Akesobio

Akeso Inc.
2025 First Half Report

2025.8

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1 Business Highlights

Leading Global IO 2.0 through Innovation and Clinical Advancement

13 Phase III/registrational trials of ivonescimab covering lung cancer and expanding to cold tumors

- The final analysis of HARMONI-A OS showed that ivonescimab achieved clinical endpoints and clinically meaningful and statistically significant OS benefits
- Global Phase III MRCT Harmoni trial

  Global clinical data are highly consistent with Chinese clinical data
- Newly approved 1L lung cancer indication, sNDA of 1L sq-NSCLC accepted by the CDE

10 phase III clinical studies of cadonilimab across lung cancer, gastric cancer, liver cancer and cervical cancer

- Newly approved 1L cervical cancer indication
- Initiated a global multicenter registrational clinical study:

  IO resistant HCC
- Included in more than 20 clinical treatment guidelines and consensus

Penpulimab receives FDA approval in the United States

Ligufalimab (CD47) is conducting trials in both solid tumors and hematological malignancies

Pulocimab (VEGFR-2) is targeting various IO-resistant indications

IO 2.0+ADC 2.0 strategic synergies

Autoimmune innovation enters a new stage of commercialization

Achieving the core strategic goal of commercialization and beginning new journey

- Commercial sales revenue in 2025H1 reached **1.402 billion**, a year-on-year increase **of 49%**
- **2 core bispecific antibodies** included in the NRDL, on goal towards 2000 hospitals by year end. Achieved dual-channel / access in **~85%** of hospitals
- New Commercial Launch in **2** metabolic and autoimmune therapeutics
- Two drivers of growth: commercial improvements in the Oncology Division and the Non-Oncology Division, **with over 1,200** sales staff
- Improving patient access through active participation in national medical insurance programs and expanding coverage by commercial insurance programs

Strong Financial Performance

- 1H 2025 Revenue **1.412** billion, a **33.7%** growth from 1H in 2024
- Cash and short-term financial assets of approximately **7.14** billion
- Continued improvement in Sales and Marketing Efficiency, with S&M expense as a percentage of sales decreased; R&D and administration expense as a percentage of sales decreased

2025 H1 Akeso's New Drug Approval and Commercialization Milestones

4 Commercialized products

Cadonilimab (PD-1/CTLA-4)

Ivonescimab (PD-1/VEGF)

Ebronucimab (PCSK9)

Ebdarokimab (IL-12/IL-23)

2 New Drug Marketing Authorization applications approved

China NMPA approval

Ebdarokimab (IL-12/IL-23)

- Moderate to severe psoriasis

US FDA approval

Penpulimab (PD-1)

- 1L advanced nasopharyngeal carcinoma
- 2L nasopharyngeal carcinoma

2 new Supplemental Indication Applications (sNDA) for Marketed Drugs approved by CDE

The only approved IO drug for 1L cervical cancer for all patient types

Cadonilimab (PD-1/CTLA-4)

- 1L Cervical cancer

First in the World to beat pembro, and the world's best therapy for NSCLC

Ivonescimab (PD-1/VEGF)

- 1L PD-L1(+) non-small cell lung cancer

3 sNDA applications under review

Ivonescimab (PD-1/VEGF)

- 1L locally advanced squamous NSCLC

Penpulimab (PD-1)

- 1L liver cancer

Gumokimab (IL-17)

- Moderate to severe psoriasis

2025 H1 Highlights of Akeso's Pipeline Clinical Development Milestones

9 Newly initiated Phase III / registrational trials

4 Products

Ivonescimab
- 1L CRC
- 1L PD-L1(-) TNBC
- 2L NSCLC (PD-(L)1 resistant)
- Post CCRT LS-SCLC consolidation therapy

Ivonescimab + Ligufalimab (CD47)
- 1L PDAC

Cadonilimab
- CCRT/SCRT progressed NSCLC
- Perioperative G/GEJ
- 2L IO-resistant HCC(global)

Manfidokimab (IL-4Rα)
- Atopic dermatitis in adolescents

6 Phase III clinical trial reached the primary endpoint

Ivonescimab
- 1L advanced sq-NSCLC
- 1L PD-(L)1 + NSCLC
- EGFR-TKI progressed NSCLC (China)
- 3rd gen. EGFR-TKI resistant NSCLC (global)

First global Phase III results readout

First Phase III OS readout - clinically meaningful and statistically significant OS benefits

Gumokimab (IL-17)
- ankylosing spondylitis

Manfidokimab (IL-4Rα)
- Moderate to severe atopic dermatitis

3 Blockbuster new drug candidates entered clinical stage

AK146D1 (TROP-2/ Nectin-4 ADC)

The world's first TROP2/Nectin-4 bispecific antibody ADC

AK139 (IL4 R/ST2)

The world's first IL4R/ST2 autoimmune bispecific antibody

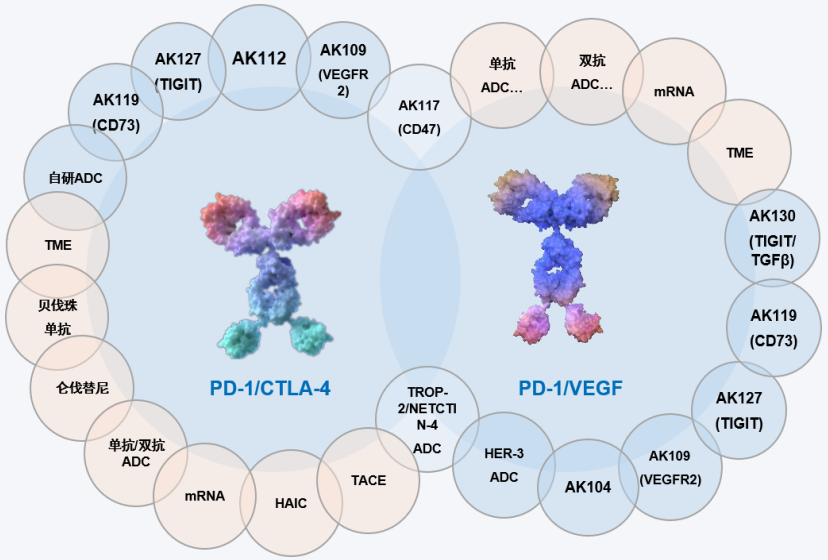
AK138D1 (HER3 ADC)

