

Keymed Biosciences *(2162.HK)*

2026 Interim Results

Aug 2026



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introduction



Key milestones of Keymed Bio in H1 2026

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

康悦达® rapid commercialization NEML inclusion

- In H1 2026, Kangyueda (康悦达®) sales amounted to **393M**, YOY+132%↑
- Commercial coverage (as of June 30, 2026), team: **~500** members, divided into dermatology and rhinology divisions; Coverage includes **>1600** hospitals (more than 1000 approved for in-hospital use) and over **670+** pharmacies
- NRDL Inclusion: **3** indications (**adult moderate-to-severe AD, CRSwNP, SAR**), effective Jan 1, 2026
- Included in the National Essential Medicines List (2026 Edition), effective from Sep 1, 2026

Outstanding financial performance and abundant cash

- In H1 2026, BD-related revenue: **224M**, milestone payments for the CMG901
- In 2026 H1, the net profit achieved **1.2B**, mainly due to the disposal of the equity of Ouro Medicines, achieving a gain of **1.68B**
- **Cash position : RMB 3.24B (as of Jun 30, 2026) vs 1.96 billion (as of Dec 31, 2025)** (incl. short-term bank wealth management products)

R&D progress

- **CMG901/ AZD0901 (Claudin 18.2 ADC) : the first MRCT Ph3** for 2L+ GC/ AEG achieved positive topline results, and the OS demonstrated statistically significant and highly clinically meaningful benefits 
- **CM336 (BCMA/CD3 BsAb):** With Gilead's support, auto-immune disease indication is leading globally 
- **CM512 (TSLPxIL-13 BsAb):** Ph2 of CRSwNP has achieved all endpoints: rapid onset, one injection maintained for half a year, and the incidence of ADA is extremely low. The indications for Asthma, COPD, CSU, AD, etc. are advancing rapidly

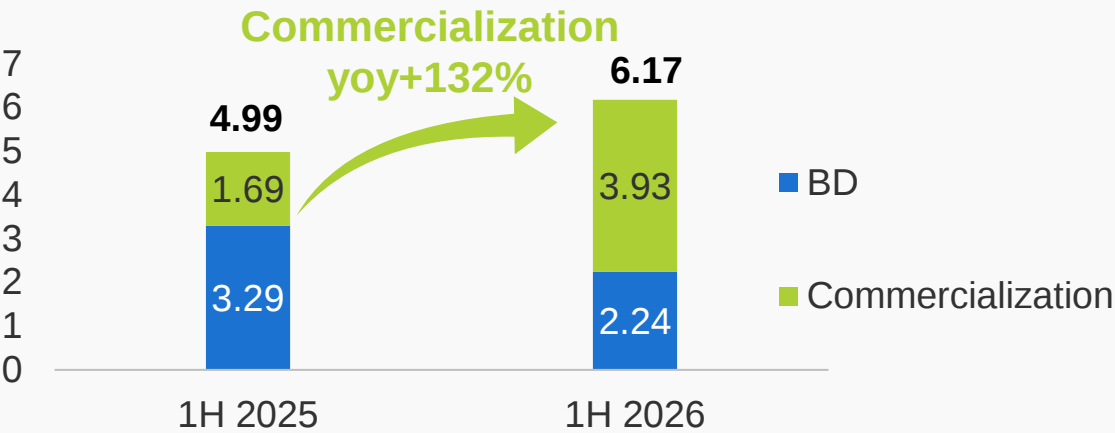
Note: All amounts are in RMB units. Minor discrepancies due to rounding may exist, please refer to the annual results announcement for exact figures

Commercialization and financial highlights in H1 2026

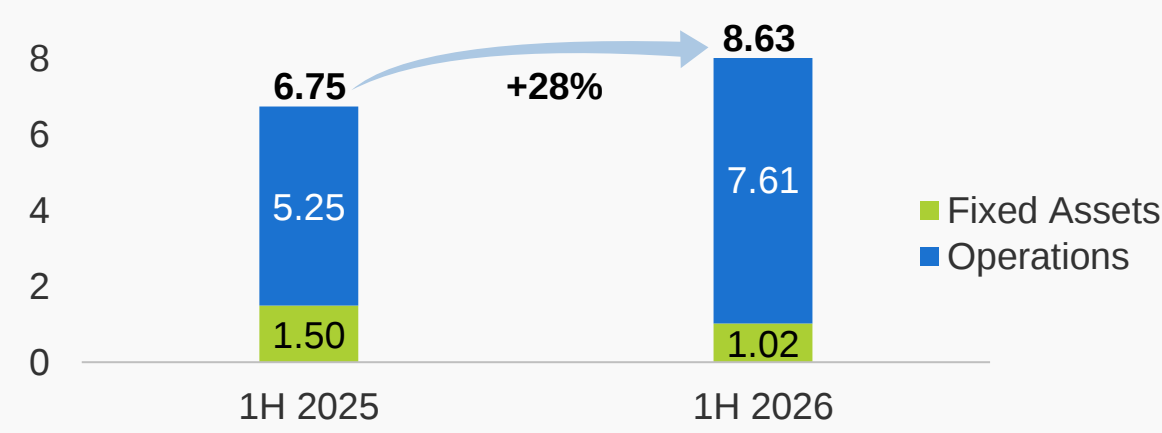
H1 2026 Financials: Robust Results from Commercial Scale-up & NewCo Closed-Loop, Ample Cash

- H1 2026 operating revenue: 616M. **Pharmaceutical sales (~393M, YoY +132%)** all from Kangyueda®; **partnership revenue (~223M)** chiefly from CMG901 R&D milestones.
- **R&D, G&A and finance expenses** edged down YoY, reflecting solid cost control. **Selling expenses** stood at 219M, with Kangyueda® revenue covering both selling expenses and production costs.
- **Net profit: 1.22B**, largely from a **1.68B** gain on disposal of Ouro Medicines equity.
- **Cash on hand** (incl. short-term bank WMPs): **3.24B** on Jun 30, 2026, versus 1.96B on Dec 31, 2025.

Revenue: Fast volume growth, BD-driven revenue (RMB 100mn)



Operating Expenses & Fixed-asset CapEx (RMB 100mn)



Note: All amounts are in RMB units. Minor discrepancies due to rounding may exist, please refer to the annual results announcement for exact figures

Significant profit in H1 2026, achieving a net profit of RMB 1.2B

(RMB'000)	1H 2026	1H 2025
Revenue	617,068	498,752
Cost of sales	-118,743	-33,476
Gross profits	498,325	465,276
Other income and gains ^(NB1)	1,705,973	75,543
R&D expenses	-338,749	-360,018
Administrative expenses	-85,551	-89,259
Selling and distribution expenses ^(NB2)	-218,387	-137,577
Other expenses ^(NB3)	-47,066	-21,600
Finance costs ^(NB4)	-6,377	-7,463
Share of loss of a joint venture	-401	-566
Income tax expense ^(NB5)	-290,154	-3,135
Net Profit / (Loss)	1,217,613	-78,799

NB1: Other income mainly includes:

- ① RMB 1.68B gain on fair-value movement of Ouro Medicines equity (disposed in-period);
- ② Government grants: RMB 37,644k;
- ③ Interest & WMP income: RMB 22,941k;
- ④ CDMO service revenue: RMB 4,205k.

NB2: Selling expenses: mainly commercial-team compensation, academic conferences and marketing costs.

NB3: Other expenses: net foreign exchange loss of RMB 34,800k.

NB4: Finance expenses: primarily interest on bank borrowings.

NB5: Income tax expenses mainly comprise:

- ① Profits tax accrued by Hong Kong subsidiary (from Ouro Medicines equity disposal gain);
- ② 10% US withholding tax accrued for CMG901 milestone payments, reversible upon successful prior-period with holding tax refund.

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 June 30, 2026, ~500 members



2 Expand channels & market access, accelerate penetration in high-potential regions and hospitals

- As of Jun 30, 2026: coverage across **30 provinces and 280+ cities**
- Over **1,600** covered hospitals; **1,600** hospitals with consistent prescription output; more than **1,000** hospitals for in-hospital drug administration
- Commercial channels: stable partnerships with 57 primary distributors, with presence in **670+ pharmacies**
- **Medical Insurance (NRDL):** 3 indications of 康悦达® and the prefilled autoinjector included
- **National Essential Medicines List:** Included in the National Essential Medicines List (2026 Edition), effective Sep 1, 2026.



