Keymed Biosciences *(2162.HK)*



Nov 2026



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Company Overview



Keymed Biosciences (2162.HK): China-rooted, Globally-minded Integrated Biopharma

Focused on immunology and oncology; building a globally competitive innovative pipeline

Innovative R&D

Leading pipeline, diverse platforms

Focus: immunology & oncology

mAbs, bispecifics, ADCs and more

Key products:

CM310	IL-4Rα mAb	☑ *1st domestic; 1 of 2 globally*
CM512	TSLP×IL-13 BsAb	☑ *FIC; 1st globally*
CM336	BCMA×CD3 BsAb	☑ *BIC; industry leading*
CMG901	CLDN18.2ADC	☑ *FIC; 1st globally*

Broad portfolio, diverse platforms

- **1** approved product, **10+** clinical assets, **50+** pipeline programs
- Antibody, bispecific, ADC, oligonucleotide, PROTAC and BBB-penetrating platforms…

Commercial Launch

In-house team, efficient execution

Kangyueda® (CM310, Stapokibart)



- **First commercial product**
- **4 indications & 2 dosage forms approved**
- **1 indication filed; 2 in Phase III**
- 3 indications & 2 dosage forms in **NRDL**
- 1 of 2 domestic novel biologics in **NEML**

Mature team and commercial network

- **550+** staff in commercial team
- Nationwide network across **~290 cities**
- Multi-tier coverage: **2,200+** hospital, **~700** pharmacies

IP Out-Licensing

MNC licensing + NewCo

CMG901 Licensed to AstraZeneca

- Total deal value >**US$ 1.1bn**
- **First CLDN18.2 ADC with positive global Phase III**
- Filed globally; **approval expected in 2027**

CM336: Gilead acquires Ouro

- Ex-Greater China rights: Ouro Medicines
- Gilead acquired Ouro for up to **US$2.175bn**
- Keymed received **US$257m upfront in cash,** plus future milestones and royalties

H1 2026: **Revenue RMB617m (Kangyueda RMB393m; collaboration RMB224m), Net profit RMB1.22bn**

Note: Operating data as of end-Sep 2026. H1 2026 net profit mainly reflects a RMB1.68bn fair value gain on disposal of the Ouro Medicines equity interest.

Disease Areas: Built on Immunology, Expanding into Oncology

Immunology: Pipeline-in-a-product, deep patient pool

Shared pathway Single molecule

Skin
Atopic dermatitis **>70m**
Chronic urticaria **36.4m**
Prurigo nodularis **1.82m**

Upper Airway
Allergic rhinitis **250m**
CRSwNP **38m**

Lower Airway
COPD **100m**
Asthma **> 60m**

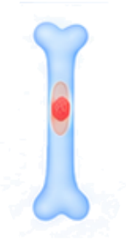
GI Tract
Food allergy **110m**

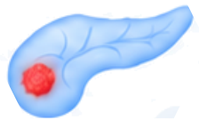
One molecule expands along shared inflammatory pathways,
maximizing core assets' lifecycle values

Oncology: China's common, underserved cancers

Gastric Cancer

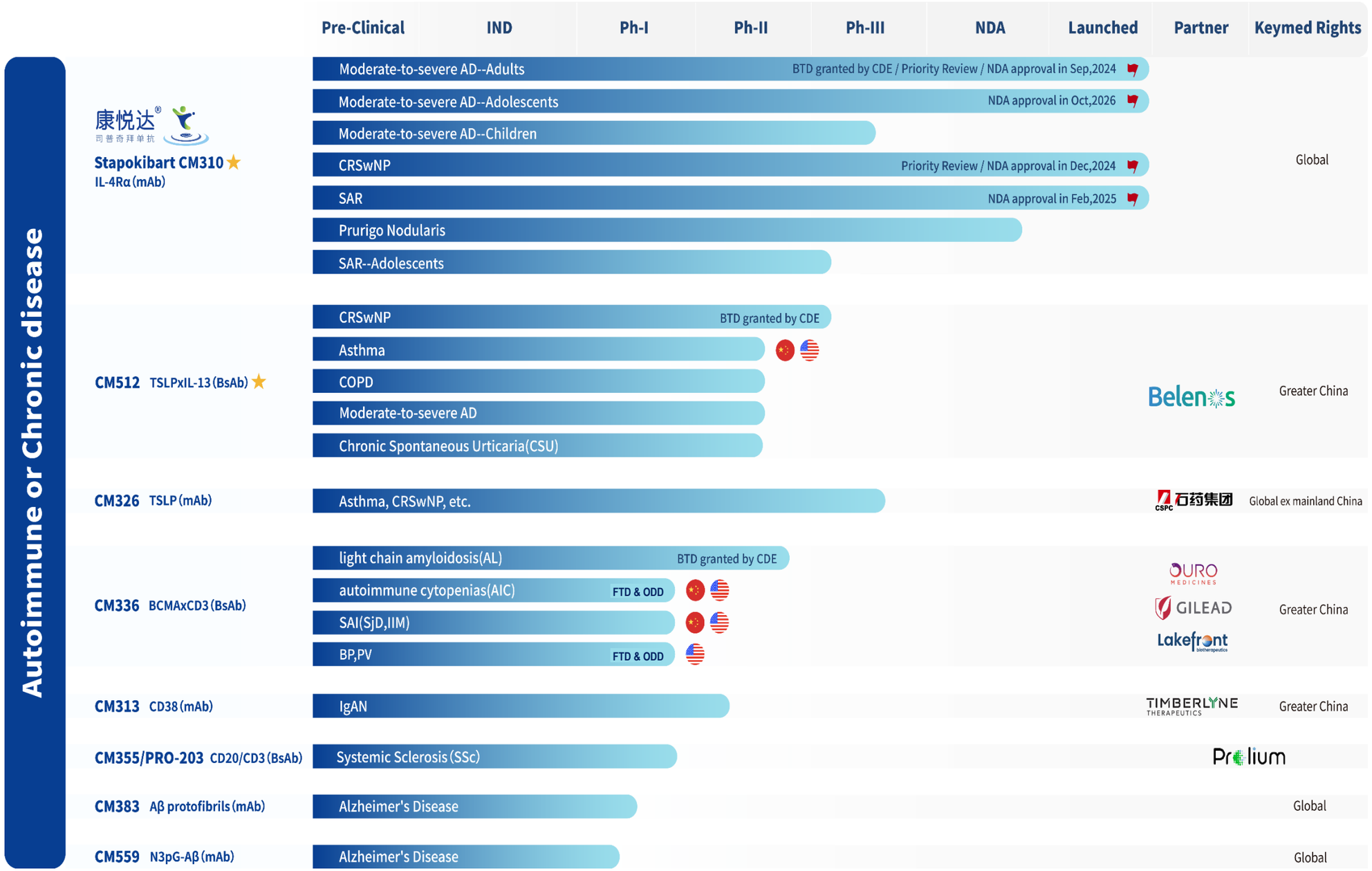
Annual incidence in China **~478k**
- Key asset: **CMG901** (CLDN18.2 ADC)
- First same-target drug (zolbetuximab) approved Q4 24; better options needed

Multiple Myeloma

Annual incidence in China **~80k**
- Key asset: **CM336** (BCMA×CD3)
- Daratumumab (same indication): 2025 China sales >RMB2bn

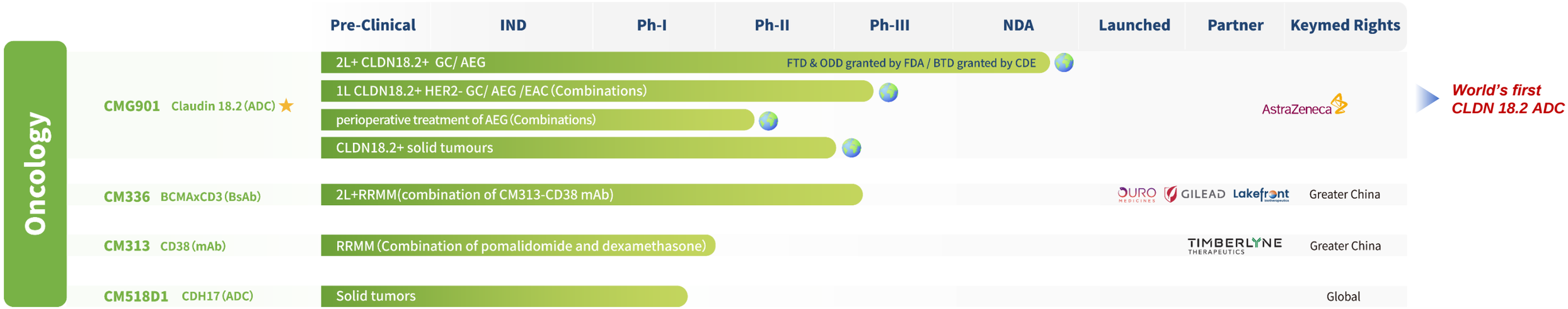
Pancreatic Cancer

Annual incidence in China **~125k**
- Key asset: **CM518D1** (CDH17 ADC)
- No targeted therapy approved in China; major unmet need

Sources: WHO, CIC, expert consensus, clinical guidelines, literature, etc.

Pipeline: 10+ Clinical Assets, Global & China Leaders



Pipeline: 10+ Clinical Assets, Global & China Leaders (cont.)



51 China Class 1 innovative drug IND approvals

2 National "Major New Drug" projects under the 13th Five-Year Plan

311 Invention patent applications

Diverse Platforms, Optimal Molecules for Unmet Medical Needs

RMB2.6bn+

Cumulative R&D spend

~25%

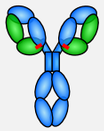
R&D and Clinical ops staff

42

Invention patents granted

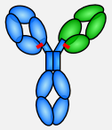
Note：Operating data as of end-Sep 2026

First decade: antibody-led R&D in autoimmune and oncology



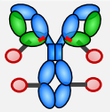
Antibody Platform

- **CM310 Marketed**
  - AD / CRSwNP / SAR / PN
- **CM313 Phase II/III**
  - IgAN / MM
- **CM512 Phase III**
  - CRSwNP / Asthma/COPD……



TCE Platform

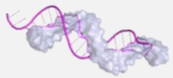
- **CM336 Phase III**
  - pAL / MM / ITP
- **CM355 Phase I/II**
  - SSc / B-NHL



ADC Platform KeyMedSTAR™

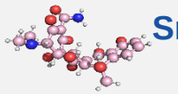
- **CM518D1 Phase I/II**
  - Advanced solid tumours
- **CM529D1 Phase I**
  - Small cell lung cancer

Next decade: diverse platforms for broader chronic diseases



Oligo Platform VESIR™

- Liver：GalNAc
- CNS：**CM805T**（Tau AOC，Alzheimer's）
- Adipose：**CM821**（ALK7，muscle loss）
- Muscle, eye, lung, kidney……



Small molecule Platform

- PROTACs with potent degradation activity
- Novel E3 fragments, linkers and POI ligands



BBB-Penetrating Antibody Delivery KeyCND™

- **CM805T Tau AOC**
- **CM616 CD98hcxAβ BsAbs**
  - Alzheimer's

R&D Pipeline: 50+ Programs

	Marketed	NDA	Phase II/III	Phase I	Pre-clinical
Allergic Diseases	**CM310 stapokibart** IL-4Rα (1st in China) **Approved** ◆ Adult moderate to severe AD 2024.9 ◆ Adult CRSwNP 2024.12 ◆ Adult SAR 2025.2 ◆ Adolescent moderate-to-severe AD, Oct 2026 ◆ Pre-filled autoinjector pen, 2025.11	**CM310 stapokibart** IL-4Rα (1st in China) ◆ Prurigo nodularis 2026.3	**CM310 stapokibart** IL-4Rα (1st in China) **Phase III ongoing** ◆ Pediatric moderate-to-severe AD ◆ Adolescent SAR	**CM512 BsAb** Long-acting TSLP×IL13 ◆ FIH, healthy volunteers (SAD/MAD) ◆ Asthma (Ib) Belenos	**CM398 mAb** IgAN **CM592 BsAb** Urticaria, Food allergy **CM821 siRNA** Metabolism
			CM512 BsAb Long-acting TSLP×IL13 **Phase III ongoing** ◆ **CRSwNP（Q24W）** **Phase II ongoing** ◆ Moderate-to-severe AD ◆ COPD ◆ Moderate-to-severe Asthma ◆ CSU		
Chronic Diseases			**CM313 mAb** CD-38 Phase II ongoing ◆ IgAN	**CM383 mAb** Aβ antibody **CM559 mAb** Aβ antibody ◆ Alzheimer's disease	**CM336 BsAb** BCMA/CD3 ◆ AIC (AIHA, ITP) ◆ Sjögren's disease **CM615 BsAb** Alzheimer's
Oncology		**CMG901 ADC** CLDN18.2 (global first) AstraZeneca ◆ 2L+ GC/GEJC 2026.9	**CM336 BsAb** BCMA/CD3 (China's first) **Phase III starting soon** ◆ 2L+ MM（with CD38） Phase II ongoing ◆ AL amyloidosis	**CM518D1 ADC** CDH17 **CM529D1 ADC** DLL3-SEZ6 **CM583 BsAb** CGRP/PACAP **CM551 BsAb** TLI-1/1L-23P19	**CM805T siRNA** Alzheimer's **CM380 BsAb** Multiple myeloma **CM600 ADC** CRC
			CMG901 ADC CLDN18.2 (global first) AstraZeneca **Phase III ongoing** ◆ 1L gastric/GEJ adenocarcinoma **Phase II ongoing** ◆ Perioperative GC ◆ 1L pancreatic cancer ◆ 2L+ cholangiocarcinoma	◆ Solid tumour ◆ Solid tumour ◆ Migraine ◆ IBD	

