

# Keymed Bio (2162.HK)

## 2022 Annual Results & Latest Updates

2023 MARCH

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CHAPTER 1

# 2022 Annual Results & Latest Updates Highlights



# Keymed Bio 2022 Highlights & Latest Updates

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

- **CM310 (IL-4R $\alpha$ ) (\**BTD*):** Phase III study for moderate-to-severe AD in adults has been initiated in 2022 Q1, patient enrollment completed in Nov 2022; We released Phase II trial data for CRSwNP on March 2022, and launched Phase III clinical trial for CRSwNP in the middle 2022; In July 2022, the IND application for the treatment of Allergic Rhinitis was approved by CDE; Phase II/ III pivotal study for Asthma has been initiated in 2023 Q1
- **CM326 (TSLP):** We initiated a Phase Ib/IIa trial in the 2022 H1 for the treatment of moderate-to-severe AD, and we also launched a Phase II for AD in adults in the 2022 H2; Phase Ib/IIa for CRSwNP is ongoing, patient enrollment was completed in Feb 2023
- **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 will receive an **upfront payment of \$63mn on transaction closing and additional development and sales-related milestone payments of up to \$1.1bn 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%. We have initiated the **dose-expansion stage** of the trial in solid tumors since the beginning of 2022 Q2
- **CM313 (CD38):** Phase I dose-escalation for RRMM is ongoing, and the **dose-expansion stage** has been initiated at the end of the 2022 Q1; Completed first patient dosing **for the treatment of SLE** in Oct 2022
- **CM338 (MASP-2):** Phase I trial completed in Nov 2022; Initiated the **Phase II trial for the treatment of IgAn** in Feb 2023

## Another Assets: CM355/ CM350/ CM336/ CM369

- CM355 (CD20xCD3) / CM350 (GPC3xCD3)/ CM336 (BCMAxCD3): Phase I stage ongoing
- CM369 (CCR8): IND application was approved by NMPA by Aug 2022, FPI in Feb 2023, co-develop with InnoCare

# Keymed Bio 2022 Highlights & Latest Updates (Continued)

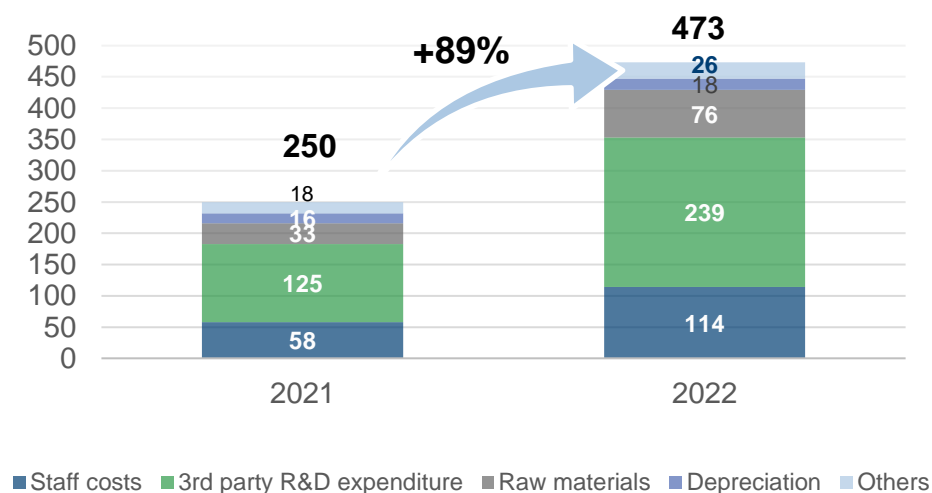
## Expand Infrastructure & Talent Team

- By the end of Dec 2022, the number of employees has been **over 600**, among which clinical development staffs **over 240**, CMC staffs **over 230**. Besides Chengdu, we are operating our offices in Shanghai, Beijing, Wuhan, Guangzhou, Nanjing, etc.
- The construction of the first phase of commercial-scale facility has been completed by the end of 2022, which will provide **16,000 L of manufacturing capacity**

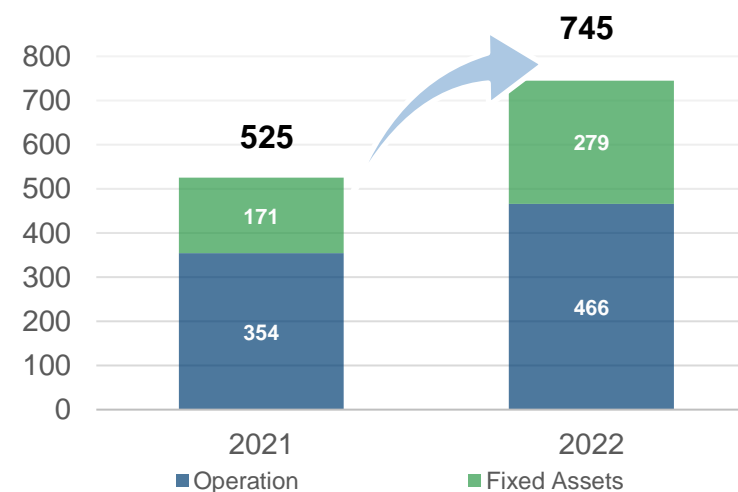
## Financial Data & Capital Market Performance

- 2022 **R&D Expense: RMB 507 million (+42% YoY)** ; **BD Income: RMB 100 million**, mainly comes from the out-licensing revenue of CM326 from CSPC; By the end of 2022.12.31, the balance of cash, time deposits and short-term wealth management products amounted to **RMB 3.2 billion**
- In March 2022, Keymed Bio (2162.HK) was included as eligible stocks of the **Shenzhen-Hong Kong Stock Connect**. In Aug 2022, we got listed in **FTSE Global Small Cap Index ex US**; In Nov 2022, we got listed in **MSCI China Small Cap Index**

## Research & Development (Excluding share based payment)



## Cash Outflow of Operation and Fixed Assets



# 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-4Rα (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
	CM326 +	TSLP (mAb)	AR								Global
			Moderate-to-severe AD								Global
			CRSwNP								Global
CM338	MASP-2 (mAb)	Moderate-to-severe asthma							石药集团 CSPC	Global ex mainland China	
		COPD								Global ex mainland China	
Oncology	CMG901 +	Claudin 18.2 (ADC)	Gastric and Other Solid tumors	FTD & ODD granted by FDA		BTD granted by CDE				AstraZeneca 东普生物 LUPU BIOPHARMA	Global
	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: 1H = first half; 2H = second half; 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; MM = multiple myeloma; Ph = Phase; RRMM = relapsed or refractory multiple myeloma

**Notes:**

- In November 2021, KeyMed granted CSPC an exclusive license to develop and commercialize CM326 for the treatment of moderate and severe asthma, COPD and other respiratory diseases (the "Field") in China (excluding Hong Kong, Macau, or Taiwan) (the "Territory"). The Company retains the exclusive rights to (i) develop and commercialize CM326 for the treatment of indications outside the Field, such as AD and CRS, in the Territory, (ii) develop and commercialize CM326 outside the Territory, and (iii) manufacture CM326 anywhere in the world, including China.
- In March 2021, KeyMed granted CSPC an exclusive license to develop and commercialize CM310 for the treatment of moderate and severe asthma, COPD and other respiratory diseases (the "Field") in China (excluding Hong Kong, Macau, or Taiwan) (the "Territory"). The Company retains the exclusive rights to (i) develop and commercialize CM310 for the treatment of indications outside the Field, such as AD and CRS, in the Territory, (ii) develop and commercialize CM310 outside the Territory, and (iii) manufacture CM310 anywhere in the world, including China.
- KeyMed started to co-develop CMG901 with Shanghai Miracogen since October 2017 and established a joint venture with Innocube to develop and commercialize CMG901, in which KeyMed and Innocube own 70% and 30% shares, respectively. Shanghai Miracogen and Innocube are under the common control of Lepu Biopharma.
- KeyMed established a 50:50 joint venture with InnoCare in August 2018 for the discovery, development and commercialization of biologics. In June 2020, the Company entered into a license and collaboration agreement with InnoCare, under which KeyMed granted to InnoCare an exclusive license for 50% ownership of CM355 to jointly develop, manufacture and commercialize CM355 globally, and KeyMed agreed to transfer all the rights to CM355 to the joint venture with InnoCare after the receipt of the IND approval for CM355.
- The "first posted date" denotes the date when the most recent clinical trial for an indication is publicly announced.
- The antibody component of CMG901 (i.e., CM311) is not separately evaluated in clinical trials.
- When more safety and efficacy data of CMG901 from China trials become available, the Company will further evaluate the clinical trial plan in the U.S. subject to communication with the FDA.