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**



中华人民共和国国家卫生健康委员会 药物政策与基本药物制度司
National Health Commission of the People's Republic of China

首页 工作动态 政策文件 关于我们 专题专栏 返回主站

政策文件

关于印发国家基本药物目录（2026年版）的通知

发布日期：2026-07-09 来源：国家卫生健康委员会

国卫药政发〔2026〕17号

各省、自治区、直辖市及新疆生产建设兵团卫生健康委、中医药局、疾控局：
为贯彻落实党中央、国务院决策部署，巩固完善国家基本药物制度，根据《基本医疗卫生与健康促进法》《药品管理法》等法律规定，国家卫生健康委组织对《国家基本药物目录（2018年版）》进行了更新调整，制定了《国家基本药物目录（2026年版）》，现印发给你们，自2026年9月1日起施行。

R&D Progress in H1 2026

R&D progress in H1 2026: focus on autoimmune, chronic diseases and oncology

Approved

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

Ph III

Stapokibart
IL-4Rα (1st domestically)

- Adolescent AD (BLA)
- Prurigo Nodularis (BLA)
- Pediatric AD
- Adolescent SAR

AstraZeneca  
CMG901
CLDN18.2 ADC

- 2L+CLDN18.2+ GC/ AEG
- 1L CLDN18.2+/HER2- GC/EGJ/EAC

CM336
BCMA/CD3 BsAb

- 2L+RRMM (with CM313)
- Light Chain Amyloidosis

Ph II

AstraZeneca  
CMG901
CLDN18.2 ADC

- perioperative treatment of AEG
- 2L+BTC、 1L PDAC

CM512
Long-acting
TSLP×IL13 BsAb

- CRSwNP
- COPD
- Asthma
- AD

CM313
CD38 antibody

- IgAN

Ph I

Belenos
CM512
Long-acting
TSLP×IL13 BsAb

 **GILEAD Lakefront**
CM336 (oversee)
BCMA/CD3 BsAb

CM383 Aβ
protofibrils
antibody

CM559 N3pG-
Aβ antibody

- Alzheimer's Disease

CM518D1
CDH17 ADC

- Colorectal Cancer

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



- In Feb 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 B, plus tiered royalties up to low double digits.
- At the end of July 2026, the first global Ph3 (CLARITY Gastric01, 2L+ CLDN18.2+ GC/ AEG) achieved positive topline results. Overall survival (OS) demonstrated statistically significant and highly clinically meaningful benefits (the proportion of CLDN18.2 expression in enrolled patients was $\geq 25\%$).
- AZ estimates the peak sales of CMG901/ AZD0901 to be USD 3 ~5 B

Indication	Clinical Stage	Expected enrollment	Expected Milestones		
2L+ CLDN18.2+ GC/ AEG	Ph 3	572	Global BLA: 2026 Q4	CDE BTD、EMA ODD FDA FTD&ODD	 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 Nov 2024: Keymed entered into a collaboration agreement with Ouro Medicines for CM336 (BCMA/CD3 BsAb) covering global rights ex-Greater China. Deal Terms: USD 16M upfront payment + minority equity stake in Ouro + maximum milestone payments of USD 610M + tiered royalty based on net sales.

In March 2026, Gilead/Lakefront acquired Ouro, securing global rights to CM336 outside Greater China. Keymed will receive an upfront payment of ~USD 257M (received as announced on June 5, 2026) , additional with milestone payments of ~USD 70M. Gilead/ Lakefront will remain responsible for up to USD 610M in milestone payments + tiered royalties based on the net sales.

It is expected that at least 2 key registration clinical studies will be initiated in 2027

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



AIHA and ITP have received FTD and ODD, PV has received ODD from FDA

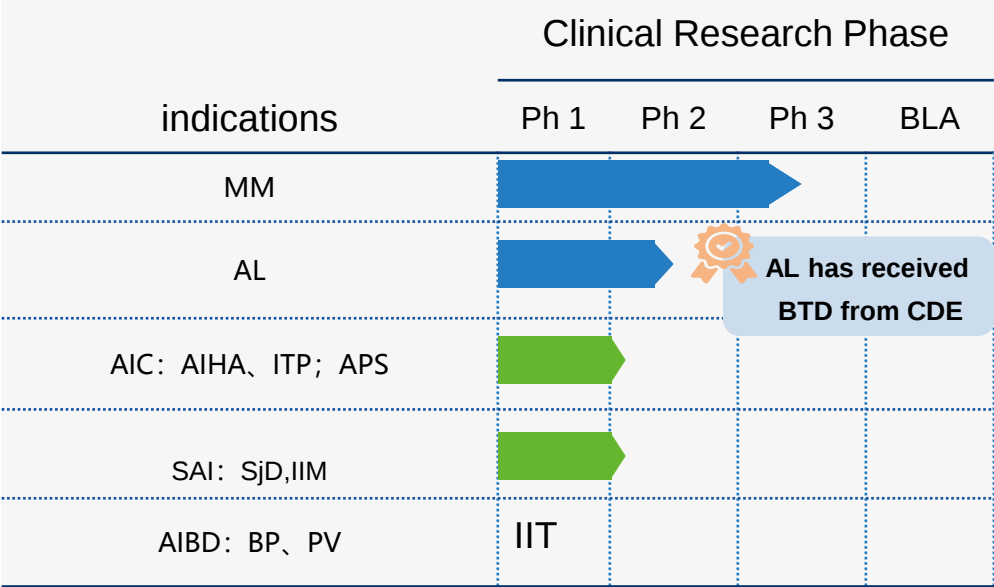
All clinical pipelines listed above are being advanced by partners within their licensed regions. For the same indication, only the highest clinical stage is shown. Data sourced from respective company websites or clinicaltrials.gov.

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

CM336 – key domestic registrational trials launched; advancing oncology & autoimmune indications

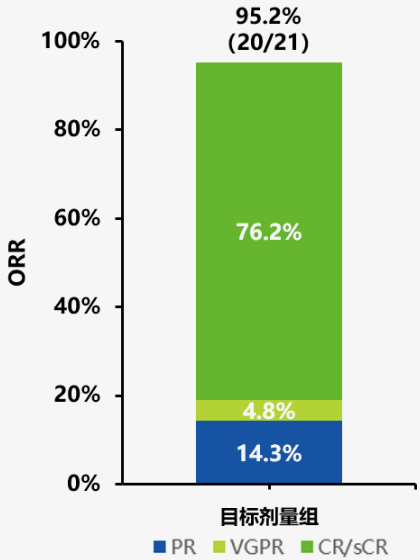
layout in oncology and autoimmune diseases

- Administered by SC, suitable for various clinical application scenarios of various diseases.
- 2L+RRMM: Ph3 ongoing.
- Light Chain Amyloidosis: Ph2 enrollment accelerating; BLA submission expected in 2027H2.
- Autoimmune pipeline advancing rapidly.



excellent clinical performance

- ✓ **MM:** In Ph2 dose-expansion cohort, only 4.7% of subjects experienced Grade 2 CRS; no ICANS. Target dose: ORR 95.2%, ≥CR 81%, 12-month PFS 82.5%. Potential BIC.
- ✓ **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.**



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CORRESPONDENCE

in ✉ 🐦

BCMA-Targeted T-Cell Engager for Autoimmune Hemolytic Anemia after CD19 CAR T-Cell Therapy

Published June 11, 2025 | N Engl J Med 2025;392:2282-2284 | DOI: 10.1056/NEJMc2502297 | VOL. 392 NO. 22
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MM data as of: May 2026; 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

Disease-area portfolio & clinical progress

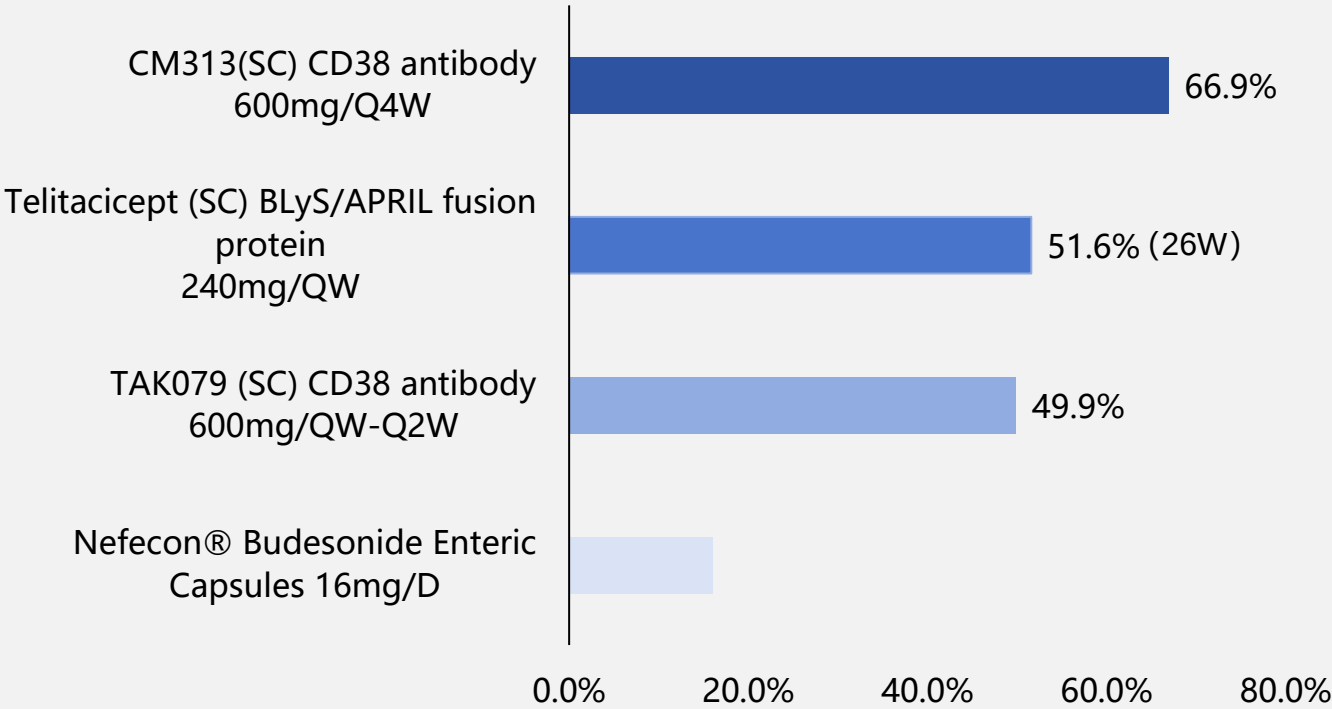
- Ph2 IgAN study advancing rapidly; Ph3 initiation expected in 2027.
- Ph 1/2 RRMM progressing rapidly; subsequent Ph3 trial in 2L+ RRMM will be conducted in combination with CM336 (BCMA/CD3).