Note: AD: atopic dermatitis; CRSwNP: chronic rhinosinusitis with nasal polyps; SAR: seasonal allergic rhinitis; GC: gastric cancer; GEJC: gastroesophageal junction cancer; FIH: first-in-human; SAD: single ascending dose; MAD: multiple ascending dose; AIC: autoimmune cytopenia; AIHA: autoimmune hemolytic anemia

BD: Strong R&D Engine Accelerating Overseas Value Realization

MNC Licensing : CMG901

Over US$1.1bn
Total transaction value

US$45m
Milestone payment in Mar 2026

US$3–5bn
AZ projected peak sales

- Exclusive global license to AZ; tiered royalties reaching up to low double digits.
- In global Phase III MRCT across GC, pancreatic cancer, and BTC.
- Mar 2026: developmental progress triggered a US$45m milestone.

AstraZeneca

The world's most advanced CLDN 18.2 ADC
1st indication expected to launch globally in 2027

NewCo Partnership Overseas

CM512 | CM536 | CM336 | CM313 | CM355

NewCo model rapidly advances overseas clinical development

CM336: NewCo comes into full cycle

OURO MEDICINES → Mar 2026 → GILEAD

Acquisition value up to US$2.175bn

US$257M upfront payment to Keymed

CM336 milestones and royalties remain in force under Gilead

Partner Ecosystem:

Belenos · orbimed · TPG · OURO MEDICINES · GILEAD · ABINGWORTH · TIMBERLYNE THERAPEUTICS · BainCapital · venrock · Prolium · rtw · GSK

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**



R&D Progress in H1 2026



2026: Going Deeper in Autoimmune, Chronic Diseases & Oncology

Marketed

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

Adult moderate-to-severe AD
First domestic; opening the EASI-90 era

CRSwNP
First in China; opening the biologics era

SAR
Only one globally; reshaping moderate-to-severe care

Adolescent moderate-to-severe AD
First domestic; Wk-54 EASI-75 > 90%

Phase III

Stapokibart
IL-4Rα (1st domestic)

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

CM512
Long-acting TSLP×IL-13 BsAb

- CRSwNP（Q24W）

AstraZeneca
CMG901 CLDN18.2 ADC

- 2L+CLDN18.2+ GC/AEG **(CN/US BLA)**
- 1L CLDN18.2+/HER2- GC/AEG/EAC

CM336
BCMA/CD3 BsAb

- 2L+RRMM (with CM313)
- AL amyloidosis

Phase II

AstraZeneca
CMG901 CLDN18.2 ADC

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

CM512
Long-acting TSLP×IL-13 BsAb

- COPD
- Asthma
- Adult AD
- CSU……

CM313
CD38 mAb

- IgAN

Phase I

Belenos
CM512
Long-acting TSLP×IL-13 BsAb

GILEAD Lakefront biotherapeutics
CM336（autoimmune）
BCMA/CD3 BsAb

CM518D1
CDH17 ADC

- Colorectal cancer

CM529D1 DLL3 /SEZ6
Bispecific ADC

- SCLC

CM583
Long-acting
CGRP/PACAP BsAb

- Migraine

CM551
Long-acting
TL1A/IL-23p19 BsAb

- IBD

Note: Key clinical programs only; see Part 1: 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

CM310：China-First, Global-Second, Potential Best-in-Class IL-4Rα mAb

Kangyueda®, Stapokibart, CM310 (IL-4Rα)



Adult AD
(approved Sep 2024)

CRSwNP
(approved Dec 2024)

SAR
(approved Feb 2025)

Adolescent AD
(approved Oct 2026)

Prurigo nodularis (BLA)

Pediatric moderate-to-severe AD
(Phase III)

Adolescent SAR
(Phase III)

Multiple 1

- ✓ **First domestic** biologic for moderate-to-severe AD
  Fills the clinical data gap on higher treatment goals in AD
- ✓ **China's first** biologic for CRSwNP
- ✓ **World's first** IL-4Rα mAb for SAR
- ✓ **First in China, 1 of 2 worldwide:** approved IL-4Rα mAb

Publications

- ✓ **SAR Phase III results** published in **Nature Medicine** (IF=58.7)
- ✓ **Severe uncontrolled CRSwNP Phase III results** published in **JAMA** (IF=55)
- ✓ **Adult moderate-to-severe AD Phase III results** published in ***Allergy*** *(IF=12.6)*

Regulatory Designations

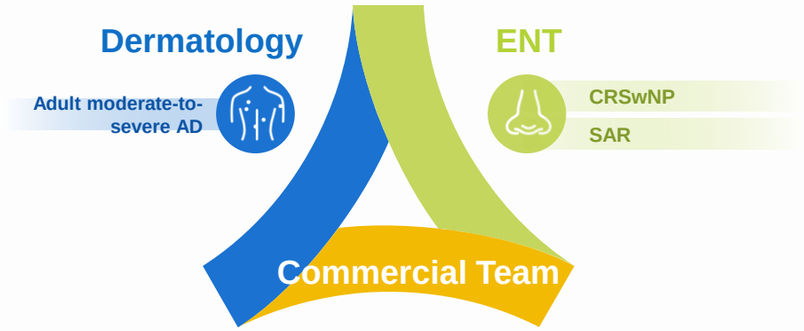
- ✓ Granted **Breakthrough Therapy Designation** by CDE
- ✓ Granted **Priority Review**

CM310：First NRDL Year: Driving Rapid Kangyueda® Uptake on Multiple Fronts

Kangyueda® sales: ~RMB **393m** in H1 2026 (+132% YoY); ~RMB **658m** in 9M 2026 (+227% YoY)

1 Dermatology & ENT Focus; Building Robust Medical Engagement

- **4 Approved Indications:** adult moderate-to-severe AD, CRSwNP, SAR(exclusive), adolescent moderate-to-severe AD
- **Targeted Marketing:** dermatology and ENT units; building a robust science-led engagement platform
- **Growing Commercial Team:** 550+ staff as of 30 Sep 2026



Marketing, Sales, Medical Affairs, Market Access, Operational Excellence

2 Expand Channels & Market Access; Accelerate Penetration in High-potential Regions and Hospitals

- As of Sep 30, 2026: **30 provinces and 290+ cities covered**
- **2,200+** hospitals covered; **2,200** actively prescribing; **1,300+** with in-hospital listing
- **Commercial channels:** 58 tier-1 distributors; nearly 700 pharmacies
- **Medical Insurance (NRDL):** **3 indications and both presentations (vial, pre-filled autoinjector pen) listed**, effective 1 Jan 2026
- **National Essential Medicines List: 3 indications included in the 2026 edition, effective 1 Sep 2026**





CMG901: AstraZeneca Speeds Global CLDN18.2 ADC Trials

- Feb 2023: **exclusive global license for CMG901/AZD0901**. AstraZeneca handles global R&D, manufacturing and commercialization; total deal value >US$1.1bn plus tiered royalties up to low double digits
- End Jul 2026: positive topline results from CLARITY-Gastric01 (2L+ CLDN18.2+ GC/AEG): **statistically significant, highly clinically meaningful OS benefit** (CLDN18.2 expression ≥25%). BLA filed with FDA and NMPA in Sep 2026: the **first CLDN18.2 ADC filed for approval worldwide**
- AZ peak sale estimate: **US$3-5bn**

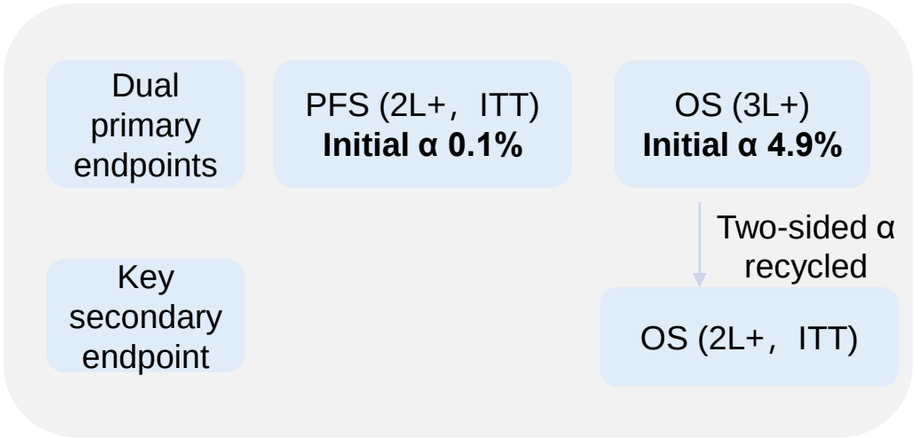
Indication	Clinical Stage	Planned enrollment	Milestones	
2L+ CLDN18.2+ GC/ AEG	Phase III	594	**Sep 2026: simultaneous China/US BLA** Oct 2026 ESMO Presidential Symposium (ESMO's top-tier session)	**CDE BTD、EMA ODD** **FDA FTD & ODD** **Most advanced globally**
1L CLDN18.2+ HER2- GC/AEG/EAC (Combination Therapy)	Phase III	2,130 (426 in China)	**FPI: Feb 2026,** triggered a **US$45m** milestone payment	
CLDN18.2+Solid Tumors (3 cohorts: GC, 1L PDAC, 2L+BTC)	Phase II	224	enrollment completed	
Perioperative treatment of AEG (Combination Therapy)	Phase II	Total 100	initiated in July 2025	

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

Note: All trials are run by the partner in its licensed territory; only the most advanced phase per indication is shown.
Sources: company websites, ClinicalTrials.gov.