A new generation differentiated ADC

Two Cornerstone I/O Bispecific Drives Sustainable Competitive Advantage in R&D strategy

Consolidating IO 2.0's leading position

Leveraging two commercial bispecific, Exploring combinations with ICIs, ADCs, mRNA, TME, other platforms



开坦尼 卡度尼利单抗 Cadonilimab

依达方®

Combination with self-developed drugs

Combination with external drugs

IO2.0+ADC 2.0

Advancing through both internal and external collaborations

ADC 2.0 platform advancement

\+ In-house ADC and bispecific ADC entered global Phase I through combo with Cadonilimab and Ivonescimab

\+ Explore combo use with leading ADC around the world

\+ **ADC 2.0 Platform** (bispecific ADC, dual payload, blood stability)

Explore new mechanisms

Key Innovator in Global Rx Trends

Accelerate development of new therapeutic platform

- Trispecific antibody
- Multiple targets
- New MOA

Next Stage in Commercialization : 2 Bispecific Antibodies Entered NRDL, and 2 Non-oncology Launched Commercially

The company's commercial sales revenue RMB 1.402 billion in the first half of 2025, an increase of 49% from 1H 2024

开坦尼® 卡度尼利单抗 Cadonilimab

(PD-1/CTLA-4)

依达方® 依沃西单抗 Ivonoscimab

(PD-1/VEGF)

Aidaluo®

(IL-12/IL-23)

Yixining®

(PCSK9)

Commercial Team Upgrade to Systematic Organization, Professional Sales Force to Drive Access Across Diversified Healthcare Provider

Systematic Sales Organization

- ✓ **Commercial team:** 1,200+ commercial sales team, covering oncology and non-oncology medicine
- ✓ **Systematic operations:** business units separation, market segmentation, professional management, and effective resource allocation

Diversified access

- ✓ **Broad access and coverage:** Both bispecific have achieved coverage in **over 2,000** hospitals , **with ~85%** access in hospital / dual-channel
- ✓ **Active preparation for next year's NRDL, including:**
  - ✓ **Oncology: Three 1L indications for two bispecific antibodies** Cadonilimab cervical cancer, Cadonilimab gastric cancer, Ivonescimab PD-L1 positive non-small cell lung cancer
  - ✓ **Non-oncology:** Ebdarokimab for moderate to severe psoriasis, Ebronucimab for hypercholesterolemia
- ✓ **Simultaneously promote access to local commercial insurance ("Hui Min Bao")**

Specialized market

- ✓ **"Patient care as core priority ",** with focus on **"academic promotion"**
- ✓ Drive business and market share growth through evidence-based clinical data
- ✓ Global value proposition through therapeutic innovation and broad clinical benefits

Cadoinlimab has been recommended in more than 20 authoritative clinical treatment guidelines

Included in more than 20 clinical treatment guidelines and consensus,
covering gynecological cancer, gastric cancer, liver cancer, esophageal cancer, nasopharyngeal cancer, biliary tract cancer

- Widely covered and reimbursed by NRDL
- Expanding adoption and access in 1L treatments
- Active engagement with payers and private insurers

NRDL indications

- 2L + cervical cancer

Approved indications

- 2L + cervical cancer
- 1L gastric cancer
- 1L Cervical cancer

The only immune checkpoint inhibitor approved in China for the first-line indication of persistent, recurrent or metastatic cervical cancer

Cervical cancer: 1L treatment received Category 1 recommendation from multiple authoritative guidelines ; 2L+ immune checkpoint inhibitors received the highest level recommendation

- Chinese Medical Association Guidelines for the Clinical Application of Immune Checkpoint Inhibitors in Gynecological Tumors (2025 Edition): CC 1L is the only Category 1 recommendation; CC 2L+ Category 2A recommendation
- CSCO Guidelines for the Clinical Application of Immune Checkpoint Inhibitors (2025 Edition): CC 1L Class I recommendation; CC 2L+ Class 2A recommendation
- CACA Brachytherapy Committee Guidelines for the Diagnosis and Treatment of Recurrent and Metastatic Cervical Cancer (2025 Edition): CC 1L is the only category 1 recommendation regardless of PD-L1 expression status ; CC 2L+ is a category 2A recommendation

The highest level of recommendation for 1L Gastric cancer, regardless of PD-L1 expression

- CSCO Gastric Cancer Diagnosis and Treatment Guidelines (2025 Edition) regardless of PD-L1 expression Catogory I recommendation
- CSCO Guidelines for the Clinical Application of Immune Checkpoint Inhibitors (2025 Edition) regardless of PD-L1 expression Catogory I recommendation
- CACA Chinese Guidelines for Integrated Diagnosis and Treatment of Oncology - Gastric Cancer (2025 Edition), regardless of PD-L1 expression, priority recommended