Drug	Indications	Clinical stage		
		Ph 1	Ph 2	Ph 3
CM313 CD38 Antibody	IgAN			
	RRMM			
	2L+ RRMM (in combo with CM336 BCMA/CD3 BsAb			

BIC potential clinical data for IgAN

- Preliminary Ph2 IgAN data: once-monthly dosing
- Greater reduction in 24h-UPCR vs marketed products for the same indication.

Percentage reduction in 24h-UPCR from baseline at 24W



CM313 IgAN DCO: 20260716, Preliminary data;
No head-to-head comparisons across products.

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.
- Half-life up to **70 days** (superior to similar products such as Lunsekimig ≈10 days).
- **Low immunogenicity**, better long-term dosing safety

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

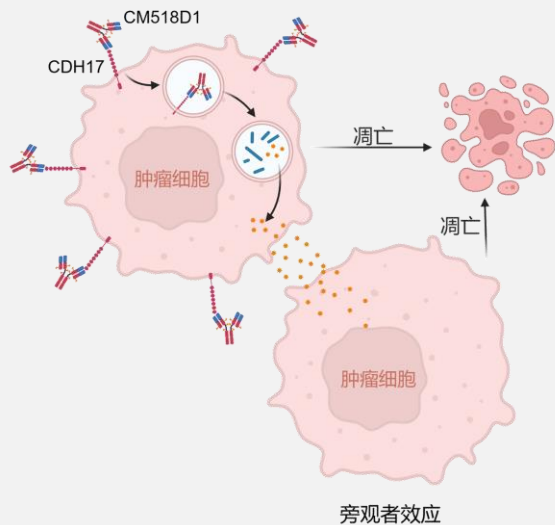
- Multiple Type 2 inflammatory biomarkers significantly reduced.
- CM512 delivers rapid, durable stable disease control in moderate-to-severe AD patients:
 - Week 6: **50%** EASI-75 in 300mg group (proposed clinical dose) vs. 7% in placebo.
 - Week 12: EASI-75 **58.3%** and EASI-90 **41.7%** in 300 mg group vs. 21.4% and 0% in placebo.

CM512 – the world's first long-acting TSLP/IL-13 BsAb achieved all endpoints in Ph2 clinical trial

- CM512 met all study endpoints: rapidly shrank nasal polyp and **significantly improved nasal congestion as early as 4W post-dosing**, alongside olfactory function recovery. Single-dose efficacy persisted for six months, with 24W nasal polyp score (NPS) baseline changes markedly better than placebo. It also significantly alleviated overall inflammation in the sinus cavities.
- The incidence of TEAEs was comparable to placebo, no SAE occurred in the CM512 groups. **The incidence of anti-drug antibodies (ADA) is extremely low.**
- Supported by these Phase 2 findings, the Company is accelerating initiation of the Phase 3 trial for CM512 injection in CRSwNP, **with 300 mg Q24W selected as the dosing regimen.**

indication	Clinical stage	Expected enrollment	Expected Progress
CRSwNP  BTDCDE	Ph 2	120	completed
	Ph 3	236	Initiated in 2026H2
Moderate-to-severe Asthma	Ph 2	200	enrollment completed at the end of 2026
Moderate-to-severe COPD	Ph 2	204	enrollment completed at the end of 2026
Moderate-to-severe adult AD	Ph 2	200	enrollment
CSU	Ph 2	48	enrollment completed in 2027

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). Ph I data will be presented at the ESMO.
- 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.

Key expected milestones for R&D in 2H2026 and 1H2027

2H2026		1H2027
Stapokibart IL-4Rα		New indication approval - Moderate-to-severe AD in adolescents - Prurigo Nodularis
CMG901 CLDN18.2 ADC 	2L+ CLDN18.2+ GC/ AEG - MRCT Ph III Data readout - Multi-country BLA	
CM512 TSLP×IL13 BsAb 	√ China Ph2 data readout、 Phase3 initiation : CRSwNP - US PhIb data readout: Asthma - China Ph2 enrollment completed : Asthma、 COPD	- Overseas Ph3 initiation : CRSwNP - China Ph3 initiation : Asthma 、 COPD
CM336 BCMA/CD3 BsAb	RRMM Ph2 clinical data、 PV& Light chain amyloidosis IIT data paper published	- Global pivotal trial initiation : ITP、 AIHA - New indications global POC Ph2a initiation
CM313 CD38 antibody	Ph2 trial enrollment completed : IgAN	Ph3 initiation: IgAN
CM518D1 CDH17 ADC	China Ph I data presented at ESMO Congress: solid tumors	
IND plans	- CM529D1 DLL3 /SEZ6 BsAb ADC SCLC - CM583 Long-acting CGRP/PACAP BsAb Migraine - CM551 Long-acting TL1-A/IL-23p19 BsAb IBD 	siRNA、 PROTAC、 Bispecific ADCs 、 Brain-penetrant Bispecific Antibody

BLA: Biologics License Application; IND: Investigational New Drug (Application); 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;

Target for 2027: 2 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 (global)

Expected to conduct pivotal registration trials

CM512
Long-acting
TSLP×IL13 BsAb

- CRSwNP (conduct in China and US)
- Asthma
- COPD
-

AstraZeneca
CMG901
CLDN18.2 ADC

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

CM313
CD38 antibody

- IgAN

 **GILEAD**  **Lakefront**
biotherapeutics
CM336
BCMA/CD3 BsAb

- AIC: AIHA and primary ITP 
- Light Chain Amyloidosis (China)
- BCMA/CD3+CD38 2L+ RRMM (China)

AD: Atopic Dermatitis; CRSwNP: Chronic Rhinosinusitis with Nasal Polyps; SAR: Seasonal Allergic Rhinitis; COPD: Chronic Obstructive Pulmonary Disease; GC: Gastric Cancer; AEG: Adenocarcinoma of the Esophagogastric Junction; EAC: Esophageal Adenocarcinoma; MM: Multiple Myeloma

At least one new product expected to be approved for market in China or globally each year during 2027-2030



Note: AD: Atopic Dermatitis; CRSwNP: Chronic Rhinosinusitis with Nasal Polyps; SAR: Seasonal Allergic Rhinitis; GC: Gastric Cancer; AEG: Adenocarcinoma of the Esophagogastric Junction; EAC: Esophageal Adenocarcinoma; AIC:autoimmune cytopenias; AIHA :autoimmune hemolytic anemia; ITP: immune thrombocytopenia; PV: pemphigus vulgaris ; RRMM: Relapsed/Refractory Multiple Myeloma.