# 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 pre-clinical/ 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 $\alpha$ ), **CM326** (TSLP), **CMG901** (Claudin18.2 ADC), **CM313** (CD38), **CM338** (MASP-2)

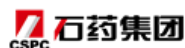


## Fully-integrated R&D platform

- 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 total capacity of **1,600 L** was built in **2019**
  - **An additional 16,000L** of manufacturing capacity commenced operation in **2022**

# Efficiently Promote Drug R&D and Commercialization

## Autoimmune

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

### ★ CM310 (IL-4R $\alpha$ ) --- BTD for AD

**CM310 (AD)** :Phase III has been initiated in 2022 Q1, we completed the recruitment of the patient by 2022 Q4, and plan to submit the BLA application in 2023; IND approval from FDA

**CM310 (CRSwNP)** : Completed Phase II & Released the data in March 2022; Initiated Phase III study at middle 2022 and plan to submit the BLA application by 2024 Q1

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

CM310 (AR): IND approved by NMPA

### ★ CM326 (TSLP)

**CM326 (AD)**: Phase Ib/IIa clinical trials in adult AD patients is ongoing, **has initiated Phase II patient enrollment**

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

### ★ CM338 (MASP-2)

Completed a Phase I clinical study of CM338 in a healthy population  
**Phase II trial in IgAn patients has been initiated**

### ★ CM313 (CD38)

CM313 (SLE): First Dosing in Oct 2022, Phase Ib/IIa trial is ongoing

## Oncology

### ★ CMG901 (CLDN18.2 ADC) with AstraZeneca

**CMG901**: In Feb 2023, We announced a global exclusive license agreement with **AstraZeneca** for CMG901

Patient enrollment of dose-escalation Phase I trial in solid tumors completed, **the latest data from the Phase Ia dose-escalation trial was presented at 2023 ASCO GI**; We have initiated the dose-expansion since the beginning of 2022 Q2

*In April 2022, CMG901 was granted the **Orphan-drug Designation & Fast Track Designation** from FDA; In Sep 2022, CMG901 was granted **BTD** from CDE*

### ★ CM313 (CD38)

**CM313 (RRMM)**: The dose-escalation part ongoing, plan to release the data through Academic Meeting/ Journal; Has initiated a dose-expansion phase trial of CM313 by the end of the 2022 Q1

### ★ CM355 (CD20xCD3)

First Dosing in Jan 2022, Phase I trial is ongoing

### ★ CM336 (BCMAxCD3)

First Dosing in Sep 2022, Phase I trial is ongoing

### ★ CM350 (GPC3xCD3)

First Dosing in May 2022, Phase I 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
- **CMG901** has completed the patient enrollment of the **dose-escalation** Phase I trial in June 2022; Has initiated the **dose-expansion stage at the beginning of the 2022 Q2**



- **【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)**, IND approved by NMPA in Aug 2022, **FPI in Feb 2023**
- **【INNOCARE】** **CM355 FPI in Jan 2022**; Phase I 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

# Proven Manufacturing Capability in Compliance with cGMP Standards

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 commercial-scale facility **has run trial production by the end of 2022.**



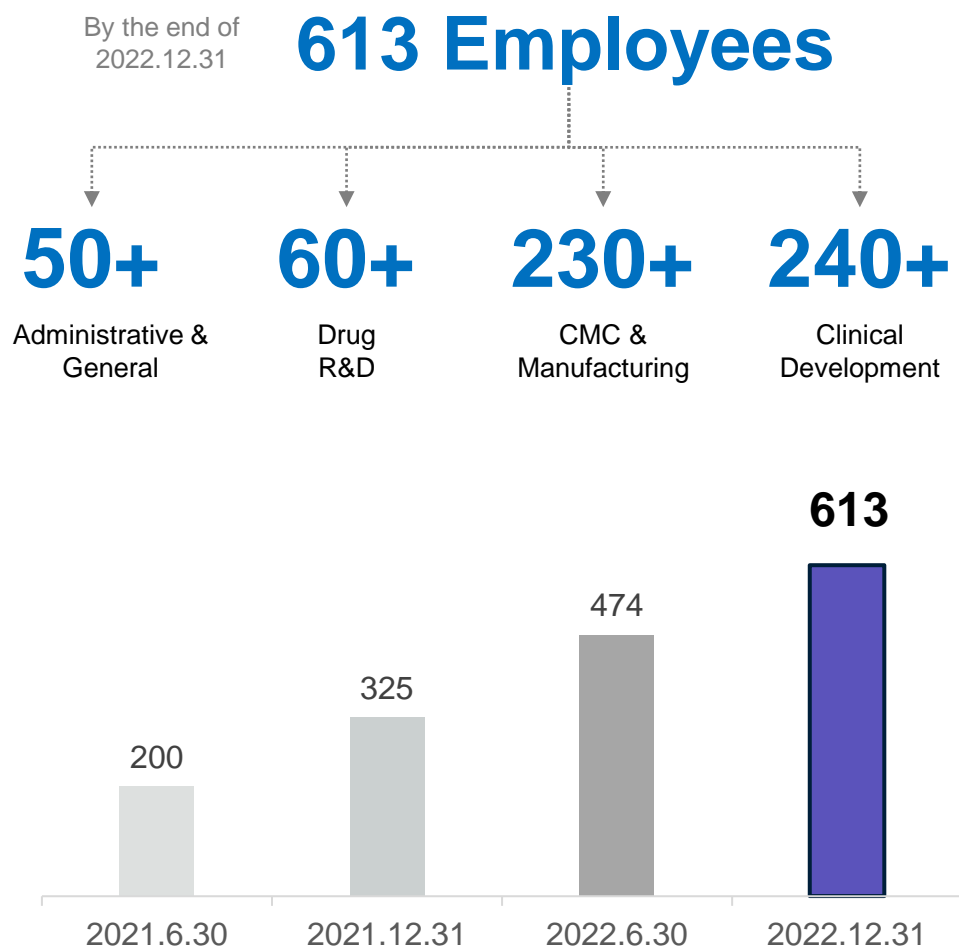
Our Chengdu facility is equipped with **three 200 L and one 1,000 L bioreactors**,  
With **one vial filling line** and **one pre-filled syringe filling line.**

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



# 康诺亚

KeyMed Biosciences

CHAPTER 2

## Pipeline Progress



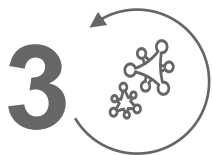
# Investment Highlights



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



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



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**



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 $\alpha$  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 1,600L**

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

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

### Growth Drivers of Allergic Diseases

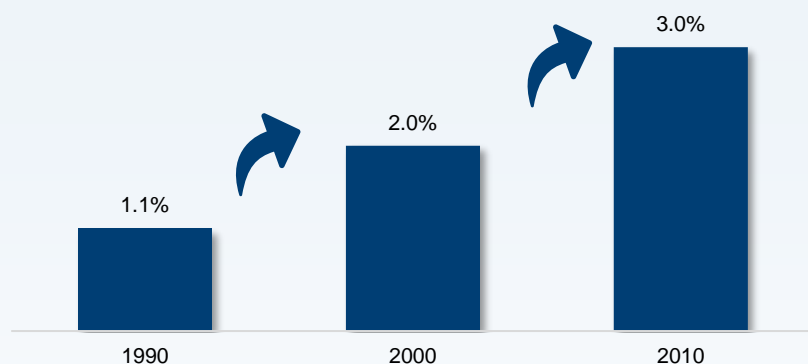


Increase in  
Urbanization

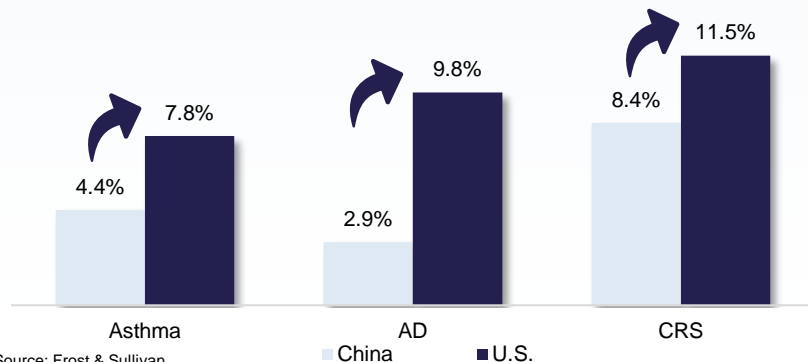


Improvement of  
Hygiene Condition

Growing Asthma Prevalence in China<sup>1</sup>



Allergic Diseases Prevalence – China vs. U.S.<sup>2</sup>



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 $\alpha$ ) has been approved for AD, Asthma, and CRSwNP

Small Molecular Targeted Therapies

JAK Inhibitor



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



## 2 IL-4R $\alpha$ -Targeted Medication Market Overview

### IL-4R $\alpha$ Antibodies as More Effective Biologic Drugs



Allergic Diseases (Asthma)



#### Biologics Treatment

**DUPIXENT<sup>®</sup>**  
(dupilumab) Injection  
200mg · 300mg

IL-4R $\alpha$   
Antibody

✓ IL-4R $\alpha$  antibodies are *More Effective* for the treatment of asthma

*Less Effective*  
in reducing exacerbation risk  
and improving forced  
expiratory volume