Continued recommendation for other therapeutic areas

- The Chinese Medical Association's Guidelines for the Clinical Application of Immune Checkpoint Inhibitors in Gynecological Tumors (2025 Edition) recommends Cadonilimab for the initial treatment
- CACA Guidelines for Integrated Diagnosis and Treatment of Tumors in China – Nasopharyngeal Carcinoma (2025 Edition)
- Chinese Expert Consensus on Immune Checkpoint Inhibitors for Biliary Tract Malignancies (2025 Edition)
- Chinese Expert Consensus on Transformative Treatment of Biliary Tract Malignancies (2025 Edition)
- China CSCO Esophageal Cancer Diagnosis and Treatment Guidelines (2024 Edition)
- China CSCO Nasopharyngeal Carcinoma Diagnosis and Treatment Guidelines (2024 Edition)
- Targeted immunotherapy combined with local treatment for advanced hepatocellular carcinoma Chinese Expert Consensus

Cadonilimab continues to expand clinical presence – higher incidence cancers, multi-line coverage, and combination therapies

开坦尼
卡度尼利单抗 Cadonilimab

Next Generation Cornerstone Immunotherapy
broad-spectrum, high-efficacy, low-toxicity, and differentiated

- Conducted **28+** clinical studies
- Covering **20+** indications
- Global clinical studies initiated...

10 Phase III / registration clinical trials ongoing,
3 Phase III reached clinical endpoints

- More China and global clinical trials under preparation
- Multiple combination therapy explorations are underway : including combination with self-developed / external ADCs , oncolytic viruses, targeted small molecules, and other novel platforms

Cadonilimab continues to expand clinical presence – broader indications, all line coverage, and extensive combination

开坦尼 卡度尼利单抗 Cadonilimab

28+ clinical trials in progress, covering 20+ indications

10 Phase III / registrational clinical studies covering gastric cancer, lung cancer, liver cancer, and cervical cancer

Cervical cancer
(new cases: ~110,000-130,000 / year)

2L+: Approved for marketing and included in NRDL
COMPASSION-13

1L : Approved for marketing in May 2025
COMPASSION-16 (+ chemotherapy ± bevacizumab)

Gastric cancer
(new cases: ~450,000-500,000 / year)

1L : Approved for marketing in September 2024
COMPASSION-15 (+ chemotherapy)

2L IO resistance: enrollment ongoing
COMPLUS-5 (+ pulocimab + chemotherapy)

Perioperative treatment: Newly initiated
COMPASSION-33 (+ chemotherapy)

Lung cancer
(new cases: ~ 1-1.1 million / year)

1L PD-L1(-) : enrollment ongoing
COMPASSION-28 (+ chemotherapy vs PD-1+ chemotherapy)

Unresectable NSCLC after concurrent sequential chemoradiotherapy: enrollment ongoing
COMPASSION-30 (+ chemotherapy vs PD-L1+ chemotherapy)

2L IO- resistant squamous NSCLC : Under preparation

Liver cancer
(new cases: ~ 400,000-450,000 / year)

Postoperative adjuvant therapy: enrollment completed
COMPASSION-22

Intermediate stage HCC: enrollment ongoing
COMPASSION-29 (+ Lenvatinib +TACE)

2L IO resistance: Global registrational Phase II, newly initiated
COMPASSION-36 (+ Lenvatinib)

Epidemiological data source: Based on National Cancer Center database and Frost & Sullivan forecasts

Ivonescimab reshapes lung cancer treatment landscape, accelerating commercial adoption and NRDL access

Global First in Class Redefining Standard of Care

- **Full market coverage for NRDL indication**
- **Expanding access for first-line indication**
- **Establish and improve insurance coverage and diversified payment systems**

Included in NRDL — NSCLC after EGFR-TKI-progression

Newly approved indication in 2025 H1 — 1L PD-L1(+) NSCLC

New indication submitted in 2025, under NDA review — 1L locally advanced squamous NSCLC

8 Authoritative Guidelines Recommendations, Covering Lung Cancer, Biliary Tract Cancer, Etc.

❑ **NSCLC after EGFR-TKI Progression: Included in First Category Recommendation**

✓ CSCO Non-Small Cell Lung Cancer Diagnosis and Treatment Guidelines (2025): Level I Recommendation

✓ CACA Guidelines for Integrative Diagnosis and Treatment of Tumors in China (2025) - Lung Cancer: Consensus Recommendation

✓ Chinese Guidelines for the Treatment of Stage IV Primary Lung Cancer (2024): Level I Recommendation

✓ Chinese Guidelines for the Standardized Application of Immunotherapy in Lung Cancer (2024): Class I Evidence

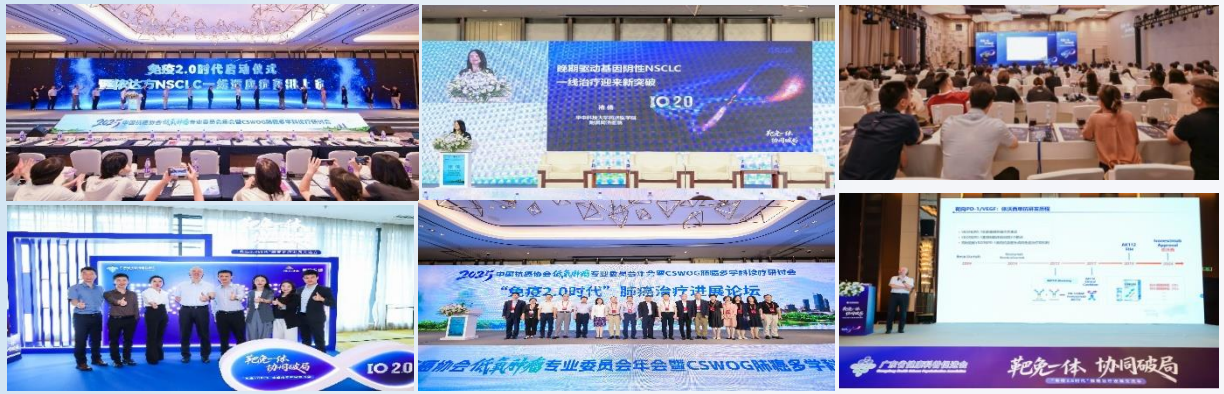
❑ **Driver gene-negative 1L NSCLC: Newly Added to Guidelines**

