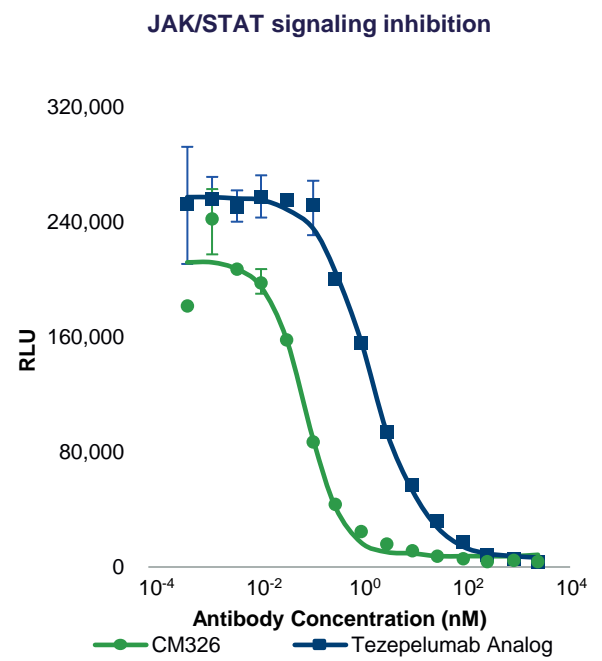
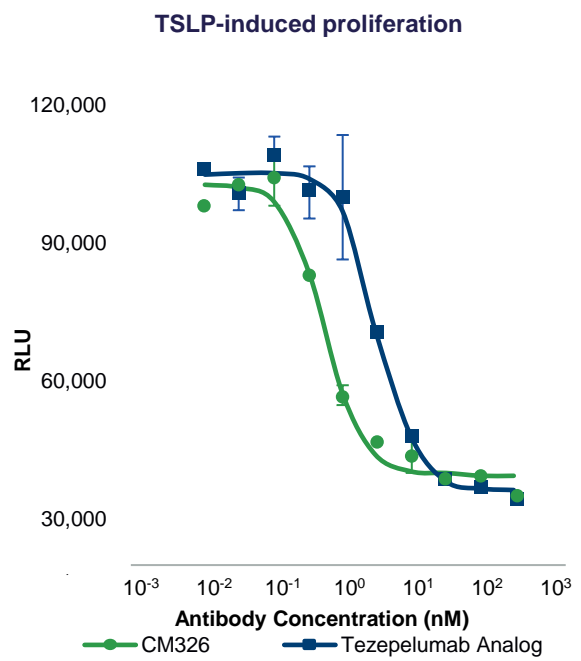
- CM326 demonstrated a **favorable safety profile and tolerability in each dosage group compared to the placebo group in phase 1 clinical studies.**

Future plan

- **Completed the patient enrollment of Phase II clinical trial in moderate-to-severe adult AD patients (June 2023)**
- **Completed the patient enrollment of Phase Ib/IIa clinical trial in CRSwNP patients (Feb 2023)**
- CM326 Asthma Phase II trial has been initiated in March 2023

2 CM326 - Higher Potency in Preclinical Studies

The potency of CM326 to inhibit TSLP-induced cell proliferation was approximately 6-fold higher than that of tezepelumab analog (which internally produced based on public data), although CM326 binds to TSLP with similar affinity to tezepelumab analog



	IC ₅₀ (nM)
CM326	0.48
Tezepelumab analog	2.63

	IC ₅₀ (nM)
CM326	0.09
Tezepelumab analog	1.72

	IC ₅₀ (nM)
CM326	0.47
Tezepelumab analog	2.52

Source: Company data

2 CM326 - Good Safety Data Obtained in a Phase I Single-dose Study

The total incidence of TEAEs in the CM326 groups and the placebo group was similar; no TEAEs ≥ 3 , SAE, SUSAR, and deaths were reported, and no subjects withdrew from the study due to drug-related TEAEs

TEAEs	CM326					CM326 Total N=34	Placebo total N=10
	22mg N=4	55mg N=8	110mg N=8	220mg N=8	330mg N=6		
Number of subjects with TEAEs (rate)	2 (50.0%)	2 (25.0%)	6 (75.0%)	2 (25.0%)	6 (100%)	18 (52.9%)	6 (60.0%)

Drug-related TEAEs:

- The total incidences of CM326 groups and placebo group are similar
- All drug-related TEAEs were Grade 1 in severity

Treatment-emergent adverse events	CM326					CM326 Total N=34	Placebo total N=10
	22mg N=4	55mg N=8	110mg N=8	220mg N=8	330mg N=6		
Number of drug-related TEAEs (rate)	0	1 (12.5%)	1 (12.5%)	0	3 (50%)	5 (14.7%)	1 (10.0%)
Grade1	0	1 (12.5%)	1 (12.5%)	0	3 (50%)	5 (14.7%)	1 (10.0%)

2

CM338 - A Humanized, Highly Potent Antagonist Antibody Against Mannose-binding Lectin-associated Serine Protease-2 (MASP-2)

Potentially breakthrough treatment for complement-mediated diseases

Role of MASP-2:

- MASP-2 is an effector enzyme and **key mediator of the lectin pathway**, which is one of the three principal pathways that activate the complement system
- The complement system plays a critical role in both innate and adaptive immunity



Omeros's Narsoplimab is currently the most advanced MASP-2 antibody candidate in multiple clinical trials



Narsoplimab has filed a BLA for Hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT-TMA) with the FDA

Favorable preclinical results



Pharmacology studies

- CM338 is **more than 50-fold potent** in inhibiting the lectin pathway in comparison with Narsoplimab analog, as measured by IC_{50}