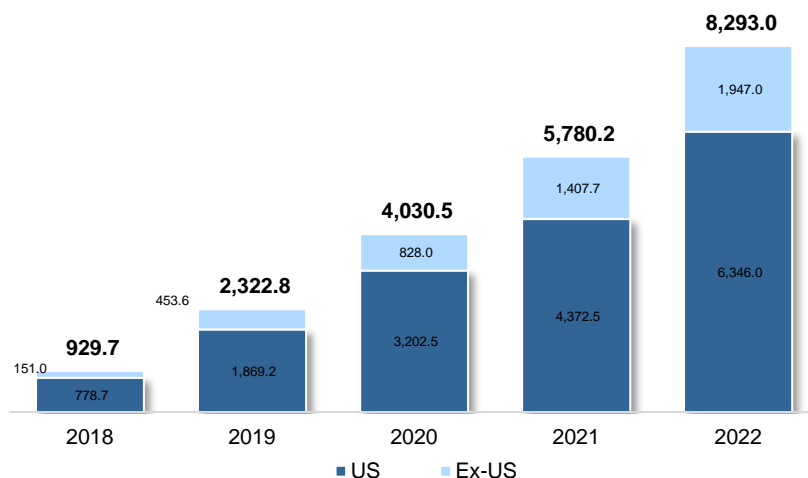
IL-5  
Antibody

IL-5R $\alpha$   
Antibody

IgE  
Antibody

### Sales and IP Rights of Dupixent

Unit: Million Euro



District	Compound	Regulatory Exclusivity
United States	<ul style="list-style-type: none"> <li>2027.10</li> <li>2031.03 with PTE</li> </ul>	2029.03
European Union	<ul style="list-style-type: none"> <li>2029.10</li> <li>2032.09 with SPC<sup>1</sup></li> </ul>	2027.09
Japan	<ul style="list-style-type: none"> <li>2029.10</li> <li>2034.05 with PTE<sup>2</sup></li> </ul>	2026.01

2

## CM310 - Most Advanced Domestically-developed IL-4R $\alpha$ Antibody Candidate in China

### Significant market potential



The first and only marketed IL-4R $\alpha$  antibody and the only approved biologic targeting IL-4R $\alpha$  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 <sup>2</sup>
EASI-75 response (treatment group <sup>1</sup> )	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

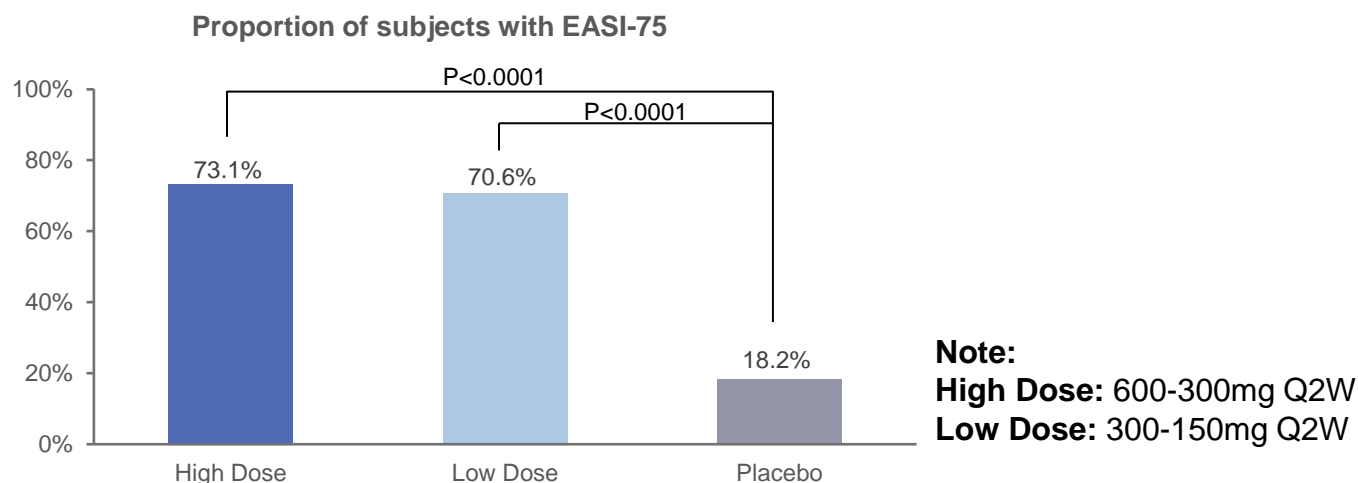
- **Phase III trial** to evaluate the efficacy in moderate-to-severe adult AD patients is ongoing
- **Phase III trial** to evaluate the efficacy in patients with CRSwNP is ongoing
- **Collaboration with CSPC:** Has initiated a **Phase II/III clinical trial** for moderate-to-severe asthma (2023 Q1)
- IND approval for the treatment of AR (Allergic Rhinitis); IND approval for the treatment of AD from FDA

Note:  
1. patients receiving three doses of 300 mg following a loading dose of 600 mg (600-300 mg);  
2. public data from a Phase III trial in China

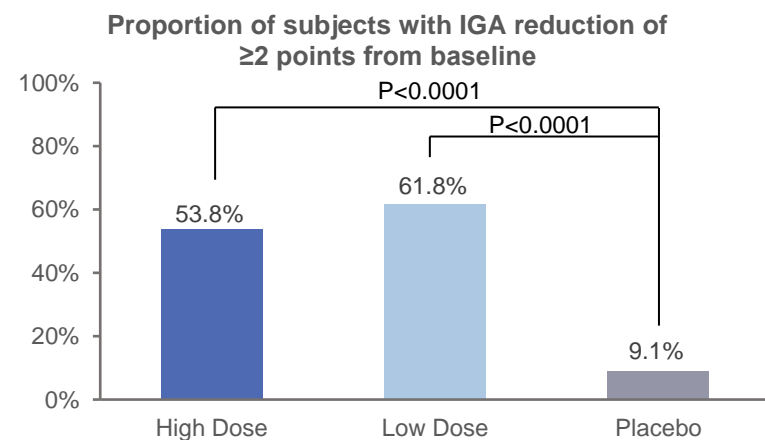
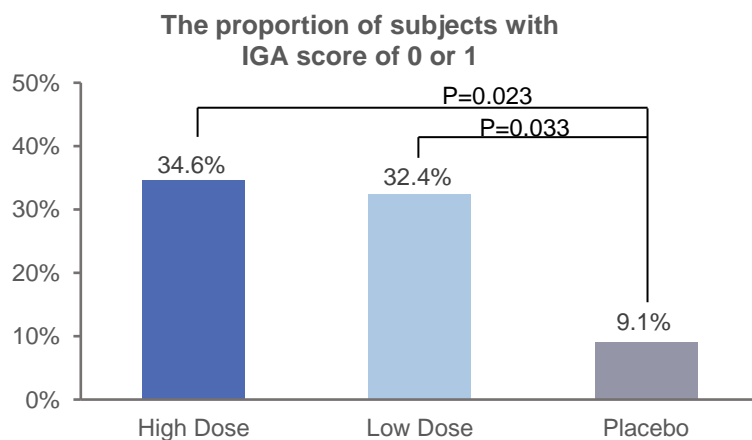
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## CM310 - Encouraging Clinical Efficacy in Phase IIb Clinical Trials, Potential BIC

