

Keymed Biosciences *(2162.HK)*

2025 Annual Results Roadshow Presentation

March 2026



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Business summary for 2025

Realizing commercial value, accelerating revenue, deepening potential pipelines, ample cash reserves

Kangyueda (康悦达®): indication expansion, rapid commercialization & NRDL inclusion

- In 2025, total revenue **716** million, YOY+**67%**[↑]; of this, Kangyueda(康悦达®) sales amounted to **315** million, YOY+**775%**[↑]; BD-related revenue: **401** million (all are RMB)
- Commercial coverage (as of March 16, 2026), team: **>480** members, divided into dermatology and rhinology divisions; Coverage includes **>1500** hospitals (more than 600 approved for in-hospital use) and over **530+** pharmacies.
- NRDL Inclusion: **3** indications (**adult moderate-to-severe AD, CRSwNP, SAR**), effective January 1, 2026.

R&D progress

- **CMG901/AZD0901 (Claudin 18.2 ADC)** :MRCT Ph III for 2L+ & 1L CLDN18.2+ GC/ AEG 
- **CM336 (BCMA/CD3 BsAb)**: Ph III for RRMM ongoing; Autoimmune indications advancing rapidly globally  
- **CM512 (TSLPxIL-13 BsAb)**: Ph I results for AD announced; Multiple Ph II trials initiated across **CRSwNP, Asthma, COPD, CSU, AD**, etc.
- **CM518D1 (CDH17 ADC)** : Phase I/II trials for advanced solid tumors progressing rapidly

Sound financial position

- **Capital raise**: Subscription of 19 million shares, raising HKD **864** million.
- **Cash position (as of Dec 31, 2025)**: **RMB 1.96 billion** (incl. short-term bank wealth management products).

First full fiscal year of commercialization: multi-dimensional strategies to accelerate sales ramp-up of Kangyueda (康悦达®)

1

Focusing on immune diseases, building a professional sales team for dermatology and rhinology

- **3 Approved Indications:** Moderate-to-Severe AD in Adults, CRSwNP, SAR (Exclusive)
- **Precision Marketing:** Segmented into dermatology and rhinology fields
- **Continuous Expansion of Commercial Team:** As of March 16, 2026, exceed 480 members



2

Deepening professional academic promotion model

- Build a comprehensive academic promotion system
- Conduct real-world studies (RWS) to benefit more patients
- Drive inclusion in expert consensus and guidelines



Commercialization year one: multi-dimensional strategies to accelerate sales ramp-up of Kangyueda(康悦达®)

3

Accelerating penetration into high-potential regions and hospitals

- As of March 16, 2026, coverage expanded to 30 provinces and 260+ cities
- Hospital coverage:
Total covered hospitals: 1,500+
Active hospitals (with continuous sales): 1,300+
Hospitals approved for in-hospital use: 600+



4

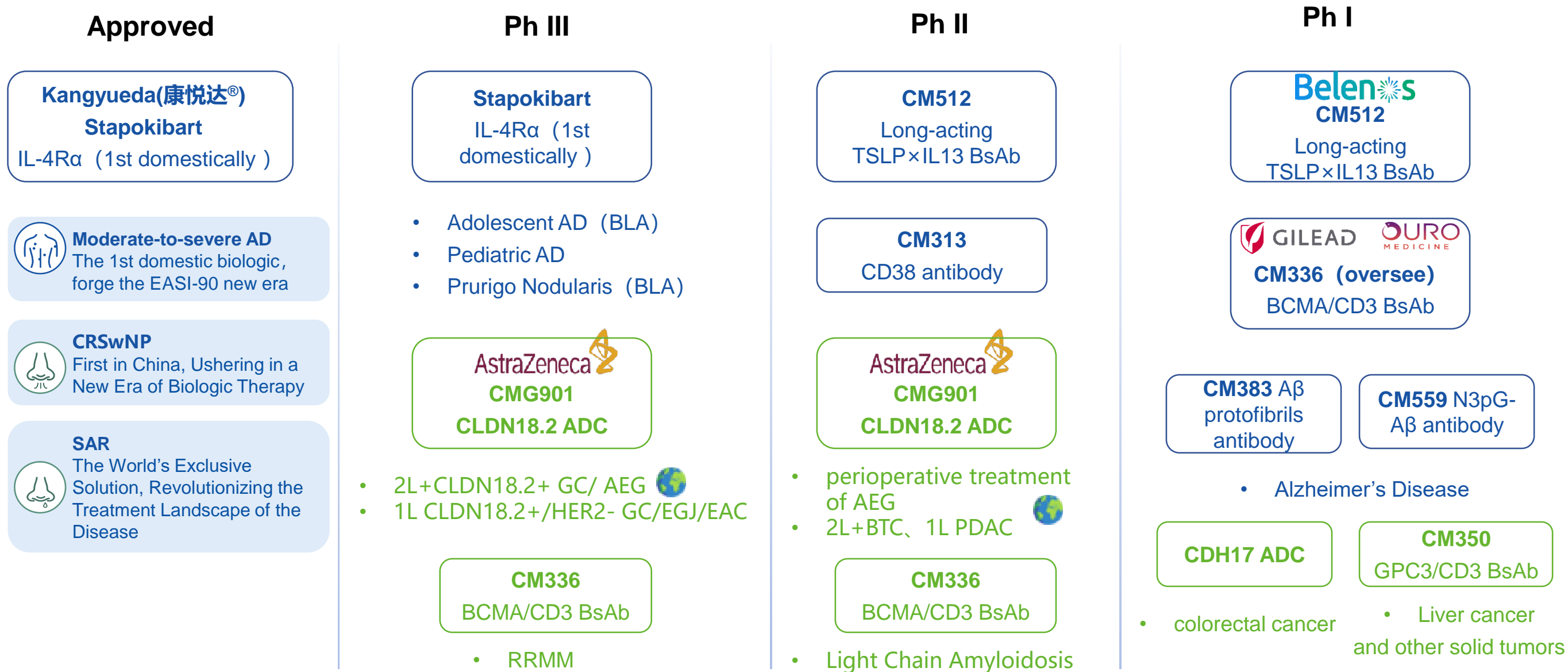
Expanding channels and market access

- **Commercial Channels:** Stable partnerships with 54 primary distributors and deployment in 650+ pharmacies
- **Medical Insurance (NRDL):** 3 indications of 康悦达® and the prefilled autoinjector included
- Vials and autoinjector listed in 31 provinces
- **Supplementary public insurance (Huimin Bao):** Included in selected cities

康悦达® (司普奇拜单抗注射液)

3项适应症 成功纳入2025年
国家基本医疗保险药品目录

R&D progress in 2026: focus on autoimmune, chronic diseases, and oncology



Note: Only key clinical pipeline items are listed. For a comprehensive clinical pipeline, please refer to Part 2: Company Overview – Clinical Pipeline.


AD: Atopic Dermatitis; BLA: Biologics License Application; GC: Gastric Cancer; AEG: Adenocarcinoma of the Esophagogastric Junction; EAC: Esophageal Adenocarcinoma; RRMM: Relapsed/Refractory Multiple Myeloma

Autoimmune & Chronic Diseases Oncology

Target for 2027: 3 marketed products , 10 plus pivotal registration trials


Expected approved for market launch

Kangyueda(康悦达®)
Stapokibart
IL-4Rα (1st domestically)

 **Moderate-to-severe AD**
The 1st domestic biologic, forge the EASI-90 new era

 **CRSwNP**
First in China, Ushering in a New Era of Biologic Therapy

 **SAR**
The World's Exclusive Solution, Revolutionizing the Treatment Landscape of the Disease

 **Adolescent AD**

 **Prurigo Nodularis**

AstraZeneca 
CMG901
CLDN18.2 ADC

2L+CLDN18.2+ GC/ AEG (China, US.....)

CM336
BCMA/CD3 BsAb

Light Chain Amyloidosis

Expected to conduct pivotal registration trials

CM512
Long-acting
TSLP×IL13 BsAb

- CRSwNP
- Asthma
- COPD
-


CM313
CD38 antibody

- IgAN


CM518D1
CDH17 ADC

- Colorectal Cancer (CRC)

AstraZeneca 
CMG901
CLDN18.2 ADC

- 1L CLDN18.2+ HER2- GC/AEG/EAC 
- 2L+ Biliary Tract Cancer(BTC)


 **GILEAD**  **OURO**
CM336
BCMA/CD3 BsAb

- AIC: AIHA and primary ITP 
- pemphigus (overseas)
- BCMA/CD3+CD38 1L MM (China)

BD asset updates: AstraZeneca accelerates MRCT for CLDN18.2 ADC



- CMG901 is Keymed's FIC Claudin 18.2-targeted ADC. In 2022, it received BTD from the CDE, FTD&ODD from the FDA.
- In February 2023: Keymed entered into a global exclusive license agreement with AZ. AZ is responsible for global R&D, manufacturing, and commercialization of CMG901. The total transaction value exceeds USD 1.1 billion, plus tiered royalties up to low double digits.

| Indication | Clinical Stage | Expected enrollment | Expected Milestones | |
|--|----------------|------------------------|---|--|
| 2L+ CLDN18.2+ GC/ AEG | Ph 3 | 572 | data readout: 2H2026 |  Fastest development progress worldwide |
| 1L CLDN18.2+ HER2- GC/AEG/EAC (Combination Therapy) | Ph 3 | 2130 (426 in China) | FPI: Feb 2026, triggered a \$45 million milestone payment | |
| CLDN18.2+Solid Tumors (3 Cohorts: GC, 1L PDAC, 2L+BTC) | Ph 2 | 224 | enrollment completed | |
| perioperative treatment of AEG (Combination Therapy) | Ph 2 | Total 100 | initiated in July 2025 | |

GC: Gastric Cancer; AEG: Adenocarcinoma of the Esophagogastric Junction; EAC: Esophageal Adenocarcinoma

Note: all clinical pipelines listed above are being advanced by partners within their licensed regions. For the same indication, only the highest clinical stage is shown. Data sourced from respective company websites or clinicaltrials.gov.



BD asset update: bolstered by Gilead's acquisition, CM336 market prospects are promising

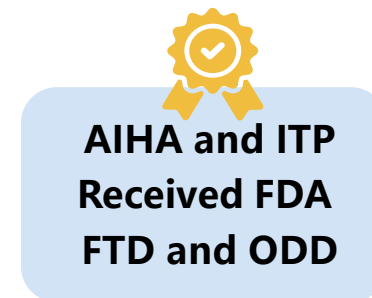


In November 2024: Keymed entered into a collaboration agreement with Ouro Medicines for CM336 (BCMA/CD3 BsAb) covering global rights ex-Greater China.

Deal Terms: USD 16 million upfront payment + minority equity stake in Ouro+ maximum milestone payments of USD 610 million + tiered royalty based on net sales.