✓ CSCO Non-Small Cell Lung Cancer Diagnosis and Treatment Guidelines (2025): TPS ≥ 1%, Squamous & Non-Squamous Cell Carcinoma Level II recommendation

✓ CACA Guidelines for Integrative Diagnosis and Treatment of Tumors in China (2025) - Lung Cancer: Recommendation

❑ **Biliary Tract Cancer: First Inclusion in Expert Consensus**

- Chinese Expert Consensus on Immune Checkpoint Inhibitors for Biliary Tract Malignancies (2025)
- Chinese Expert Consensus on Transformative Treatment of Biliary Tract Malignancies (2025)



Ivonescimab can Upgrade Standard of Care Across Multiple Cancers, Leading IO 2.0 in China and the World

Next Generation Cornerstone Immunotherapy
broad-spectrum, high-efficacy, low-toxicity, and differentiated

Broaden & solidify leadership in lung cancer markets, expand benefit to multiple types of cancer , and upgrade current best-in-class or standard-of-care

依达方
依沃西单抗 Ivonescimab

30+ clinical trials,
30*+ indications

13 phase III registrational trials ongoing,
4 achieved primary endpoints

6 head-to-head phase III trials vs. PD-(L)1 therapies

- **Additional Phase III Global and China trials** ongoing
- Combination studies* with ADCs, bispecific ADCs, small molecules, mRNA vaccines

* Includes indications and studies from collaborations with external partners

Ivonescimab Leadership in IO 2.0, Full Coverage of Global Lung Cancer Markets across Different Treatment Lines

依达方 依沃西单抗 Ivonescimab

8 phase III trials on lung cancer, 4 achieved positive results

First phase III MRCT delivers positive results, showing high consistency in the data across global and Chinese studies

1L	1L PD-L1-positive / high-expression NSCLC	1L sqNSCLC + nsqNSCLC
	China **Harmoni-2/AK112-303** 1L PD-L1 positive (TPS≥1%) NSCLC ***Ivonescimab vs pembrolizumab*** **Approved in April 2025**	**China** **Harmoni-6/AK112-306** 1L locally advanced sqNSCLC ***Ivonescimab + chemo vs tislelizumab + chemo*** **Positive PFS read-out in April 2025, sNDA in July 2025**
	Global **Harmoni-7/AK112-3007** 1L PD-L1 high (TPS≥50%) NSCLC ***Ivonescimab vs pembrolizumab*** **Enrollment ongoing**	**Global** **Harmoni-3/AK112-3003** 1L metastatic sqNSCLC+nsqNSCLC ***Ivonescimab + chemo vs pembro + chemo*** **Enrollment ongoing**
2L	**Post EGFR-TKI progression** ***(Chinese population: ~45%)***	**Post PD-1/L1 resistance** ***(est. new market > $ 19 billion)***
	China **Harmoni-a/AK112-301** ***Ivonescimab + chemo vs chemo*** **Approved, in NRDL, PFS & OS dual endpoints reached**	**China** **Harmoni-8a/AK112-305** sqNSCLC+nsqNSCLC ***Ivonescimab plus chemo vs chemo*** **Enrollment ongoing**
	NSCLC after 3rd-gen EGFR-TKI progression ***(US/EU population ~15%)***	**Post cCRT Limited Stage-SCLC consolidation therapy**
	Global **Harmoni** ***Ivonescimab plus chemo vs chemo*** **Global and Chinese data highly consistent**	**China** **AK112-311** Post cCRT LS-SCLC consolidation therapy ***Ivonescimab vs. placebo*** **Enrollment ongoing**

cCRT: concurrent chemoradiotherapy; SCLC: small cell lung cancer

Ivonescimab Expands into “Cold Tumors”, Broadening Benefit Across Multiple First Line Indications

依达方 依沃西单抗 Ivonescimab

Broad indication layout, 5 phase III trials ongoing

1L biliary tract cancer *(~ $5.7 billion market)*

AK112-309/Harmoni-GI1
Ivonescimab + chemo vs. durvalumab + chemo
Enrollment completed

1L pancreatic cancer *(~ $9 billion market)*

AK112-310/Harmoni-GI2
Ivonescimab + chemo ± ligufalimab vs chemo
Enrollment ongoing

1L PD-L1(-) TNBC *(~ $2 billion market)*

AK112-308/Harmoni-BC1
Ivonescimab + chemo vs. chemo
Enrollment ongoing

1L colorectal cancer *(~ $18 billion market)*

AK112-312/Harmoni-GI3
Ivonescimab + chemo vs bevacizumab + chemo
Enrollment ongoing

1L PD-L1(+) Head and Neck* *(~ $3 billion market)*

AK117-302/Harmoni-HN1
Ivonescimab + ligufalimab vs Keytruda
Enrollment ongoing

HNSCC: head and neck squamous cell carcinoma

Additional tumor types

Phase III global/China clinical trials in preparation

Epidemiological data source: Research Nester, Modor Intelligence, Global Market Insights, Data Bridge Market

Penpulimab Approved by US FDA for Two Indications: Key Milestone in International Development and Approval

In April 2025, Penpulimab approved by US FDA for

- ✓ 1L nasopharyngeal carcinoma
- ✓ 2L+ nasopharyngeal carcinoma

AACR ANNUAL MEETING 2025 CHICAGO — Global Phase III data published in April 2025

- ➢ Akeso's first self-developed innovative biologic approved by US FDA
- ➢ The First US FDA-approved innovative biologic fully independently led by a Chinese company throughout the entire process (R&D, clinical trials, manufacturing, supply, and regulatory filing)