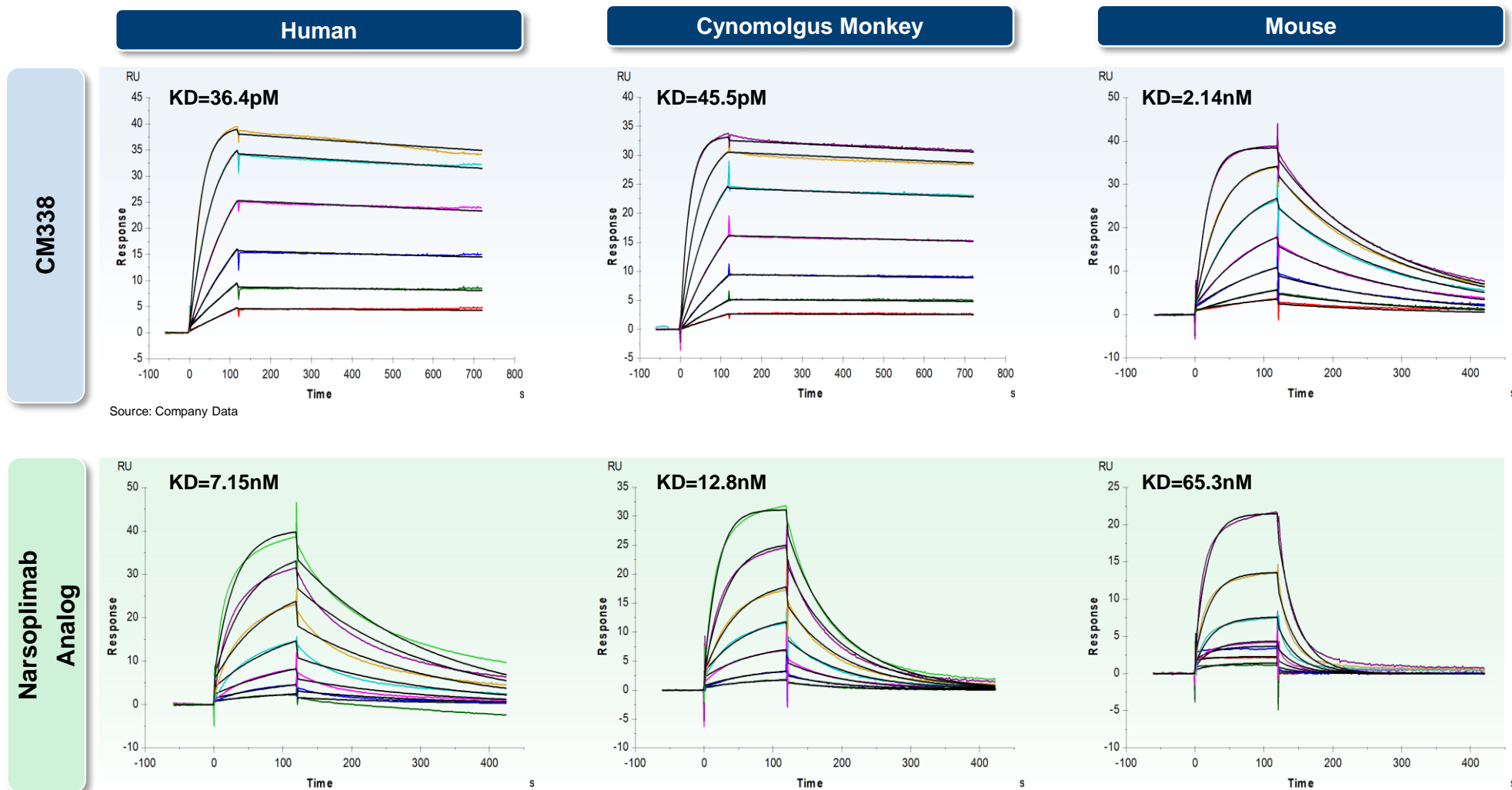
Toxicity studies

- **No severe adverse event** has been observed while assessing the toxicity of CM338 in monkeys

Future plan

- IND approved for IgA nephropathy in China, Phase I clinical trial completed
- **Phase II study for the treatment of IgAN** has been initiated in **March 2023**

2 CM338 - Much Higher Binding Affinity Across Species Against Narsoplimab Analog

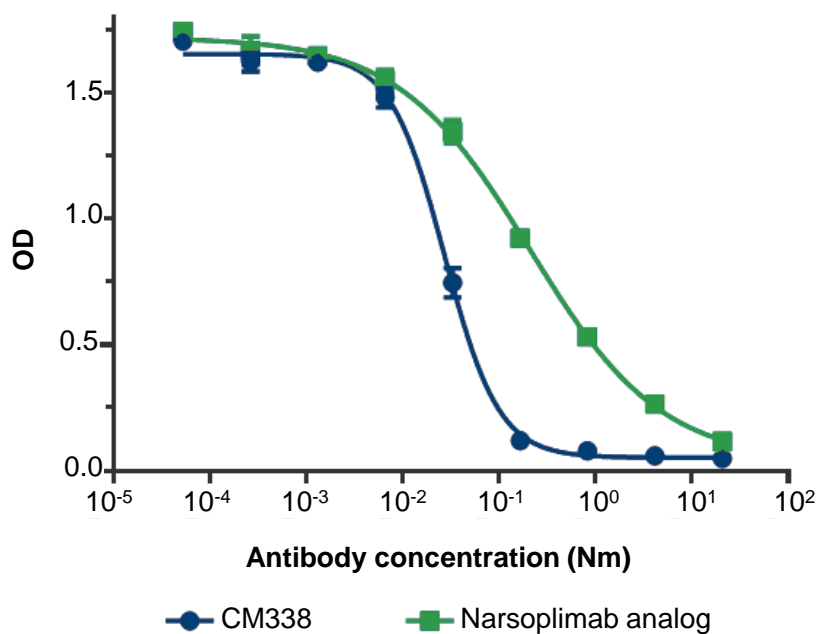


Source: Company Data

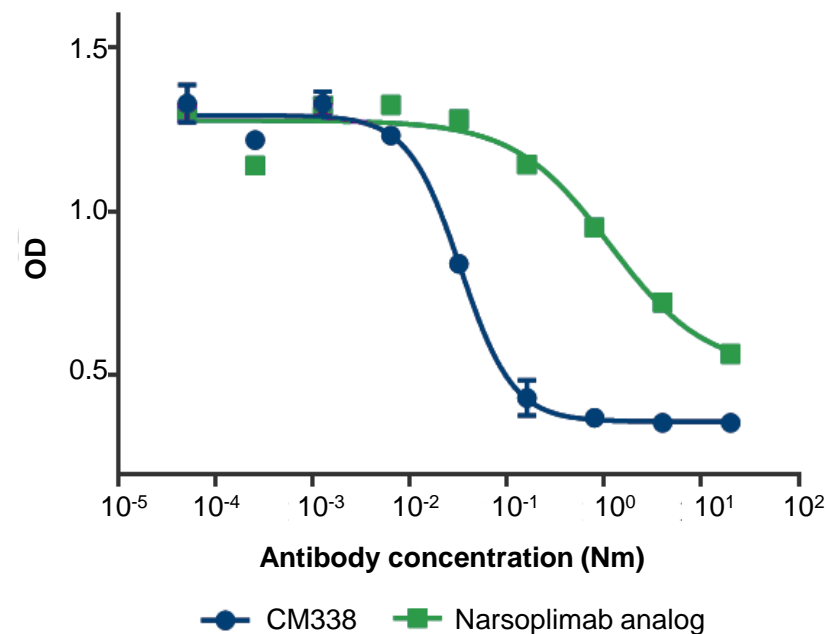
2 CM338 - More Effective in Inhibiting the Activation of the Lectin Pathway