In March 2026, Gilead acquired Ouro Medicines, securing global rights to CM336 outside Greater China. Keymed will receive an upfront payment of approximately USD 250 million plus milestone payments of approximately USD 70 million. Gilead will remain responsible for up to USD 610 million in milestone payments plus tiered royalties based on the net sales.

| Indication | Clinical Stage |
|-------------------------------|---|
| | Ph 1B/2A |
| AIC: AIHA and primary ITP、APS |  |
| SAI (SjD、IIM) |  |
| AIBD (BP、PV) | Investigator Initiated Trial |



All clinical pipelines listed above are being advanced by partners within their licensed regions. For the same indication, only the highest clinical stage is shown. Data sourced from respective company websites or clinicaltrials.gov.

AIC:autoimmune cytopenias; AIHA :autoimmune hemolytic anemia; ITP: immune thrombocytopenia; APS: antiphospholipid syndrome

SAI: seropositive autoimmune diseases; SjD:Sjögren's disease; IIM: idiopathic inflammatory myopathy;

AIBD: autoimmune bullous diseases; BP: bullous pemphigoid; PV: pemphigus vulgaris

Key expected milestones for R&D in 2026



Stapokibart IL-4R α

- New indication BLA submission
- √ Moderate-to-severe AD in adolescents
 - √ Prurigo Nodularis

CMG901 CLDN18.2 ADC

- √ 1L CLDN18.2+ HER2- GC/EGJ/EAC : MRCT Ph III FPI

- 2L+ CLDN18.2+ GC/ AEG
- MRCT Ph III Data readout
- Multi-country BLA

CM512 TSLP \times IL13 BsAb

- China Ph II data readout: CRSwNP
- US Ph I/II trial enrollment: Asthma

- China Ph III: CRSwNP
- China Ph II Interim analysis: Asthma, COPD

CM336 BCMA/CD3 BsAb

- RRMM Ph II clinical data paper published

- China BLA: AL Amyloidosis

CM518D1 CDH17 ADC

- China Ph I data presented at ESMO Congress: solid tumors

Innovative pipeline IND plans

- siRNA、PROTAC、Bispecific ADCs 、Brain-penetrant Bispecific Antibody

Company overview

A comprehensive biotechnology company dedicated to addressing significant unmet medical needs through diversified technology platforms



Robust Clinical Pipelines

Continuously providing innovative solutions for disease areas with significant unmet needs.

- 1 approved product, 3 Indications
- 12+ assets in clinical development
- 50+ assets in preclinical development



Proprietary Commercialization Capabilities

- Fully integrated, self-built commercialization system covering the entire value chain
- Deep focus on therapeutic areas such as **Dermatology** and **Rhinology**



Comprehensive R&D Capabilities

- Proven end-to-end experience in innovative drug R&D and commercialization
- Platforms include: antibodies, ADCs, oligonucleotides, small molecules (e.g., PROTACs), and blood-brain barrier (BBB) Penetrating Antibody Delivery Platform
- Strong clinical development capabilities



In-house Manufacturing Capabilities

Production capabilities compliant with FDA and NMPA cGMP requirements

- Total capacity now: **21,800L**
- New capacity: **24,000L** stainless steel production line is ready
- Future planned capacity exceeds **100,000L**



Expanding talent pool to support long-term growth and commercialization needs 康诺亚

Actively advancing the commercial sales of Kangyueda (康悦达®) and R&D work for additional pipeline assets

As of March 16, 2026

1696

Full-time Employees

131

Administration &
Back-office Support

429

Drug R&D & Clinical
Operations

656

CMC &
Manufacturing

480

Commercial Team



In addition to our Chengdu headquarters, we have established offices in Shanghai, Beijing, Nanjing, Wuhan, Guangzhou, and other locations.






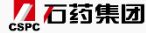






Diversified innovative technology platforms, with the best molecular modality, addressing unmet medical needs

Diversified innovative technology platforms empowering drug R&D with 50+ assets in pipeline



Clinical Pipeline: 12 candidates in clinical trials, leading in the R&D process

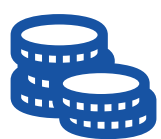
Autoimmune or Chronic disease

| | Pre-Clinical | IND | Ph-I | Ph-II | Ph-III | NDA | Launched | Partner | Keymed Rights |
|---|-------------------------------------|-----|------|-------|--------|-----|---|--|--------------------------|
|  <p>康悦达® 司普奇单抗 Stapokibart CM310 ★</p> | Moderate-to-severe AD--Adults | | | | | | BTD granted by CDE / Priority Review / NDA approval in Sep,2024 | | Global |
| | Moderate-to-severe AD--Adolescents | | | | | | | | |
| | Moderate-to-severe AD--Children | | | | | | | | |
| | CRSwNP | | | | | | Priority Review / NDA approval in Dec,2024 | | |
| | SAR | | | | | | NDA approval in Feb,2025 | | |
| | Prurigo Nodularis | | | | | | | | |
| <p>CM512 TSLPxIL-13 (Bispecific) ★</p> | CRSwNP | | | | | | |  | Greater China |
| | Asthma | | | | | |  | | |
| | COPD | | | | | | | | |
| | Moderate-to-severe AD | | | | | | | | |
| | Chronic Spontaneous Urticaria(CSU) | | | | | | | | |
| <p>CM326 TSLP (mAb)</p> | Asthma, CRSwNP, etc. | | | | | | |  | Global ex mainland China |
| <p>CM336 BCMAxCD3 (Bispecific)</p> | light chain amyloidosis(AL) | | | | | | |   | Greater China |
| | autoimmune cytopenias(AIC) | | | | | | FDT&ODD  | | |
| | SAI(SjD,IIM) | | | | | |  | | |
| | BP,PV | | | | | |  | | |
| <p>CM383 Aβ protofibrils (mAb)</p> | Alzheimer's Disease | | | | | | | | Global |
| <p>CM559 N3pG-Aβ (mAb)</p> | Alzheimer's Disease | | | | | | | | Global |
| <p>CM313 CD38 (mAb)</p> | ITP | | | | | | |  | Greater China |
| | IgAN | | | | | | | | |
| | SLE | | | | | | | | |
| | Aplastic Anemia | | | | | | | | |
| | Platelet Transfusion Refractoriness | | | | | | | | |

Clinical Pipeline: 12 candidates in clinical trials, leading in the R&D process

Oncology

| | Pre-Clinical | IND | Ph-I | Ph-II | Ph-III | NDA | Launched | Partner | Keymed Rights |
|------------------------------------|--|-----|---|-------|--------|-----|----------|-------------------------|---------------|
| CMG901 Claudin 18.2 (ADC) ★ | 2L+ CLDN18.2+ GC/ AEG | | FTD & ODD granted by FDA / BTD granted by CDE | | | | | | |
| | 1L CLDN18.2+ HER2- GC/ AEG /EAC (Combinations) | | | | | | | | |
| | perioperative treatment of AEG (Combinations) | | | | | | | | AstraZeneca |
| | CLDN18.2+ solid tumours | | | | | | | | |
| CM336 BCMAxCD3 (Bispecific) | RRMM | | | | | | | GILEAD OURO MEDICINES | Greater China |
| CM518D1 CDH17 (ADC) | Solid tumors | | | | | | | | Global |
| CM313 CD38 (mAb) | RRMM | | | | | | | TIMBERLYNE THERAPEUTICS | Greater China |
| CM355 CD20xCD3 (Bispecific) | Lymphoma | | | | | | | Prolium | Asia: 天诺健成 |
| CM350 GPC3xCD3 (Bispecific) | Solid tumors | | | | | | | | Global |
| CM369 CCR8 (mAb) | Tumors | | | | | | | INNOCARE | Global |



Cumulative R&D investment exceeds RMB 2.3 billion



51 Clinical trial approvals obtained for China class 1 new drugs



259 invention patent applications filed

AD: Atopic Dermatitis; CRSwNP: Chronic Rhinosinusitis with Nasal Polyps; GC: Gastric Cancer; AEG: Adenocarcinoma of the Esophagogastric Junction; EAC: Esophageal Adenocarcinoma; COPD: chronic obstructive pulmonary disease; RRMM: Relapsed/Refractory Multiple Myeloma

Large-scale commercial manufacturing system, cost advantages creating a commercial barrier

- The first-stage project involved a fixed asset investment exceeding **RMB 800 million**
- **High yield: 5-10 g/L**
- **Cost Efficiency**



- Total Capacity now: **21,800L**
3 pilot production lines and 3 commercial production lines
- New Capacity: **24,000L** stainless steel production line is ready (as below)
- Future capacity Planning **100,000L** supporting commercial production for 5-15 antibody drugs.



Quality System Compliant with US, China, and EU cGMP Standards

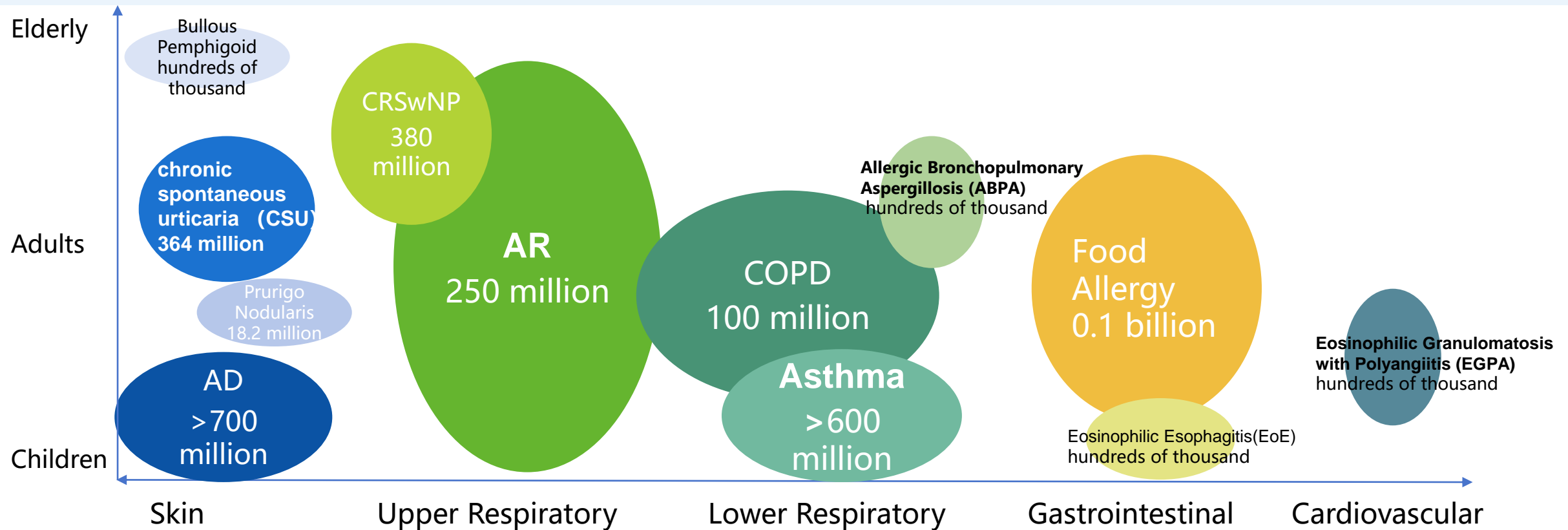
- **World-class advanced technology, ranked #1 in Western China**



Kangyueda (康悦达[®], Stapokibart) introduction

Keymed Bio : A Leader in immunological diseases with significant blue-ocean market potential

- Depending on the site of inflammation, dysregulation of the Type 2 immune pathway can manifest as various allergic diseases, including dermatological, respiratory, gastrointestinal, and cardiovascular conditions. **A single drug candidate holds the potential for multiple indications (Pipeline-in-a-Product).**
- Chinese epidemiological data indicates an adult prevalence of AD at 4.6% and 13% for children aged 1-7, with a total AD patient population exceeding 70 million. The patient populations for Allergic Rhinitis, Food Allergy, COPD, Asthma, and CRSwNP in China reach 250 million, 112 million, 100 million, over 60 million, and 38 million, respectively.