CMG901: First CLDN18.2 ADC Phase III to Show a Statistically Significant OS Benefit in 2L+ Gastric Cancer

Trial Design



Results

OS (3L+)	Sone-Ve 2.2 mg/kg (n=178)	Investigator's choice of standard therapy (n=177)	P-value	HR (95% CI)
Result	**mOS=10 months**	mOS=5 months	< 0.000001	**0.47** (0.36-0.62)

OS (2L+ overall population)	Sone-Ve 2.2 mg/kg (n=267, incl. 89 in 2L)	Investigator's choice of standard therapy（n=265）	P-value	HR (95% CI)
Result	**mOS=10.6 months**	mOS=6.4 months	0.000004	**0.58** (0.47-0.73)

	PFS (BICR)		**PFS (Investigator-assessed)**	
Arm	Sone-Ve 2.2 mg/kg (n=267)	Investigator's choice of standard therapy (n=265)	Sone-Ve 2.2 mg/kg (n=267)	Investigator's choice of standard therapy (n=265)
mPFS (months)	4.2	3.8	4.4	3
HR(95% CI)	0.77		**0.59**	
P-value	0.053		-	
Interpretation	60% of patients had peritoneal metastases, which lack clear measurable margins. Investigators could see symptom relief, ascites resolution or falling tumour markers; investigator-assessed PFS is consistent with the OS benefit			

Note: ITT： Intention-To-Treat； Sone-Ve: sonesitatug vedotin (CMG901/AZD0901); OS: overall survival;
PFS: progression-free survival; BICR: blinded independent central review;
HR: hazard ratio

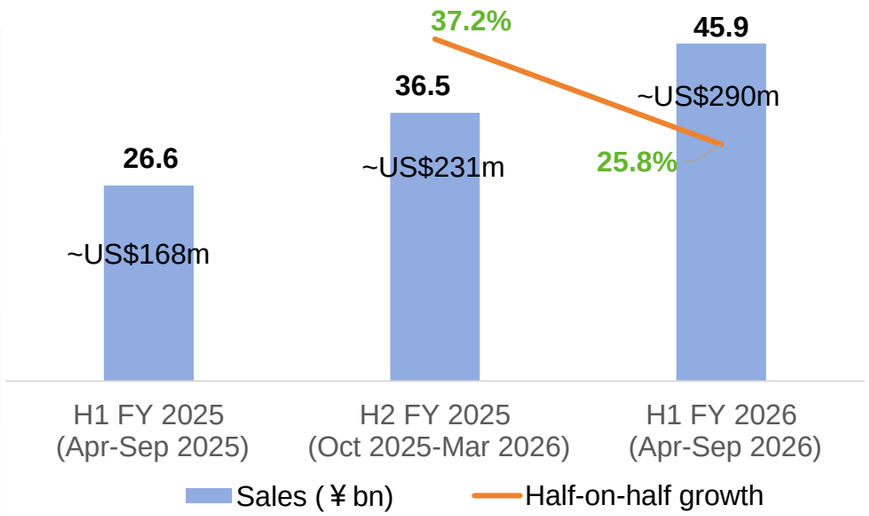
CMG901: ≥25% CLDN18.2 Cut-Off Doubles the Eligible Population; Strong US/EU Potential

Comparison	Zolbetuximab (Astellas, Vyloy)	CMG901 / AZD0901 (CLARITY-Gastric 01)
Line and regimen	1L; with fluoropyrimidine + platinum chemotherapy	2L+, prior zolbetuximab allowed; monotherapy, Q3W
CLDN18.2 positivity cut-off	**≥75%** of tumour cells with membrane staining, moderate-to-strong (2+/3+)	**≥25%** of tumour cells with membrane staining, any intensity
Test Method	IHC; companion diagnostic VENTANA CLDN18 (43-14A) Roche, approved	IHC; companion diagnostic developed for this cut-off; to be filed with the product
Screening yield at each CLDN18.2 cut-off	SPOTLIGHT: 2,735 screened → 922 CLDN18.2+ → 565 enrolled **34% positive** GLOW: 2,333 screened → 808 CLDN18.2 + → 507 enrolled **35% positive**	922 screened → 594 enrolled **64% positive**

Addressable gastric cancer patients: Vyloy in 1L vs Sone-Ve in 2L+

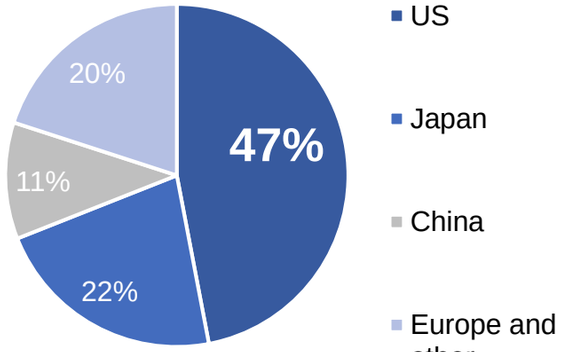
Patients (10,000)	Peri-operative	1L	2L	3L
G7 gastric cancer patients (US, Canada, UK, France, Germany, Italy, Japan)	5	9	6	3
Vyloy (≥75% cut-off; 35% of patients) potential 1L patients		**9*35%= 3.15**		
Sone-Ve (≥25% cut-off; 60% of patients) potential 2L+ patients			**9*60%= 5.4**	

Vyloy global sales by half-year



Note: converted at ¥158 per US$ for simplicity; actual rates may differ.

Vyloy FY 2025 global sales by region (first full fiscal year after launch)



CM512: World's First Long-acting TSLP x IL-13 Dual Blocker, Phase I Data

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** (vs ~10 days for Sanofi's lunsekimig).
- **Low immunogenicity**, better long-term dosing safety

Phase I: Favorable Safety and Tolerability

- Healthy subjects (n=64): Single and multiple ascending doses showed **good safety and tolerability.** No TEAEs met dose-escalation stopping criteria
- Moderate-to-severe AD patients (n=46): The overall incidence of TEAEs and SAEs was comparable to the placebo group.

Phase I: Rapid, Durable, Stable Efficacy

- Multiple Type 2 inflammatory biomarkers markedly reduced.
- CM512 delivers rapid, durable and stable disease control in moderate-to-severe AD patients:
  - Week 6: **50%** EASI-75 in 300mg group (proposed recommended 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: World's First Long-acting TSLP/IL-13 BsAb Meets All Phase II Endpoints

Shrinks nasal polyps rapidly and significantly relieves nasal congestion in **~4 weeks** after dosing

One dose, **6-month** sustained efficacy: significantly greater reduction from baseline in Nasal Polyp Score (NPS) at Week 24 vs. control

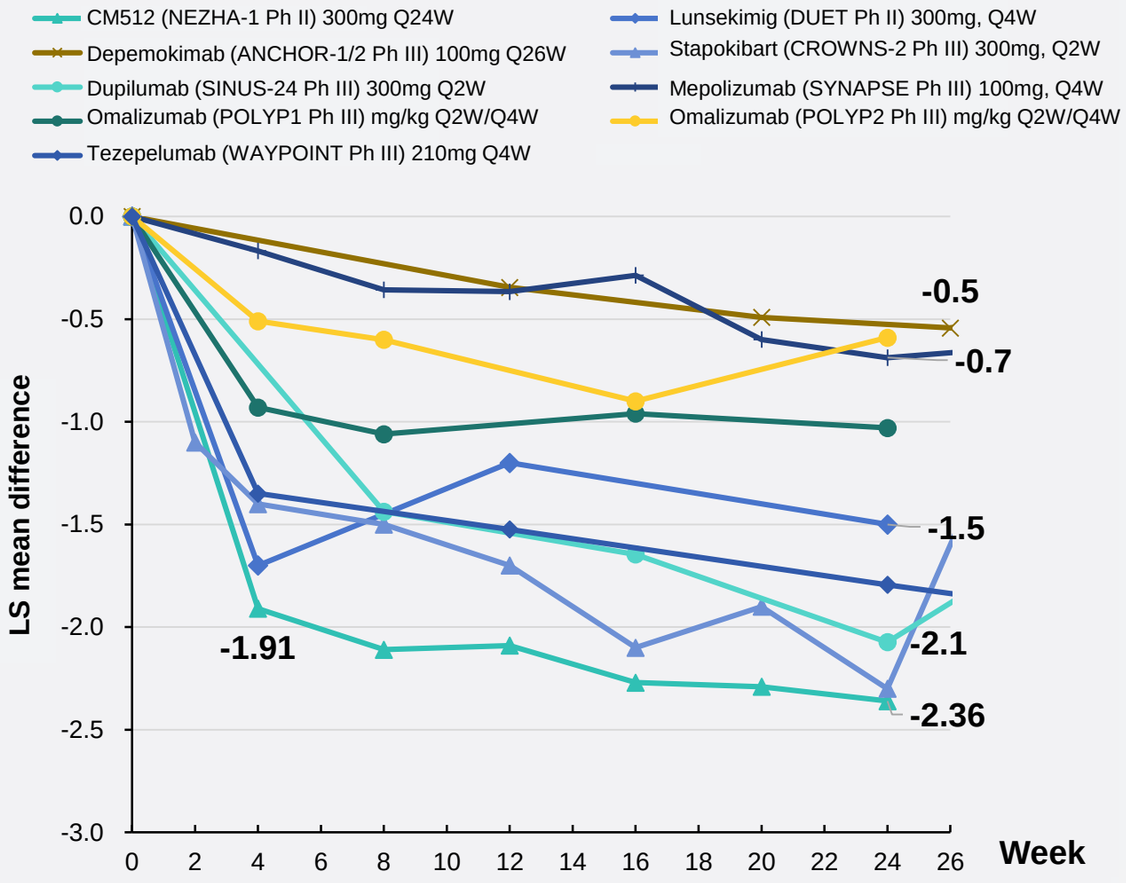
Zero serious adverse events with CM512 during treatment; anti-drug antibody (ADA) incidence was extremely low.

Supported by these Phase II results, the Company is rapidly starting a CRSwNP Phase III trial, with 300 mg **dose** once every six months (Q24W) as the regimen.

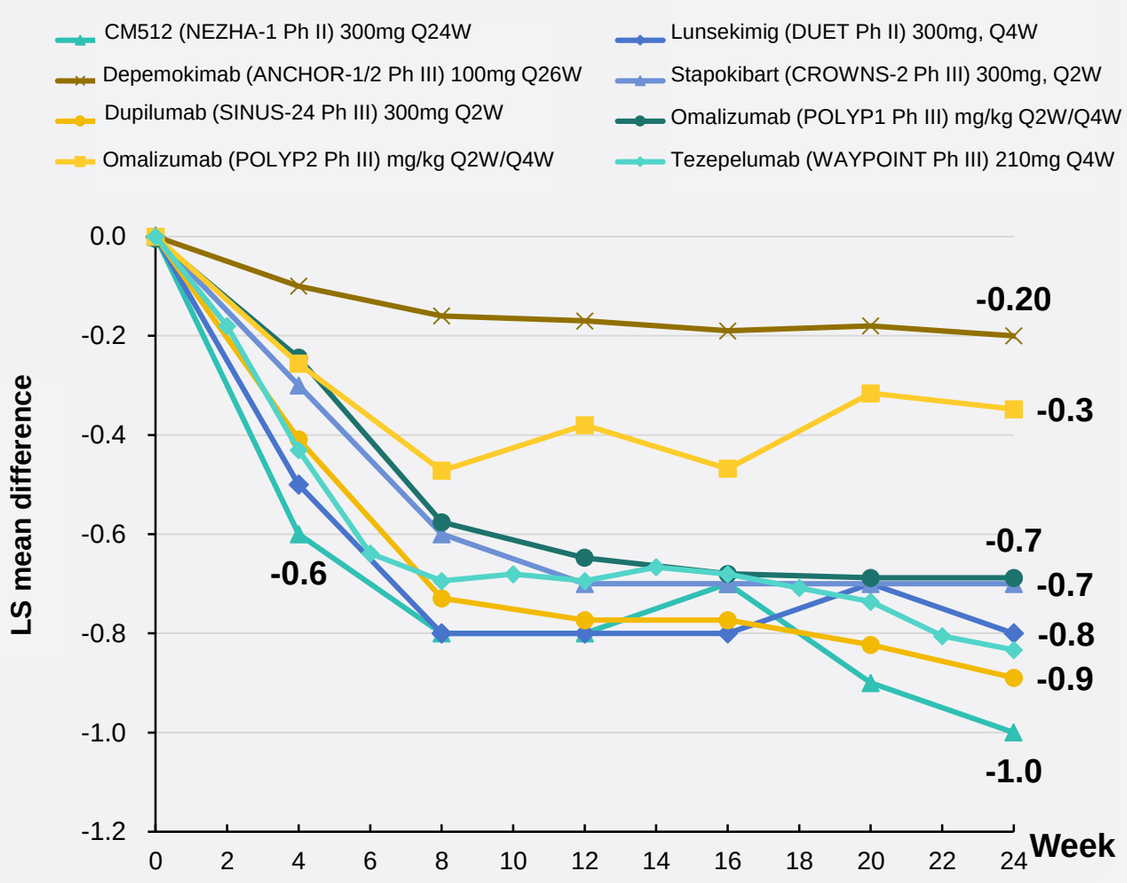
Indication	Clinical stage	Expected enrollment	Expected Progress
CRSwNP BTD from CDE	Phase II	120	Completed
	Phase III	216	Initiated in H2 2026
Moderate-to-severe asthma	Phase II	200	Enrollment to complete by end-2026
Moderate-to-severe COPD	Phase II	204	Enrollment to complete by end-2026
Moderate-to-severe adult AD	Phase II	200	Enrolling
CSU	Phase II	48	Enrollment complete in 2027

CM512: 24-Weekly Dosing; Rapid, Durable Polyp & Congestion Relief

Change from Baseline in Nasal Polyp Score (NPS)



Change from Baseline in Weekly Average NCS



Note: NPS = Nasal Polyp Score; NCS = Nasal Congestion Score. Lower scores indicate less severe disease; "improvement" here denotes a decrease in score.
Marked polyp shrinkage: ≥1-point decrease from baseline in NPS; ≥50% reduction in polyp size: ≥2-point decrease from baseline in NPS.
Improved nasal airflow: ≥0.5-point decrease from baseline in weekly mean NCS; marked improvement in nasal airflow: ≥1-point decrease from baseline in weekly mean NCS.