In comparison with Narsoplimab analog, CM338 is more than 50-fold potent in inhibiting the activation of the lectin pathway

Inhibition on formation of C3 convertase (C4b2a)



Inhibition on C3b deposition



	IC ₅₀ (nM)	
	C4b2a	C3b
CM338	0.026	0.033
Narsoplimab analog	0.202	1.151

Source: Company Data

CMG901 - World's 1st Claudin 18.2 ADC Obtained IND Approval

CMG901 is a Claudin 18.2-targeting ADC for the treatment of advanced gastric cancer, pancreatic cancer and other solid tumors. It enables selective cancer killing by attaching a highly potent payload to a Claudin 18.2-specific antibody

Strong antitumor activity

- CMG901 can effectively kill tumor cells through **two mechanisms**:
 - i. the release of cytotoxic molecules (**MMAE**) after internalization by tumor cells, and
 - ii. the induction of ADCC and CDC effects of the immune system
- Compared with zolbetuximab analog, CMG901's unconjugated antibody specifically binds to Claudin 18.2 with **higher affinity**, as measured by EC₅₀ in the preclinical studies, resulting in **more potent cell killing by ADCC and CDC**
- MMAE is highly cytotoxic and can potentially exert **bystander killing effects** on nearby Claudin 18.2-negative tumor cells
- In animal models of gastric and pancreatic cancers, CMG901 exhibited **much stronger antitumor activity** in comparison with CMG901's unconjugated antibody or Zolbetuximab analog at the same dose levels

Favorable preliminary efficacy results

SAFETY

- Drug-related grade ≥3 adverse events occurred in 3/27 (11.1%) patients. No drug-related grade ≥4 AEs were reported.
- Patients received CMG901 at dose levels up to 3.4 mg/kg, and maximum tolerated dose (MTD) was not reached.

EFFICACY

- Preliminary efficacy results demonstrated that in the 8 Claudin 18.2-positive gastric/GEJ cancer patients receiving CMG901, ORR and DCR were 75.0% and 100%

CLDN18.2 positive patients (N=8)	
ORR [#]	6(75%)
DCR [*]	8(100%)
Median PFS, day	NR [§]
Median OS, day	NR [§]

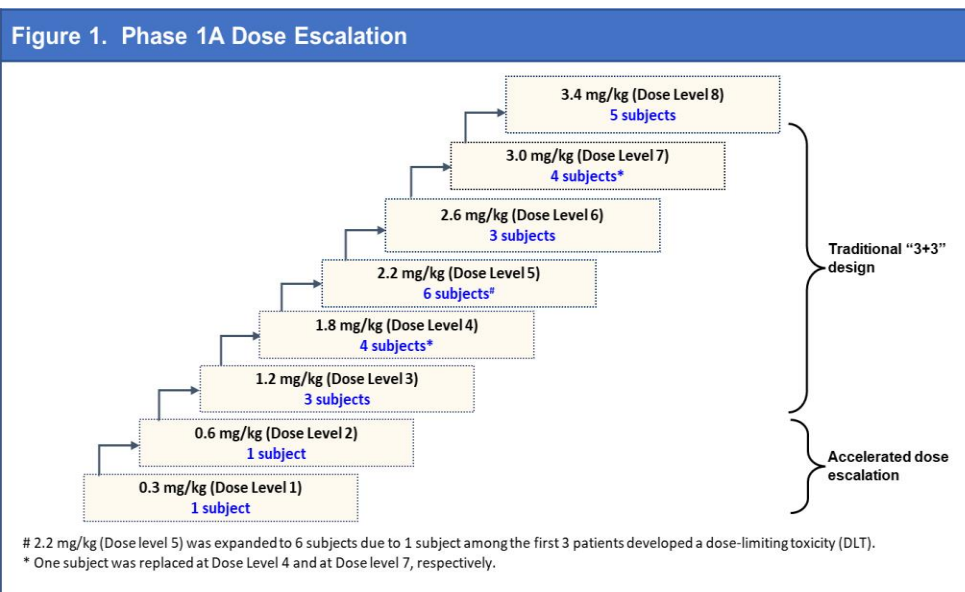
Future plan

- The **Phase 1 trial** in gastric/ GEJ cancer, pancreatic cancer, and other solid tumors is ongoing, with multiple registrational (Phases 2 and 3) trials planned **with AstraZeneca**
- Have been granted **Orphan-Drug Designation** and **Fast Track Designation** for the treatment of relapsed/ refractory gastric cancer and gastroesophageal junction adenocarcinoma by FDA at April, 2022; CMG901 was granted the **BTD** in Sep 2022 from CDE

CMG901 - The Latest 1a Results Presented at the 2023 ASCO GI

Drug-related grade ≥ 3 adverse events occurred in 3/27 (11.1%) patients. No drug-related grade ≥ 4 AEs were reported. Patients received CMG901 at dose levels up to 3.4 mg/kg, and maximum tolerated dose (MTD) was not reached.

- As of August 4, 2022, totally 27 patients (13 gastric/gastroesophageal junction (gastric/GEJ) cancer and 14 pancreatic cancer patients) were enrolled in the Phase Ia clinical study of CMG901. Received at least one dose of CMG901 up to 3.4 mg/kg.
- Well-tolerated with a favorable safety profile:** Patients received CMG901 at dose levels up to 3.4 mg/kg, and maximum tolerated dose (MTD) was not reached. One patient in the 2.2 mg/kg cohort developed a dose-limiting toxicity. No drug-related grade 4 or 5 AEs were reported.
- The most common AEs (occurred in $\geq 20\%$ of patients) were vomiting, nausea, flatulence, diarrhea, decreased appetite, fatigue, anemia, proteinuria, hypoalbuminemia, decreased white blood cell and neutrophil counts, occult blood positive, elevated AST and ALT.