First-in-China, Second-in-Global, potential Best-in-Class IL-4R α antibody

Kangyueda (康悦达[®]), Stapokibart, CM310 (IL-4R α)



Moderate-to-severe AD
(Approved in Sept 2024)



CRSwNP
(Approved in Dec 2024)



SAR
(Approved in Jan 2025)



Adolescent AD
(BLA)



Pediatric AD
(Ph III)



Prurigo Nodularis
(BLA)

多项第1

- ✓ **1st domestically produced biologic** for treating moderate-to-severe AD
Fills the gap in clinical trial data regarding higher treatment goals in the AD field.
- ✓ **1st biologic in China** for treating CRSwNP
- ✓ **1st IL-4R α antibody drug globally** for treating SAR
- ✓ **1st in China and 2nd Globally** approved self-developed IL-4R α antibody drug

Academic Publications

- ✓ Phase III clinical study results for SAR published in **Nature Medicine** (IF=58.7).
- ✓ Phase III clinical study results for CRSwNP published in **JAMA** (IF=55).
- ✓ Phase III clinical study results for Moderate-to-severe AD in adults published in **Allergy** (IF=12.6).

Regulatory Designations

- ✓ Granted **Breakthrough Therapy Designation** by CDE
- ✓ Included in the **Priority Review and Approval Program**

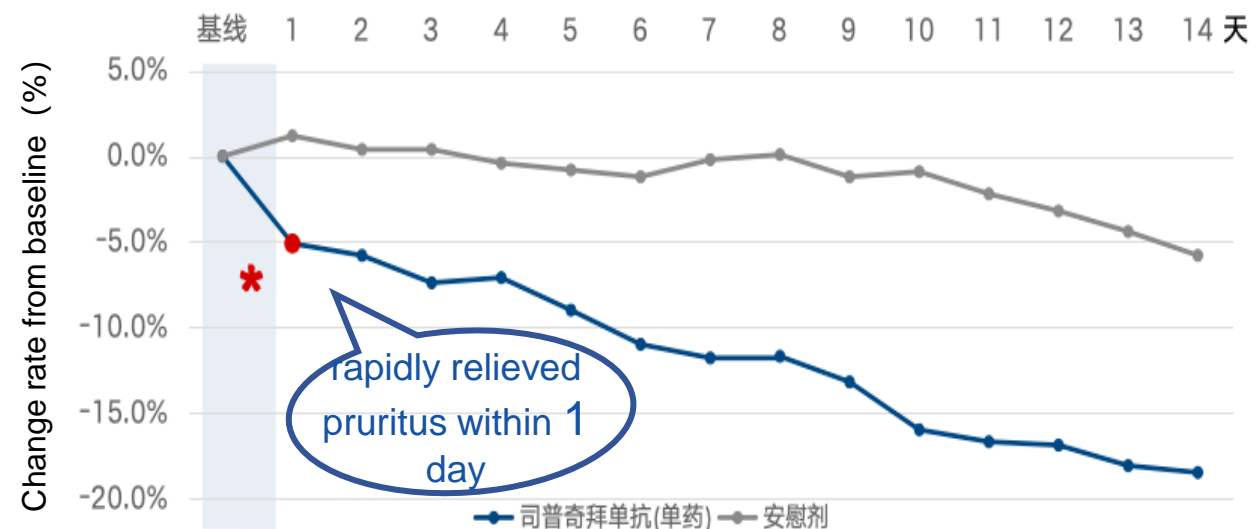
- In the Ph III clinical study of Stapokibart for the treatment of AD, 500 subjects were randomized 1:1 to receive dosing Q2W for 16 weeks (double-blind treatment period). Subsequently, all subjects received Stapokibart treatment for 36 weeks (maintenance treatment period).
- Monotherapy with the first dose of Stapokibart rapidly relieved pruritus (itching) symptoms within 1 day; after 2 weeks of treatment, it demonstrated potent improvement in skin lesions across all body areas.

Fast-acting from the first dose

Rapid pruritus relief within 24 hours after the first dose¹



The rate of change of daily PP-NRS from the baseline

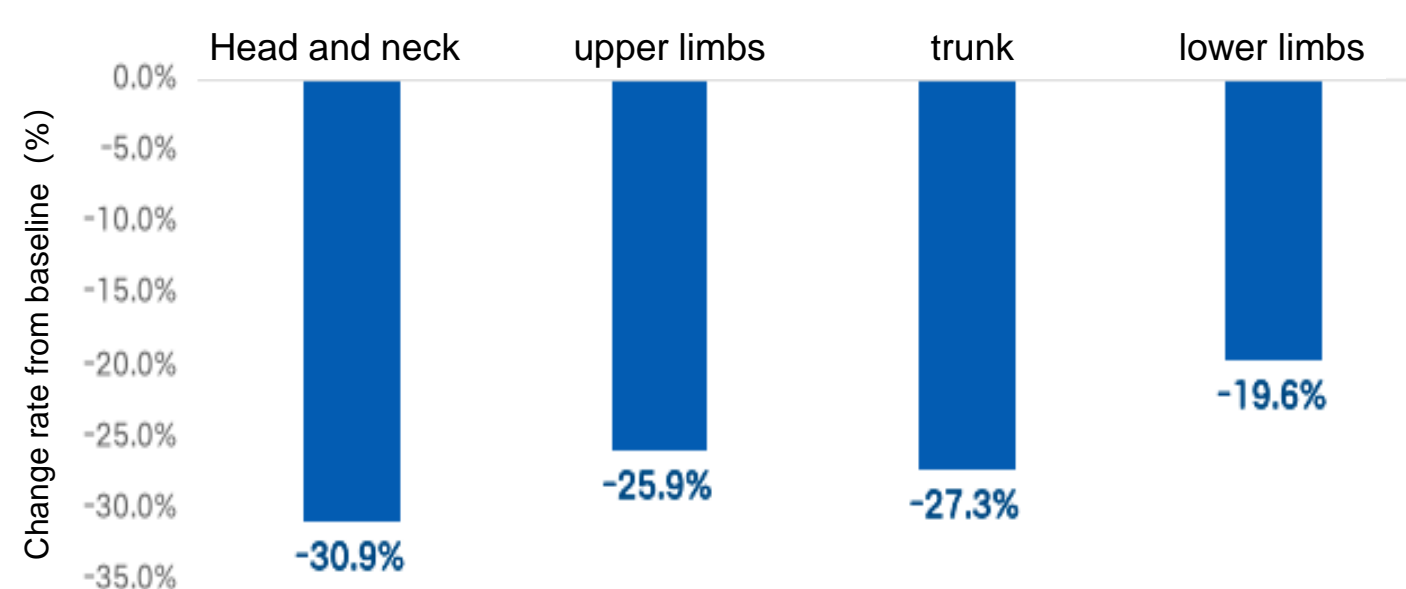


*: 司普奇拜单抗组显著优于安慰剂组, $p=0.0006$

Comprehensive improvement of skin lesions following the first dose²



The rate of change in EASI at different sites from the baseline



*: 司普奇拜单抗组显著优于安慰剂组, $p<0.0001$

1. Jianzhong Zhang, et al. 2024EADV, P0475.

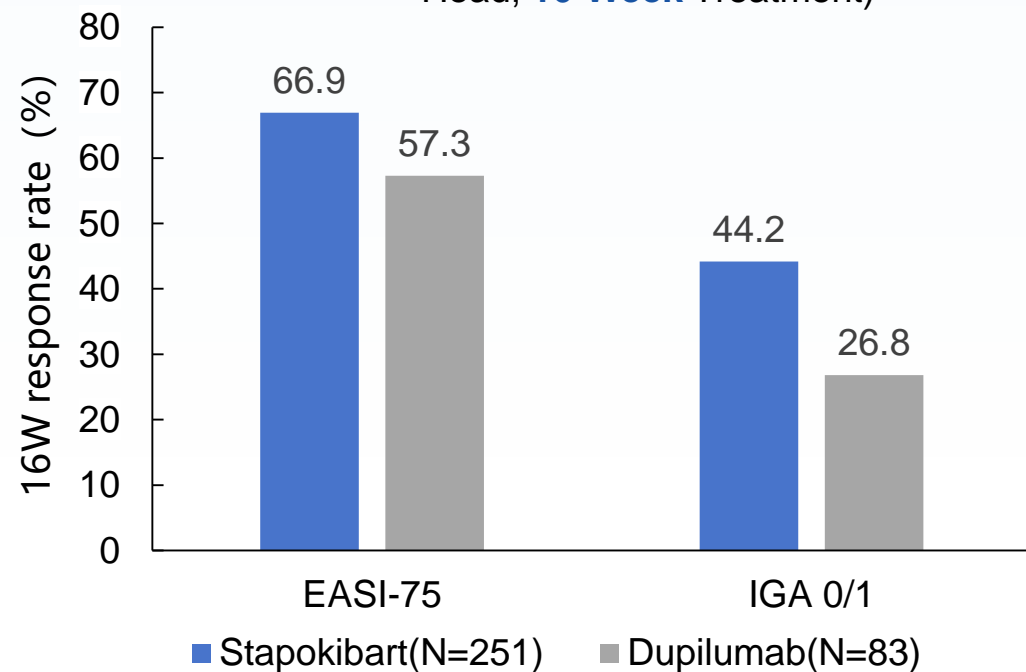
2. Yan Zhao, et al. Int J Dermatol. 2025 May 2. doi: 10.1111/ijd.17820.

- **Dual primary endpoints and all secondary efficacy endpoints were met in the Phase III clinical study.** At Week 16, the EASI-75 response rate ($\geq 75\%$ improvement from baseline in Eczema Area and Severity Index) reached **66.9%**, and the IGA response rate (score of 0 or 1 with ≥ 2 -point improvement from baseline) reached **44.2%**.
- After 52 weeks of treatment, **dual "9" efficacy** was achievable, with an EASI-75 response rate of **92.5%** and an EASI-90 response rate ($\geq 90\%$ improvement from baseline) of **77.1%**.