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

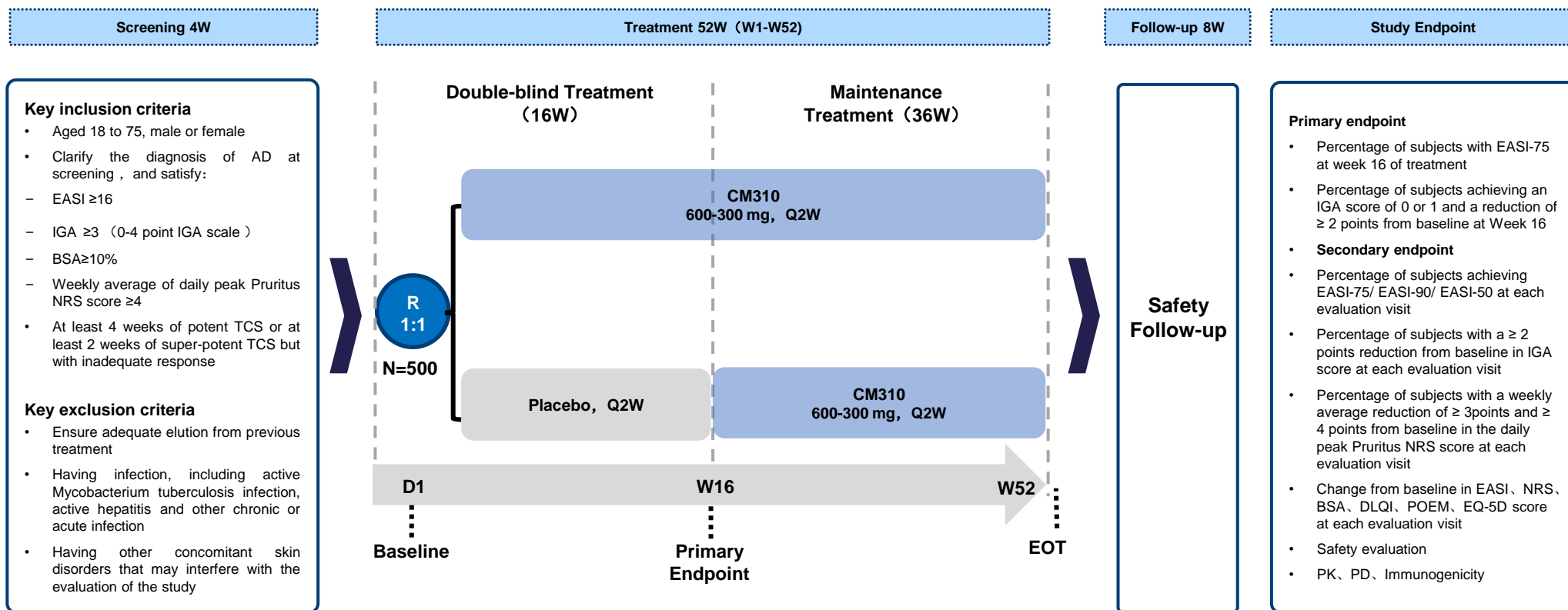


Secondary Endpoints: In term of the proportion of subjects with IGA score of 0 or 1 and the proportion of subjects with IGA reduction of  $\geq 2$  points from baseline, the treatment groups are also significantly superior to the placebo group



## 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

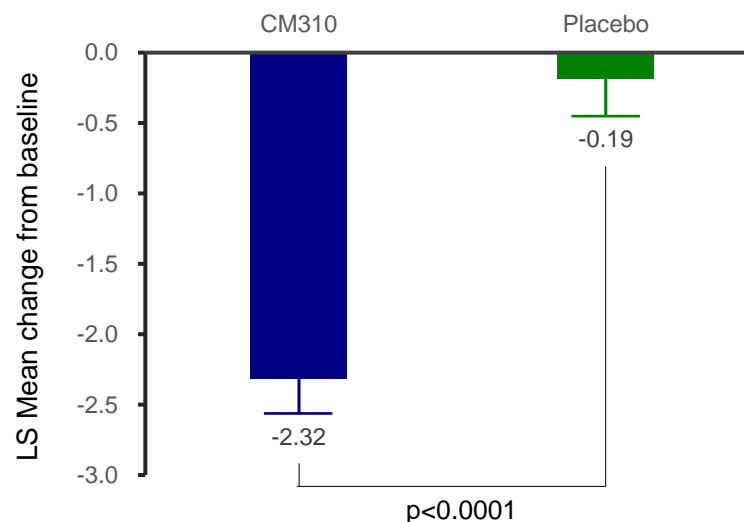
**EQ-5D:** Europe Five Dimensions Questionnaire

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

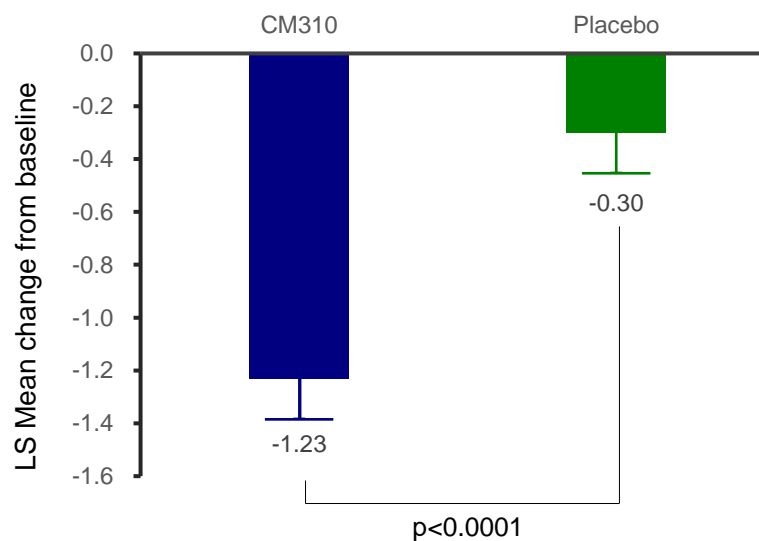
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## CM310 – Phase II in Patients with CRSwNP Meets Co-Primary Endpoints

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)



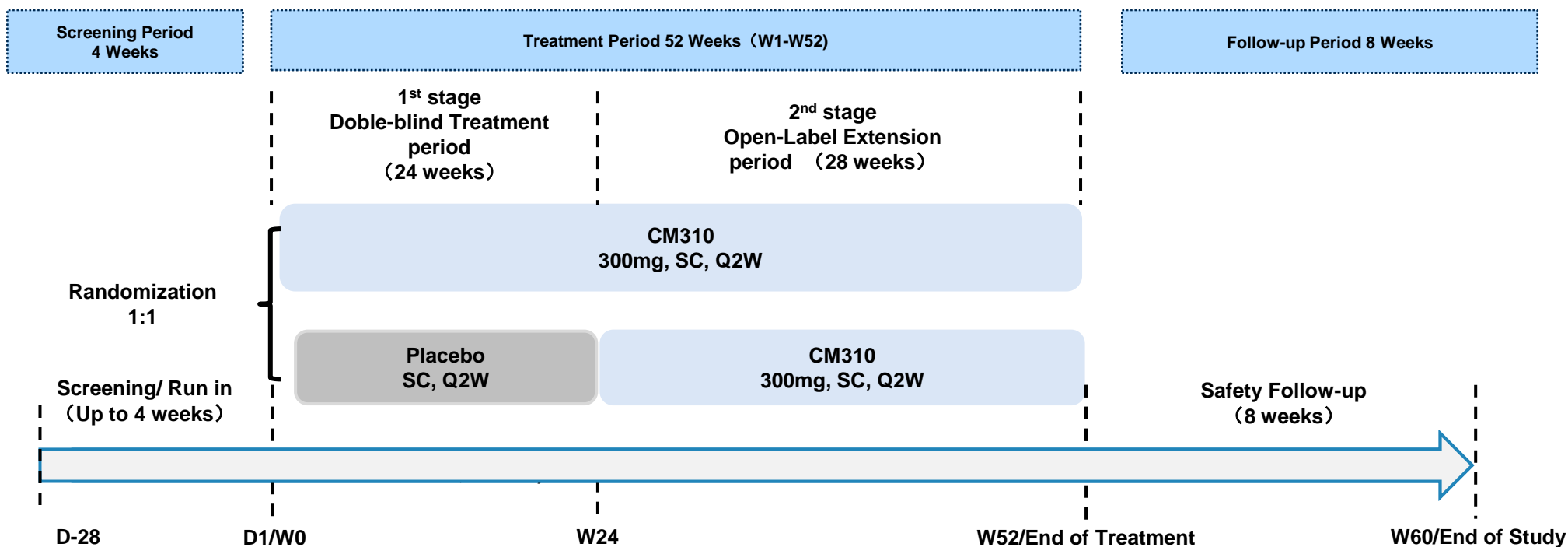
MMRM: Mixed model for repeated measures  
 LS Mean: Least square mean

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

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

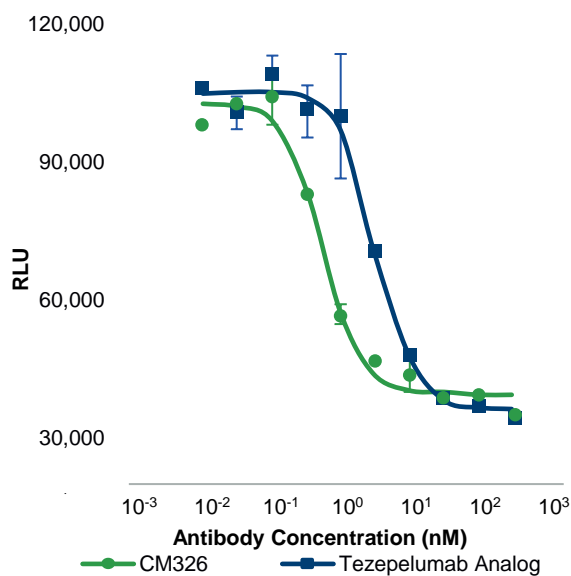
- Initiated **Phase Ib/IIa** clinical trial in **moderate-to-severe AD patients** (2022 H1), has initiated the **patient enrollment of Phase II trial**
- **Completed the patient enrollment of Phase Ib/IIa** clinical trial in **CRSwNP patients** (Feb 2023)
- CM326 Asthma trial: **NMPA IND Approved**