Demographics and Baseline Characteristics	Overall (N=27)	Gastric/GEJ (N=13)
Median age (min, max)	58(31, 70)	58(31, 70)
Gender, n(%)		
Male	14(51.9%)	6(46.2%)
Primary tumor type, n(%)		
Gastric adenocarcinoma	12(44.4%)	12(92.3%)
Gastroesophageal junction adenocarcinoma	1(3.7%)	1(7.7%)
Pancreatic adenocarcinoma	14(51.9%)	NA
CLDN18.2 expression*, n(%)		
Positive	14(51.9%)	8(61.5%)
Negative	7(25.9%)	3(23.1%)
Unknown	6(22.2%)	2(15.4%)
ECOG performance score, n(%)		
0	8(29.6%)	5(38.5%)
1	19(70.4%)	8(61.5%)
Prior lines of systemic therapies, n(%)		
1	3(11.1%)	2(15.4%)
2	12(44.4%)	4(30.8%)
≥ 3	12(44.4%)	7(53.8%)

* CLDN18.2 positive is defined as $\geq 5\%$ tumor cells with $\geq 2+$ CLDN18.2 immunohistochemical staining.

3

CMG901 - The Latest 1a Results Presented at the 2023 ASCO GI

Preliminary efficacy results demonstrated that in the 8 Claudin 18.2-positive gastric/GEJ cancer patients receiving CMG901, objective response rate (ORR) and disease control rate (DCR) were 75.0% and 100%

CMG901 preliminary efficacy results on 18.2-positive gastric/GEJ cancer patients :

- 8 Claudin 18.2-positive gastric/GEJ cancer patients receiving CMG901, objective response rate (ORR) and disease control rate (DCR) were **75.0% and 100%**, respectively, with **ORR of 100% in the 2.6, 3.0, and 3.4 mg/kg cohorts**.
- Median progression free survival (mPFS) and median overall survival (mOS) were not reached yet.

<i>CLDN18.2 positive patients (N=8)</i>	
ORR#	6(75%)
DCR*	8(100%)
Median PFS, day	NR&
Median OS, day	NR&

Proportion with complete response (CR) + partial response (PR)

* Proportion with CR+PR+stable disease

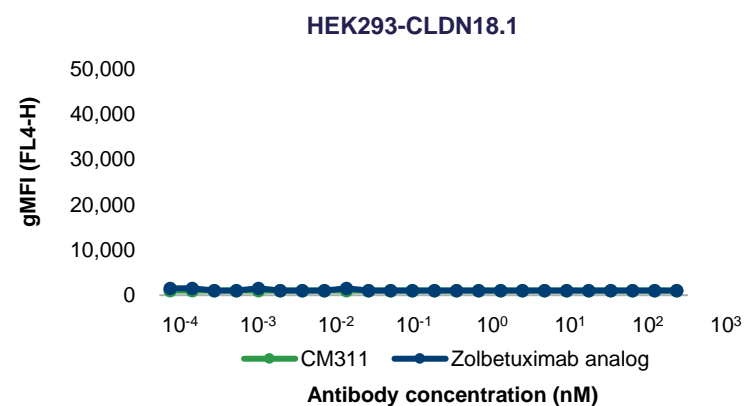
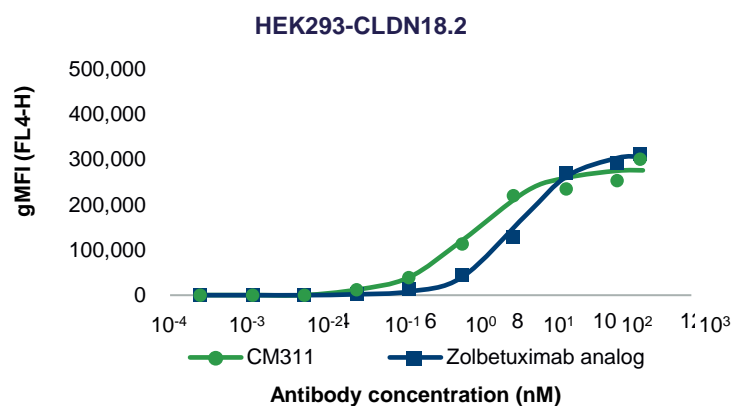
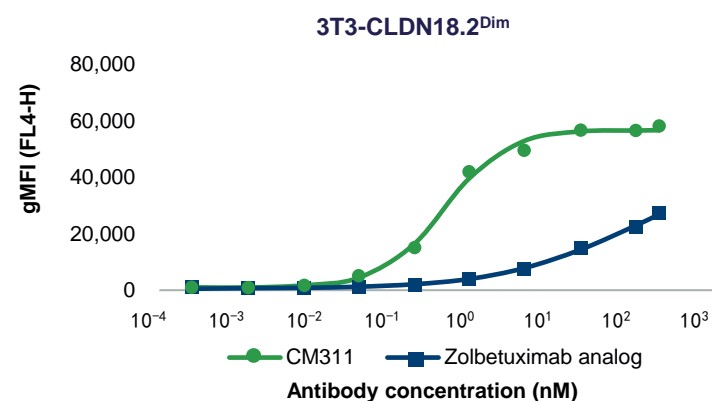
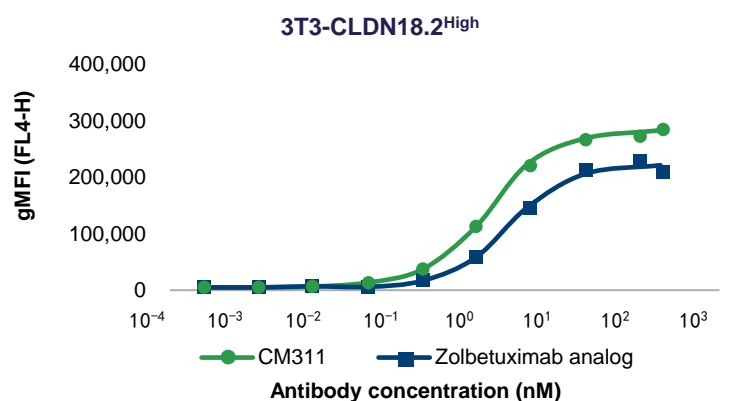
& mPFS and mOS were not reached.