Potent response, Durable remission

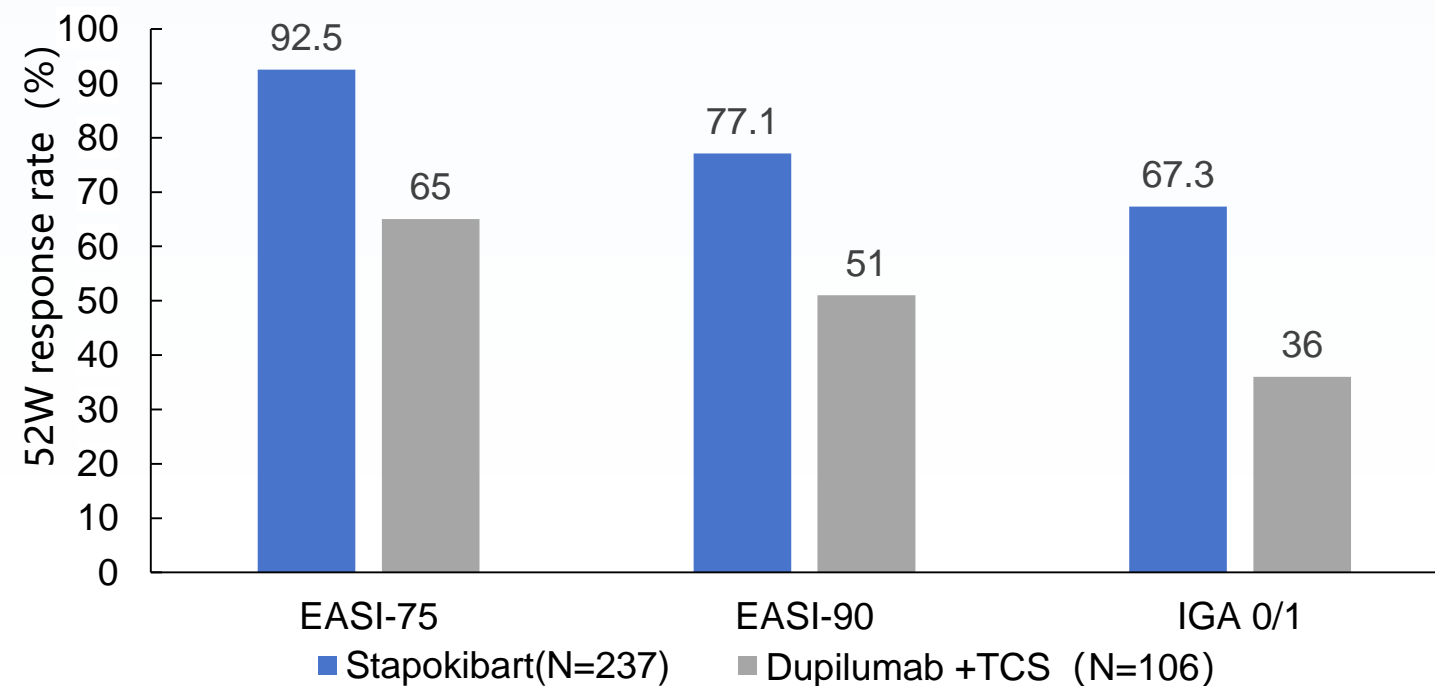
16W

Comparison of Phase III Primary Endpoint Data for Stapokibart in the Treatment of AD (Non-Head-to-Head, **16-Week** Treatment)



52W

Comparison of **52-Week** Clinical Data for Stapokibart in the Treatment of AD (Non-Head-to-Head) ^{1,2}

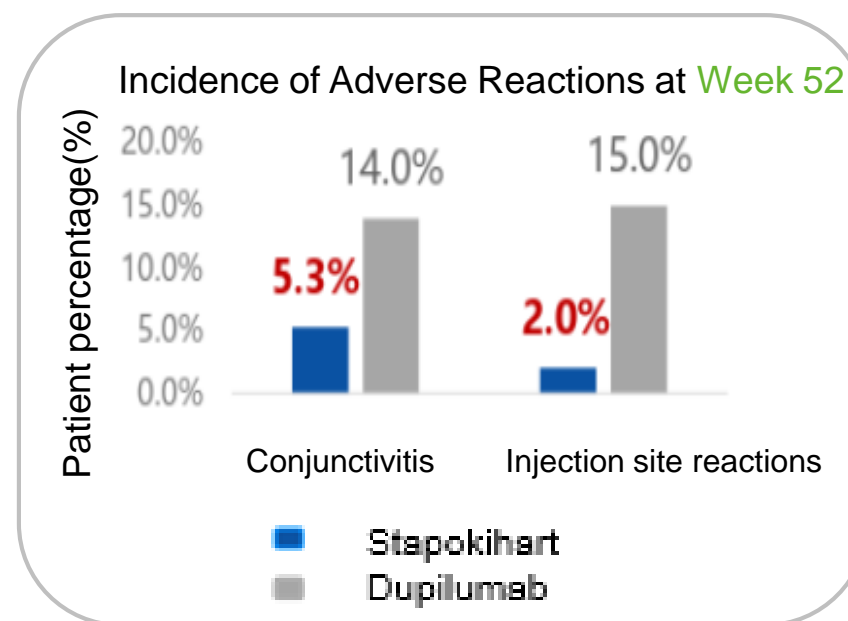
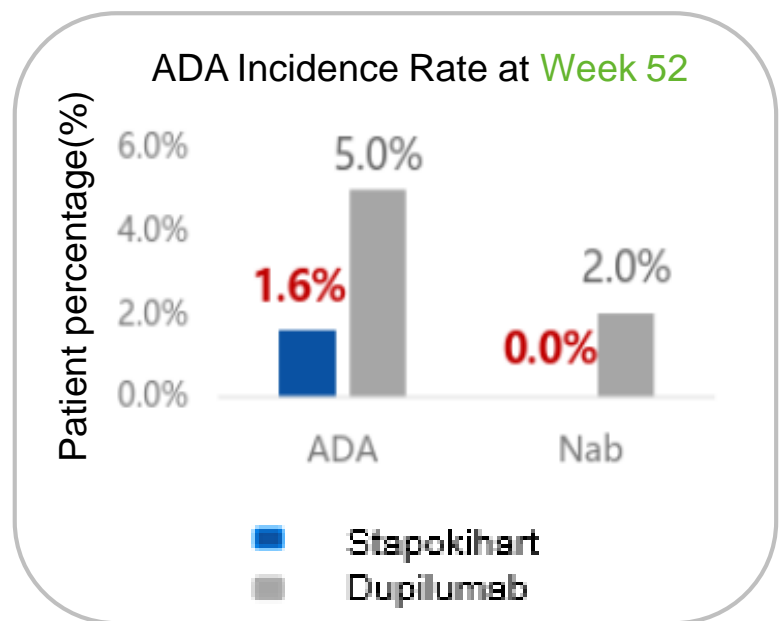


1. Yan Zhao, et al. Allergy. 2025 May;80(5):1348-1357.
 2. Andrew Blauvelt, et al. Lancet. 2017 Jun 10;389(10086):2287-2303.

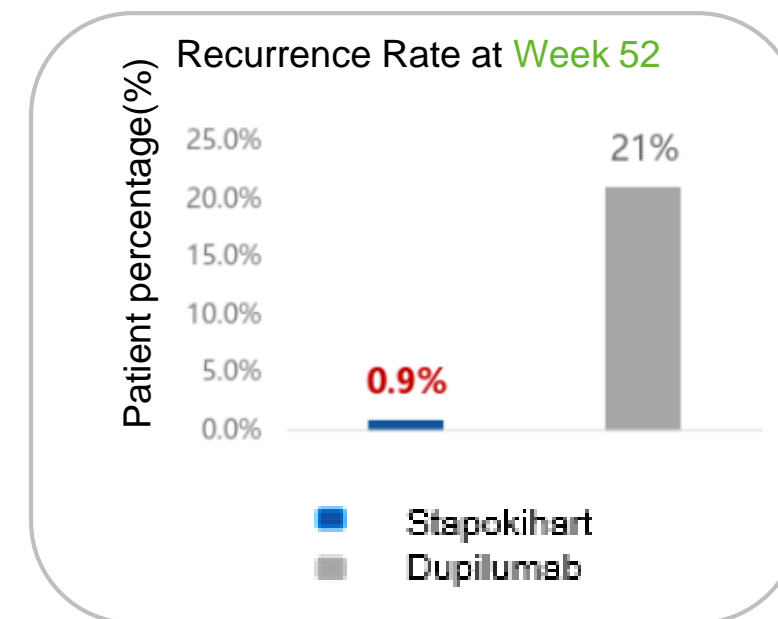
➤ **Stapokibart demonstrated a favorable safety and tolerability profile.** Compared to Dupilumab—a widely used agent with the same indication and target—Stapokibart effectively reduces the risk of recurrence while maintaining excellent safety and tolerability. The recurrence rate was only **0.9%** after 52 weeks of treatment and remained at **0.9%** even 8 weeks post-discontinuation. The incidence of conjunctivitis was low at **5.3%**.