Approved indications	2L+ classical Hodgkin Lymphoma		1L squamous non-small cell lung cancer		2L+ nasopharyngeal carcinoma
Newly approved in 2025 H1	1L nasopharyngeal carcinoma		1L nasopharyngeal carcinoma 2L+ nasopharyngeal carcinoma		**US FDA approval**
Under NDA review	1L liver cancer				

Commercial Expansion into Non-Oncology Medicine: Ebdarokimab (IL-12/IL-23) Approved and Launched for Plaque Psoriasis

爱达罗® (Ebdarokimab, IL-12/IL-23)

China's first and only self-developed innovative IL-12/IL-23 dual-target monoclonal antibody

6.7 million Chinese psoriasis patients

USD 9.5bn Chinese market size*

Approved in April 2025

Indication: Moderate to severe plaque psoriasis

Excellent short-term efficacy
Significant improvement after 2 doses

- ✓ Strong and durable efficacy
  - ✓ Short-term and potent skin lesion clearance
  - ✓ Long-term high response
- ✓ Only four doses per year for safety and convenience
- ✓ Better outcomes in patients with comorbidities (cardiovascular, metabolic diseases)

Strong & sustained long-term efficacy
Quality of life improvement

** Data source: Frost & Sullivan, 2017-2030 China Psoriasis Drug Market*
Ebdarokimab: AK101-302 Phase III (52-week) data published in 2024 EADV 1 – PHONEX 1

Ebronucimab (PCSK9) Expands Non-Oncology Franchise

伊喜宁® (ebronucimab, PCSK9)
The only mAb focus on ultra-high-risk cardiovascular populations

110 million Chinese hypercholesterolemia patients

USD1.34bn Chinese market value*

Benefit across all Patients: regardless of stratification (ultra-high, very high, high, or mediate-low risk), and regardless of LDL-C level or other indicators

Approved in Sept. 2024

Indications:

- **Primary hypercholesterolemia and mixed hyperlipidemia**
- **Heterozygous familial hypercholesterolemia (HeFH)**

Key Benefits

- ✓ **High Rate in LDL-C reduction**: **> 90%**
- ✓ **Rapid Onset**: Peak concentration reached in **2 days**
- ✓ **Potent Effect**: **66%** LDL-C Reduction at Week 12
- ✓ **Comprehensive Benefits:** Significantly reduction in non-HDL-C, Lp(a), ApoB and TC levels
- ✓ **Sustained Response:** Long-term and stable reduction of LDL-C, with maximum reduction **> 70%**

Guidelines / Expert Consensus

- ✓ Chinese Expert Consensus on Comprehensive Management of Lipid-Related Cardiovascular Risk (2025)
- ✓ County-level Guidelines for Rational Medication Use and Comprehensive Management of Dyslipidemia (2025)

** Data source: Frost & Sullivan, Estimated PCSK9 Chinese market in 2023*
Ebronucimab AK102-301 Phase III data published in Pharmacological Research 2– LAPLACE-2, ODYSSEY

Gumokimab (IL-17): NDA Under Review for Psoriasis, and Primary Endpoints Reached for Ankylosing Spondylitis

Psoriasis

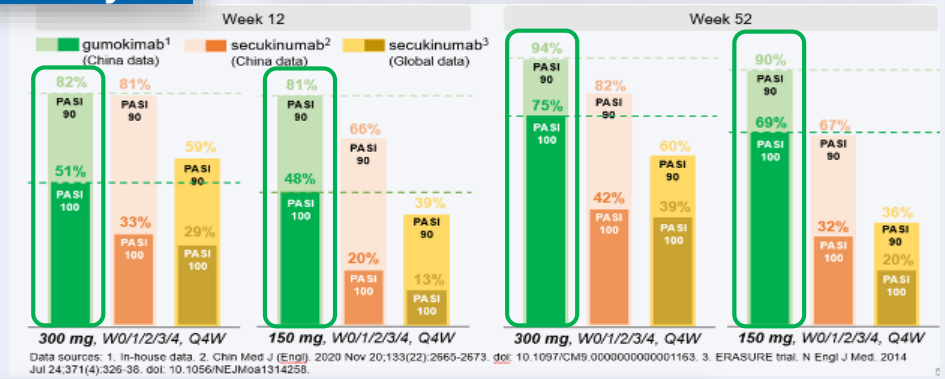
NDA accepted by CDE in Jan 2025

Indication:

- Moderate to severe plaque psoriasis

Best-in-class efficacy

At W12 and W52, both PASI90 and PASI100 response rates outperform secukinumab



Convenient dosing and durable efficacy

6.7 million Chinese psoriasis patients

USD 9.5bn Chinese market value*

** Data source: Frost & Sullivan, 2017-2030 China Psoriasis Drug Market*

Ankylosing Spondylitis

Phase III Positive Results

- Primary and secondary efficacy endpoints reached, with clinically meaningful and statistically significant improvements
- Plan to present data at an academic conference

Regulatory Filing Plan

NDA planned in 2026

~4 million Chinese ankylosing spondylitis patients

USD 90bn Chinese market value**

*** Data source: Frost & Sullivan and epidemiological data, estimated market size in 2030*

2

Core R&D progress

Cadonilimab Approved in First-Line Treatment of Cervical Cancer, Reshaping the Treatment Landscape

COMPASSION-13
Cadonilimab monotherapy
2L+ Cervical cancer

Approved by NMPA in June 2022
Included in NRDL in January 2025

- **The world's first approved dual checkpoint inhibitor for cancer treatment**
- **Filling the gap in IO drugs for advanced cervical cancer in China**