CM336: Accelerating Ex-China Trials, Adding New Indications

Global Deals & Milestones

Nov 2024

康诺亚 Keymed Biosciences × OURO MEDICINES

CM336（BCMA/CD3 BsAb）
Ex-Greater China rights partnered

US$16m upfront

Plus Ouro minority stake, up to **US$610m** milestones, tiered royalties on net sales

Mar 2026

GILEAD Lakefront biotherapeutics × OURO MEDICINES

Gilead/Lakefront
acquires Ouro Medicines
Total deal value up to
US$2.175bn

Milestones and tiered royalties remain in force

2027E

Clinical progress & indication expansion

Pivotal AIHA & ITP trials expected to start in **2027**

US$273m+

Upfront cash secured

AIHA & ITP: FDA **Fast Track** and **Orphan Drug Designations**

Indication Map: Dozens of Potential Indications

Hematology	Rheumatology	Dermatology	Neurology	Nephrology/Transplant
AIHA	SjD	BP	MG	IgAN
ITP	IIM	PV	CIDP	PMN
APS	RA	DM	NMOSD	AMR
FNAIT	SLE	CLE	MS	DSAs

R&D Progress

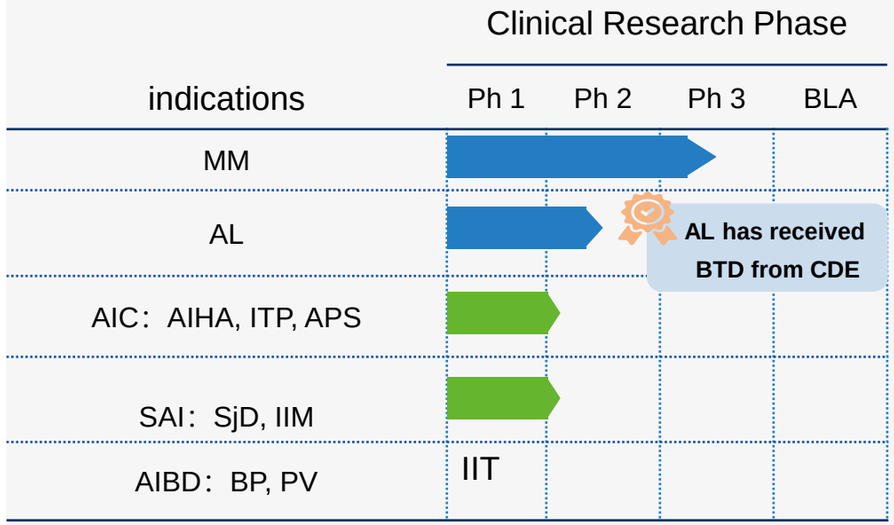
- Phase Ib/IIa
- IIT
- Planned

Note: AD: atopic dermatitis; CRSwNP: chronic rhinosinusitis with nasal polyps; SAR: seasonal allergic rhinitis; GC: gastric cancer; GEJC: gastroesophageal junction cancer; FIH: first-in-human; SAD: single ascending dose; MAD: multiple ascending dose; AIC: autoimmune cytopenia; AIHA: autoimmune hemolytic anemia

CM336: China Pivotal Trials Started in Oncology & Autoimmune

Oncology & Autoimmune Programs

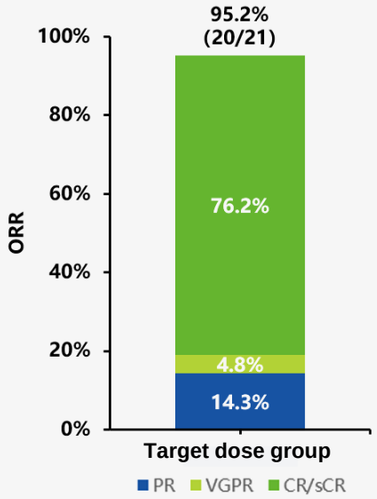
- Subcutaneous dosing, suited to use across many diseases.
- 2L+RRMM: Ph III ongoing.
- Light Chain Amyloidosis: Ph II enrollment accelerating; BLA submission expected in **H2 2027**.
- Autoimmune pipeline advancing rapidly.



Strong Clinical Results

✓ **MM:** In Ph II 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.**




The NEW ENGLAND JOURNAL of MEDICINE

CURRENT ISSUE SPECIALTIES TOPICS

CORRESPONDENCE

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 cytopenias: 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: Anti-CD38 mAb, Potential Best-in-Class in IgAN

Disease-area portfolio & clinical progress

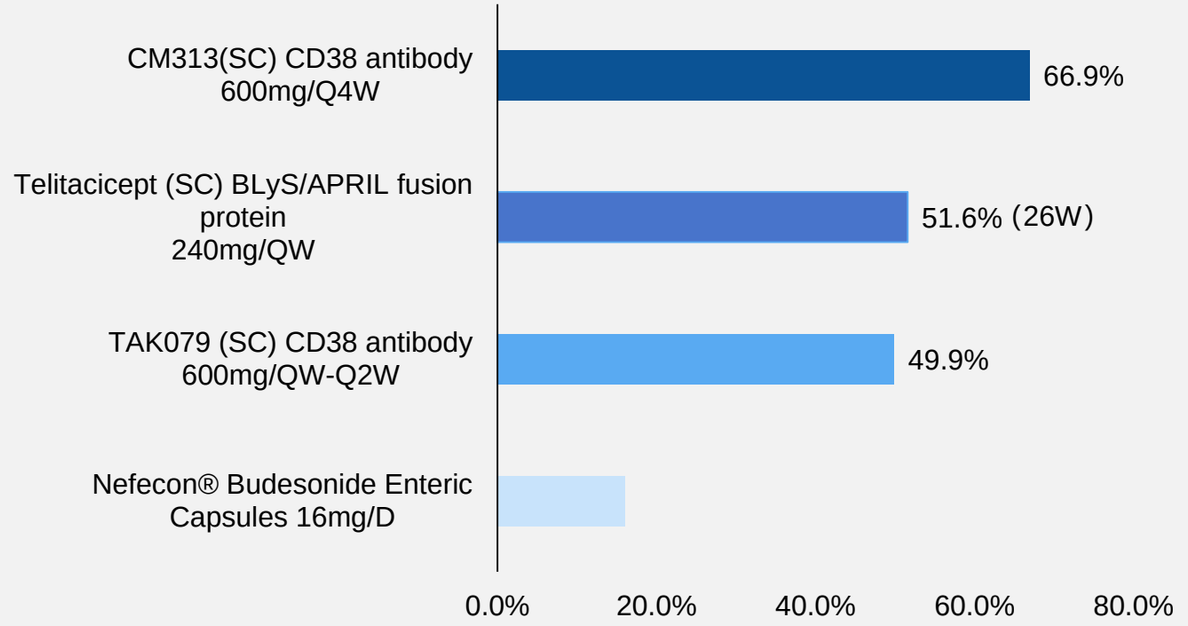
- Phase II IgAN study advancing rapidly; Ph3 initiation expected in 2027.
- Phase I/II RRMM progressing rapidly; subsequent Ph III in 2L+ RRMM with CM336 (BCMA/CD3) to follow

Drug	Indication	Clinical Stage: Ph 1	Ph 2	Ph 3
CM313 CD38 mAb	IgAN	➡		
	RRMM	➡		
	2L+ RRMM (in combo with CM336 BCMA/CD3 bsAb)	➡		
	CIDP	IIT Study		
	SSc	IIT Study		

BIC potential clinical data for IgAN

- Preliminary Phase II 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

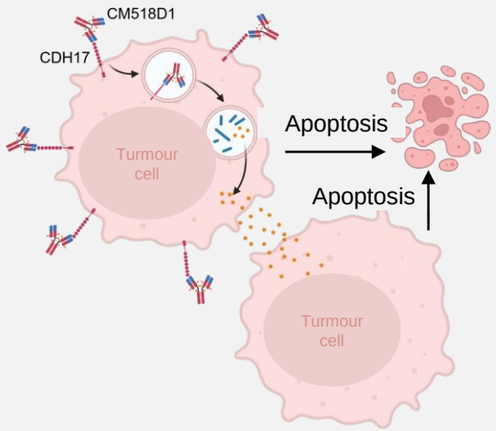


CM313 IgAN DCO: 20260716, Preliminary data;
No head-to-head comparisons across products.

Note: IgAn: IgA Nephropathy RRMM: Relapsed Refractory Multiple Myeloma CIDP: Chronic Inflammatory Demyelinating Polyneuropathy SSC: Systemic Sclerosis; IIT: Investigator-initiated trial

CM518D1: Globally Leading CDH17 ADC, Potentially Best-in-Class

In-House CDH17 ADC



Bystander effect

The next blockbuster ADC target:

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

Potential BIC for GI Tumours

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

Topoisomerase I Inhibitor Advantages:

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

Excellent Preclinical Data

- Potent efficacy: effective dose **<1 mg/kg** in gastric/pancreatic cancer models.
- Safety: HNSTD 30 mg/kg, **safety window >30-fold**, potential best-in-class.

Clinical Progress

- June 2025: Initiated Phase I/II trial in advanced solid tumors (planned enrollment: 434 patients). Phase I data presented at the ESMO.
- July 2025: received FDA IND clearance

Key R&D Milestones Expected in H2 2026 and H1 2027

	H2 2026	H1 2027
Stapokibart **IL-4Rα**	New indications approval √ Adolescent moderate-to-severe AD • Prurigo nodularis	
CMG901 **CLDN18.2 ADC** AstraZeneca	2L+ CLDN18.2+ GC/ AEG √ Global Phase III readout √ Global BLA	
CM512 **TSLP×IL13 BsAb** Belen○s	√ China Phase II readout, Phase III start: CRSwNP √ US Phase Ib readout: Asthma • China Phase II enrollment completed: Asthma, COPD	• Overseas Phase III start: CRSwNP • China Phase III start: Asthma, COPD
CM336 **BCMA/CD3 BsAb**	• Publications: RRMM Phase II clinical data, PV& Light chain amyloidosis IIT data	• Global pivotal trial start: ITP, AIHA • New indications global POC Phase IIa start
CM313 CD38 mAb	• Phase II trial enrollment complete : IgAN	• Phase III start: IgAN
CM518D1 CDH17 ADC	√ Chinese Phase I data presented at ESMO: solid tumours	
IND plans	√ CM529D1 DLL3/SEZ6 bispecific 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;

2027: 2 Approved Products, 10+ Pivotal Trials Expected

Expected Approvals

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

- **Moderate-to-severe AD**
  First domestic; opening the EASI-90 era
- **CRSwNP**
  First in China; opening the biologics era
- **SAR**
  Only one globally; reshaping moderate-to-severe care
- **Adolescent AD**
- **Prurigo Nodularis**

AstraZeneca
CMG901
CLDN18.2 ADC

2L+CLDN18.2+ GC/ AEG (global)

Expected Pivotal Trials

CM512
Long-acting TSLP×IL13 BsAb

- CRSwNP **(CN & US in parallel)**
- Asthma
- COPD

CM313
CD38 mAb

- IgAN

AstraZeneca
CMG901
CLDN18.2 ADC

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

GILEAD Lakefront biotherapeutics
CM336
BCMA/CD3 BsAb

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

Autoimmune & Chronic Diseases
Oncology

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

Commercial Portfolio: From Single-Product Growth to Portfolio-Driven

Keymed Biosciences | 2016-2026 KEYMED 10th

Approved | Stapokibart: Adult AD, CRSwNP, SAR, Adolescent AD

Oncology
Autoimmune & Chronic Disease

China Approved
Ex-China Approval

	2027E	2028E	2029E	2030E
Stapokibart Kangyueda 康悦达® IL-4Rα mAb	Adult AD CRSwNP SAR Adolescent AD PN	Adult AD CRSwNP SAR Adolescent AD PN Pediatric AD	Adult AD CRSwNP SAR Adolescent AD PN Pediatric AD Adolescent SAR	Adult AD CRSwNP SAR Adolescent AD PN Pediatric AD Adolescent SAR
CM512 TSLP/IL-13 BsAb			CRSwNP	CRSwNP Asthma
CM313 CD38 mAb				IgAN
CM336 BCMA/CD3 BsAb		AL	AL ITP PV	AL ITP AIHA 2L+ RRMM PV
CMG901 CLDN18.2 ADC	2L+ GC/AEG	2L+ GC/AEG 2L+ BTC	2L+ GC/AEG 2L+ BTC	2L+ GC/AEG 2L+ BTC 1L GC/AEG/EAC

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.