3

CMG901 - High Affinity and Specificity for Claudin 18.2

CM311 binds to the target cells with higher binding activity ($EC_{50} = 1.2$ nM), compared to zolbetuximab analog ($EC_{50} = 2.2$ nM). Most notably, in Claudin 18.2 low-expression cells (3T3-CLDN18.2^{Dim}), CM311 shown much higher binding activity than zolbetuximab analog

Binding Affinity and Specificity of CM311 and Zolbetuximab Analog for Claudin 18.2 Protein

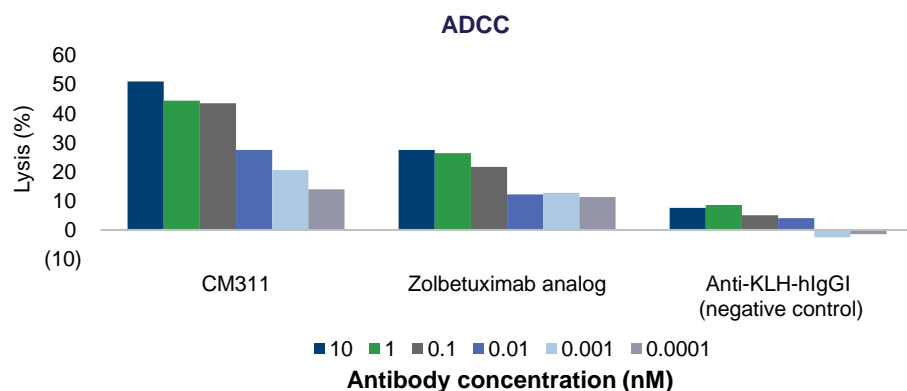


Source: Company data

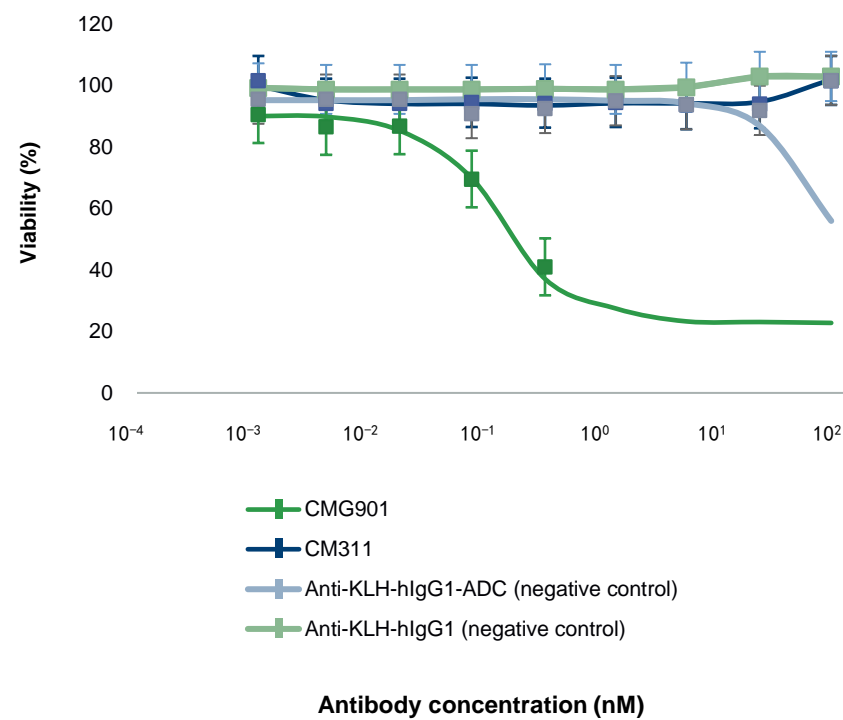
3

CMG901 - Highly Potent ADCC and CDC Effects and Highly Active Cytotoxic Payload with Potential By-stander Killing Effects

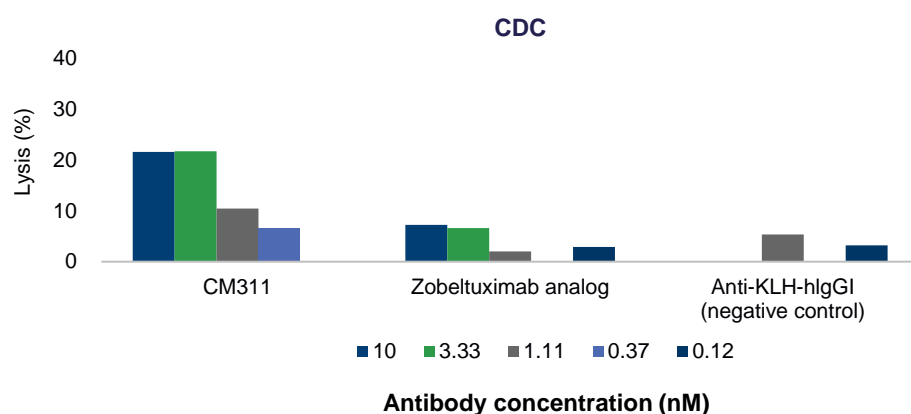
CM311-mediated ADCC is highly efficient against Claudin 18.2-expressing tumor cells with killing rate reaching ~50% vs. 30% with zolbetuximab analog



CMG901 is significantly more potent in killing Claudin 18.2-positive tumor cells



CM311 induced higher CDC activity against Claudin 18.2-expressing tumor cells than zolbetuximab analog