Phase II registrational clinical data published

THE LANCET Oncology

ANNUAL MEETING ON WOMENS' CANCER® BUILDING BRIDGES // BREAKING BARRIERS

CR **13.4%**, ORR **33%**, mPFS **3.75m**, mOS **17.5m**

Data cutoff : August 2021

COMPASSION-16
Cadonilimab + chemotherapy ± bevacizumab
1L cervical cancer

New indication approved in May 2025

- **The only approved IO drug for 1L CC in China**
- **Significant efficacy across entire population, filling treatment gap for cervical cancer with low or negative PD-L1 expression**

Phase III data published at

IGCS 2024 Annual Global Meeting DUBLIN | THE LANCET | 2025 ASCO ANNUAL MEETING

CR **35.6%** vs 22.9%; ORR **82.9%** vs 68.6%

mPFS **13.3m** vs 8.2m, HR **0.62** — PFS data cutoff : Sep 2023

mOS **NR** vs 22.8m, HR **0.64** — OS data cutoff : April 2024

Cadonilimab is Advancing for Lung Cancer, Targeting the PD-1 Market

COMPASSION-28
Cadonilimab + chemotherapy
1L PD-L1(-) NSCLC

Phase II/III clinical trial enrollment ongoing

vs PD-1 + chemotherapy

Continue the unique and differentiated treatment benefit in
PD-L1 negative population

COMPASSION-30
Cadonilimab concurrent sequential chemoradiotherapy for NSCLC

Phase II/III clinical trial enrollment ongoing

vs PD-L1 + chemotherapy

The current standard of care has limited effect on improving overall survival, and there is still a huge unmet clinical need

COMPLUS-6
Cadonilimab + Pulocimab
IO-resistant squamous NSCLC

Breakthrough Therapy Designation in April 2025

Cadonlimab + Pulocimab

Chemo-free

Cadonilimab + ivonescimab
NSCLC

Phase II data demonstrated
Superior efficacy and safety profile

Phase III trial in planning

Cadonilimab + chemotherapy
1L PD-L1(-) NSCLC (N=47)

IIT study data published at

AACR ANNUAL MEETING 2025 CHICAGO

2024 World Conference on Lung Cancer

ORR 66.0% (sq 87.0%/ nsq 45.8%)

DCR 100%

Data cutoff: March 2025

Cadonilimab + Pulocimab
IO-resistant squamous NSCLC (N=26)

Phase II data will be published at

2025 World Conference on Lung Cancer

mPFS 7.1m , mOS 16.7m

Data cutoff: January 2025

Cadonilimab Reshape 1L Treatment of Gastric Cancer and has Broad Coverage of Gastric Cancer with Multiple Indications

COMPASSION-15
Cadonilimab + chemotherapy
1L G/GEJ adenocarcinoma

Approved in September 2024

Bringing a new and effective treatment option to all patients, addressing the huge unmet clinical needs of patients with low or negative PD-L1 expression

COMPLUS-5
Cadonilimab+ Pulocimab + chemo
IO-resistant G/GEJ adenocarcinoma

Phase III clinical trial enrollment ongoing

Significant clinical unmet need
Expected to become the best solution to overcome IO resistance in gastric cancer

COMPASSION-33
Cadonilimab + chemo
perioperative G/GEJ adenocarcinoma

Phase III clinical trial enrollment ongoing

Significant market potential for entire population of patients with resectable gastric cancer

Phase II data will be presented at an upcoming academic conference

COMPASSION-15 Cadonilimab + chemotherapy 1L G/GEJ adenocarcinoma

Phase III data published at nature medicine; AACR ANNUAL MEETING 2024 • SAN DIEGO

ITT mPFS 7.0m vs 5.3m, HR 0.53
mOS 15.0 vs 10.8m, HR 0.62
CPS<5 PFS HR 0.6 vs 0.93[1]/0.83[2]/ 0.82[3]
OS HR 0.7 vs 0.94[1] /0.85[2] / 0.89[3]
CPS<1 PFS HR 0.6 vs 0.93[1] /0.9[2] / 0.8[3]
OS HR 0.84 vs 0.92[1]/0.92[2]/1.01[3]

Data cutoff: April 2023

Note: 1- Checkmate-649, 2-Keynote-859, 3-Rationale-305

COMPLUS-5 Cadonilimab+Pulocimab+chemo IO-resistant G/GEJ adenocarcinoma

Phase II data published at 2024 ASCO ANNUAL MEETING

ORR 48%/ 16%[1] , DCR 96%/ 64%[1]

mPFS 6.8m/ 2.9m[1] , mOS 13.0m/ 7.4m[1]

Update data cutoff: Feb 2025

Note: 1. RAINBOW, Paclitaxel

Advancing Three Registrational Trials of Cadonilimab for Liver Cancer Initiating First Global Registrational Study

COMPASSION-22
Cadonilimab
HCC postoperative adjuvant therapy

Phase III clinical trial enrollment has been completed

Currently, no IO drug is approved in this indication globally, demonstrating significant unmet clinical need

COMPASSION-29
Cadonilimab + Lenvatinib + TACE
Intermediate-stage HCC

Phase III clinical trial enrollment ongoing

Addressing high heterogeneity of liver cancer, angiogenesis and liver function damage caused by liver cancer embolization

Potential to effectively control tumor progression and bring durable survival benefits

COMPASSION-36
Cadonilimab + Lenvatinib
IO- resistant HCC

Approved by US FDA to start the global multi-center registrational trial

Expanding global clinical and commercial value

Cadonilimab + Lenvatinib
1L HCC

Phase II data published at ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

6mg/kg Q2W: mPFS 8.61m, mOS 27.1m

15mg/kg Q3W: mPFS 9.82m, mOS NR

Data cut-off: February 2023, median follow-up: 27.4 months

Cadonilimab + Lenvatinib + TACE
Intermediate-stage HCC

Phase II data published at 

6-month recurrence-free survival rate ~75.6%
9-month recurrence-free survival rate ~60.4%