Published Academic Papers



Key Academic Publications

Stapokibart



1 Stapokibart SAR Phase III results published in *Nature Medicine*

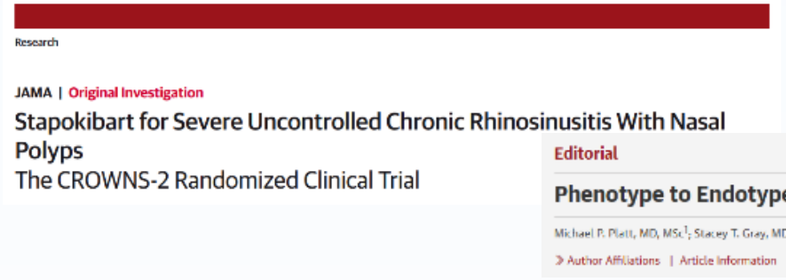

nature medicine

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

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

Title: Stapokibart for moderate-to-severe seasonal allergic rhinitis: a randomized phase 3 trial
Journal: Nature Medicine

2 CRSwNP Phase III results published in JAMA
Same-day JAMA editorial backs stapokibart as practice-changing


Research

JAMA | Original Investigation

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

Editorial

Phenotype to Endotype—The Future of Chronic Rhinosinusitis

Michael P. Platt, MD, MSc[1]; Stacey T. Gray, MD[2]; Anju T. Peters, MD[3]

Author Affiliations | Article Information

Title: Stapokibart for Severe Uncontrolled Chronic Rhinosinusitis With Nasal Polyps: The CROWNS-2 Randomized Clinical Trial
Journal: JAMA (The Journal of the American Medical Association)

3 Stapokibart adult moderate-to-severe AD Phase III results published in *Allergy*


Allergy WILEY

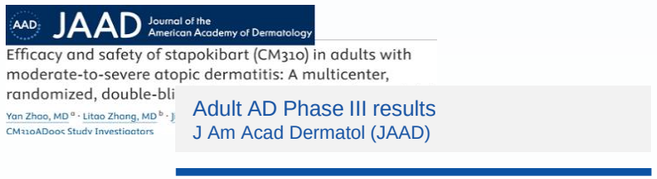
ORIGINAL ARTICLE

Atopic Dermatitis, Urticaria and Skin Disease

Long-term efficacy and safety of stapokibart for moderate-to-severe atopic dermatitis: 52-week results from a phase 3 trial

Title: Long-term efficacy and safety of stapokibart for moderate-to-severe atopic dermatitis: 52-week results from a phase 3 trial
Journal: Allergy

More publications

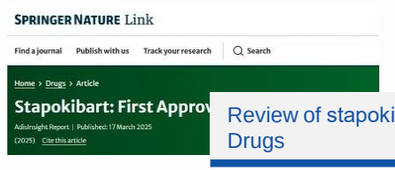

JAAD Journal of the American Academy of Dermatology

Efficacy and safety of stapokibart (CM310) in adults with moderate-to-severe atopic dermatitis: A multicenter, randomized, double-bli

Yan Zhao, MD[a] · Litao Zhang, MD[b] ·

CM310ADooc Study Investigators

Adult AD Phase III results
J Am Acad Dermatol (JAAD)


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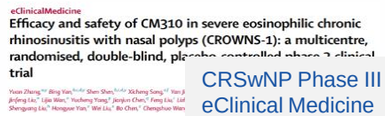
Home > Drugs > Article

Stapokibart: First Approv

Adisinsight Report | Published: 17 March 2025

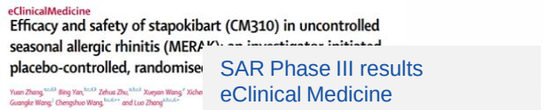
(2025) Cite this article

Review of stapokibart's development
Drugs


eClinicalMedicine

Efficacy and safety of CM310 in severe eosinophilic chronic rhinosinusitis with nasal polyps (CROWNS-1): a multicentre, randomised, double-blind, placebo-controlled phase 3 clinical trial

CRSwNP Phase III results
eClinical Medicine


eClinicalMedicine

Efficacy and safety of stapokibart (CM310) in uncontrolled seasonal allergic rhinitis (MERA

placebo-controlled, randomise

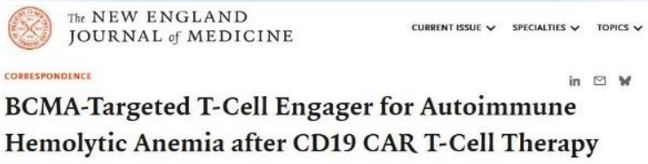
SAR Phase III results
eClinical Medicine

Key Academic Publications (cont.)

Other Key Products

Clinical Papers

CM336 (BCMA×CD3 BsAb) in autoimmune hemolytic anemia: published in NEJM

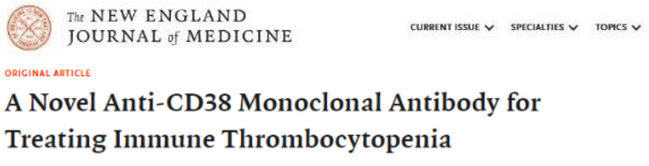

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

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

Title: BCMA-Targeted T-Cell Engager for Autoimmune Hemolytic Anemia after CD19 CAR T-Cell Therapy
Journal: The New England Journal of Medicine

CD38 mAb CM313 in immune thrombocytopenia: published in NEJM

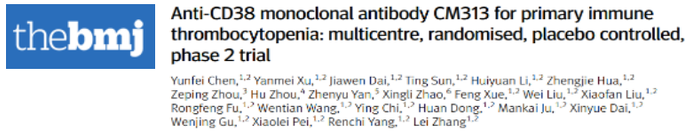

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Novel Anti-CD38 Monoclonal Antibody for Treating Immune Thrombocytopenia

Title: A Novel Anti-CD38 Monoclonal Antibody for Treating Immune Thrombocytopenia
Journal: The New England Journal of Medicine

CD38 mAb CM313 in immune thrombocytopenia: published in The BMJ


thebmj

Anti-CD38 monoclonal antibody CM313 for primary immune thrombocytopenia: multicentre, randomised, placebo controlled, phase 2 trial

Yunfei Chen,[1,2] Yanmei Xu,[1,2] Jiawen Dai,[1,2] Ting Sun,[1,2] Huiyuan Li,[1,2] Zhengjie Hua,[1,2] Zeping Zhou,[3] Hu Zhou,[4] Zhenyu Yan,[5] Xingli Zhao,[6] Feng Xue,[1,2] Wei Liu,[1,2] Xiaofan Liu,[1,2] Rongfeng Fu,[1,2] Wentian Wang,[1,2] Ying Chi,[1,2] Huan Dong,[1,2] Mankai Ju,[1,2] Xinyue Dai,[1,2] Wenjing Gu,[1,2] Xiaolei Pei,[1,2] Renchi Yang,[1,2] Lei Zhang[1,2]

Title: Anti-CD38 monoclonal antibody CM313 for primary immune thrombocytopenia: multicentre, randomised, placebo controlled, phase 2 trial
Journal: The BMJ

CMG901, a potential world-first Claudin 18.2 ADC: published in The Lancet Oncology


THE LANCET Oncology

This journal Journals Publish Clinical Global health Multimedia Events About

ARTICLES · Volume 26, Issue 2, P227-238, February 2025 Download Full Issue

Claudin 18.2-targeting antibody–drug conjugate CMG901 in patients with advanced gastric or gastro-oesophageal junction cancer (KYM901): a multicentre, open-label, single-arm, phase 1 trial

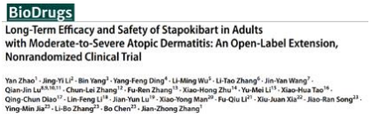
Title: Claudin 18.2-targeting antibody–drug conjugate CMG901 in patients with advanced gastric or gastro-oesophageal junction cancer (KYM901): a multicentre, open-label, single-arm, phase 1 trial Journal: The Lancet Oncology


American Journal of Hematology AJH

CORRESPONDENCE Free Access

CM313 Monotherapy in Patients With Relapsed/Refractory Multiple Myeloma or Marginal Zone Lymphoma: A Multicenter, Phase 1 Dose-Escalation and Dose-Expansion Trial

Title: CM313 Monotherapy in Patients With Relapsed/Refractory Multiple Myeloma orMarginal Zone Lymphoma: A Multicenter, Phase 1 Dose-Escalation and DoseExpansion Trial
Journal: American Journal of Hematology


BioDrugs

Long-Term Efficacy and Safety of Stapokibart in Adults with Moderate-to-Severe Atopic Dermatitis: An Open-Label Extension, Nonrandomized Clinical Trial

Title: Long-Term Efficacy and Safety of Stapokibart in Adults with Moderate-to-SevereAtopic Dermatitis: An Open-Label Extension, Nonrandomized Clinical Trial
Journal: BioDrugs


International Journal of Dermatology

LETTER TO THE EDITOR

Stapokibart Rapidly and Consistently Improves the Clinical Signs Across All Body Regions in Adults With Moderate-to-Severe Atopic Dermatitis

Title: Stapokibart Rapidly and Consistently Improves the Clinical Signs Across All Body Regions in Adults with Moderate-to-Severe Atopic DermatitisJournal: International Journal of Dermatology


Chinese Medical Journal

Efficacy and safety of CM310 in moderate-to-severe atopic dermatitis: A multicenter, randomized, double-blind, placebo-controlled phase 2b trial

Title: Efficacy and safety of CM310 in moderate-to-severe atopic dermatitis: A multicenter, randomized, double-blind, placebo-controlled phase 2b trial Journal: Chinese Medical Journal


ORIGINAL RESEARCH ARTICLE

Translational Investigation of CM326 from Preclinical Studies to Randomized Phase I Clinical Trials in Healthy Adults

Title: Translational Investigation of CM326 from Preclinical Studies to Randomized Phase I Clinical Trials in Healthy Adults
Journal: BioDrugs


Advances in Therapy

Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Stapokibart in Healthy Volunteers and Adult Subjects with Atopic Dermatitis

Title: Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Stapokibart in Healthy Volunteers and Adult Subjects with Atopic Dermatitis
Journal: Advances in Therapy

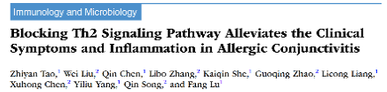
Non-clinical Papers


Cell Reports Medicine CellPress OPEN ACCESS

Article

CMG901, a Claudin18.2-specific antibody-drug conjugate, for the treatment of solid tumors

Title: CMG901, a Claudin18.2-specific antibody-drug conjugate, for the treatment of solid tumors
Journal: Cell Reports Medicine | Impact factor: 11.7


Immunology and Microbiology

Blocking Th2 Signaling Pathway Alleviates the Clinical Symptoms and Inflammation in Allergic Conjunctivitis

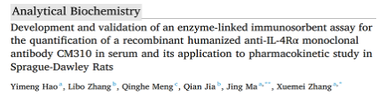
Title: Blocking Th2 Signaling Pathway Alleviates the Clinical Symptoms and Inflammation in Allergic Conjunctivitis
Journal: Investigative Ophthalmology & Visual Science
| Impact factor: 5


iScience CellPress OPEN ACCESS

Article

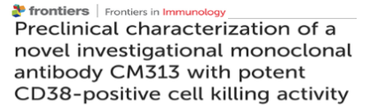
Stapokibart (CM310) targets IL-4Rα for the treatment of type 2 inflammation

Title: Stapokibart (CM310) targets IL-4Rα for the treatment of type 2 inflammation
Journal: iScience | Impact factor: 4.8


Analytical Biochemistry

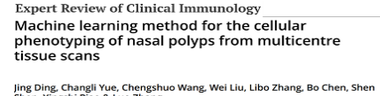
Development and validation of an enzyme-linked immunosorbent assay for the quantification of a recombinant humanized anti-IL-4Rα monoclonal antibody CM310 in serum and its application to pharmacokinetic study in Sprague-Dawley Rats

Title: Development and validation of an enzyme-linked immunosorbent assay for the quantification of a recombinant humanized anti-IL-4Rα monoclonal antibody CM310 in serum and its application to pharmacokinetic study in Sprague-Dawley rats
Journal: Analytical Biochemistry | Impact factor: 2.6


frontiers | Frontiers in Immunology

Preclinical characterization of a novel investigational monoclonal antibody CM313 with potent CD38-positive cell killing activity