Lower Recurrence Rate and Favorable Safety Profile

Safety Data Comparison of Stapokihart (Phase III, Non-Head-to-Head) in AD



Recurrence Rate Comparison of Stapokihart (Phase III, Non-Head-to-Head) in AD



ADA: Anti-drug Antibody

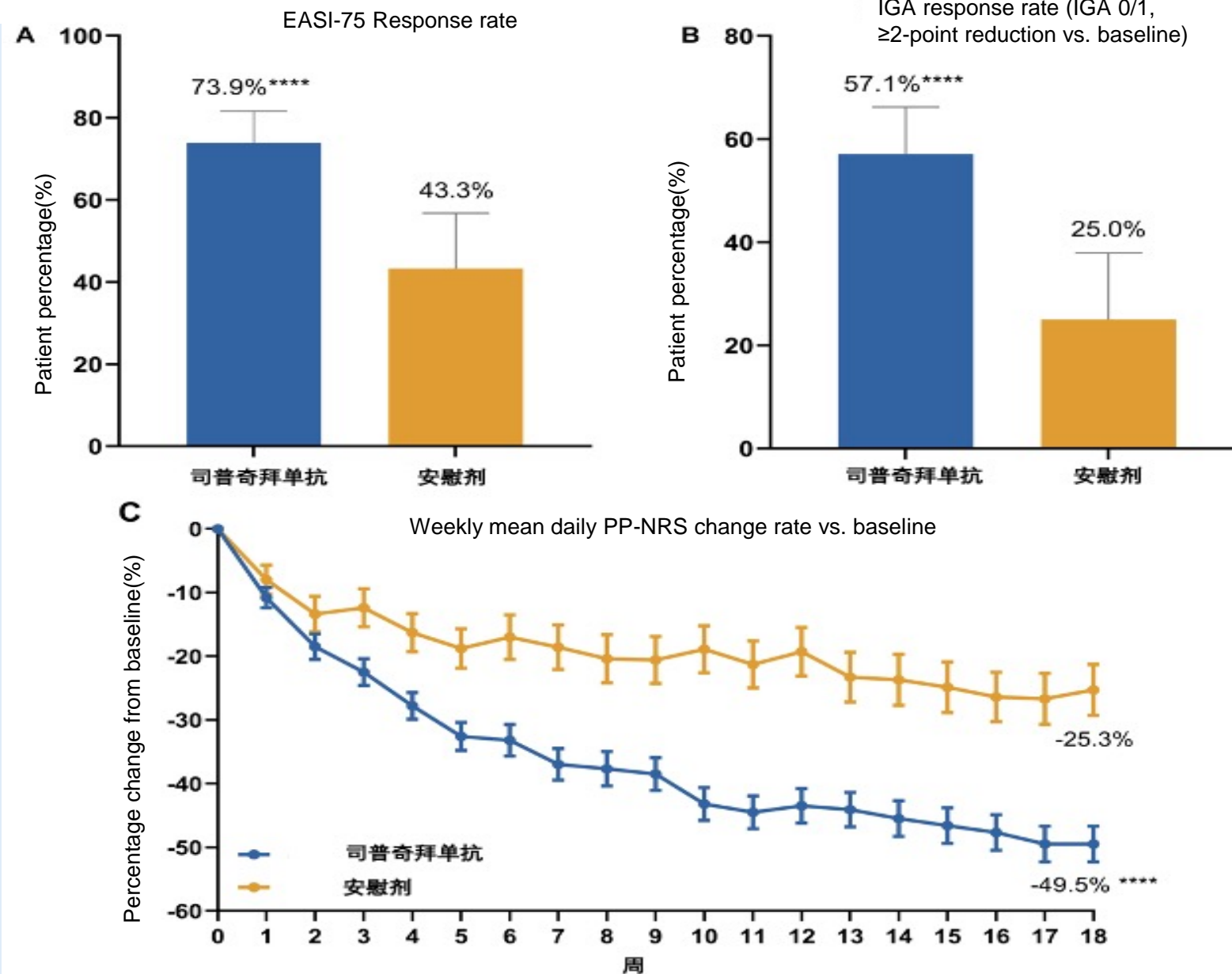
Nab: Neutralizing Antibody

Recurrence: Subjects who achieved EASI-75 and IGA 0/1 at Week 16 of treatment had a <50% reduction in EASI score from baseline and an IGA score ≥ 2 at a certain follow-up visit during the maintenance phase.

Stapokibart | Phase III clinical data in adolescent AD : The EASI-75 response rate reached 73.9% at 18W



- In September 2025, pivotal Phase III clinical data for Stapokibart in adolescent AD were prominently featured at the 34th Congress of the EADV.
- **All Primary Endpoints Met (Week 18):** Stapokibart Significantly Improved Skin Lesions and Pruritus in Adolescent Patients
- **EASI-75 Response Rate:** In the Stapokibart group (n=120), **73.9%** of patients achieved an EASI-75 response, significantly higher than the placebo group (43.3%, $P < 0.0001$). (Figure A)
- **IGA Response Rate:** The IGA response rate in the Stapokibart group reached **57.1%**, significantly superior to the placebo group (25.0%, $P < 0.0001$). (Figure B)
- **PP-NRS Improvement:** At Week 18 of Stapokibart treatment, PP-NRS (Peak Pruritus Numerical Rating Scale) improved by **49.5%** compared to baseline. (Figure C)
- **Stapokibart demonstrated a favorable safety and tolerability profile in the treatment of adolescent AD.**



JAMA®

JAMA | Original Investigation

Stapokibart for Severe Uncontrolled Chronic Rhinosinusitis With Nasal Polyps

The CROWNS-2 Randomized Clinical Trial



日内瓦国际发明展 金奖

NPS: Nasal Polyp Score; NCS: Nasal Congestion Score; UPSIT:

University of Pennsylvania Smell Identification Test;

Significant shrinkage of nasal polyps: ≥1-point improvement in NPS from baseline;

Halving of nasal polyp size: ≥2-point improvement in NPS from baseline;

Improvement in nasal ventilation: ≥0.5-point improvement in weekly NCS from baseline;

Significant improvement in nasal ventilation: ≥1-point improvement in weekly NCS from baseline;

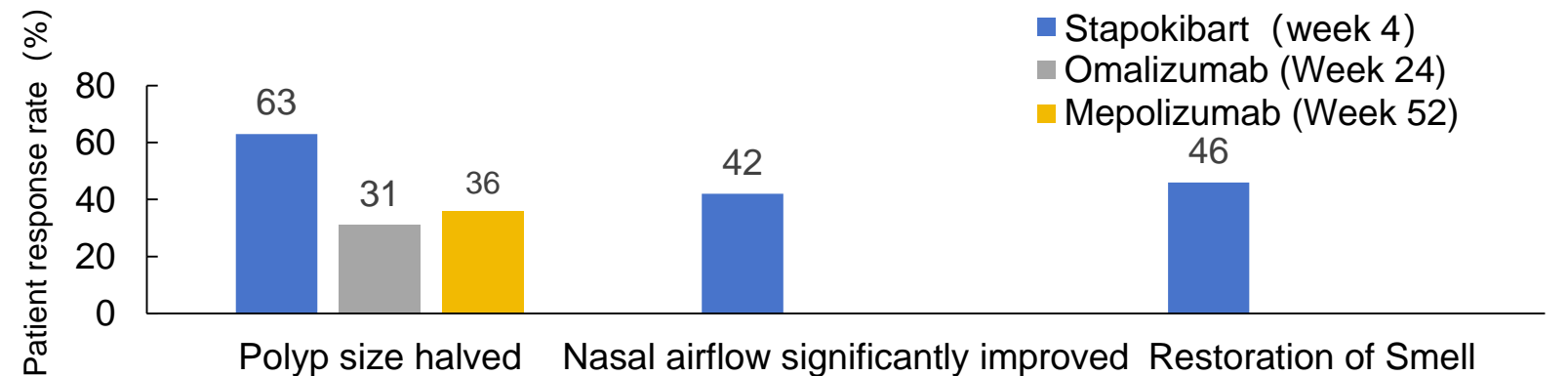
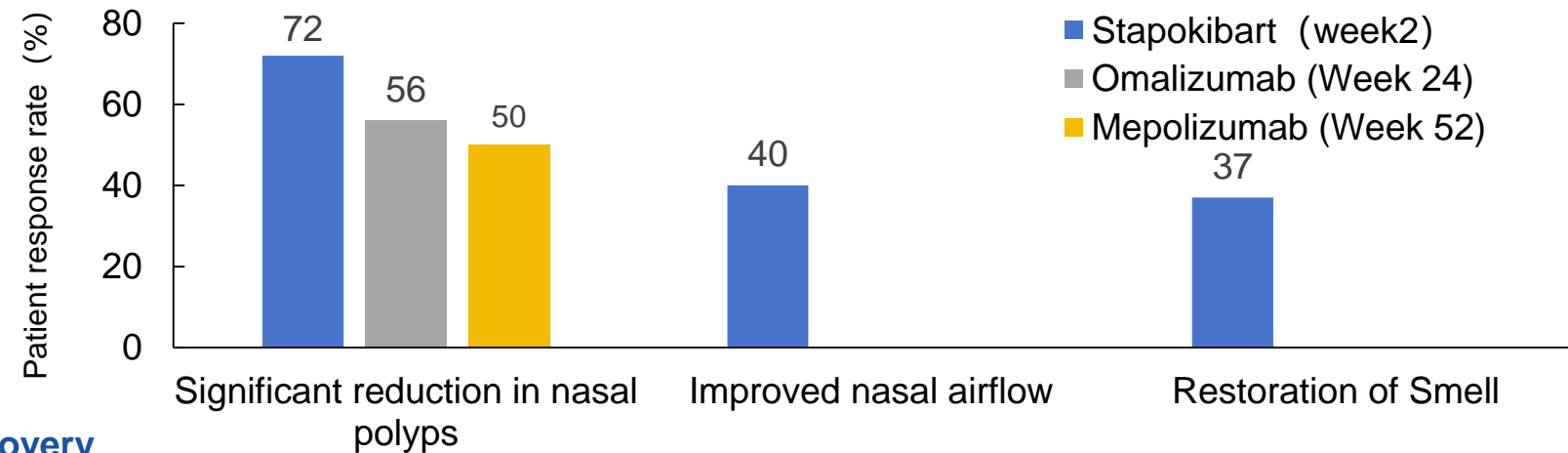
Olfactory recovery: UPSIT score > 18;

Gevaert P et al., Allergy. 2023 Apr;78(4):912-922; Han JK, et al. Lancet Respir Med. 2021 Oct;9(10):1141-1153; Mu Xian et al., Allergy. 2025 Mar 5.; 司普奇拜单抗注射液慢性鼻窦炎伴鼻息肉III期临床研究报告; Data in file

- CRSwNP is a common chronic inflammatory disease of the upper respiratory tract, characterized by severe nasal congestion, anosmia (loss of smell), purulent nasal discharge, and facial pain.
- Stapokibart rapidly alleviates comprehensive nasal symptoms: After 2 weeks of treatment: Nasal polyp size is significantly reduced. After 4 weeks of treatment: Comprehensive nasal symptoms (including nasal congestion, rhinorrhea, and hyposmia or anosmia) show significant improvement.

1 injection/2W
Quick onset

2 injection/4W
Olfactory recovery



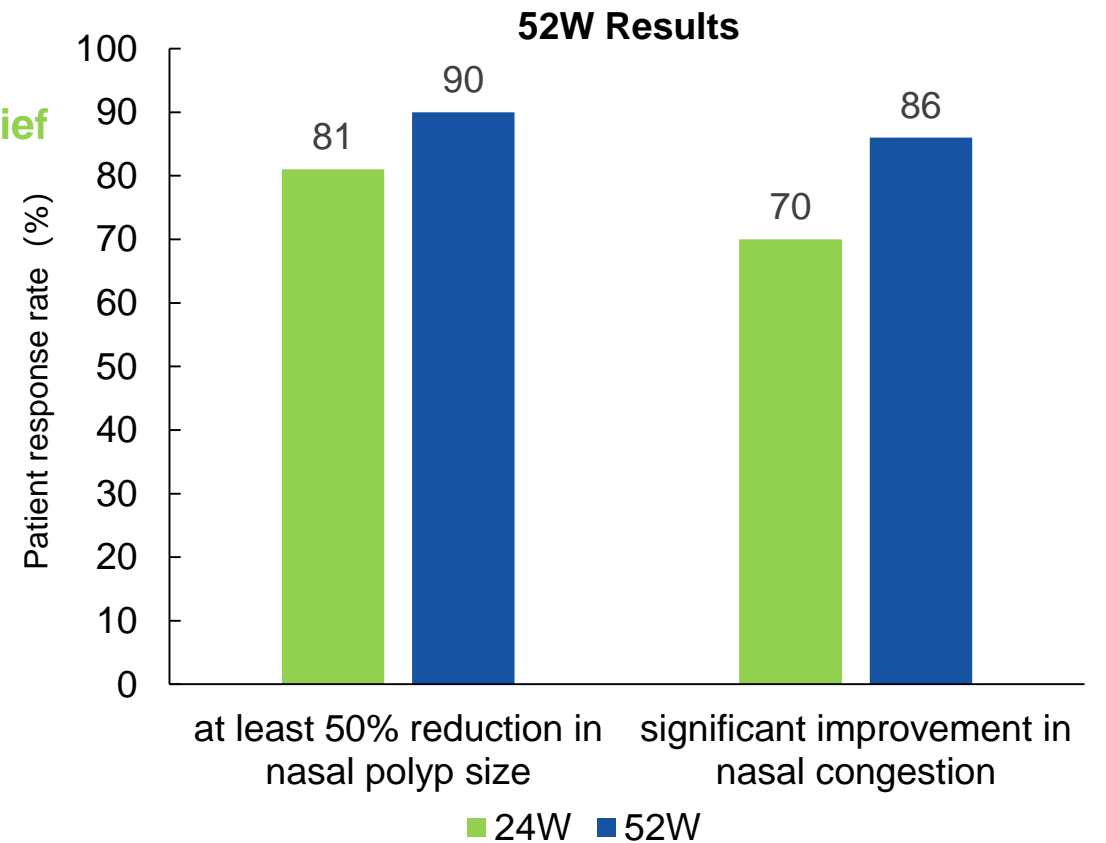
The above studies represent indirect comparisons; data are not head-to-head.