Data cutoff: August 2023

Ivonescimab's First Global Phase III Trial Received Positive Results Consistency Across Global Data to be Released at WCLC 2025

AK112-301 / HARMONi-A: Ivonescimab+ chemotherapy EGFR-TKI resistant NSCLC

The first indication approved in May 2024

Successful inclusion in NRDL in 2025

Significant PFS benefit

mPFS 7.1m vs 4.8m , HR 0.46

Subgroup with prior use of third-generation TKI PFS HR: 0.48

Data cutoff: March 2023

Significant OS benefit

- **Final OS analysis showed ivonescimab reached clinical endpoint, demonstrating clinical benefit and statistical OS benefit**

Data cutoff: July, 2025

HARMONi: Ivonescimab + chemotherapy 3rd Gen EGFR-TKI resistant NSCLC

2025 World Conference on Lung Cancer

Data will be presented at the Plenary Chair's Symposium and officially released as an oral report

Global data consistency

- Harmoni and Harmoni-A results are consistent , demonstrating the consistent clinical efficacy of Ivonescimab across regions and ethnic groups
- ~38% of patients were from Europe and USA, consistent with the patient distribution of previous similar global Phase III studies.

PFS Dual significance

PFS HR 0.52 (P < 0.0001)
Statistically significant, significant clinical benefit

OS Benefit Trend

OS HR 0.79
Clear trend of OS benefit

Data announcement date: May 30, 2025

Ushering the Era of Global IO 2.0 - Ivonescimab Approved for First-Line Monotherapy of PD-L1 Positive NSCLC

AK112-303 / HARMONi-2 :
Ivonescimab monotherapy vs. Pembrolizumab monotherapy
1L PD-L1(+) NSCLC

Indication approved in April 2025

Entering 1L treatment of lung cancer, providing patients with a better chemo-free treatment

---

The primary clinical endpoint of PFS showed statistically significant and substantial clinical benefit

PFS HR 0.51, Ivonescimab group mPFS 11.14m compared to the Pembrolizumab group 5.82m, significant improved PFS for 5.3m

PFS subgroups All showed positive results

PFS HR

- Squamous **0.48** , Non-squamous **0.54**
- With / without liver metastasis **0.47 / 0.53**
- With / without brain metastasis 0.55 / 0.53
- PD-L1 TPS 1-49% 0.54
- PD-L1 TPS ≥ 50% 0.46

Data cutoff: January 29, 2024

Significant clinical benefit

OS analysis results at (39% event maturity):
OS HR 0.777

Data release time: 2025.4

Good safety

Good overall safety profile, with no new safety signals

- **Overcomes clinical contra-indication**
- **Synergistic effect of IO + anti-angiogenesis delivers superior anti-tumor treatment**

HARMONi-7 **AK112-3007**

Ivonescimab vs. Keytruda

1L PD-L1 TPS ≥ 50% NSCLC

Global Phase III enrollment ongoing

Overcomes Anti-Angiogenesis' Clinical Contra-Indication

Ivonescimab: 1L Sq NSCLC Achieved Strong Positive Phase III Results

AK112-306 / HARMONi-6:
Ivonescimab + chemo vs. Tislelizumab + chemo
1L squamous NSCLC

sNDA submission accepted by NMPA in July 2025

Superior treatment option that overcomes clinical contra-indications and achieves synergistic anti-tumor effects of IO + anti-angiogenesis

Decisively positive result

- The primary endpoint of PFS was achieved , with statistically significance and substantial clinical benefit, OS data is not yet matured
- Central squamous cell carcinoma accounts for ~63% which is consistent with the real-world patient distribution

Significant benefits in all subgroups

- Ivonescimab treatment demonstrated clinically significant PFS benefits regardless of PD-L1 positive or PD-L1 negative population

Good safety

- Incidence of treatment-related serious adverse reactions and ≥3 grade bleeding events similar to those in the control group
- Further validating safety of Ivo over VEGF targeting therapies

HARMONi-6 data will be published at BERLIN 2025 ESMO congress

Summit therapeutics
HARMONi-3

Akesobio
AK112-3003

Ivonescimab + chemo (vs Keytruda + chemo)

1L non-small cell lung cancer (squamous + non-squamous)

Global Phase III enrollment is ongoing

Expanding Coverage of the Lung Cancer market: New Phase III Trials for IO-resistant NSCLC and post cCRT LS-SCLC Initiated

AK112-305 / HARMONi-8A: Ivonescimab + chemotherapy IO-resistant NSCLC (sq & nsq)

Phase III clinical trial enrollment ongoing

- **The only bispecific IO therapy currently in registrational Phase III clinical trial for this indication**
- **Most patients face recurrence or drug resistance**
- **Significant and critical unmet need since current standard treatment is still chemotherapy**

USD ~19 bn global market *

Phase II data published at

2022 ASCO ANNUAL MEETING
ADVANCING EQUITABLE CANCER CARE THROUGH INNOVATION

AK112-311 / HARMONi-9: Monotherapy LS-SCLC that has not progressed after cCRT

Phase III clinical trial enrollment ongoing

- **The first Phase III registrational clinical trial in SCLC for Ivonescimab, further expanding coverage in lung cancer market**

USD ~ 5.6 bn global market *

Phase II data will be published in a future academic conference

** Data source: Credence Research, estimated market size of 2030-2032*

Ivonescimab Targets Cold Tumors: Enrollment for New Phase III Trials in 1L Colorectal Cancer and 1L Pancreatic Cancer

AK112-312 : Ivonescimab + chemo 1L MSS/pMMR[1] mCRC

Enrollment ongoing for the phase III trial

- 1L MSS/pMMR mCRC (~95% of patients)
- Current standard of care is chemo±bevacizumab or targeted therapy, with immunotherapy showing limited efficacy
- Significant and critical unmet clinical need