2

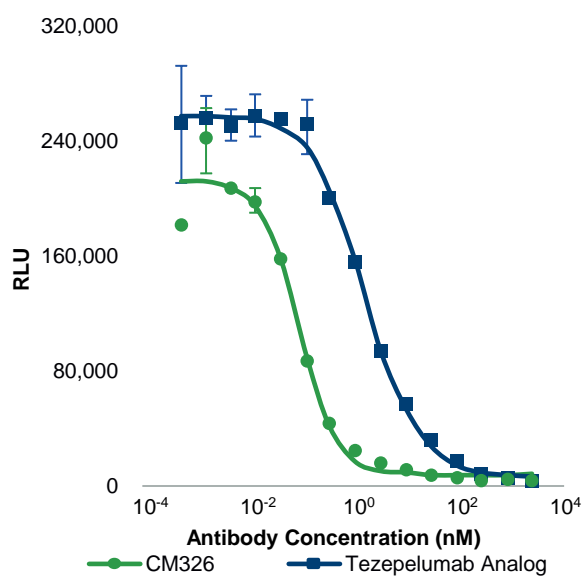
## CM326 - Higher Potency in Preclinical Studies

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

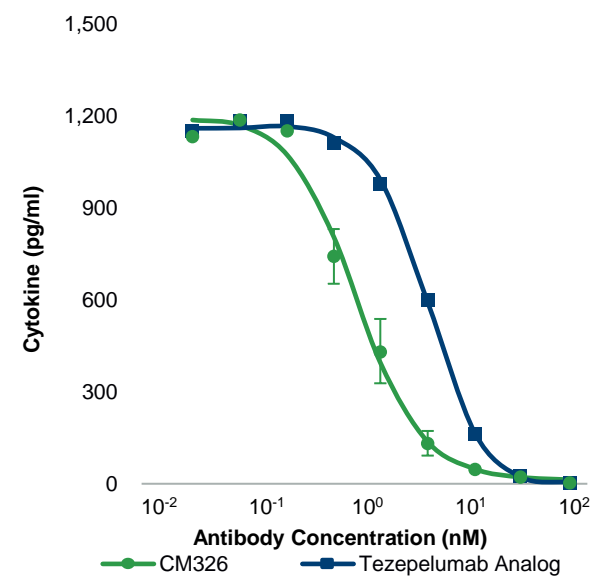
TSLP-induced proliferation



JAK/STAT signaling inhibition



TSLP induced T<sub>h</sub>2 cytokine release



	IC <sub>50</sub> (nM)
CM326	0.48
Tezepelumab analog	2.63

	IC <sub>50</sub> (nM)
CM326	0.09
Tezepelumab analog	1.72

	IC <sub>50</sub> (nM)
CM326	0.47
Tezepelumab analog	2.52



2

## CM326 - Good Safety Data Obtained in a Phase I Single-dose Study of Healthy People

The total incidence of TEAEs in the CM326 groups and the placebo group was similar; no TEAEs  $\geq 3$ , 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  $IC_{50}$



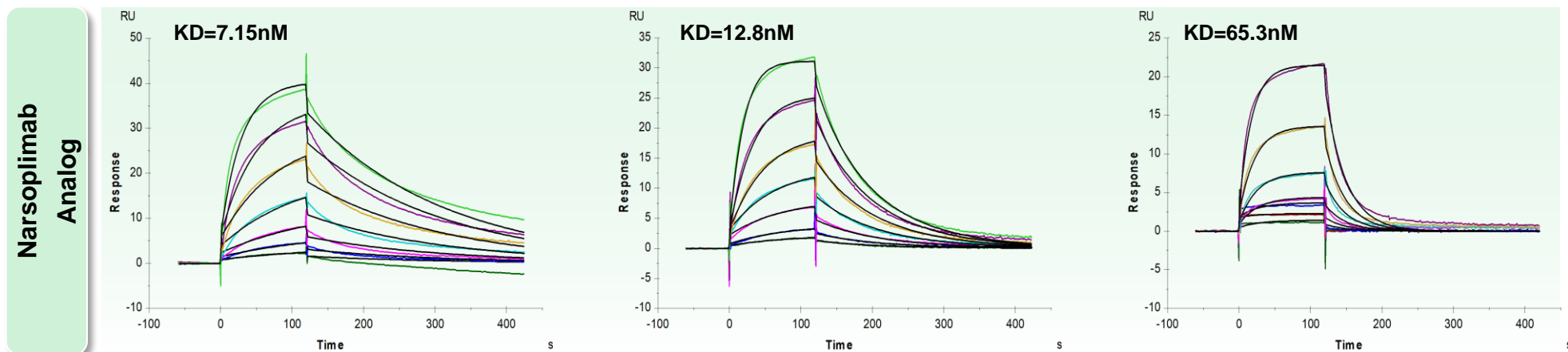
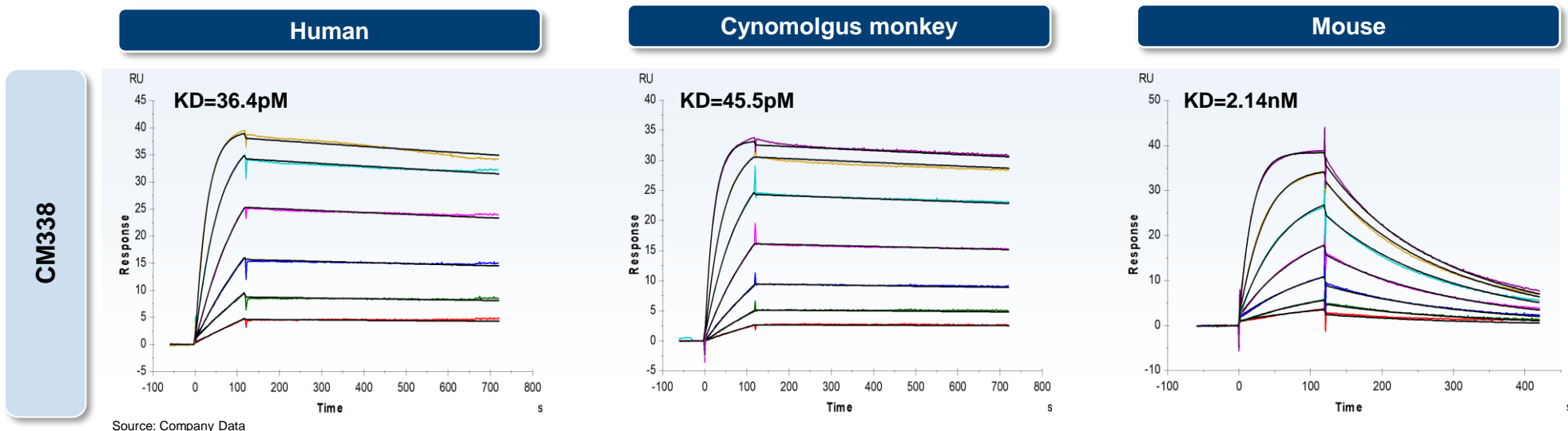
#### Toxicity studies

- **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 1 clinical trial completed
- **Phase II study for the treatment of IgAn** has been initiated in **Feb 2023**

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

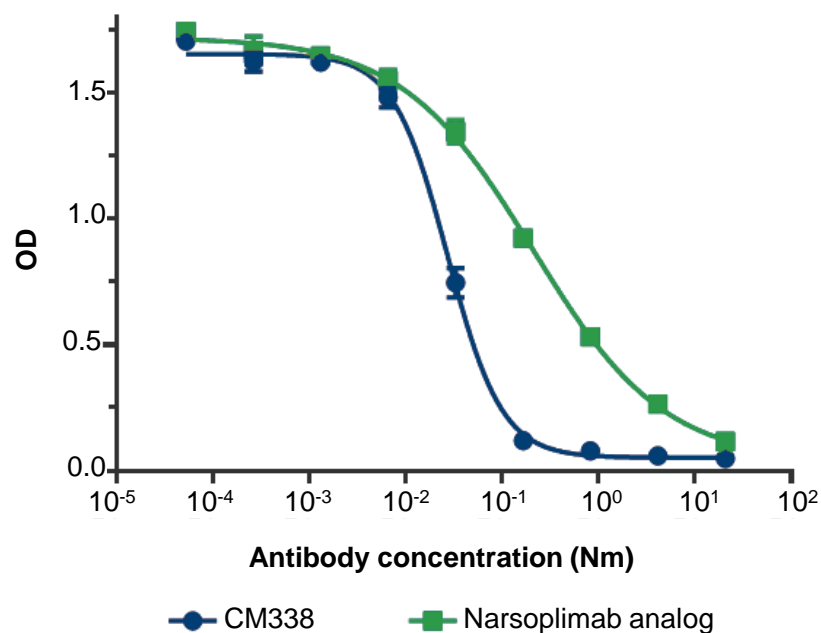


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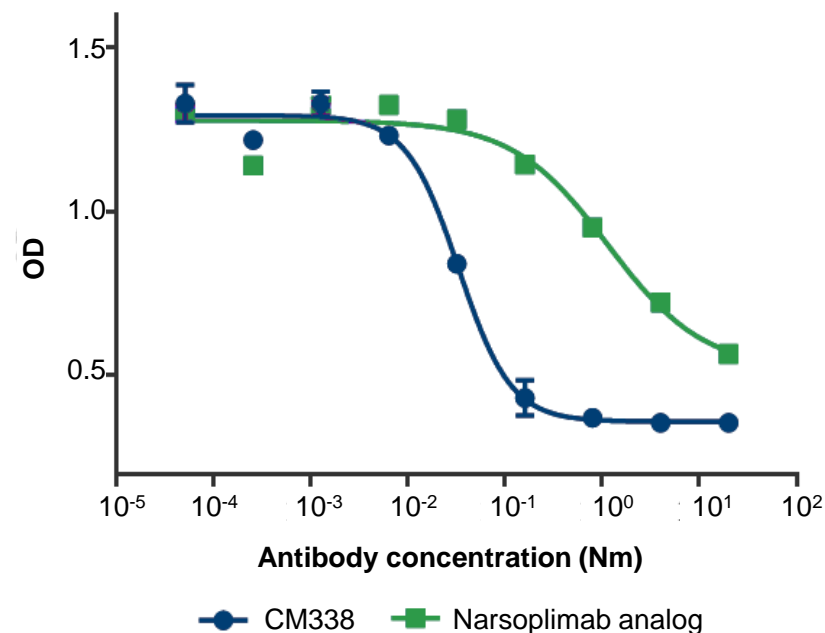
# CM338 - More Effective in Inhibiting the Activation of the Lectin Pathway