	IC ₅₀ (nM)
CMG901	0.13

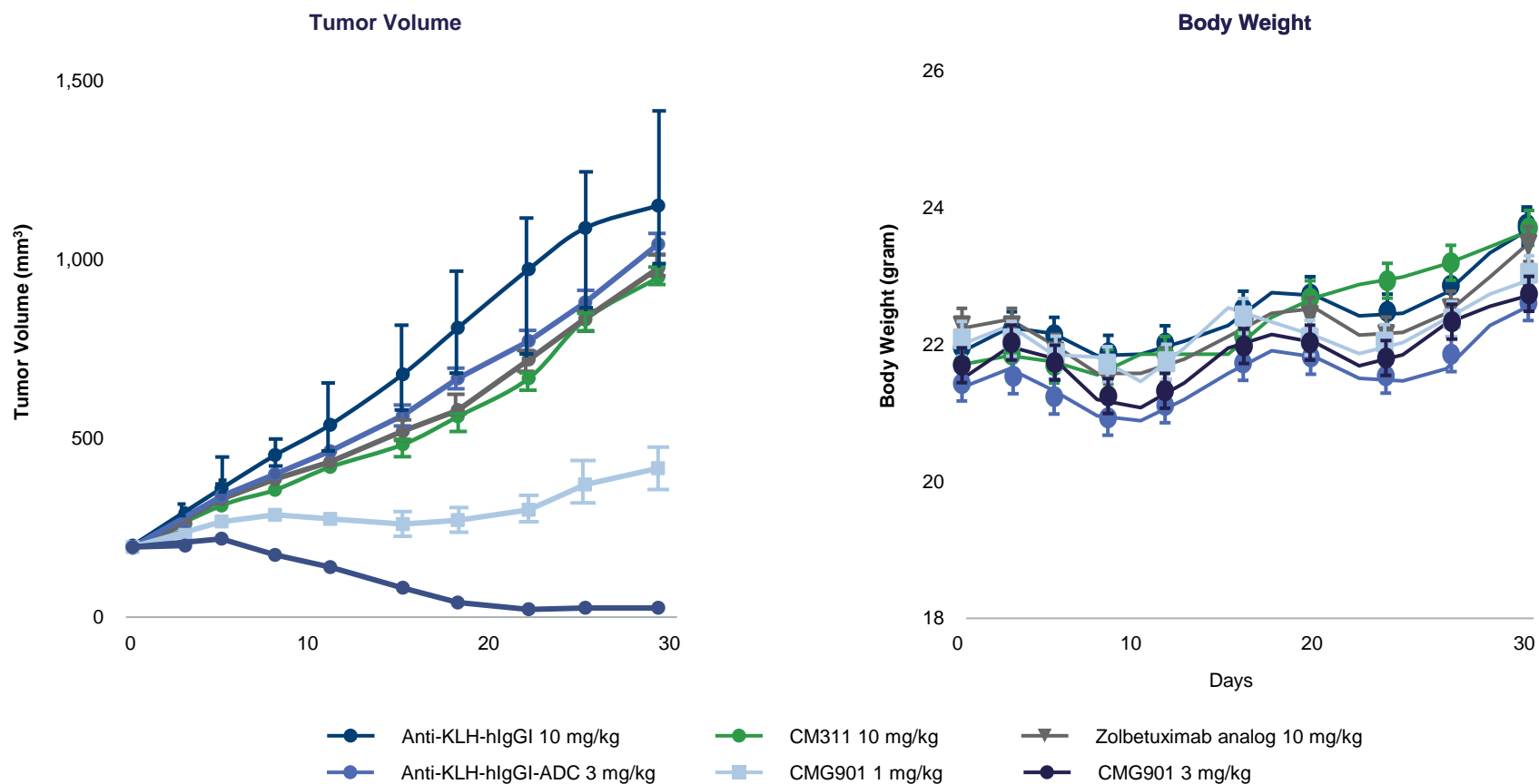
Source: Company data

3

CMG901 - High Potency in Tumor Growth Inhibition *in Vivo*

3 mg/kg of CMG901 led to complete regression of the tumor, while 1 mg/kg of CMG901 resulted in significant tumor growth inhibition of 77%. Notably, CMG901 showed much stronger antitumor effects even at a low dose of 1 mg/kg as compared to 10 mg/kg of zolbetuximab analog or unconjugated antibody CM311

Gastric Cancer PDX Model



Source: Company data

CM313 - Highly Potent Anti-CD38 Monoclonal Antibody

Promising Drug for RRMM

The role of CD38:

- CD38 is a type II glycoprotein receptor involved in regulating lymphocyte migration, activation and proliferation, and B-cell differentiation. In hematological tumors, CD38 is mainly expressed on myeloma cells, lymphoma cells and plasma cells;
- Daratumumab (trade name Darzalex, developed by J&J) and isatuximab (trade name Sarclisa, developed by Sanofi), antibody drugs targeting CD38, were approved by the FDA for the treatment of relapsed and refractory multiple myeloma in 2015 and 2020, respectively. **Daratumumab-based combination therapy with immunomodulators or protease inhibitors has become the first-line treatment option for multiple myeloma.**

Favorable preclinical results



- CM313 can bind with high affinity to CD38-expressing multiple myeloma cells, Burkitt's lymphoma cells, diffuse large B-cell lymphoma cells, B-cell acute lymphoblastic leukemia cells, and T-cell acute lymphoblastic leukemia cells. It can kill tumor cells and inhibit their growth through ADCC, CDC, and ADCP. It also induces tumor cell apoptosis through Fc crosslinking and inhibits extracellular enzymatic activity of CD38. **The biological activity of CM313 mAb is comparable to daratumumab, a targeted drug marketed in 2015;**
- CM313 inhibits dose-dependently tumor growth in multiple tumor models, showing comparable tumor growth inhibition effect with daratumumab. **CM313 mAb in combination with dexamethasone or lenalidomide inhibit synergistically tumor growth in the subcutaneous xenograft nude mouse model of multiple myeloma.**



- In the 4-week repeated-dose toxicity study in cynomolgus monkeys, **no significant toxic and side effects related to CM313 mAb were observed in each dose group**
- CM313 has **no stimulating effect on human blood cells** and has **no risk of causing significant cytokine release syndrome.**
- The results of the tissue cross-reactivity assay with CM313 mAb are consistent with daratumumab

Future plan

- Phase I clinical trial ongoing for RRMM
- **The latest data of Phase I has been published at 2023 EHA (Data as of October 10, 2022)**
- **Phase Ib/IIa for the treatment of SLE is ongoing**

CM313 - The Latest Phase 1 Result Presented at the 2023 EHA

As of October 10, 2022, 34 patients (including 31 RRMM and 3 MZL) were enrolled and 16 remained on treatment
The maximum tolerated dose was not reached, and no DLTs up to 16 mg/kg occurred

- Most common treatment-related AEs (TRAEs) occurring in $\geq 20\%$ of patients were infusion-related reaction and decreased cell counts in lymphocytes, white blood cell count, and neutrophils
- Patients had received a median of 3 prior lines of therapies (range 1-10)

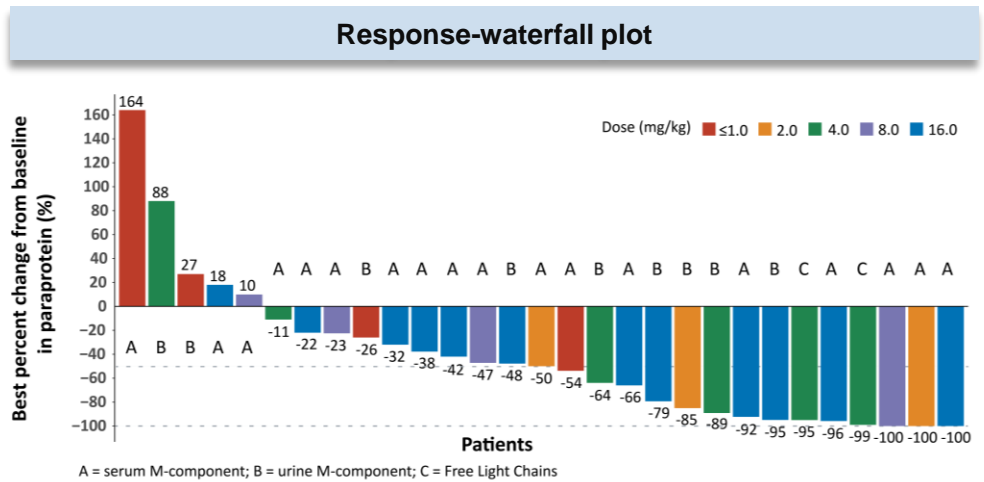
Demographics and Baseline Characteristics