- All primary endpoints of the Phase III clinical study were met: At Week 24, 81% of patients achieved $\geq 50\%$ reduction in nasal polyp size, and 70% achieved significant improvement in nasal congestion.
- At Week 52, **90% of patients achieved $\geq 50\%$ reduction in nasal polyp volume**. Compared with pivotal Phase III results of similar biologics (dupilumab, mepolizumab, and omalizumab) (where NPS response rates ranged from only 31%–65%) [1-3], Stapokibart demonstrated significantly superior long-term efficacy, setting a new benchmark for biologic treatment of CRSwNP.
- **Stapokibart showed a favorable safety profile** : incidence of TEAEs was comparable to placebo, and no treatment-related SAEs.

12 Injections/24W
Potent Nasal Relief

26 Injections/52W
Durable Clinical Benefit

Stapokibart CRSwNP Efficacy Data: 24W and



1. Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. *Lancet*. 2019;394(10209):1638-1650. doi:10.1016/S0140-6736(19)31881-1
2. Han JK, Bachert C, Fokkens W, et al; SYNAPSE Study Investigators. Mepolizumab for chronic rhinosinusitis with nasal polyps (SYNAPSE): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2021;9(10): 1141-1153. doi:10.1016/S2213-2600(21)00097-7
3. Gevaert P, Omachi TA, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. *J Allergy Clin Immunol*. 2020;146(3):595-605. doi: 10.1016/j.jaci.2020.05.032

nature medicine

Article <https://doi.org/10.1038/s41591-025-03651-5>
Stapokibart for moderate-to-severe seasonal allergic rhinitis: a randomized phase 3 trial



Gold Medal (of the Geneva International Exhibition of Inventions)

The world's **only** IL-4R α -targeted antibody drug

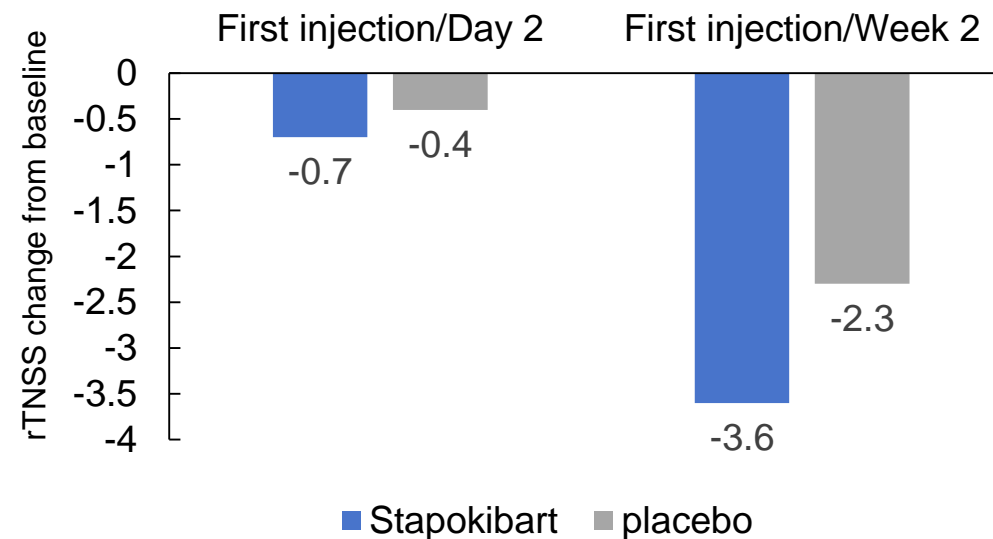
The **first** biological agent with Phase III data in Chinese population



A randomized, double-blind, multicenter, placebo-parallel controlled study that enrolled adult patients with moderate to severe SAR

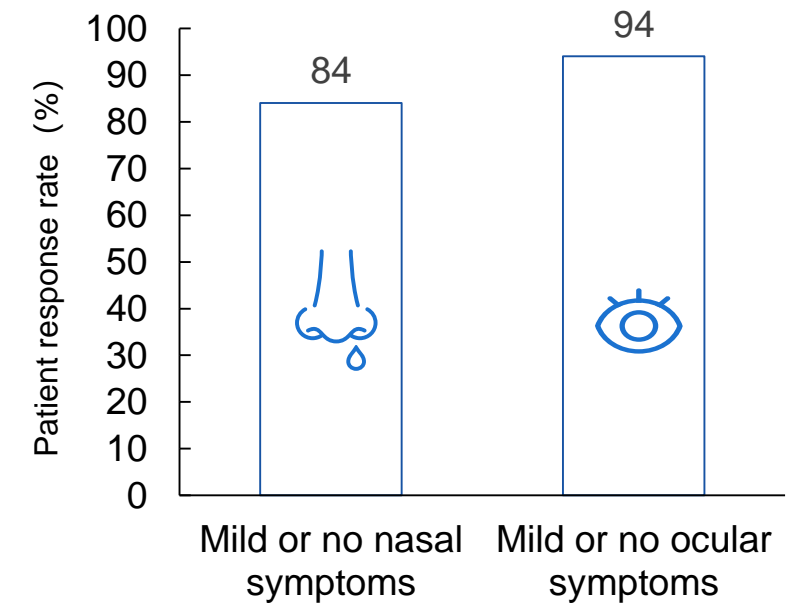
First injection/Day 2, Week 2
 Rapid relief of nasal congestion

rTNSS score improvement was significantly better than the placebo group



Two injections /Week 4
 Sustained improvement of rhino-ocular allergy

Stapokibart significantly relieved nasal and ocular allergic symptoms at Week 4



rTNSS: Reflective Total Nasal Symptom Score, including runny nose, nasal congestion, nasal itching and sneezing. Each symptom is scored out of 3 points, with a total score of 12 points.

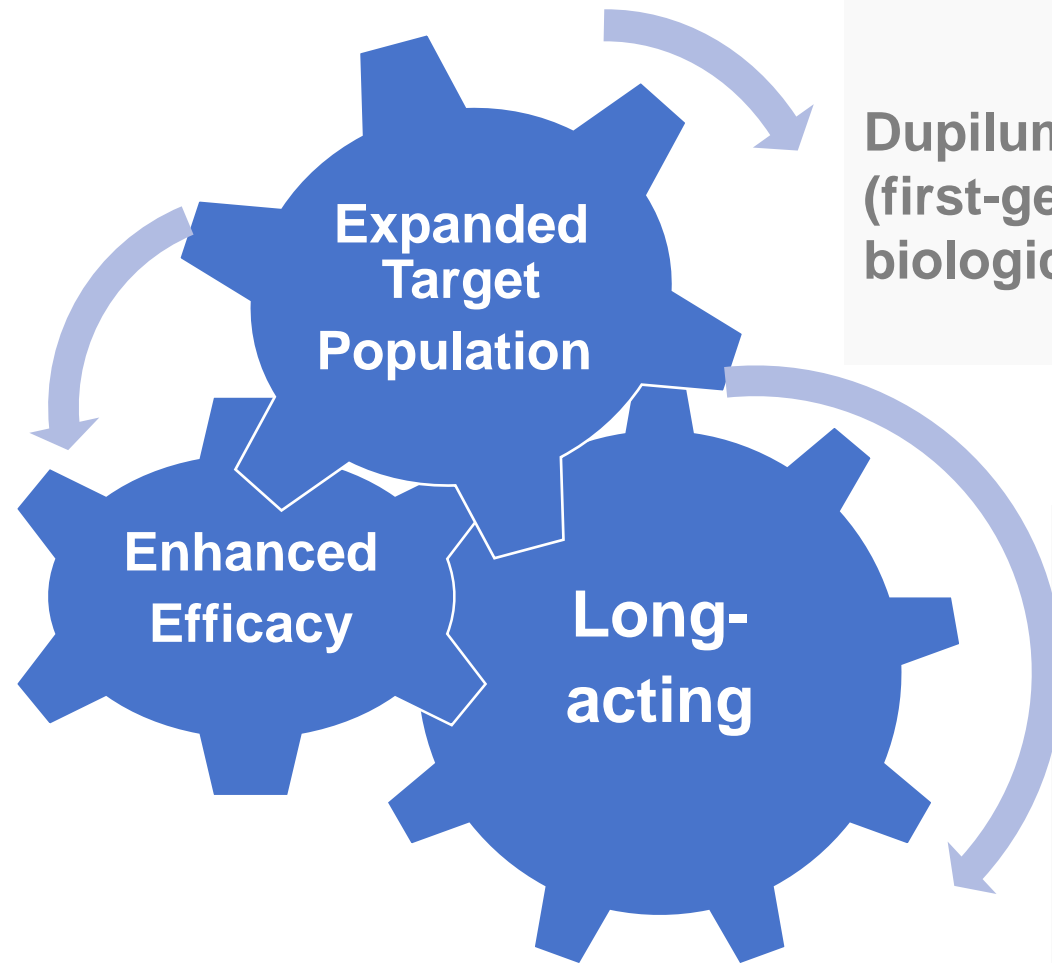
rTOSS: Reflective Total Ocular Symptom Score, including itchy/burning eyes, lacrimation and conjunctival hyperemia. Each symptom is scored on a scale of 0 to 3 points, with a total score of 9 points.

Mild or no ocular symptoms: The score of each symptom in the daily rTOSS is ≤ 1 point.



Mild or no nasal symptoms: The score of each symptom in the daily rTOSS is ≤ 1 point.