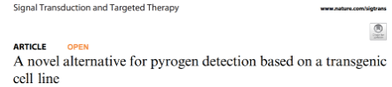
Title: Preclinical characterization of a novel investigational monoclonal antibody CM313 with potent CD38-positive cell killing activity
Journal: Frontiers in Immunology | Impact factor: 5.7


Expert Review of Clinical Immunology

Machine learning method for the cellular phenotyping of nasal polyps from multicentre tissue scans

Jing Ding, Changli Yue, Chengshuo Wang, Wei Liu, Libo Zhang, Bo Chen, Shen Shen, Yingshi Piao & Luo Zhang

Title: Machine learning method for the cellular phenotyping of nasal polyps from multicentre tissue scans
Journal: Expert Review of Clinical Immunology | Impact factor: 3.9


Signal Transduction and Targeted Therapy

ARTICLE OPEN

A novel alternative for pyrogen detection based on a transgenic cell line

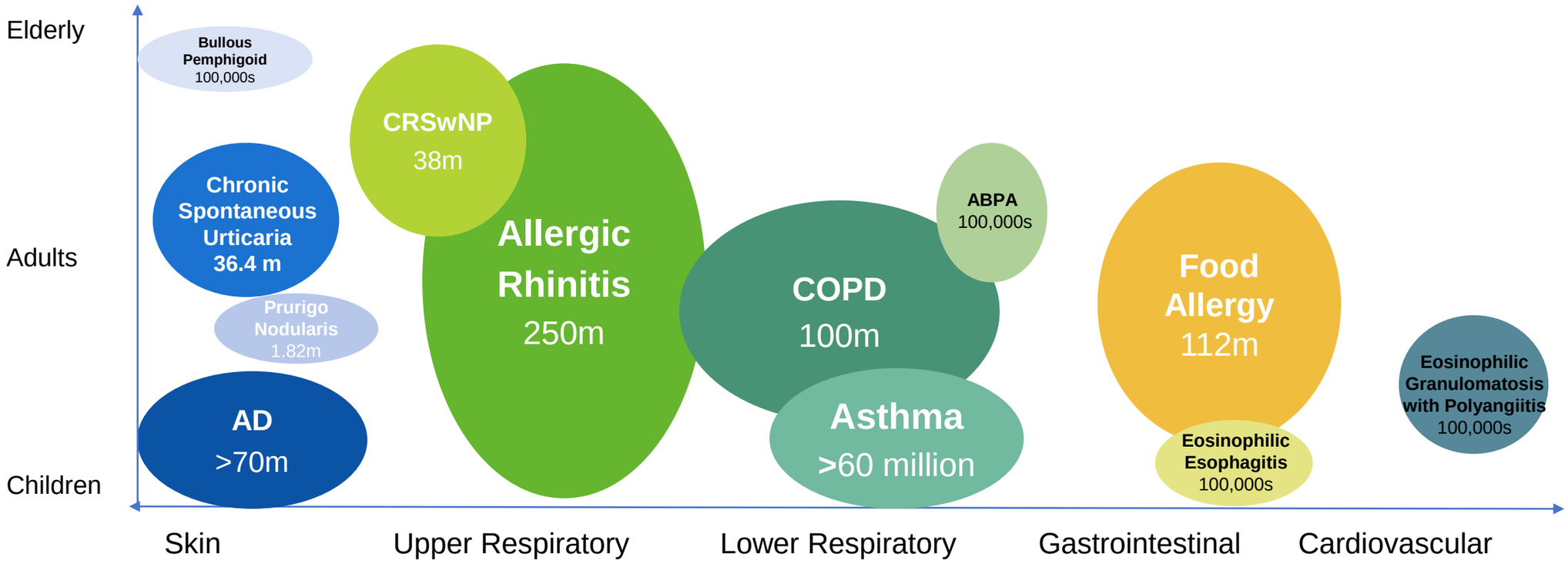
Title: A novel alternative for pyrogen detection based on a transgenic cell line
Journal: Signal Transduction and Targeted Therapy | Impact factor: 40.8

Clinical Data of Kangyueda (康悦达®, Stapokibart)



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 triggers various allergic diseases, including skin, respiratory, gastrointestinal, and cardiovascular and more. **A single drug candidate holds the potential for multiple indications (Pipeline-in-a-Product).**
- China epidemiology: AD prevalence is 4.6% in adults and 13% in ages 1–7, with >70m patients. Allergic rhinitis 250m, food allergy 112m, COPD 100m, asthma >60m, CRSwNP 38m.



Note: ABPA: Allergic Bronchopulmonary Aspergillosis
Data Sources: WHO, Expert Consensus, Diagnosis and Treatment Guidelines, Literature, etc.

Kangyueda (康悦达®) | AD: 1st Domestic, Opening the EASI-90 Era

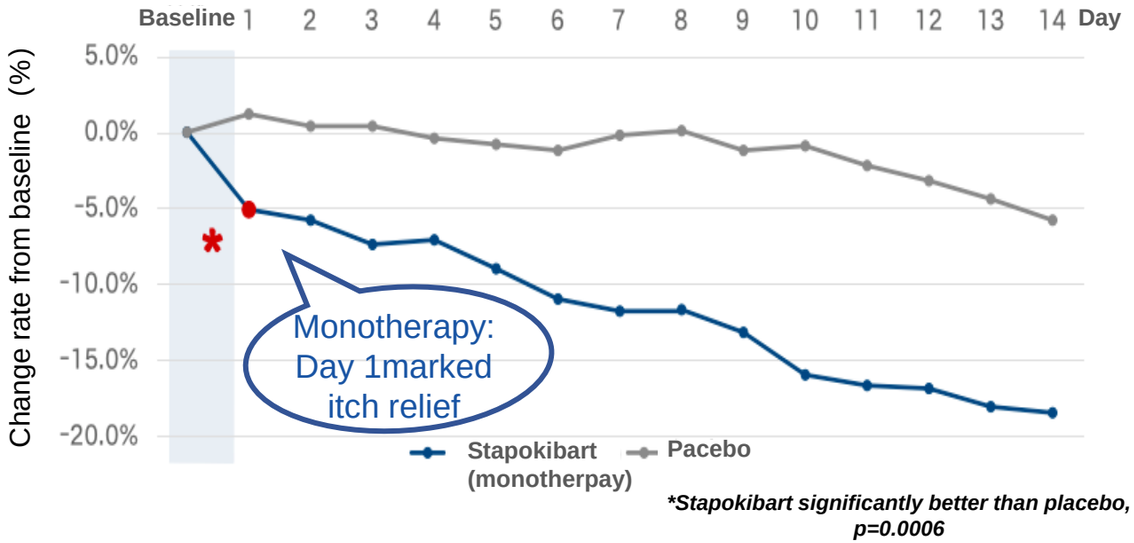
- Phase III trial: 500 patients were randomized 1:1 and dosed every two weeks for 16 weeks (double-blind period); all then received stapokibart for 36 weeks (maintenance period).
- Day 1: marked itch relief after the first monotherapy dose; by Week 2, skin lesions improved strongly across all body regions.

Fast-onset from the first dose

Itch relief within 24 hours of first dose[1]

Day 1

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

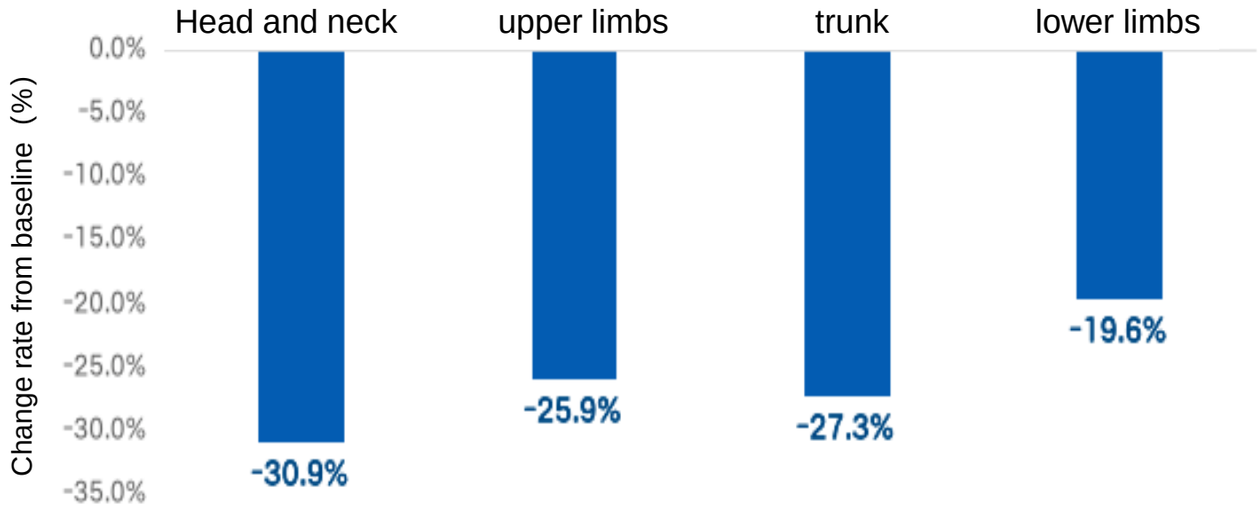


***Stapokibart significantly better than placebo, p=0.0006**

Broad lesion improvement after first dose[2]

Week 2

EASI by body region: % change from baseline



***Stapokibart significantly better than placebo, 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.

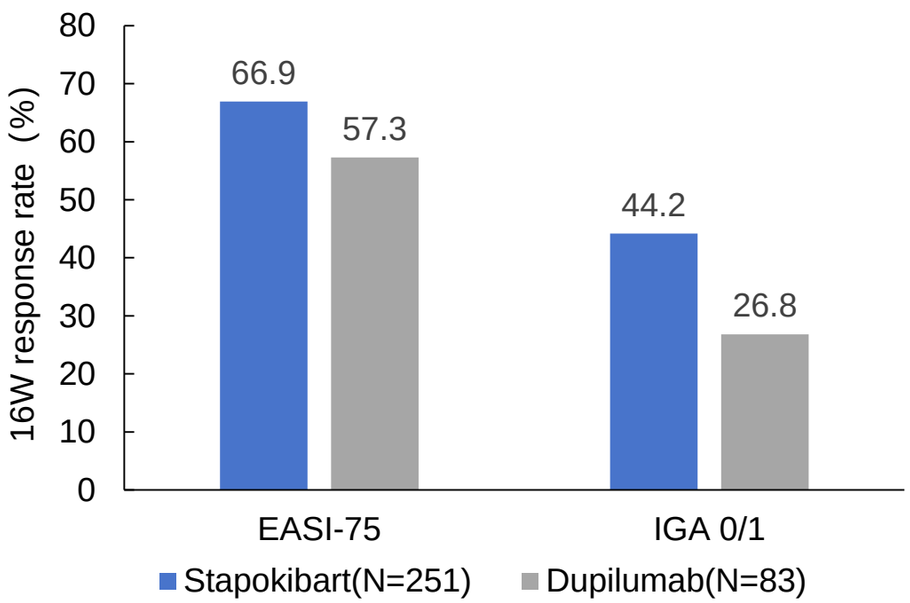
Kangyueda (康悦达®) | AD：1st Domestic, Opening the EASI-90 Era

- **Dual primary endpoints and all secondary efficacy endpoints were met in the Phase III clinical study.** At Week 16, **66.9%** achieved EASI-75 (≥75% improvement in Eczema Area and Severity Index) reached, and **44.2%** achieved IGA 0/1 with a ≥2-point reduction from baseline.
- Week 52: **double "9" efficacy** was achievable, with EASI-75 response at **92.5%** and EASI-90 at **77.1%**.