	Dose escalation (N=17)	Dose expansion (N=17)
Multiple myeloma, n (%)	17 (100)	14 (82.4)
Median age (min, max)	59 (45, 70)	60.5 (39, 74)
Sex, male/female, n (%)	8 (47.1)/9 (52.9)	10 (71.4)/4 (28.6)
ECOG performance score, n (%)		
0	11 (64.7)	3 (21.4)
1	6 (35.3)	11 (78.6)
Type of multiple myeloma, n (%)		
IgG	7 (41.2)	5 (35.7)
IgA	5 (29.4)	4 (28.6)
IgD	1 (5.9)	1 (7.1)
light-chain κ	2 (11.8)	2 (14.3)
light-chain λ	2 (11.8)	2 (14.3)
Relapse to Pls*, n (%)	17 (100)	14 (100)
Relapse to IMiDs**, n (%)	17 (100)	14 (100)
Refractory to Pls and IMiDs, n (%)	14 (82.4)	14 (100)
Prior SCT, n (%)	3 (17.6)	3 (21.4)
Marginal zone lymphoma#, n (%)	0	3 (17.6)

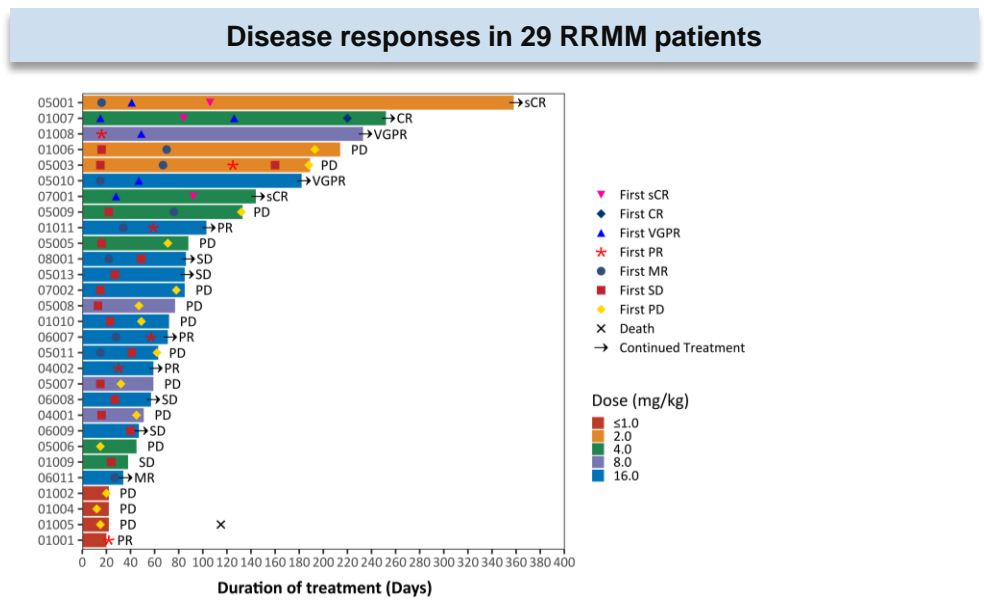
3 CM313 - The Latest Phase 1 Result Presented at the 2023 EHA

Among the 29 out of 31 RRMM patients who had at least one post-baseline efficacy assessment, ORR was 34.5%
 At a median follow-up of 6 months, the mPFS for the 29 RRMM patients was 132 days, the mOS was not reached yet

- Among the 29 out of 31 RRMM patients (93.5%) who had at least one post-baseline efficacy assessment, **ORR was 34.5%** (95%CI: 17.94-54.33; 10 of 29), with an ORR of 33.3% at a dose of 16 mg/kg.



- At a median follow-up of 6 months (range 0.4-17.5), the **median progression free survival for the 29 RRMM patients was 132 days** (95%CI: 49.0-193.0), and the median overall survival was not reached yet.



3

T cell Engaging Bispecific Antibodies Developed from Proprietary nTCE Platform

Maximal T cell-mediated cell killing effects

Bispecific antibodies developed from proprietary nTCE platform

Minimal cytokine release syndrome



CM355

CD20xCD3 bispecific antibody co-developed with InnoCare

- Indication: lymphoma
- Demonstrated stronger TDCC activities with less cytokine release compared to its leading competitors in preclinical studies
- **IND application for SC was approved by March 2023, Phase I/II ongoing**



CM336

BCMAxCD3 bispecific antibody

- Indication: RRMM (Relapsed or Refractory Multiple Myeloma)
- Demonstrated high affinity for BCMA and strong antitumor activity
- **Phase I/II is ongoing**