Company overview



A comprehensive biopharma 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



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



Proprietary Commercialization Capabilities

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



In-house Manufacturing Capabilities

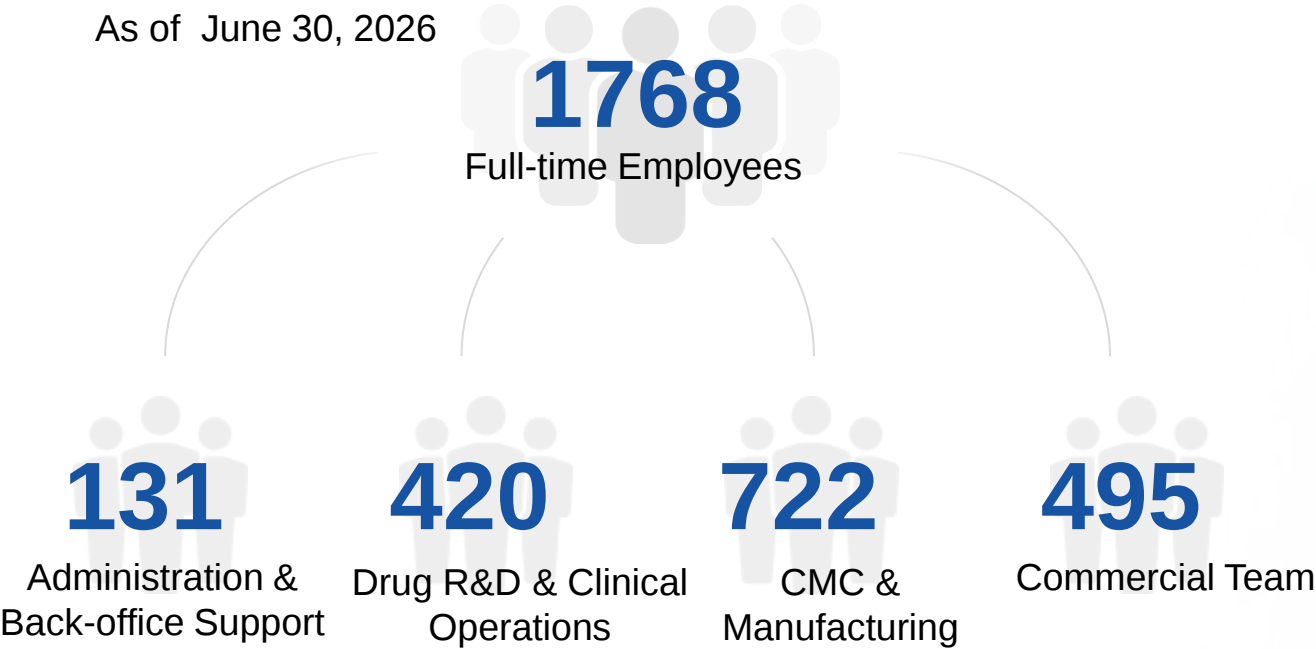
Production capabilities compliant with FDA and NMPA cGMP requirements

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



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

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



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

Antibodies Platform

- integrated R&D process and independent innovation capability

KeyMedSTAR™ ADCPlatform

- Proprietary novel toxin and linker platform: superior bystander killing effect and wide therapeutic window
- Proprietary GMP manufacturing facilities

nTCE Bispecific Antibodies Platform

- High specificity and potent mechanism of action
- Research published in NEJM

Small Molecule Platform

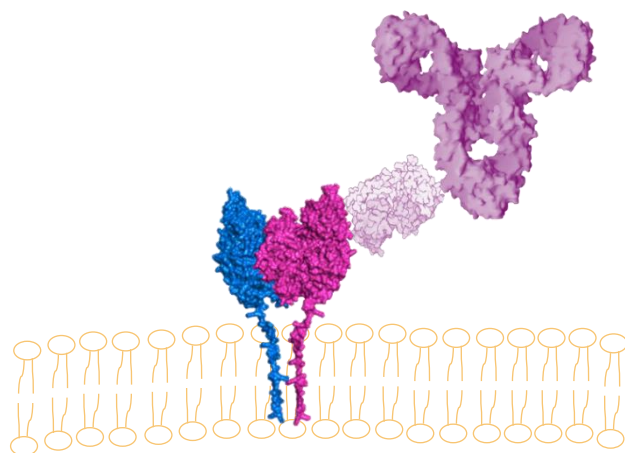
- PROTAC molecules with potent degradation activity
- Candidate molecules with high potency, stability, favorable pk and bioavailability

VESIR™ Oligonucleotide Platform

- Innovative Chemical Modifications
- Liver-Targeting and Extrahepatic Delivery
- AI-Assisted Design, High-Throughput Oligonucleotide Synthesis and Screening

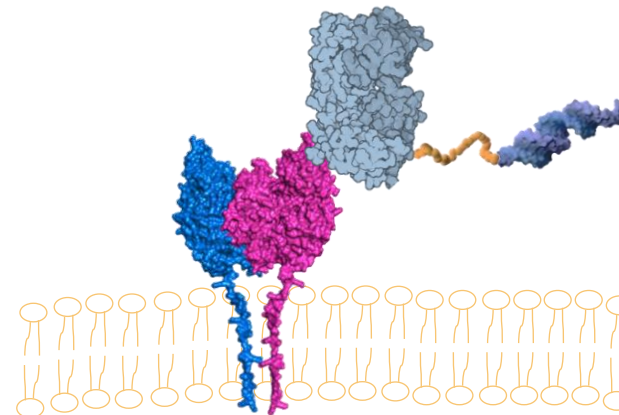
KeyCND™ BBB-Penetrating Antibody Delivery Platform

- Targeting Alzheimer's Disease and various neurological disorders
- Targeted delivery of macromolecules, nucleic acids, and small molecules



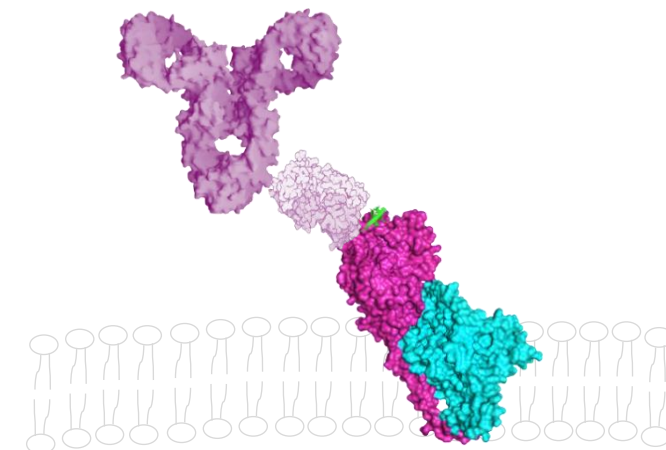
■ TfR-Targeted Antibody Delivery

- ✓ Rapid brain entry, with a 20-fold increase in brain uptake
- ✓ Drug distribution across the entire brain
- ✓ Enhanced efficacy
- ✓ Favorable safety profile
- ✓ Subcutaneous injection, convenient and fast



■ TfR-Targeted siRNA Delivery

- ✓ 115-fold increase in brain siRNA exposure
- ✓ Highly efficient neuronal endocytosis
- ✓ No risk of anemia or infusion-related reactions (IRR)
- ✓ Subcutaneous injection, convenient and fast



■ CD98hc-Targeted Antibody Delivery

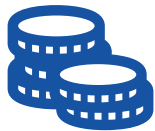
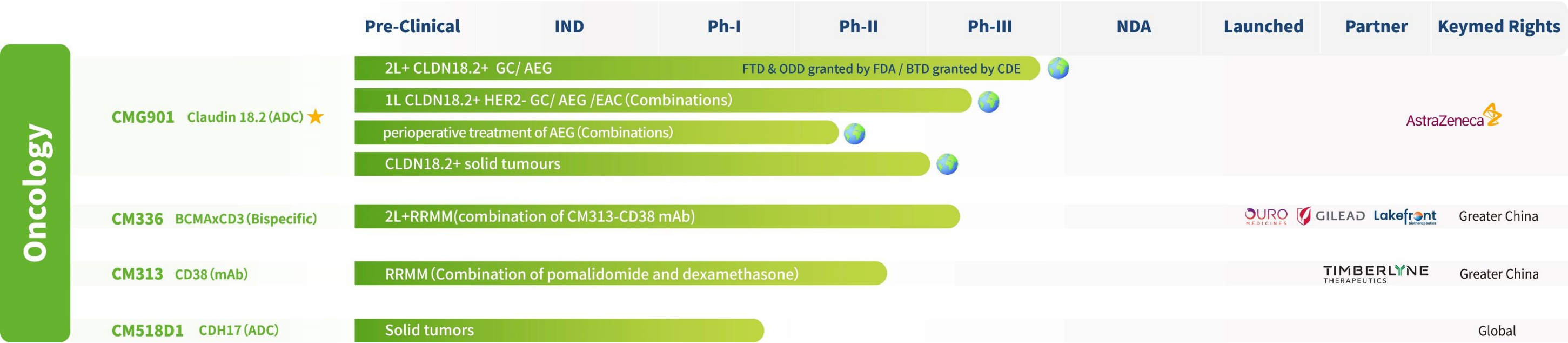
- ✓ Rapid brain entry with sustained exposure, 77-fold increase in brain uptake
- ✓ Enhanced A β plaque clearance
- ✓ No risk of anemia or IRR
- ✓ Subcutaneous injection, convenient and fast

Keymed leverages the KeyCND™ platform to achieve multimodal brain-targeted drug delivery, dedicated to the R&D of therapies for CNS diseases.