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 <sub>50</sub> (nM)	
	C4b2a	C3b
CM338	0.026	0.033
Narsoplimab analog	0.202	1.151

## 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 EC<sub>50</sub> 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 <sup>#</sup>	6(75%)
DCR <sup>*</sup>	8(100%)
Median PFS, day	NR <sup>&amp;</sup>
Median OS, day	NR <sup>&amp;</sup>

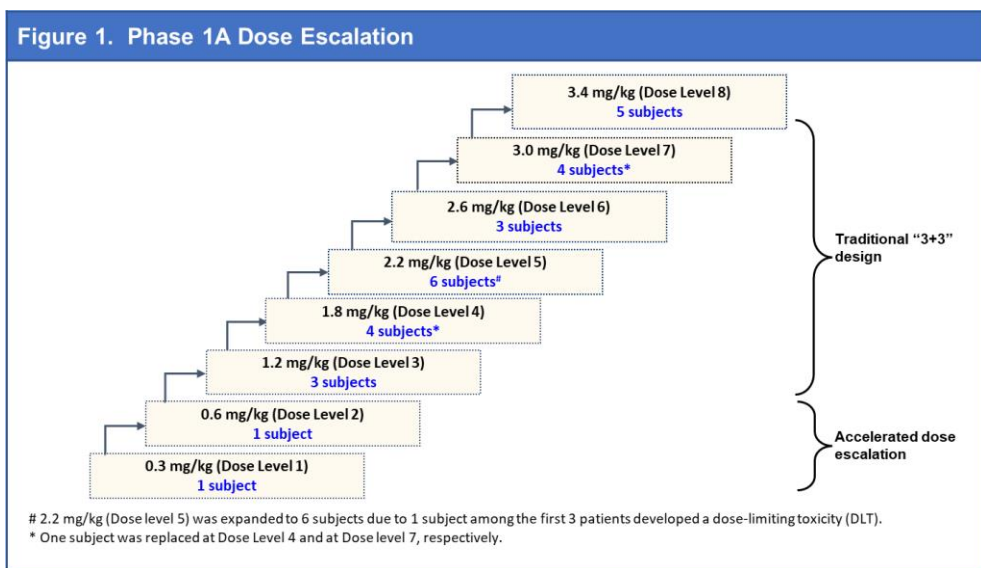
### Future plan

- Completed patient enrollment of the **dose-escalation stage of Phase I clinical trial** in 2022
- The **Phase 1b dose-expansion trial** in gastric/GEJ cancer, pancreatic cancer, and other solid tumors is rapidly enrolling, 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  $\geq 3$  adverse events occurred in 3/27 (11.1%) patients. No drug-related grade  $\geq 4$  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)
<b>Median age (min, max)</b>	58(31, 70)	58(31, 70)
<b>Gender, n(%)</b>		
Male	14(51.9%)	6(46.2%)
<b>Primary tumor type, n(%)</b>		
Gastric adenocarcinoma	12(44.4%)	12(92.3%)
Gastroesophageal junction adenocarcinoma	1(3.7%)	1(7.7%)
Pancreatic adenocarcinoma	14(51.9)	NA
<b>CLDN18.2 expression*, n(%)</b>		
Positive	14(51.9%)	8(61.5%)
Negative	7(25.9%)	3(23.1%)
Unknown	6(22.2%)	2(15.4%)
<b>ECOG performance score, n(%)</b>		
0	8(29.6%)	5(38.5%)
1	19(70.4%)	8(61.5%)
<b>Prior lines of systemic therapies, n(%)</b>		
1	3(11.1%)	2(15.4%)
2	12(44.4%)	4(30.8%)
$\geq 3$	12(44.4%)	7(53.8%)

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

## 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.

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

<sup>#</sup> Proportion with complete response (CR) + partial response (PR)

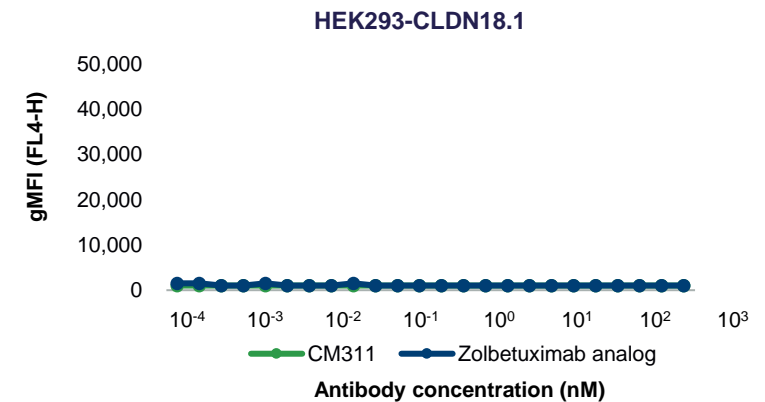
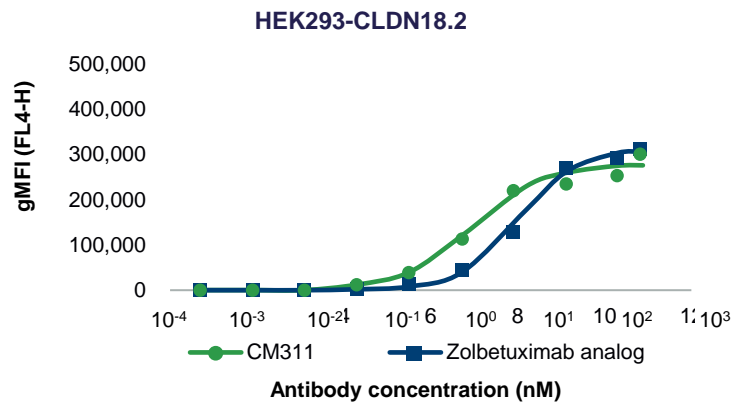
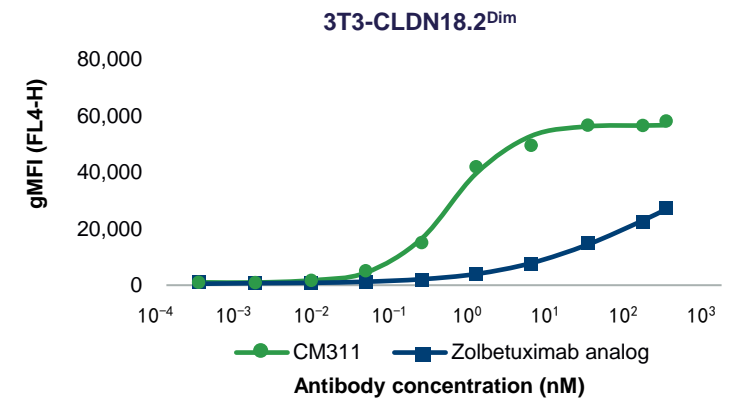
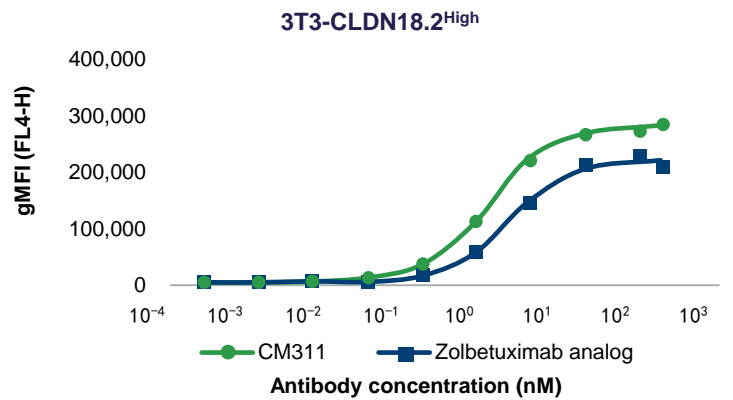
<sup>\*</sup> Proportion with CR+PR+stable disease

<sup>&</sup> mPFS and mOS were not reached.