Late-stage pipeline updates

- **Dermatology:**
Enhanced skin lesion repair and improved anti-pruritic (itch-relief) efficacy
- **Asthma/COPD:**
Improvement in multiple functional parameters



| | |
|---|--|
| CM512 | Full population coverage of moderate-to-severe asthma and COPD |
| Dupilumab etc. (first-generation biologics) | Screening of populations with increased eosinophils and/or elevated FeNO |

| | | |
|---|----------------------------|---|
| CM512 | 2-4 injections/year |  |
| Dupilumab etc. (First-generation biologics) | 26 injections /year |  |

CM512 – The world's first long-acting TSLP x IL-13 dual blocker

TSLP x IL-13 BsAb: advantages & highlights

- **World's first IgG-like long-acting TSLP x IL-13 BsAb:** Inhibits TSLP-induced early inflammation and blocks IL-13-driven skin and respiratory pathology.
- Similar PK profiles in healthy subjects and moderate-to-severe AD patients.
- Half-life up to **70 days** (superior to similar products such as Lunsekimig ≈10 days).

Ph I clinical study demonstrates favorable safety and tolerability

- Healthy Subjects (n=64): Single and multiple ascending doses showed **good safety and tolerability**. No TEAEs met criteria for dose-limiting toxicity; no SAEs were reported.
- Moderate-to-severe AD Patients (n=46): The overall incidence of TEAEs and SAEs was comparable to the placebo group.

Ph I clinical study results indicate rapid, durable, and stable efficacy

- Multiple Type 2 inflammatory biomarkers significantly reduced.
- Week 6: **50%** EASI-75 in 300mg group (proposed clinical dose) vs. 7% in placebo.
- Week 12: EASI-75 **58.3%** and EASI-90 **41.7%** in 300 mg group vs. 21.4% and 0% in placebo.

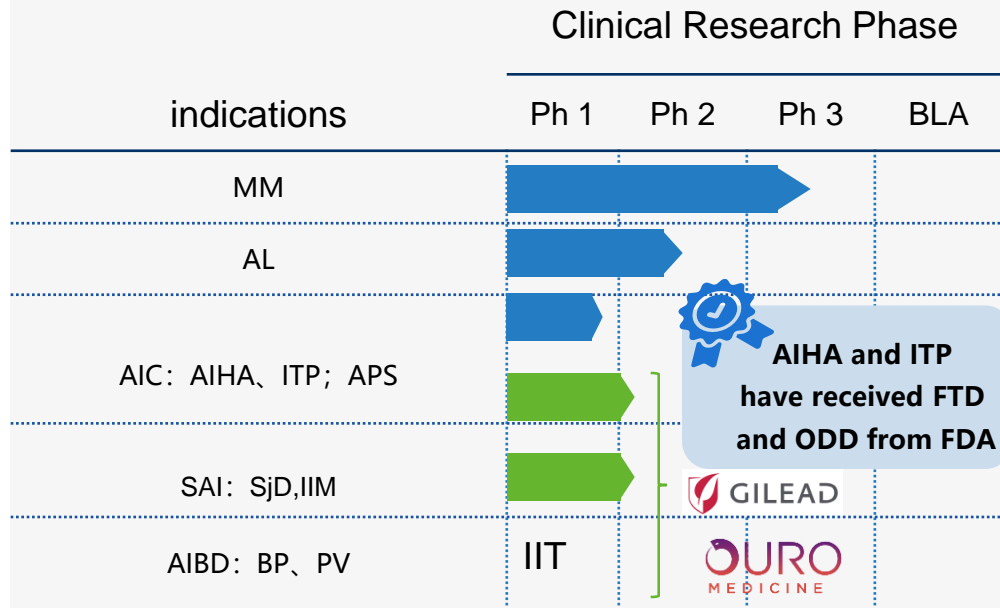
Milestones & future development plans

- Ph II CRSwNP trial enrollment completed , data release is expected in 1H2026.
- Multiple Ph II trials advancing in CRSwNP, asthma, COPD, AD, CSU, etc.
- In 2025H1, Belenos initiated Ph I/II trial in the US (healthy subjects & asthma patients).

CM336 – Potential best-in-class BCMA/CD3 BsAb

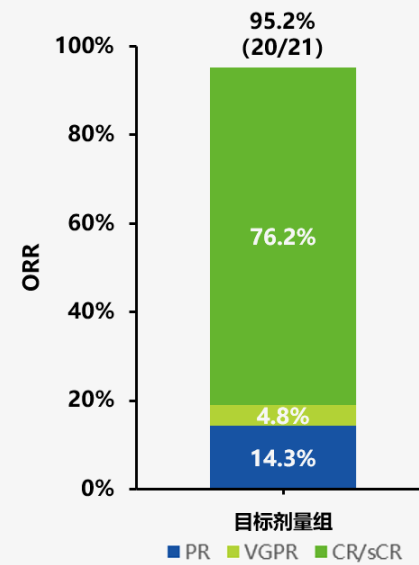
Layout in Oncology and Autoimmune Diseases

- Multiple Myeloma: Phase III ongoing.
- Light Chain Amyloidosis: Phase II enrollment accelerating; BLA submission expected in **2H2026**.
- Autoimmune pipeline advancing rapidly.



Excellent Clinical Performance

- ✓ **MM:** In Ph II dose-expansion cohort, only 4.7% of subjects experienced Grade 2 CRS; no ICANS. Target dose: ORR 95.2%, ≥CR 76.2%, MRD negativity 100%, 12-month PFS 95.2%. Potential Best-in-Class.
- ✓ **AIHA:** In 2 patients with prior multiple treatments, no CRS or ICANS. Hemoglobin levels returned to normal in 1 patient by Day 17, and 1 patient achieved CR by Day 21. **Results published in NEJM.**



MM data as of: July 2025; AIHA data sourced from NEJM

AIC: Autoimmune Hematological Disorders: Includes autoimmune hemolytic anemia (AIHA) and immune thrombocytopenia (ITP) ; SAI: Seropositive Autoimmune Diseases; AIBD : Autoimmune Bullous Diseases

ORR: Objective Response Rate; CR: Complete Response; MRD: Minimal Residual Disease; PFS: Progression-Free Survival

CM313 – Humanized potent anti-CD38 monoclonal antibody

Portfolio in Multiple Autoimmune Disease Areas

- Continuously advancing multiple autoimmune disease studies; several Phase III trials (ITP, IgAN, etc.) progressing rapidly.
- Expected to provide new treatment options across various autoimmune diseases.

| Drug | Indications | Clinical stage | | | |
|-----------------------------|-------------|----------------|------|------|-----|
| | | Ph 1 | Ph 2 | Ph 3 | BLA |
| CM313 Antibody (CD38) | ITP | ▶ | | | |
| | IgAN | ▶ | | | |
| | SLE | ▶ | | | |
| | PTR | ▶ | | | |
| | AA | ▶ | | | |
| | MM | ▶ | | | |

Potentially Best-in-Class Autoimmune Clinical Data



The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

in 

A Novel Anti-CD38 Monoclonal Antibody for Treating Immune Thrombocytopenia

Authors: Yunfei Chen, M.D., Yanmei Xu, M.D., Huiyuan Li, M.D., Ting Sun, M.D., Xuan Cao, M.D., Yuhua Wang, M.D., Feng Xue, M.D., Wei Liu, M.D., Xiaofan Liu, M.D., Huan Dong, M.D., Rongfeng Fu, M.D., Xinyue Dai, M.D., Wentian Wang, M.D., Yueshen Ma, M.S., Zhen Song, M.S., Ying Chi, M.D., Mankai Ju, M.D., Wenjing Gu, M.D., Xiaolei Pei, M.D., Renchi Yang, M.D., and Lei Zhang, M.D. [Author Info & Affiliations](#)

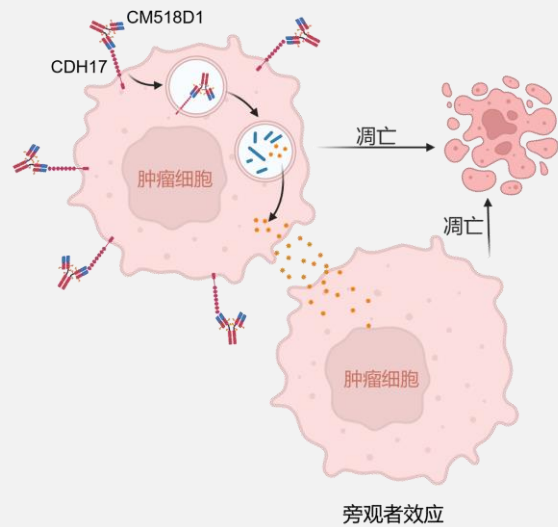
Published June 19, 2024 | N Engl J Med 2024;390:2178-2190 | DOI: 10.1056/NEJMoa2400409

VOL. 390 NO. 23

- IIT (Investigator-Initiated Trial) data for primary immune thrombocytopenia (ITP) published in The New England Journal of Medicine (NEJM), sustained platelet response rate >60%.
- 95.5% of patients achieved platelet count $\geq 50 \times 10^9/L$ within 8 weeks after first dose; median cumulative time for sustained response was 23 weeks.

CM518D1 – A global leading CDH17 ADC molecule with potential BIC profile

Independently Developed CDH17 ADC



The next blockbuster ADC target:

- Clear membrane protein localization
- Favorable internalization properties
- High specificity

Potential BIC Molecule for Treating Gastrointestinal Tumors

CM518D1 utilizes a cleavable linker + Topoisomerase I inhibitor, DAR=8

Topoisomerase I Inhibitor Advantages:

- Stronger cell membrane permeability
- Significant bystander effect
- Wider dosing window

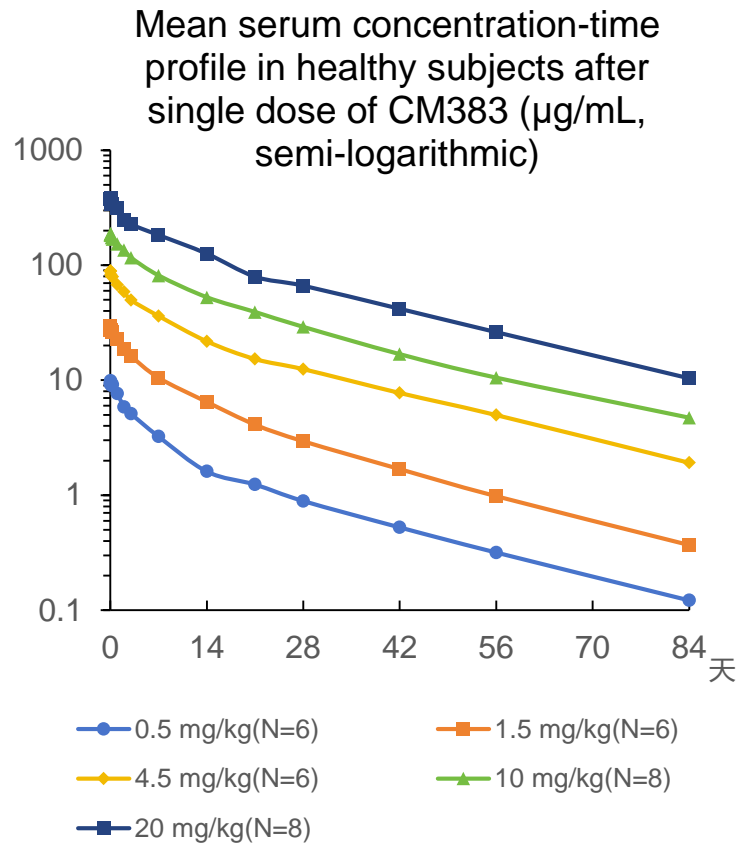
Clinical Progress

- June 2025: Initiated Phase I/II trial in advanced solid tumors (planned enrollment: 434 patients). As of December 2025, safe and tolerable with preliminary efficacy observed.
- July 2025: received FDA clinical trial approval.