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

Autoimmune or Chronic disease	康悦达® 司普奇拜单抗 Stapokibart CM310 ★ IL-4Rα (mAb)	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				
		SAR--Adolescents				
	CM512 TSLPxIL-13 (Bispecific) ★	CRSwNP	BTD granted by CDE			Belenos Greater China
		Asthma	🇨🇳 🇺🇸			
		COPD				
		Moderate-to-severe AD				
		Chronic Spontaneous Urticaria(CSU)				
	CM326 TSLP (mAb)	Asthma, CRSwNP, etc.	CSPC 石药集团			Global ex mainland China
	CM336 BCMAxCD3 (Bispecific)	light chain amyloidosis(AL)	BTD granted by CDE			OURO MEDICINES GILEAD Lakefront biotherapeutics Greater China
		autoimmune cytopenias(AIC)	FDT&ODD 🇨🇳 🇺🇸			
		SAI(SjD,IIM)	🇨🇳 🇺🇸			
		BP,PV	🇺🇸			
	CM313 CD38 (mAb)	IgAN	TIMBERLYNE THERAPEUTICS			Greater China
CM355/PRO-203 CD20/CD3 (Bispecific)	Systemic Sclerosis (SSc)	Prolium				
CM383 Aβ protofibrils (mAb)	Alzheimer's Disease				Global	
CM559 N3pG-Aβ (mAb)	Alzheimer's Disease				Global	

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



Cumulative R&D investment exceeds RMB 2.6 billion



51 Clinical trial approvals obtained for China class 1 new drugs



288 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 process validation is currently underway (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

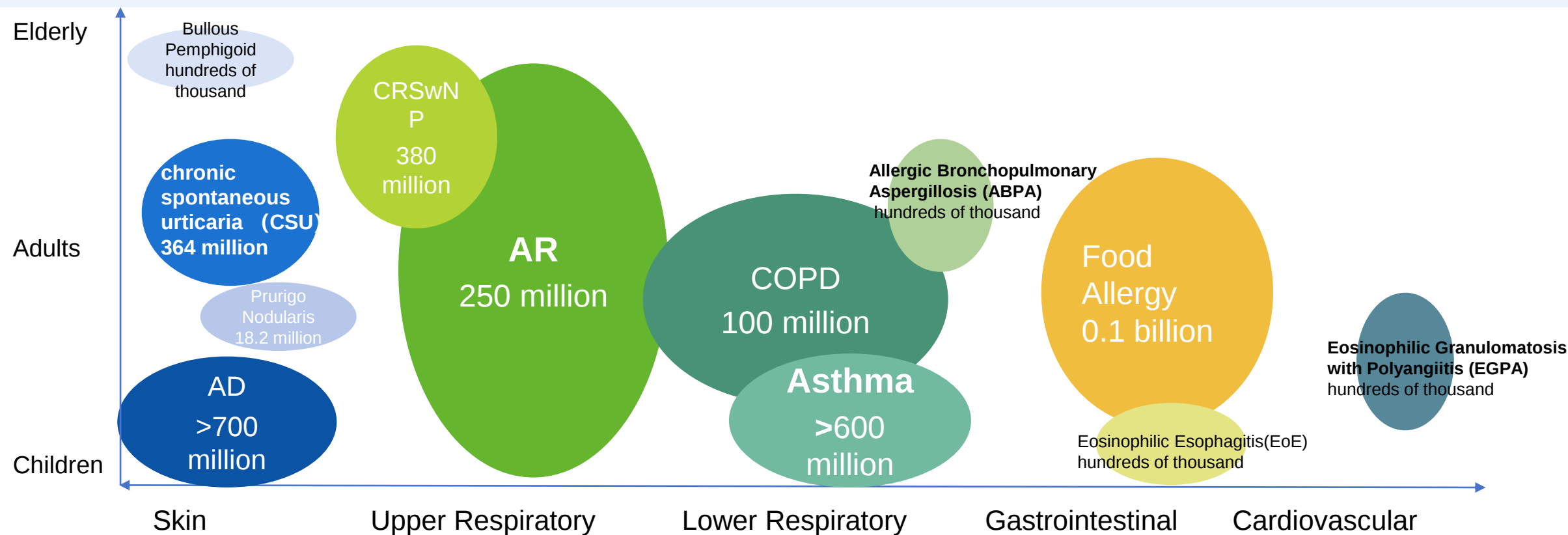
- **World-class advanced technology, ranked #1 in Western China**



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 700 million. The patient populations for Allergic Rhinitis, Food Allergy, COPD, Asthma, and CRSwNP in China reach 250 million, 112 million, 100 million, over 600 million, and 38 million, respectively.



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)



Prurigo Nodularis
(BLA)



Pediatric AD
(Ph III)



Adolescent SAR
(Ph III)

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**

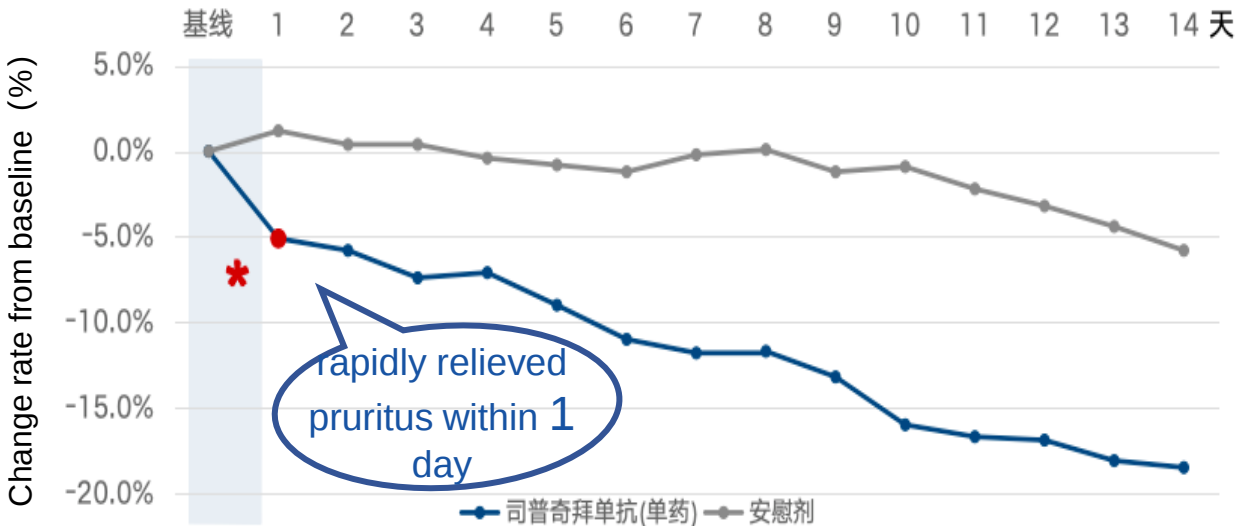
- In the Ph III clinical study of Stapokibart for the treatment of AD, 500 subjects were randomized 1:1 to receive dosing Q2W for 16 weeks (double-blind treatment period). Subsequently, all subjects received Stapokibart treatment for 36 weeks (maintenance treatment period).
- Monotherapy with the first 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