Potent response, Durable remission

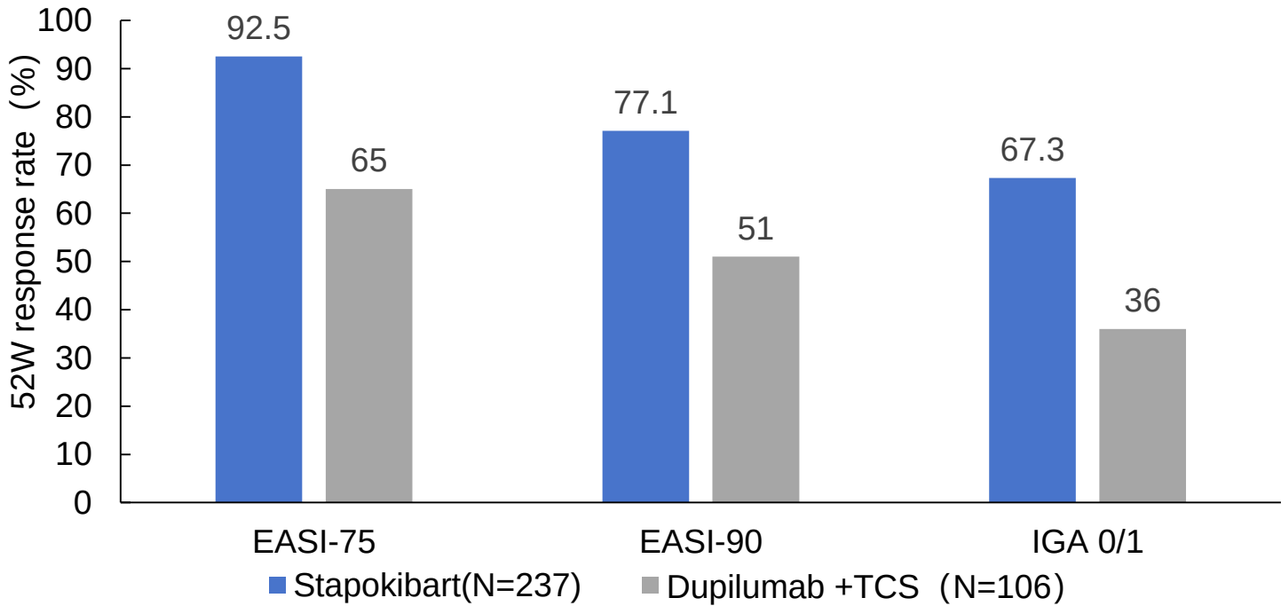
16W

Stapokibart in AD: Phase III primary endpoints (non-head-to-head, **Week 16**)[1]



52W

Stapokibart in AD: Week-52 data comparison (non-head-to-head)[1]



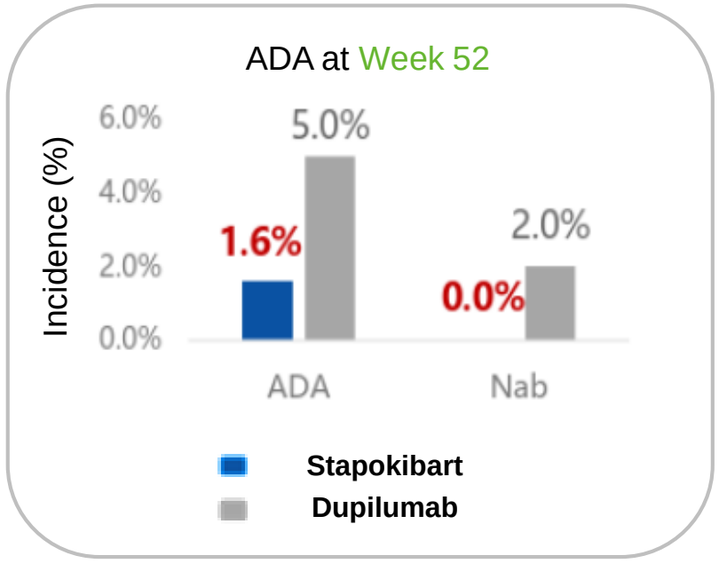
1. Yan Zhao,et al. Allergy. 2025 May;80(5):1348-1357.
2. Andrew Blauvelt,et al. Lancet. 2017 Jun 10;389(10086):2287-2303.

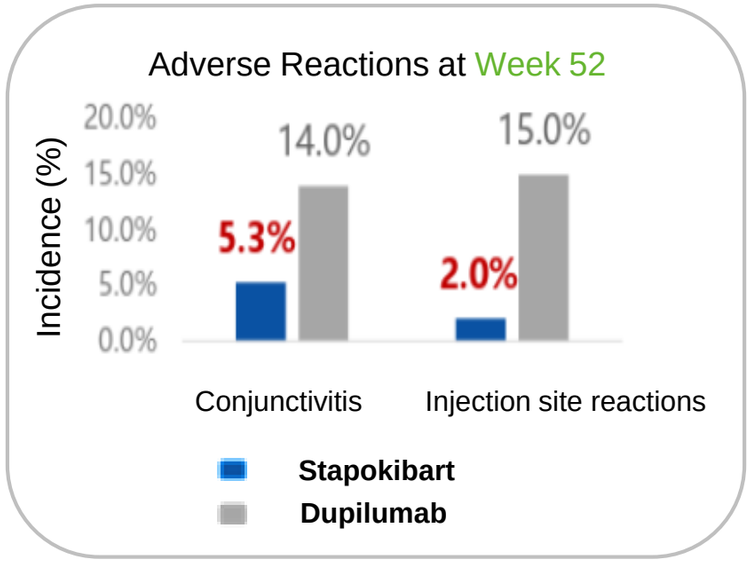
Kangyueda (康悦达®) | AD：1st Domestic, Opening the EASI-90 Era

- **Stapokibart demonstrated a favorable safety and tolerability profile.** Versus dupilumab (same target and indication, widely used), it effectively lowers relapse risk with good safety and tolerability: relapse of only **0.9%** over 52 weeks on treatment and 0.9% at 8 weeks off treatment; conjunctivitis in only **5.3%**.

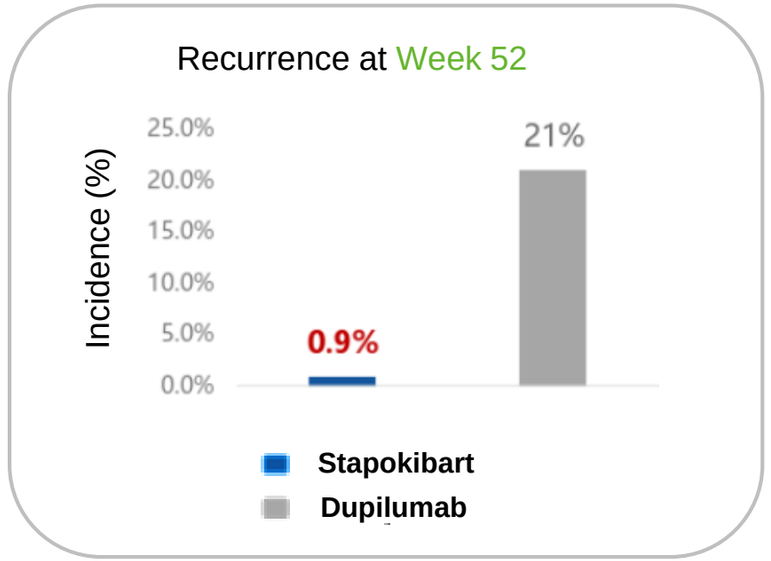
Lower Recurrence Rate and Favorable Safety Profile

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





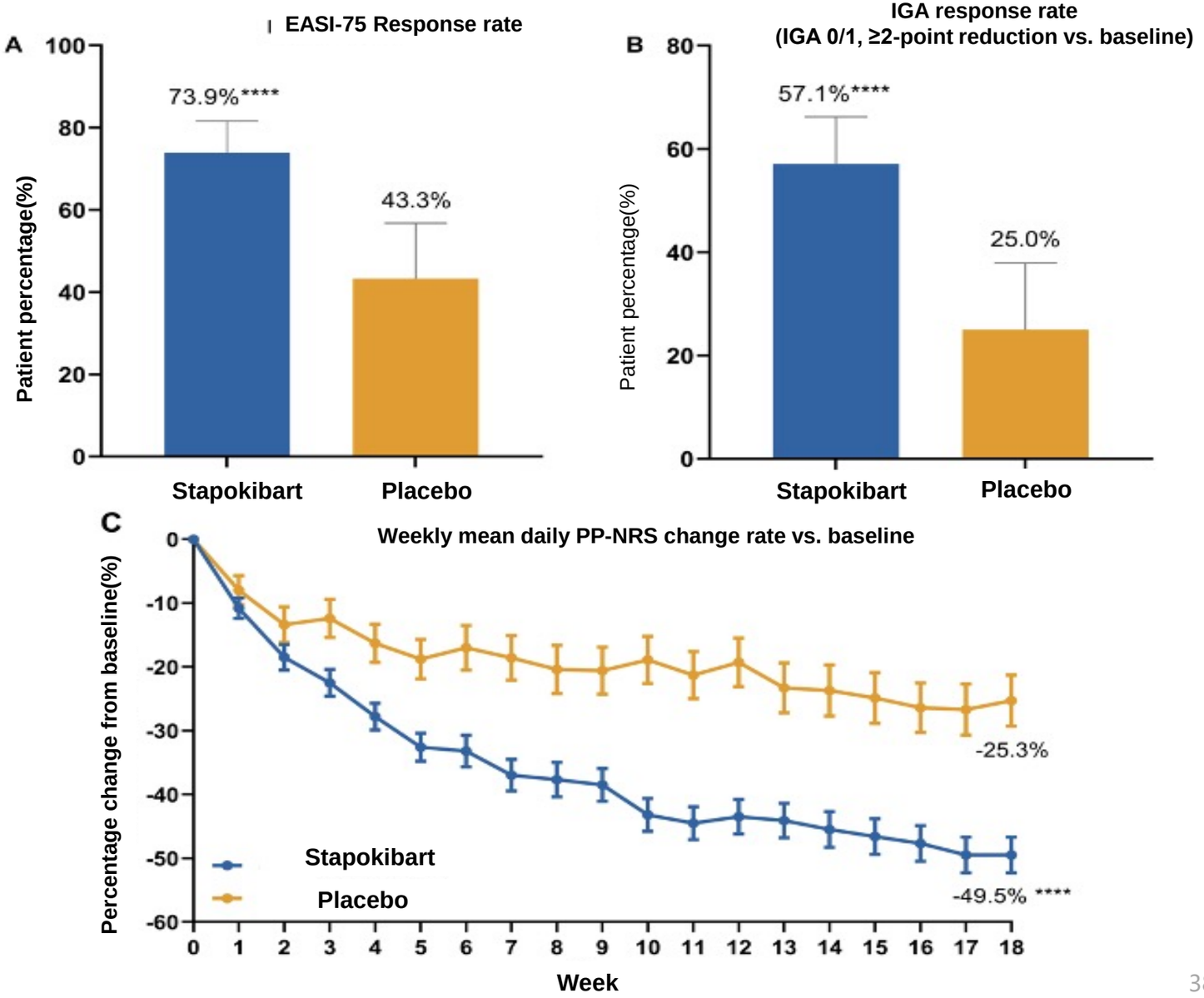
Recurrence Rate Comparison of Stapokibart in AD (Phase III, Non-Head-to-Head)



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.