# 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<sup>Dim</sup>), CM311 shown much higher binding activity than zolbetuximab analog

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

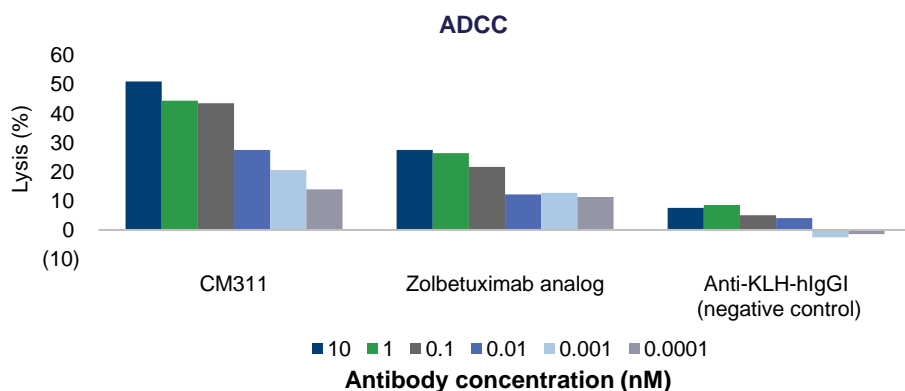




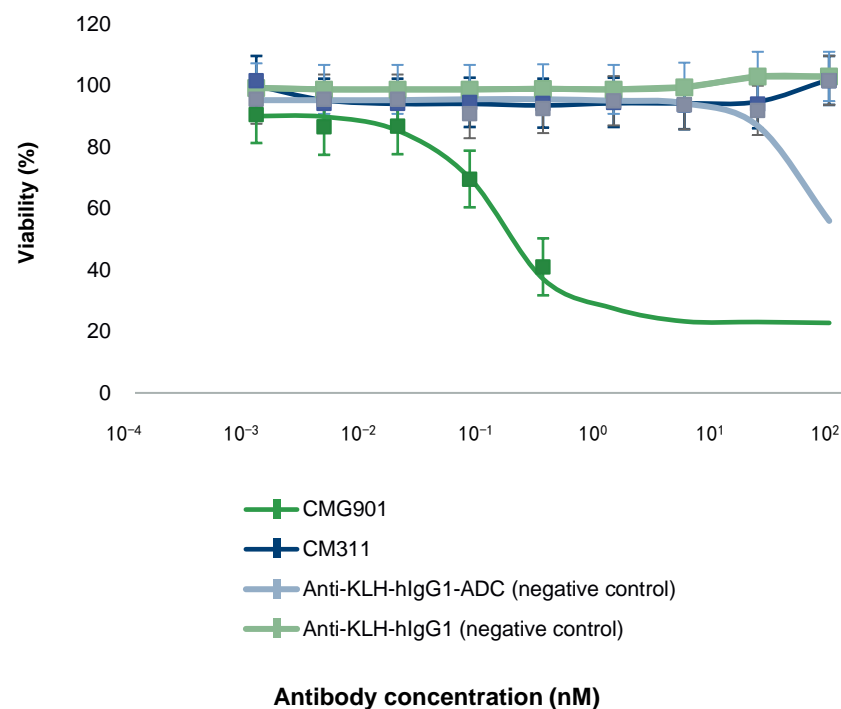
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# CMG901 - Highly Potent ADCC and CDC Effects and Highly Active Cytotoxic Payload with Potential By-stander Killing Effects

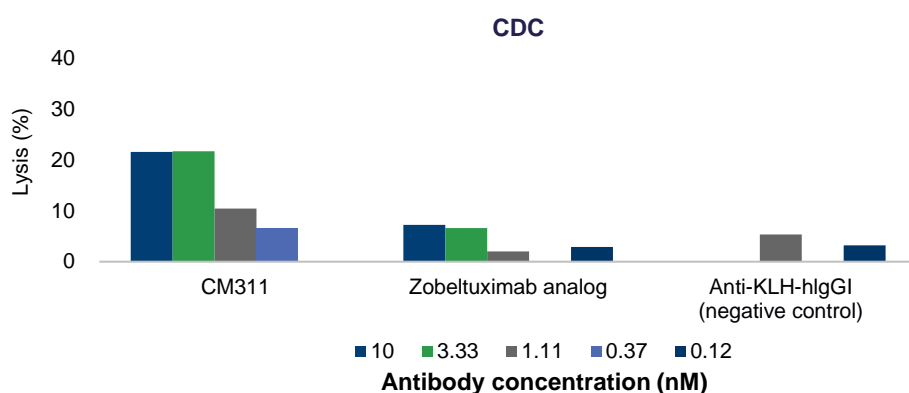
CM311-mediated ADCC is highly efficient against Claudin 18.2-expressing tumor cells with killing rate reaching ~50% vs. 30% with zolbetuximab analog



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



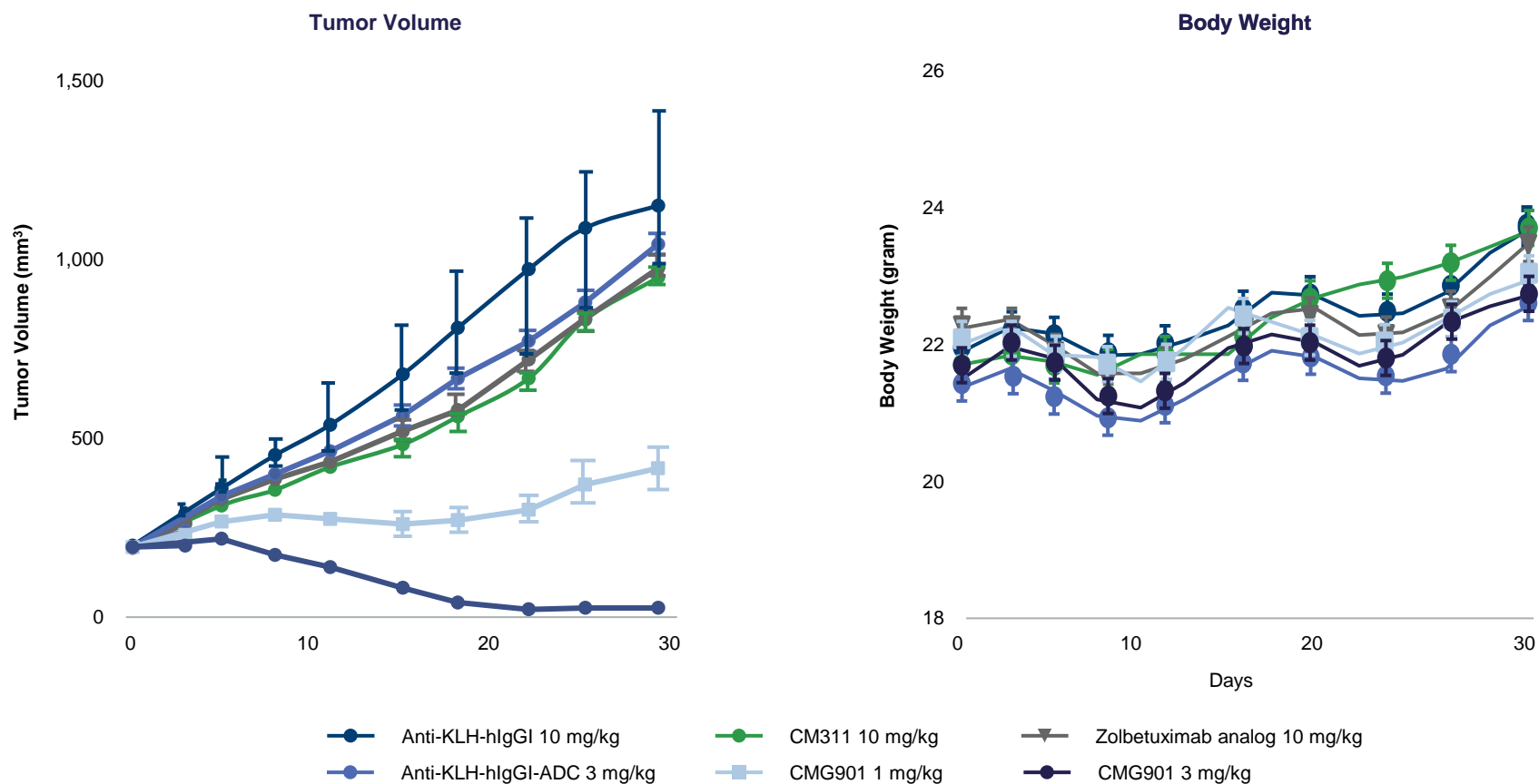
	IC <sub>50</sub> (nM)
CMG901	0.13

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



## 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



PD

- 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.**



Safety

- 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

- **Dose escalation Phase 1 clinical trial ongoing for RRMM**
- **Dose expansion trial** has been initiated in the late stage of **2022 Q1**
- IND approved for **SLE** in China in Apr 2022; Dosing in First Patient (2022.10)