Day1

Rapid pruritus relief within 24 hours after the first dose¹

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

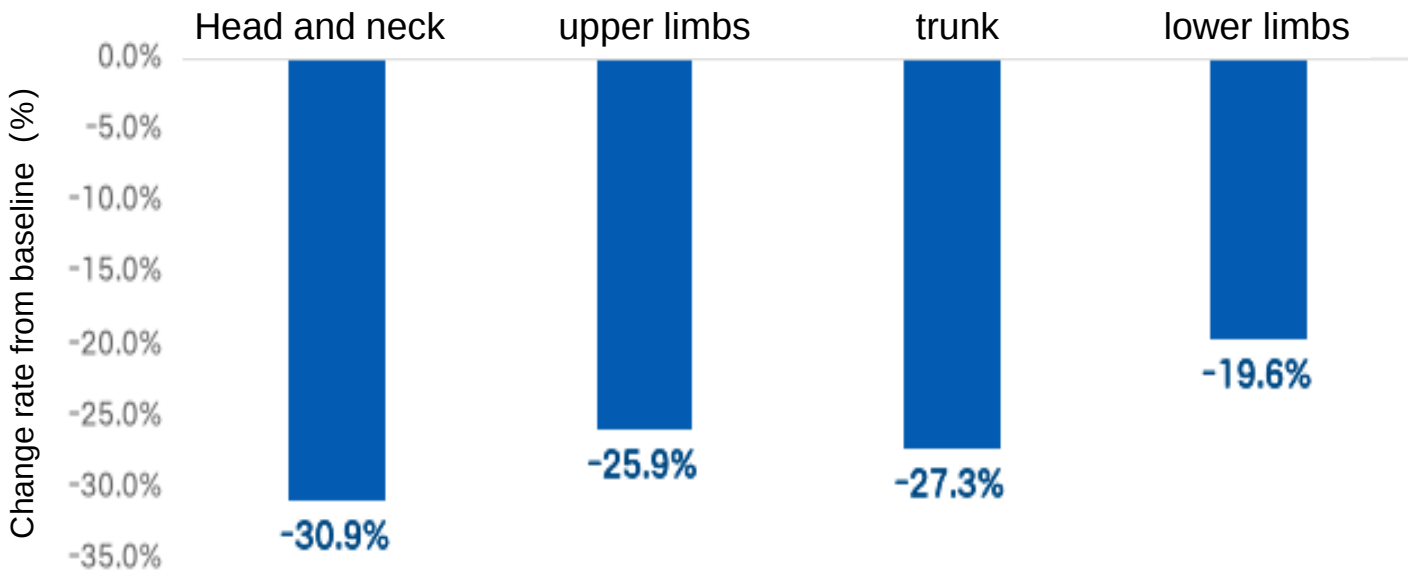


*: 司普奇拜单抗组显著优于安慰剂组, $p=0.0006$

2W

Comprehensive improvement of skin lesions following the first dose²

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

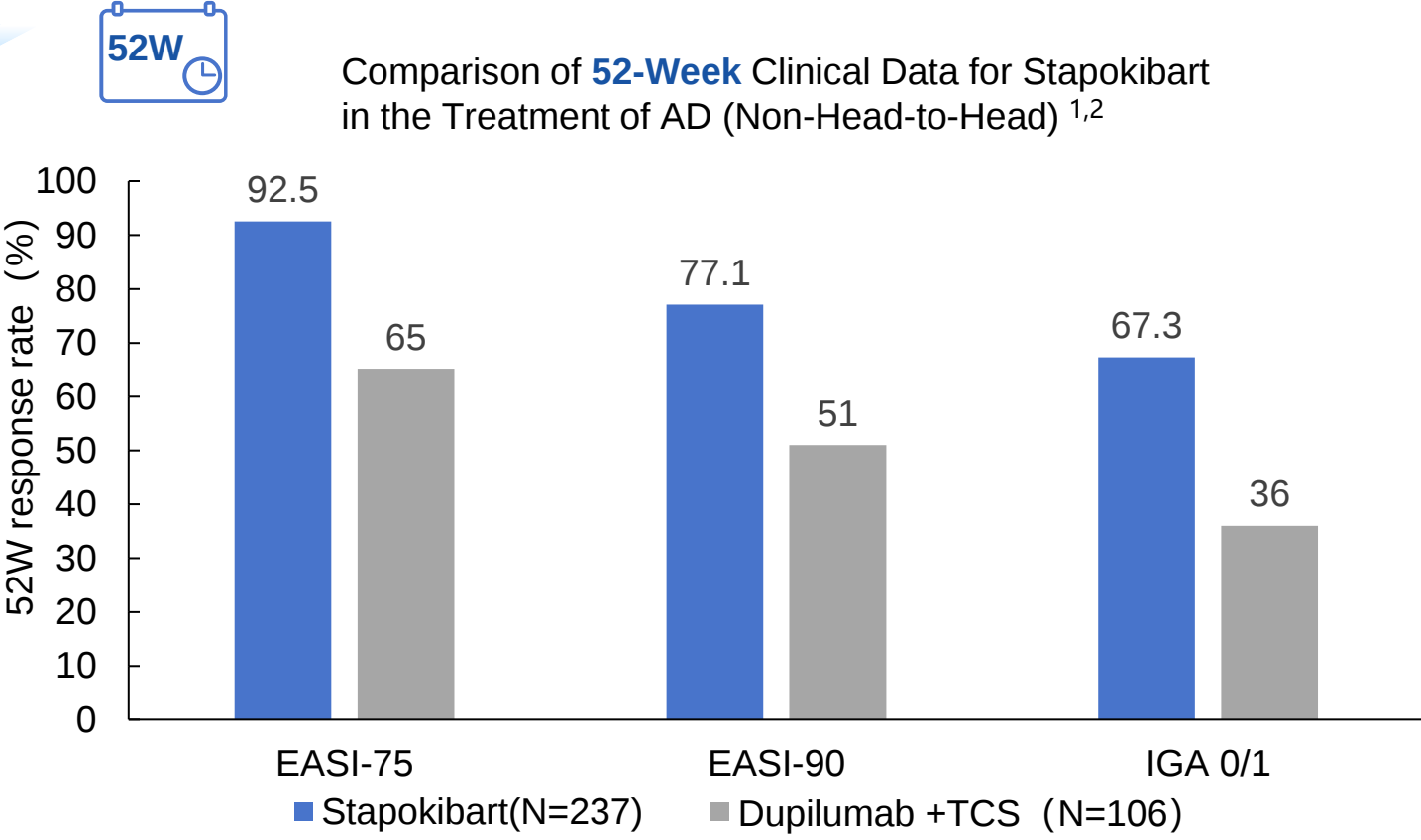
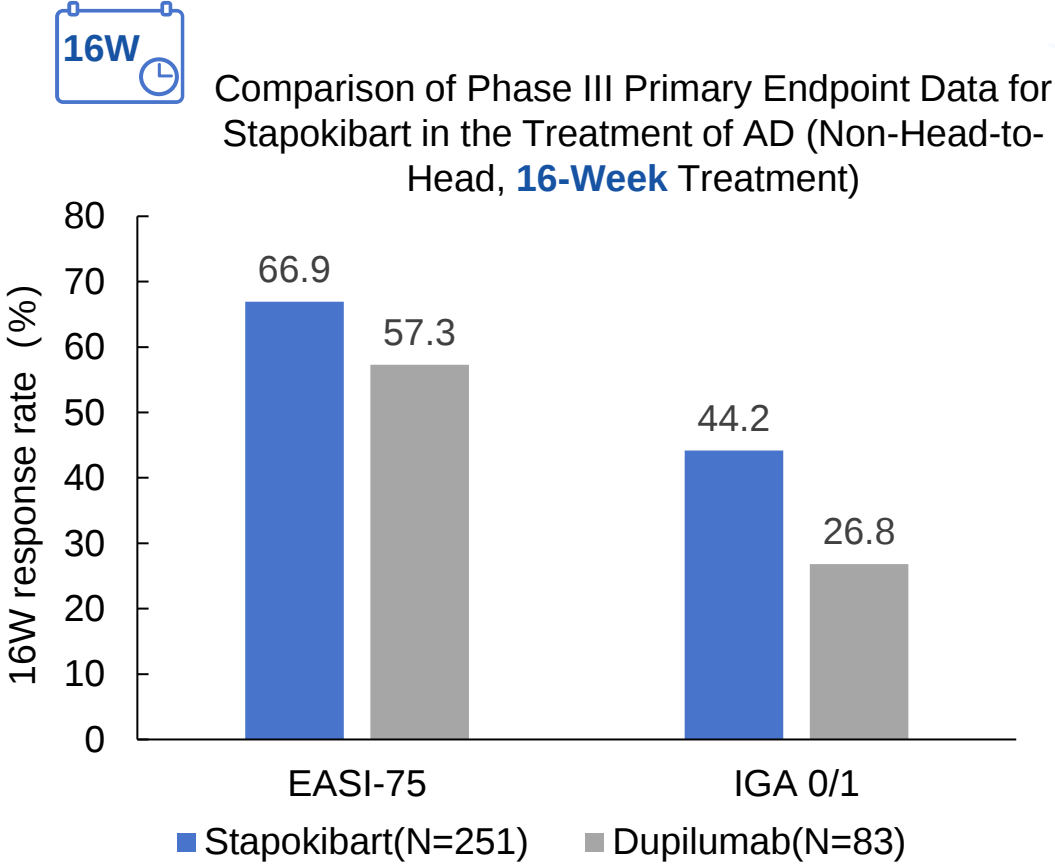


*: 司普奇拜单抗组显著优于安慰剂组, $p<0.0001$

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 (≥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 (≥90% improvement from baseline) of **77.1%**.

Potent response, Durable remission

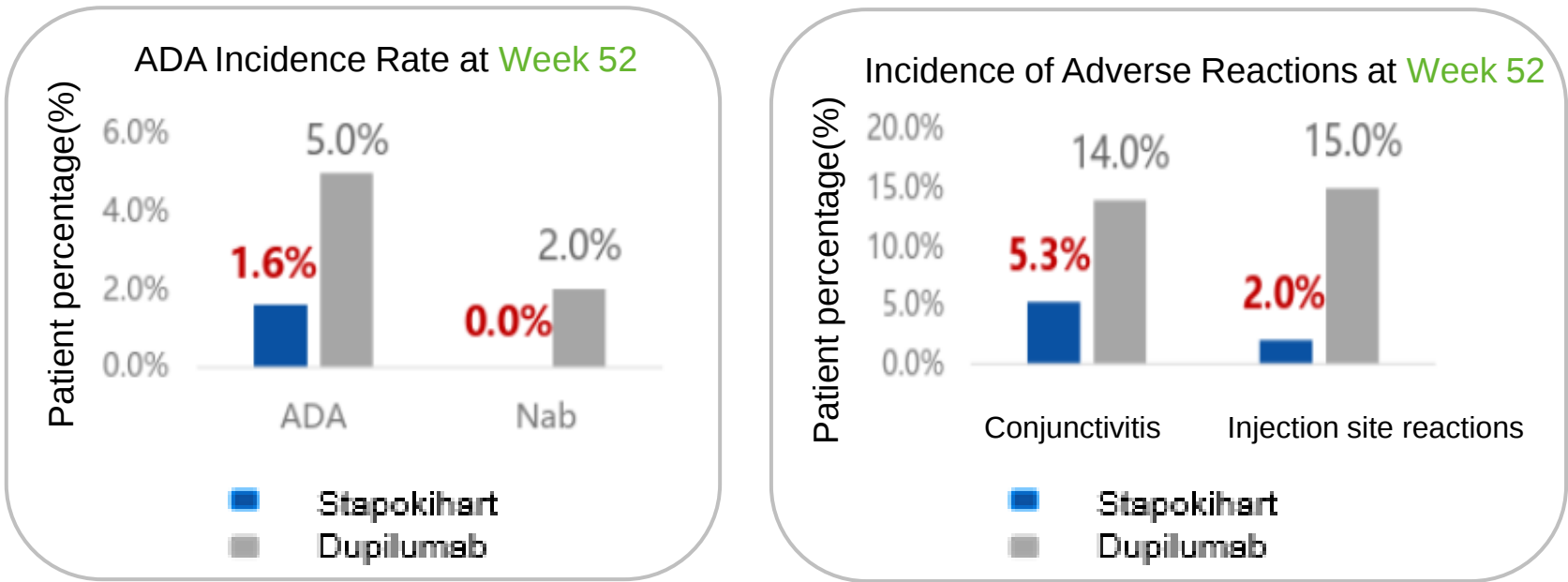


1. Yan Zhao, et al. Allergy. 2025 May;80(5):1348-1357.
2. Andrew Blauvelt, et al. Lancet. 2017 Jun 10;389(10086):2287-2303.