Excellent Preclinical Data

- Superior efficacy: effective dose **<1 mg/kg** in gastric/pancreatic cancer models.
- Safety: HNSTD 30 mg/kg, **safety window >30-fold**, positioning it as a potential Best-in-Class.

CM383 – China's leading A β antibody



Potential BIC molecule for treating Alzheimer's Disease

- CM383 targets A β protofibrils with higher neurotoxicity, promoting A β clearance
- CM383 is specifically engineered to address limitations of peer drugs, such as short half-life, high immunogenicity, and weak A β clearance activity, poised to become Best-in-Class.

Excellent preclinical and early clinical data

- Study in healthy subjects (N=56) demonstrated CM383 has superior safety and tolerability in humans, longer drug half-life, and lower immunogenicity.



CM383 half-life: 18.8-21.2 days, superior to donanemab (12.1 days) and lecanemab (5-7 days)

Development plan

- Ph Ib study in patients with mild cognitive impairment and mild Alzheimer's disease: enrollment completed

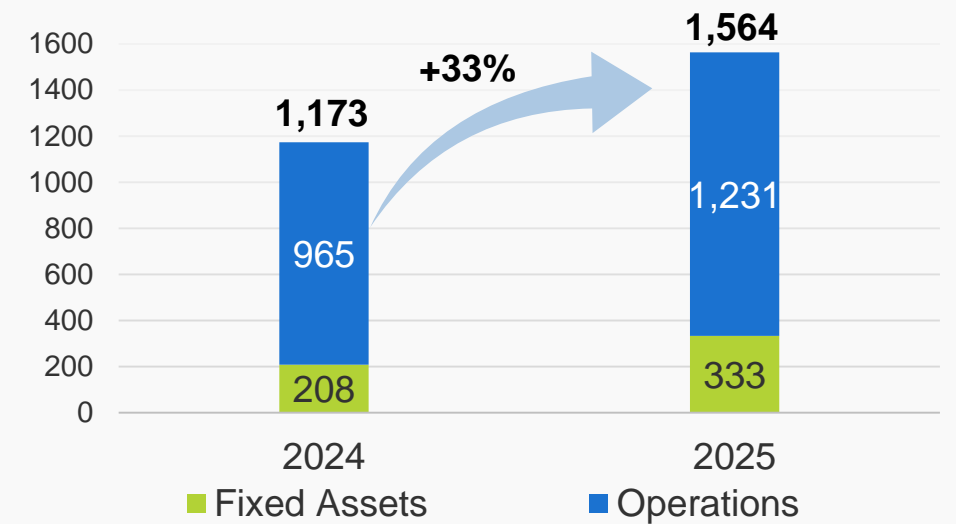
FY2025 financial data

2025 financial highlights: dual revenue drivers of collaboration and commercialization

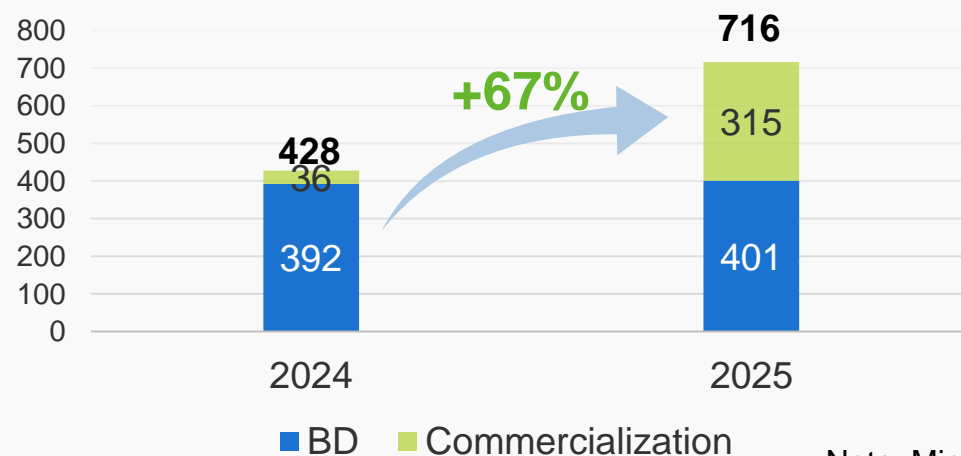
Financial & capital market performance

- **Drug sales revenue: approximately RMB 315 million**, entirely from commercial sales of Kangyueda (康悦达®).
- **Revenue from out-license arrangements: RMB 401 million**, primarily from collaboration revenue of CM313, CM355, CM512/CM536 and CM336, including equity interests in Newcos of RMB 125 million.
- **R&D investment: RMB 724 million** (similar to 2024).
- As of 31 December 2025, the Group **held cash (including short-term bank wealth management products) of RMB 1.96 billion**.

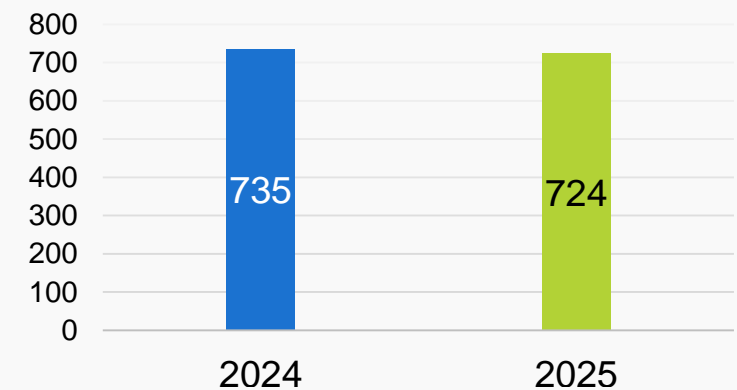
Cash Outflow of Operations and Fixed Assets (Unit: RMB million)



Revenue: a substantial growth in sales, steadily generating cashflows (Unit: RMB million)



R&D investments: continuously advancing clinical studies, while cultivating high-potential pipelines (Unit: RMB million)



Loss for the year of 2025

| (RMB'000) | 2025 | 2024 |
|--|-----------------|-----------------|
| Revenue | 716,313 | 428,124 |
| Cost of sales ^(NB1) | -88,048 | -12,200 |
| Gross profits | 628,265 | 415,924 |
| Other income and gains ^(NB2) | 159,224 | 141,154 |
| R&D expenses | -723,529 | -735,192 |
| Administrative expenses | -182,209 | -187,933 |
| Selling and distribution expenses ^(NB3) | -321,987 | -110,897 |
| Other expenses ^(NB4) | -62,905 | -7,987 |
| Finance costs ^(NB5) | -16,908 | -18,460 |
| Share of loss of a joint venture | -674 | -5,256 |
| Income tax expense | -1,874 | -6,260 |
| Loss for the year | -522,597 | -514,907 |

NB1: The cost of sales mainly represent manufacturing costs of Kangyueta (康悦达®) of RMB84 million and R&D costs of RMB4 million under the out-license arrangements;

NB2: Other income and gains mainly includes:

- ① Government grants of RMB52 million;
- ② Interest income on time deposits and wealth management products of RMB70 million;
- ③ Fair value gains on Newcos of RMB31 million;

NB3: Selling and distribution expenses mainly consisted of salaries of commercialization staff and expenditures on various academic meetings and marketing activities;

NB4: Other expenses mainly consisted of net exchange losses of RMB31 million;

NB5: Finance costs mainly represent interest on bank borrowings.

Financial position as of 31 December 2025

| (RMB'000) | 31 December 2025 | 31 December 2024 |
|--|------------------|------------------|
| Non-current assets | | |
| Fixed Assets, right-of-use assets and other intangible assets ^(NB1) | 1,307,381 | 1,057,853 |
| Prepayments and other receivables ^(NB2) | 67,174 | 32,662 |
| Financial assets at FVTOCI / FVTPL ^(NB3) | 417,744 | 209,459 |
| Investment in a joint venture | 2,392 | 566 |
| Subtotal | 1,794,691 | 1,300,540 |
| Current assets | | |
| Inventories | 195,976 | 111,422 |
| Trade receivables | 100,850 | 62,851 |
| Prepayments and other receivables ^(NB2) | 162,679 | 136,141 |
| Cash, time deposits and bank wealth management products | 1,963,337 | 2,155,612 |
| Subtotal | 2,422,842 | 2,466,026 |
| Total assets | 4,217,533 | 3,766,566 |

| (RMB'000) | 31 December 2025 | 31 December 2024 |
|---|------------------|------------------|
| Current liabilities | | |
| Trade and other payables ^(NB4) | 314,229 | 261,413 |
| Bank borrowings | 509,369 | 472,371 |
| Other current liabilities | 12,696 | 13,942 |
| Subtotal | 836,294 | 747,726 |
| Non-current liabilities | | |
| Deferred income ^(NB5) | 336,668 | 274,778 |
| Lease liabilities | 11,618 | 11,315 |
| Bank borrowings | 258,030 | 257,188 |
| Deferred tax liabilities | - | 347 |
| Subtotal | 606,316 | 543,628 |
| Total liabilities | 1,442,610 | 1,291,354 |
| Total equity | 2,774,923 | 2,475,212 |

NB1: The fixed assets mainly consist of costs of buildings, production equipment and building improvements in Chengdu plant;

NB2: The balance mainly consists of prepaid R&D expenses of RMB48 million, prepayments for raw materials of RMB16 million, prepayments for fixed assets of RMB33 million, recoverable VAT of RMB57 million and loans to a collaboration partner of RMB28 million;

NB3: The balance mainly consists of equity interests in Belenos, Ouro, Prolium and Timberlyne under the out-license arrangements;

NB4: The balance mainly represents payroll payables of RMB90 million, accrued R&D expenses of RMB39 million, amounts due to partners of collaboration arrangements of RMB29 million, and payables for fixed assets of RMB86 million;

NB5: Deferred income mainly represents government grants related to fixed assets.

High Tech, High Value

Affordable Innovative Treatment For Everybody!



Scan the QR code to follow the official WeChat account of Kangnuoya
Investor Relations Contact Information: IR@KEYMEDBIO.COM