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*



**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
- **Dosing in First Patient (2022.1)**



**BCMAxCD3 bispecific antibody**

- Indication: RRMM (Relapsed or Refractory Multiple Myeloma)
- Demonstrated high affinity for BCMA and strong antitumor activity
- **Dosing in First Patient (2022.9)**



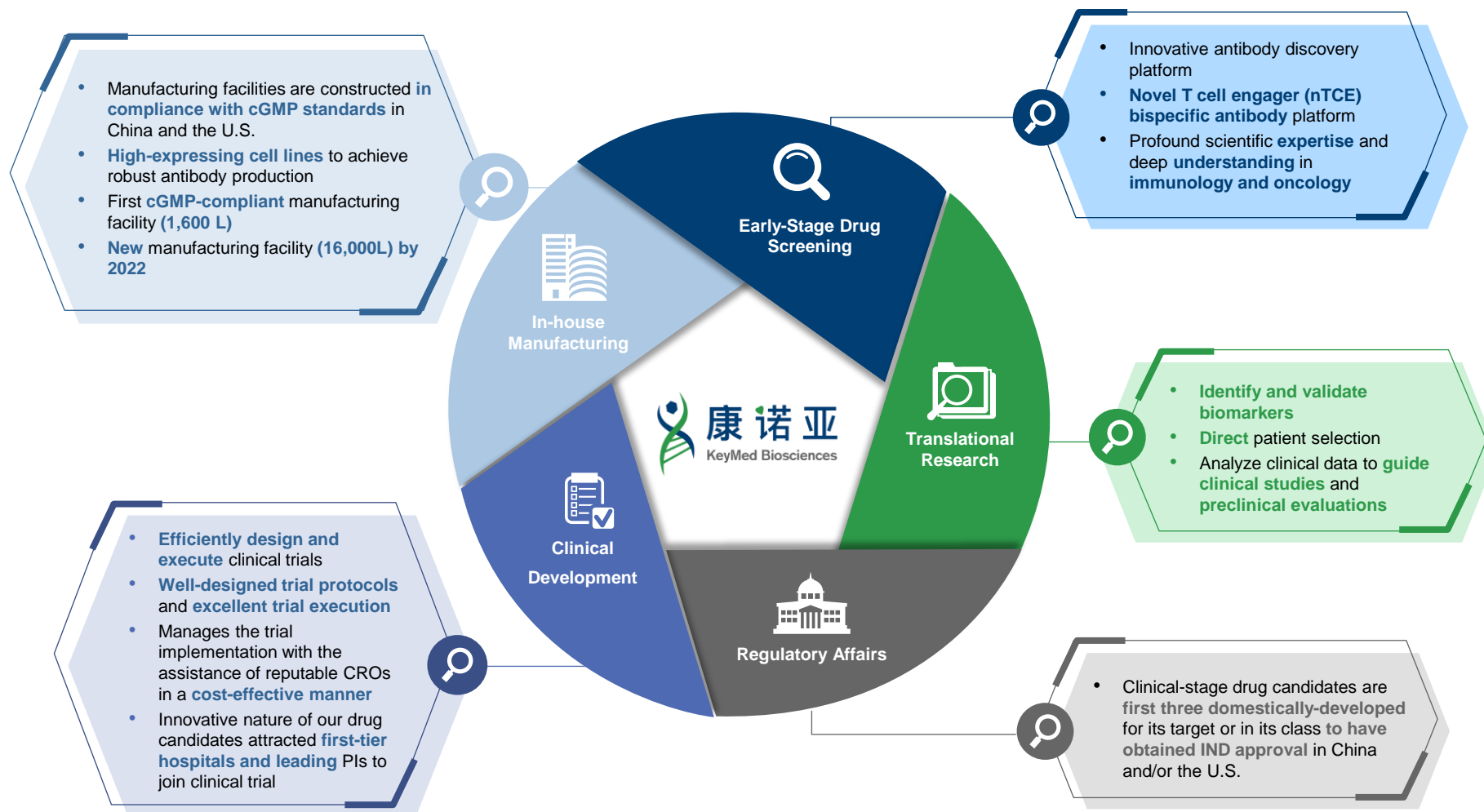
**Glypican 3 (GPC3)xCD3 bispecific antibody**

- Indication: solid tumors
- Induced stronger TDCC as compared to its leading competitor
- **Dosing in First Patient (2022.5)**

Oncology portfolio also includes **CM369 (CCR8 antibody)**  
the IND application has been approved by NMPA in Aug 2022, co-develop with INNOCARE, **First patient dosing in Feb 2023**

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## 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 Loss for 2022

(RMB'000)	2022	2021
Revenue	100,063	110,269
Cost of sales	(2,585)	(17,200)
Gross Profits <sup>(NB1)</sup>	97,478	93,069
Other Income and gains <sup>(NB2)</sup>	259,002	52,667
R&D Expenses*	(473,018)	(250,493)
Administrative Expenses* <sup>(NB3)</sup>	(119,701)	(83,294)
Listing Expenses	-	(37,932)
Other Expenses	(683)	(57,680)
Finance Costs <sup>(NB4)</sup>	(8,397)	(11,133)
Share Of Loss Of A Joint Venture	(9,711)	(719)
<b>Adjusted Loss</b>	<b>(255,030)</b>	<b>(295,515)</b>
Less:		
Share Based Payments	48,567	116,823
Fair Value Loss On Preferred Shares	-	3,480,294
<b>Net Loss</b>	<b>(303,597)</b>	<b>(3,892,632)</b>

**NB1:** The revenue of RMB 100 million 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 RMB65 million;
- ② interest income of RMB54 million;
- ③ Exchange gains of RMB139 million;

**NB3:** Administrative expenses mainly include staff costs of RMB62 million, professional fees of RMB24 million and other administrative costs;

**NB4:** Finance costs mainly represent interest on other financial liabilities.

\* Excluding of share based payments

## Financial Position as at 31 December 2022

(RMB'000)	31 December 2022	31 December 2021
<b>Non-current assets</b>		
Fixed assets <sup>(NB1)</sup>	553,556	139,419
Right of use assets	30,878	38,111
Intangible assets	1,496	1,104
Prepayments and other receivables <sup>(NB2)</sup>	15,841	153,591
FVTOCI <sup>(NB2)</sup>	10,001	-
Investment in a joint venture	10,570	20,281
<b>Total</b>	<b>622,342</b>	<b>352,506</b>

(RMB'000)	31 December 2022	31 December 2021
<b>Current assets</b>		
Inventories	44,495	16,393
Contract assets	-	3,980
Prepayments and other receivables <sup>(NB1)</sup>	90,153	36,997
Cash, Time Deposits and Bank wealth management products	3,175,326	3,524,579
<b>Total</b>	<b>3,309,974</b>	<b>3,581,949</b>
<b>Total assets</b>	<b>3,932,316</b>	<b>3,934,455</b>

**NB1:** The fixed assets mainly represent costs of production equipment and decoration in Chengdu new plant;

**NB2:** The balance mainly represents prepaid R&D expenses of RMB37 million, prepayment for fixed assets in Chengdu new plant of RMB12 million, recoverable VAT of RMB30 million, rental deposits of RMB2 million and advances to employees of RMB4 million;

**NB3:** The balance represents investment cost in Shanghai Duoning Biotechnology Co., Ltd.



## Financial Position as at 31 December 2022 (Continued)

(RMB'000)	31 December 2022	31 December 2021
<b>Current liabilities</b>		
Trade and other payables <sup>(NB1)</sup>	161,121	98,186
Amount due to related parties	225	553
Deferred income	-	1,612
Other financial liabilities <sup>(NB2)</sup>	146,112	-
Bank borrowings	61,163	-
Lease liabilities	11,078	11,724
<b>Total</b>	<b>379,699</b>	<b>112,075</b>

(RMB'000)	31 December 2022	31 December 2021
<b>Non-current liabilities</b>		
Deferred income	163,671	8,719
Lease liabilities	20,928	26,985
Bank borrowings	28,800	-
Other financial liabilities <sup>(NB2)</sup>	-	141,294
<b>Total</b>	<b>213,399</b>	<b>176,998</b>
<b>Total liabilities</b>	<b>593,098</b>	<b>289,073</b>
<b>Total equity</b>	<b>3,339,218</b>	<b>3,645,382</b>

**NB1:** The balance mainly represents payroll payables of RMB35 million, accrued R&D expenses of RMB53 million and payables for fixed assets of RMB52 million;

**NB2:** The balance represents loan from Chengdu Hi-tech New Economy Venture Capital Co., Ltd and Chengdu Bio-town Equity Investment Co., Ltd.



# 康诺亚

KeyMed Biosciences

CHAPTER 4

## Development Strategy



# 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*

**THANKS FOR  
WATCHING**

*CONTACT US: [IR@KEYMEDBIO.COM](mailto:IR@KEYMEDBIO.COM)*