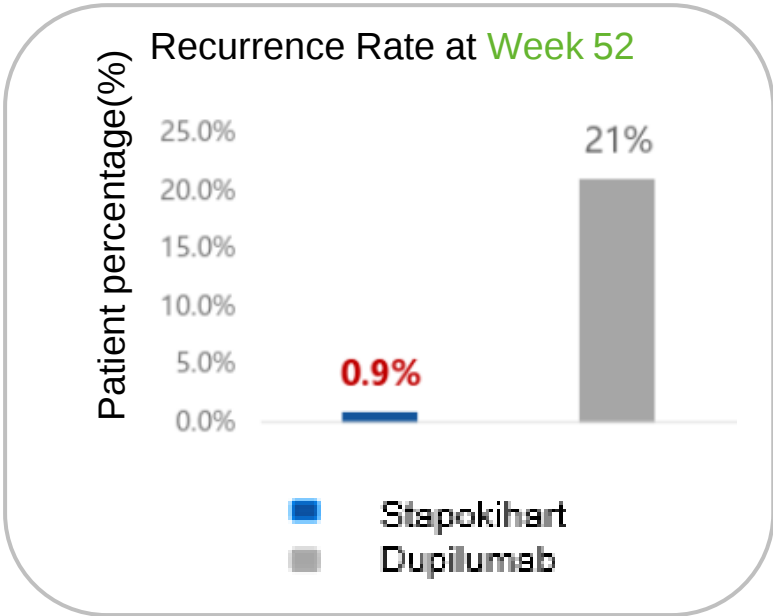
➤ **Stapokibart demonstrated a favorable safety and tolerability profile.** Compared to Dupilumab—a widely used agent with the same indication and target—Stapokibart effectively reduces the risk of recurrence while maintaining excellent safety and tolerability. The recurrence rate was only **0.9%** after 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



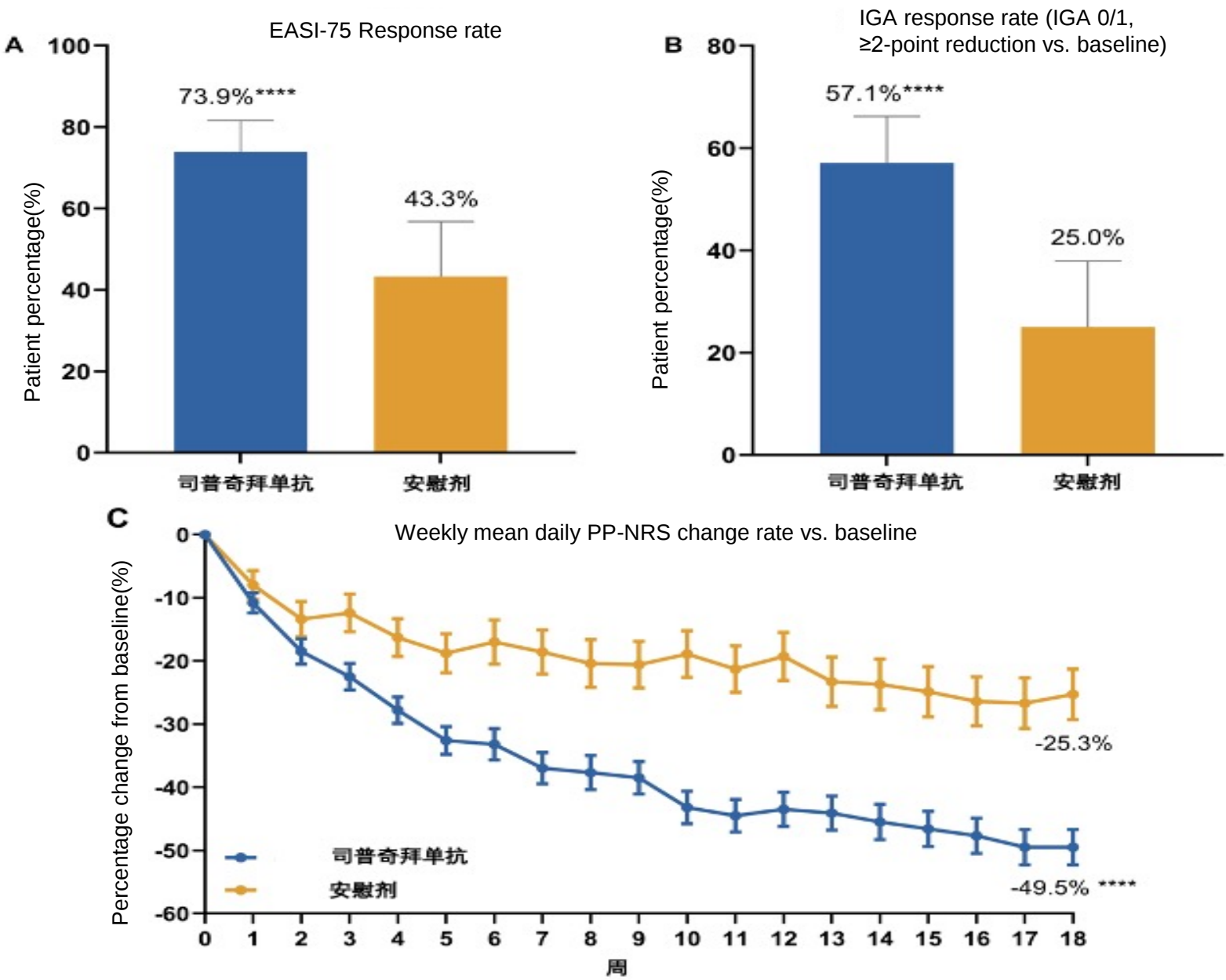
Recurrence Rate Comparison of Stapokihart (Phase III, Non-Head-to-Head) in AD



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.**



- 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.

JAMA®

JAMA | Original Investigation
Stapokibart for Severe Uncontrolled Chronic Rhinosinusitis With Nasal Polyps
The CROWNS-2 Randomized Clinical Trial



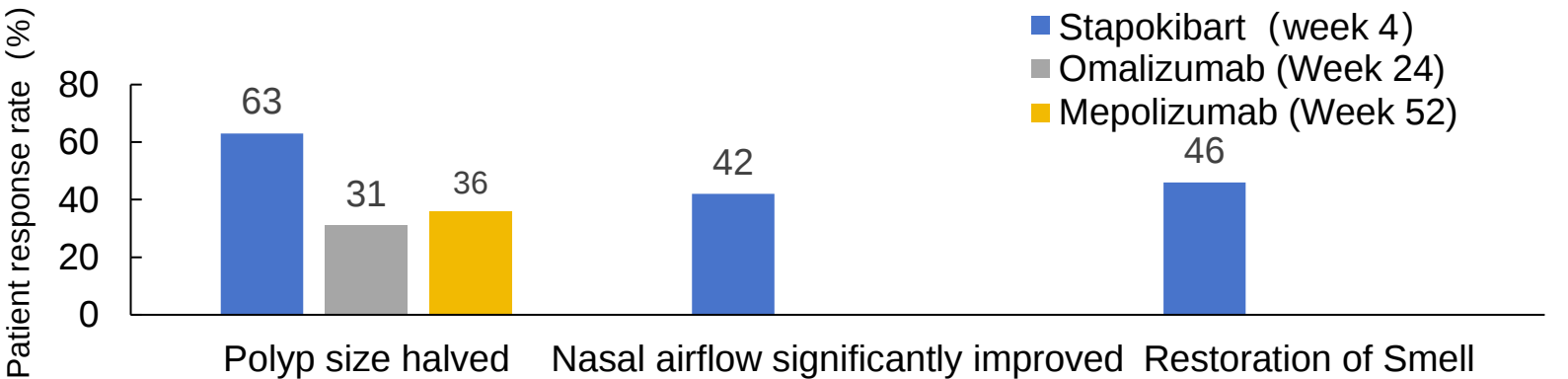
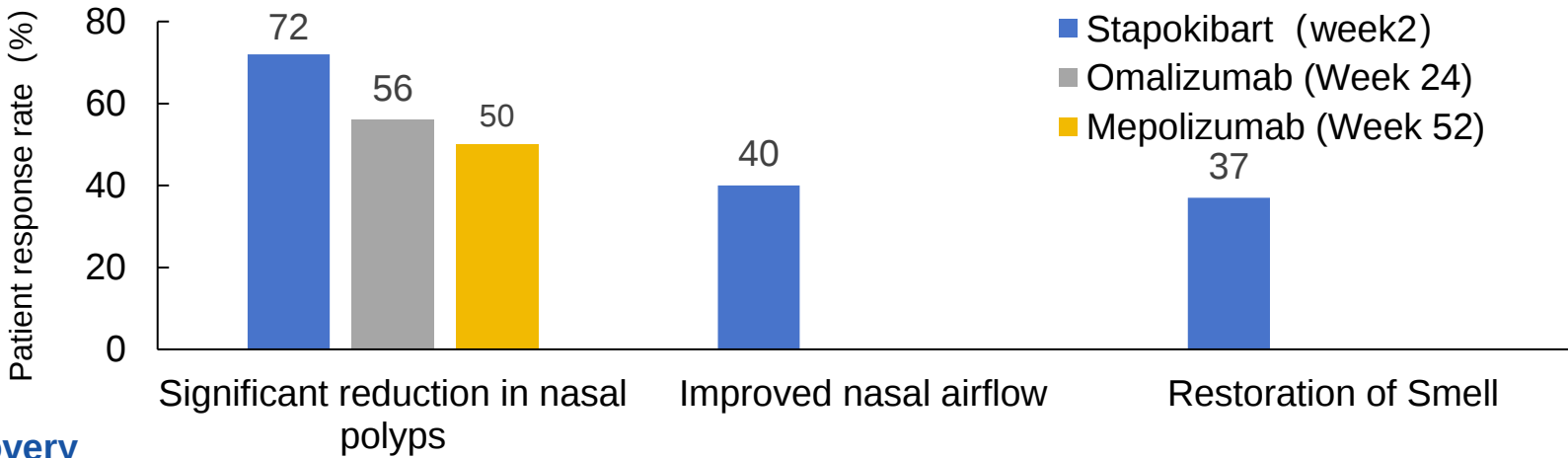
日内瓦国际发明展 金奖