CM350

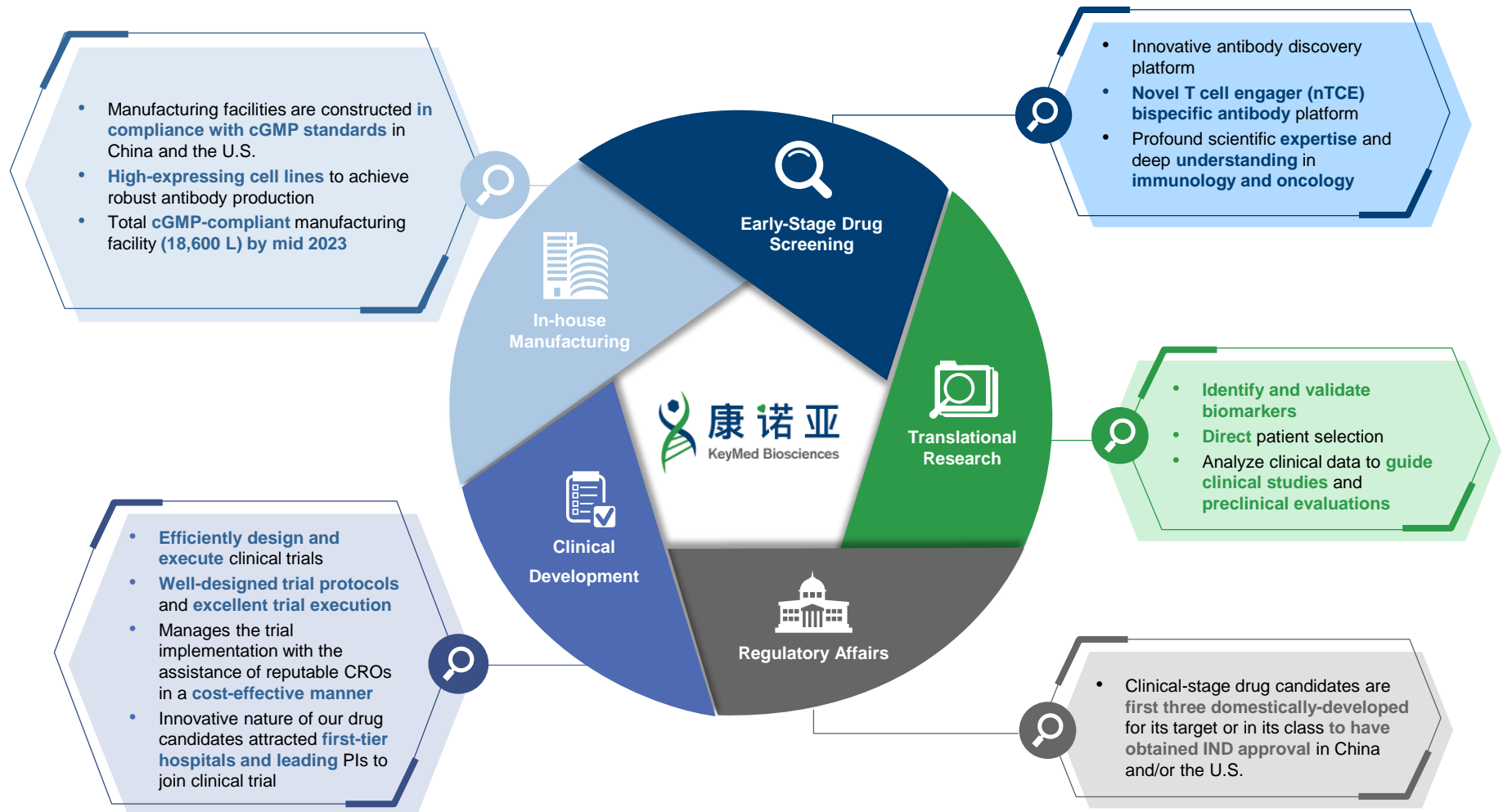
Glypican 3 (GPC3)xCD3 bispecific antibody

- Indication: Solid tumors
- Induced stronger TDCC as compared to its leading competitor
- **Phase I/II is ongoing**

Oncology portfolio also includes **CM369 (CCR8 antibody)**
Co-develop with INNOCARE, **First patient dosing in Feb 2023**

4

Fully-integrated In-house Capabilities that Well Position Our Drug Candidates for Efficient, Cost Effective Development and Manufacturing





康诺亚

KeyMed Biosciences

CHAPTER 3

Financial Data



Adjusted Net Profit for the First Half of 2023

(RMB'000)	2023 1H	2022 1H
Revenue	327,124	100,000
Cost of sales	(15,017)	(2,537)
Gross Profits ^(NB1)	312,107	97,463
Other Income and gains ^(NB2)	79,981	130,259
R&D Expenses*	(238,085)	(146,812)
Administrative Expenses* ^(NB3)	(78,361)	(45,048)
Other Expenses	(381)	-
Finance Costs ^(NB4)	(9,336)	(1,331)
Share Of Loss Of A Joint Venture	(2,097)	(8,811)
Adjusted Net Profit	63,828	25,720
Less:		
Share Based Payments	15,683	23,196
Net Profit	48,145	2,524

NB1: The revenue of RMB 327 million for 2023H1 represents collaboration income from AZ in respect of granting the relevant license of CMG901;

The revenue of RMB 100 million for 2022H1 represents collaboration income from CSPC in respect of granting asthma and COPD licenses of CM326;

NB2: Other income and gains mainly includes:

- ① government grant of RMB6 million;
- ② interest income of RMB42 million;
- ③ Exchange gains of RMB31 million;

NB3: Administrative expenses mainly include staff costs of RMB44 million, professional fees of RMB9 million, Depreciation & amortization of RMB5 million and other administrative costs;

NB4: Finance costs mainly represent interest on other financial liabilities and bank borrowings.

* Excluding of share based payments

Financial Position as at 30 June 2023

(RMB'000)	30 June 2023	31 December 2022
Non-current assets		
Fixed assets ^(NB1)	777,730	553,556
Right of use assets	98,912	30,878
Intangible assets	1,303	1,496
Prepayments and other receivables ^(NB2)	17,889	15,841
FVTOCI ^(NB3)	16,771	10,001
Investment in a joint venture	8,473	10,570
Total	921,078	622,342

(RMB'000)	30 June 2023	31 December 2022
Current assets		
Inventories	80,431	44,495
Account receivables	5,621	
Contract assets	2,680	-
Prepayments and other receivables ^(NB2)	79,168	90,153
Cash, Time Deposits and Bank wealth management products	2,978,750	3,175,326
Total	3,146,650	3,309,974
Total assets	4,067,728	3,932,316

NB1: The fixed assets mainly represent costs of buildings, production equipment and decoration in Chengdu new plant; Increased costs of RMB 220 million due to the repurchase of the Chengdu new plant;

NB2: The balance mainly represents prepaid R&D expenses of RMB 47 million, prepayment for fixed assets of RMB 12 million, recoverable VAT of RMB 5 million, rental deposits of RMB 7 million and advances to employees of RMB3 million;

NB3: The balance represents equity interests in Rona Therapeutics Inc. and Shanghai Duoning Biotechnology Co., Ltd.

Financial Position as at 30 June 2023 (Continued)

(RMB'000)	30 June 2023	31 December 2022
Current liabilities		
Trade and other payables ^(NB1)	199,168	161,121
Amount due to related parties	-	225
Other financial liabilities ^(NB2)	-	146,112
Bank borrowings	11,758	61,163
Lease liabilities	18,027	11,078
Total	228,953	379,699

(RMB'000)	30 June 2023	31 December 2022
Non-current liabilities		
Deferred income	162,865	163,671
Lease liabilities	30,515	20,928
Bank borrowings	271,102	28,800
Total	464,482	213,399
Total liabilities	693,435	593,098
Total equity	3,374,293	3,339,218

NB1: The balance mainly represents payroll payables of RMB21 million, accrued R&D expenses of RMB78 million and payables for fixed assets of RMB45 million;

NB2: The balance represents loans from Chengdu Hi-tech New Economy Venture Capital Co., Ltd and Chengdu Bio-town Equity Investment Co., Ltd.. As of June 2023, the Group has repaid this amount in full.

Our Strategies



We focus on the in-house discovery and development of innovative biological therapies that address large underserved medical needs in the autoimmune and oncology therapeutic areas

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