Kangyueda (康悦达®) | Adolescent AD: 73.9% EASI-75 Response at Week 18 (Phase III)

- Sep 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.**



****p<0.0001 vs placebo.
Source: 34th EADV Congress, Sep 2025

Kangyueda (康悦达®) | CRSwNP: 1st Domestic, Opening a New Era of Biologic Therapy

- 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

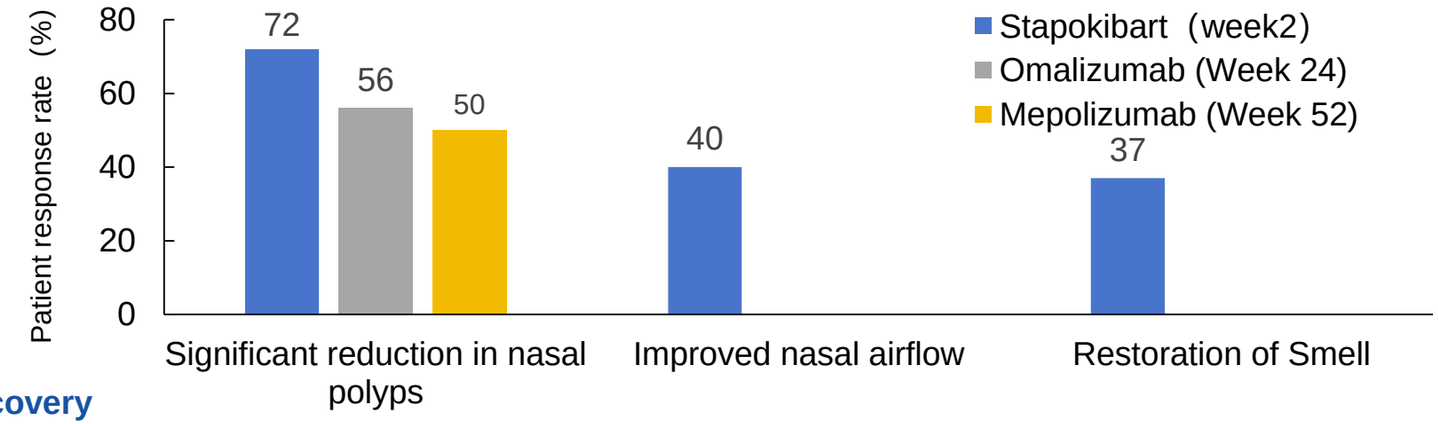
Stapokibart for Severe Uncontrolled Chronic Rhinosinusitis With Nasal Polyps
The CROWNS-2 Randomized Clinical Trial

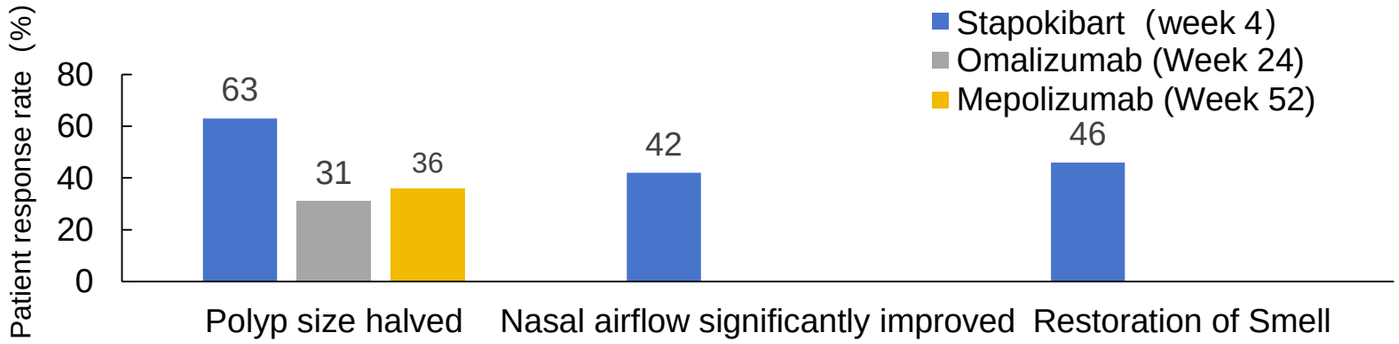
Gold Medal

Geneva International Exhibition of Inventions

1 injection/2W
Quick onset

2 injection/4W
Olfactory recovery





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 at. Lancet Respir Med. 2021 Oct;9(10):1141-1153; Mu Xian et al., Allergy. 2025 Mar 5.;
Stapokibart CRSwNP Phase III clinical study report

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

Kangyueda (康悦达®) | CRSwNP: 1st Domestic, Opening a New Era of Biologic Therapy

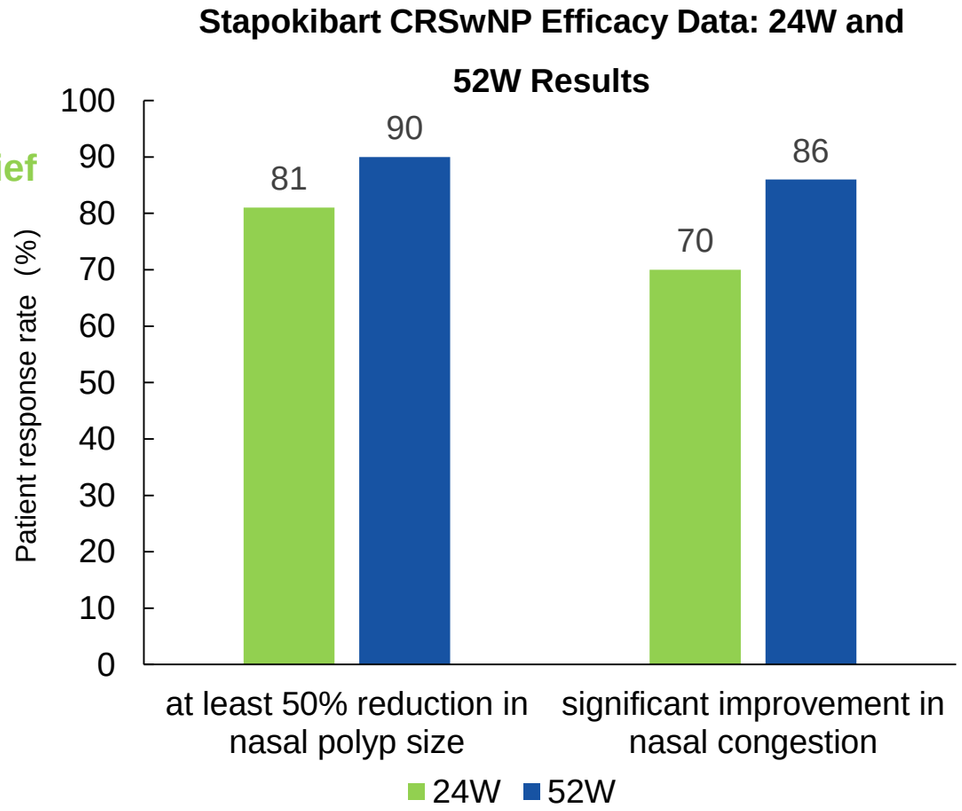
- **All primary endpoints of the Phase III clinical study were met:** At Week 24, 81% of patients achieved ≥50% reduction in nasal polyp size, and 70% achieved significant improvement in nasal congestion.

- At Week 52, **90% of patients achieved ≥50% reduction in nasal polyp volume**. In pivotal Phase III trials of other biologics biologics (dupilumab, mepolizumab, and omalizumab), the NPS response rates were 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

Kangyueda (康悦达®) | SAR: World's Exclusive Solution, Revolutionizing the Treatment Landscape

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)

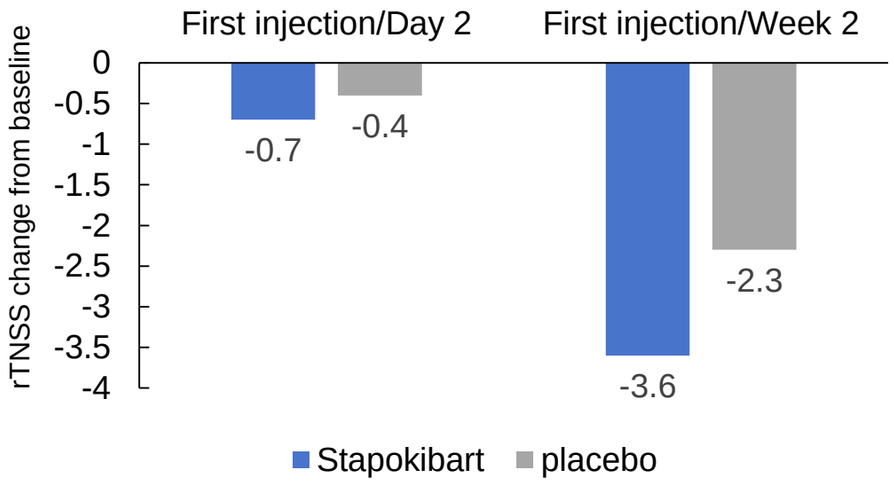
The world's only IL-4Rα antibody approved for SAR

The first biological agent with Phase III data in Chinese population

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

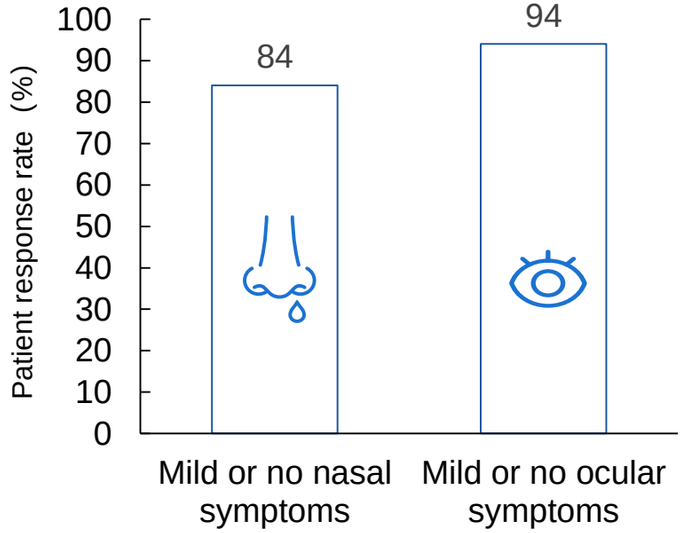
First injection/Day 2 Week 2
Rapid relief of nasal congestion

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 rTNSS is ≤ 1 point.

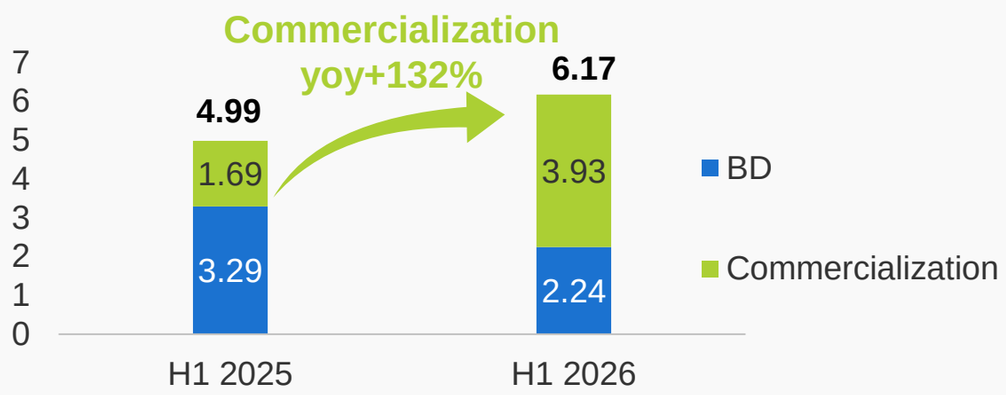
H1 2026 Financial Highlights



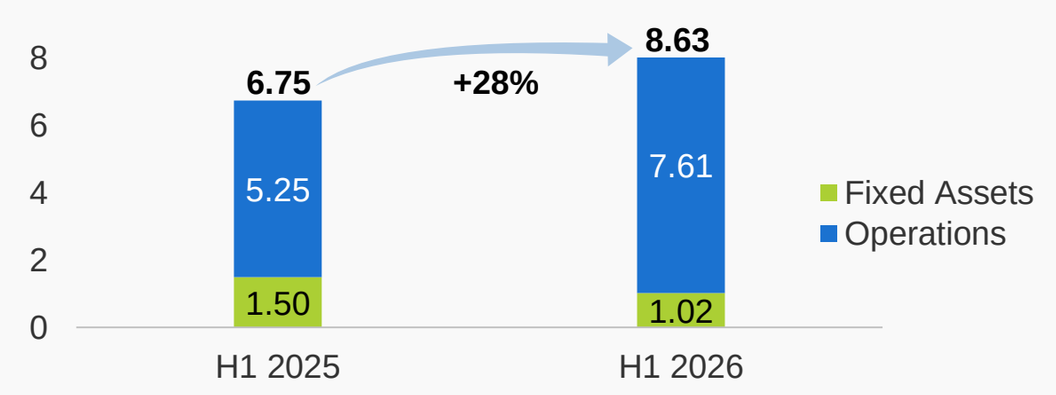
H1 2026 Financials: Robust Results from Commercial Scale-up & NewCo Closed-Loop, Ample Cash

- H1 2026 operating revenue: RMB616m. **Pharmaceutical sales** **(~RMB393m, YoY +132%)** all from Kangyueda®; **partnership revenue (~RMB223M)** chiefly from CMG901 R&D milestones.
- **R&D, G&A and finance expenses** edged down YoY, reflecting solid cost control. **Selling expenses** stood at RMB219m, with Kangyueda® revenue covering both selling expenses and production costs.
- **Net profit:** **RMB1.22bn**, largely from a **RMB1.68bn** gain on disposal of Ouro Medicines equity.
- **Cash on hand** (incl. short-term bank WMPs): **RMB3.24bn** on Jun 30, 2026, versus RMB1.96BN on Dec 31, 2025.

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



Operating Expenses & Fixed-asset CapEx (RMB100m)



Note: 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 RMB1.2bn

(RMB'000)	H1 2026	H2 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.

Keymed Biosciences | 2016-2026 KEYMED 10th

High Tech, High Value

Affordable Innovative Treatment For Everybody!



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