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

1 injection/2w
Quick onset

2 injection/4w
Olfactory recovery

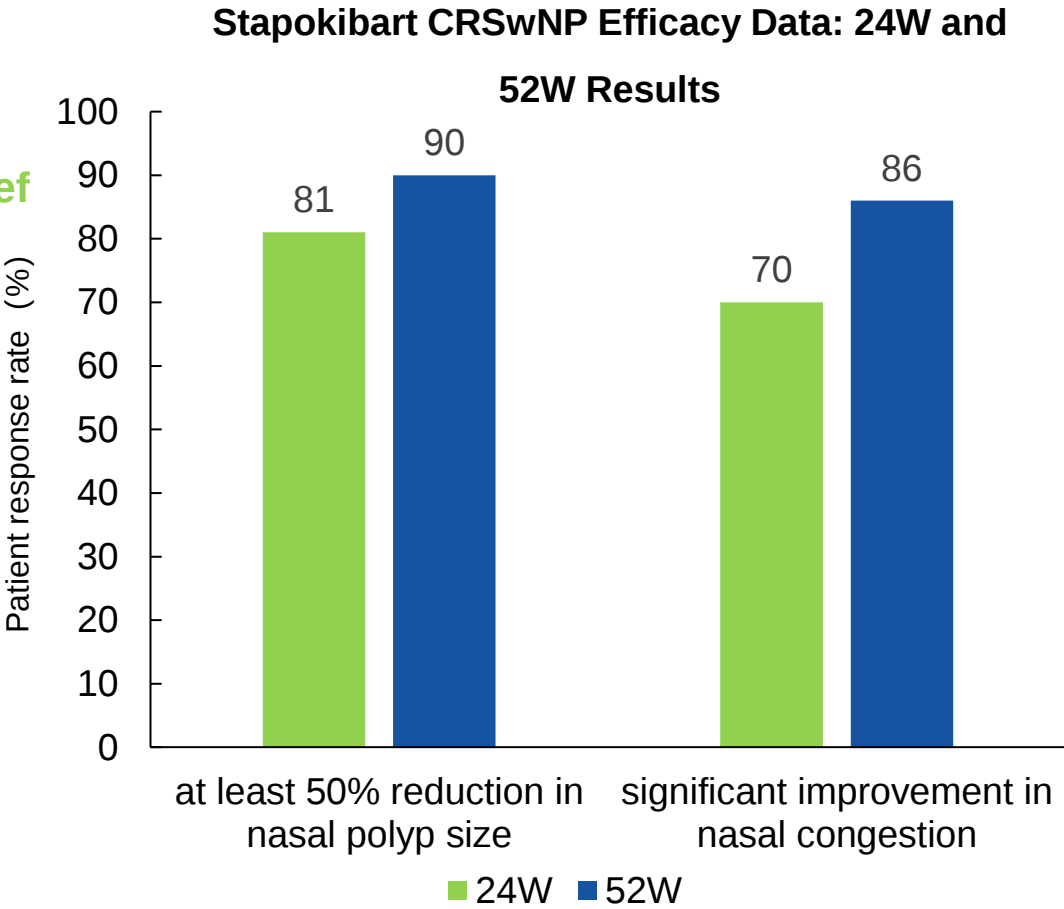


The above studies represent indirect comparisons; data are not head-to-head.

- 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



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 **Stapokibart for moderate-to-severe seasonal allergic rhinitis: a randomized phase 3 trial**

Article <https://doi.org/10.1038/s41591-025-03651-5>



Gold Medal (of the Geneva International Exhibition of Inventions)

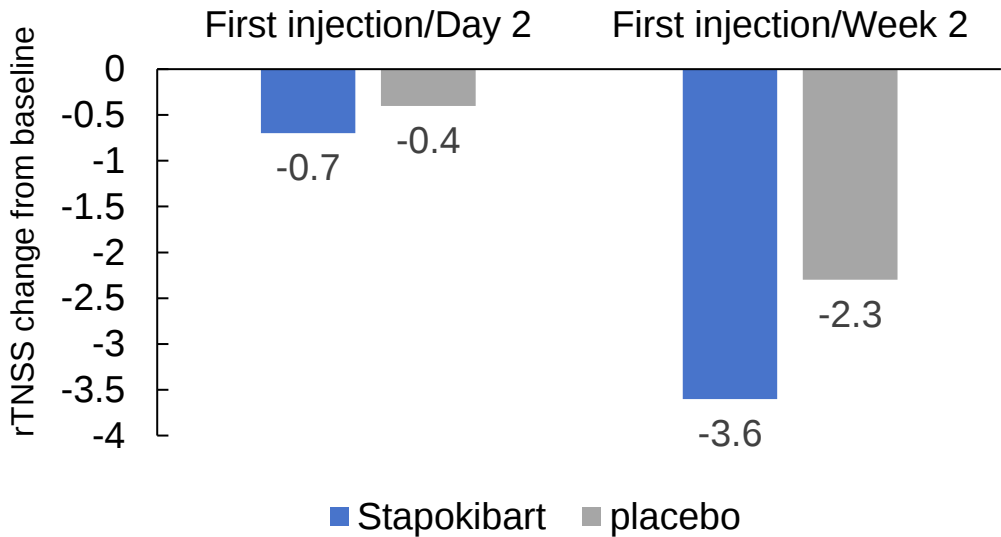
The world's **only** IL-4Rα-targeted antibody drug

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

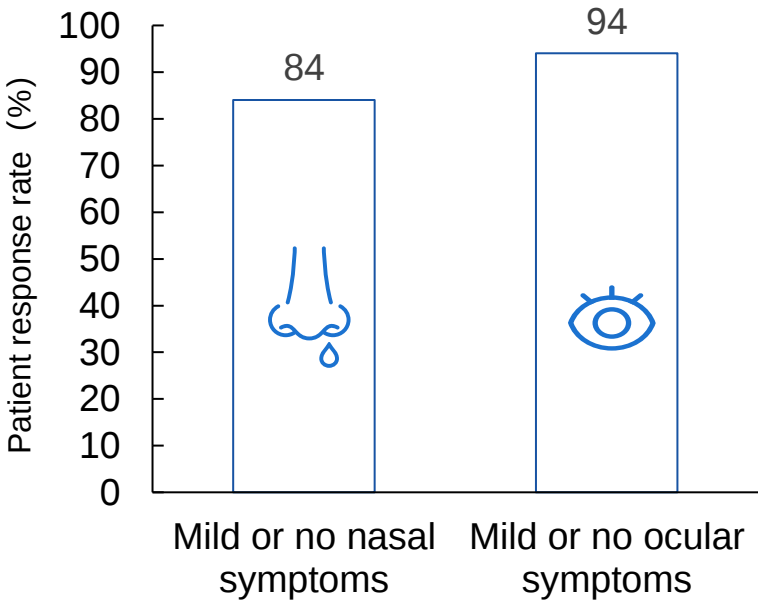
First injection/Day 2, Week 2
Rapid relief of nasal congestion

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.

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