USD ~18bn global market[2]

Phase II data published

BARCELONA 2024 ESMO congress
BARCELONA SPAIN
13-17 SEPTEMBER 2024

AK112-310 : Ivonescimab + chemo ± ligufalimab 1L metastasis pancreatic cancer

Enrollment ongoing for phase III trial

- Chemo is currently the standard of care, and immunotherapy has yet to make a breakthrough in pancreatic cancer
- Significant and critical unmet clinical need

USD ~9bn global market[3]

Phase II data to be presented at upcoming academic conferences

1. Microsatelitte stability/mismatch repair proficient
2. *Data source: Mordor Intelligence, estimated market size in 2030*
3. *Data source: Global Market Insights, estimated market size in 2030*

Ivonescimab: Multiple Phase III Trials for 1L indications

AK112-309: Ivonescimab + chemo vs durvalumab + chemo 1L biliary tract cancer

Enrollment completed for the phase III trial

Challenge global standard of care

Phase II data published

2024 ASCO ANNUAL MEETING

AK117-302: Ivonescimab + AK117 vs pembrolizumab 1L PD-L1(+) Head and Neck*

Enrollment ongoing for the phase III trial

Challenge global standard of care

Phase II data published

BARCELONA 2024 ESMO congress
BARCELONA SPAIN
13-17 SEPTEMBER 2024

AK112-308: Ivonescimab + chemo vs chemo 1L PD-L1(-) TNBC*

Enrollment ongoing for the phase III trial

- **No IO agents approved to date**
- **Differentiated focus on PD-L1 negative populations**

Phase II data published

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

SAN ANTONIO BREAST CANCER SYMPOSIUM DECEMBER 10–13, 2024

*TNBC: Triple-negative breast cancer; Head and neck squamous cell carcinoma

Ligufalimab (AK117, CD47): Two Phase III Trials in Solid Tumors Ongoing and Enrollment Completed for a Global Phase II Trial in Hematologic Cancer

Solid tumor: The world's only CD47 mAb in phase III clinical trials

Enrollment ongoing for **2** registrational phase III trials

1L PD-L1+ HNSCC

AK117-302
Ligufalimab + Ivonescimab (vs Keytruda)
Phase III, enrollment ongoing

1L pancreatic cancer

AK112-310
Ivonescimab + chemo ± Ligufalimab (vs chemo)
Phase III, enrollment ongoing

Combined with Cadonilimab or Ivonescimab in solid tumors

10 clinical trials initiated, covering **8** indications

...

HNSCC: Head and neck squamous cell carcinoma

Hematologic cancer: Enrollment completed for a MRCT phase II randomized double-blind trial

Multiple phase II trials in hematologic cancer progressing efficiently globally and in China

1L MDS

Ligufalimab + Azacitidine
MRCT phase II randomized double-blind
Enrollment completed

1L AML

Ligufalimab + Azacitidine + Venetoclax
Phase II randomized double-blind
Enrollment completed

1L PD-(L)1 resistant cHL

Ligufalimab + AK129 (PD-1/LAG-3)
Phase I/II
Enrollment ongoing

MDS: High-risk myelodysplastic syndrome AML: Acute myeloid leukemia
cHL: Classical hodgkin lymphoma

Pulocimab (VEGFR2): Targeting IO-resistant indications

COMPLUS-5
Pulocimab + Cadonilimab + chemo
IO-resistant G/GEJ adenocarcinoma

Enrollment completed for phase III trial

For second-line treatment of patients progressed on IO + chemo

Significant critical unmet need due to no effective standard of care

Phase II data published

2024 ASCO ANNUAL MEETING

ORR 48%/ 16%[1] , DCR 96%/ 64%[1]

mPFS 6.8m/ 2.9m[1] , mOS 13.0m/ 7.4m[1]

Note:
1. RAINBOW, paclitaxel

Updated data cut-off date: 2025.2

Pulocimab + Cadonilimab
IO-resistant squamous NSCLC

Focus on multiple lines of therapy in lung cancer, advancing into IO-resistant space

Complete Phase II data to be published

2025 World Conference on Lung Cancer

mPFS 7.1m, mOS 16.7m (N=26)

Data cut-off date: 2025.1

Granted breakthrough therapy designation in April 2025

Phase III trial in planning

Manfidokimab (IL-4Rα) Reached Endpoints in the Registrational Phase III Trial for Atopic Dermatitis

Manfidokimab (AK120, IL-4Rα)

Positive efficacy in atopic dermatitis, with **promising clinical potential**

70 million Chinese atopic dermatitis patients

~USD 5bn Chinese market value*

Phase III Positive Results

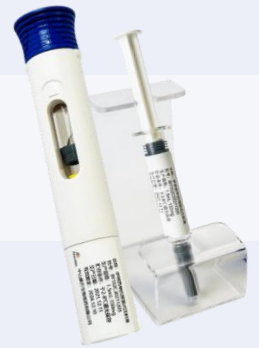
- Achieved positive outcomes in the Phase III trial. The study met all primary endpoints, key secondary endpoints, several pre-specified secondary endpoints, and demonstrated statistically significant and clinically relevant improvements in patients.
- Better efficacy than Dupi.

Regulatory Filing Plan

NDA planned in 2026 H1

Phase I/II clinical study results published in

Phase III results will be published at an upcoming academic conference



Adolescent atopic dermatitis

- Phase II / pivotal Phase III enrollment ongoing

** Data source: Frost & Sullivan's forecast about China's moderate to severe atopic dermatitis drug market in 2030*

Autoimmune Bispecific Antibody AK139 (IL-4Rα/ST2): Phase I

AK139 (IL-4Rα/ST2)

World's first clinical IL-4Rα/ST2 bispecific

Overcome limitation of single cytokines, and benefit a broader patient population

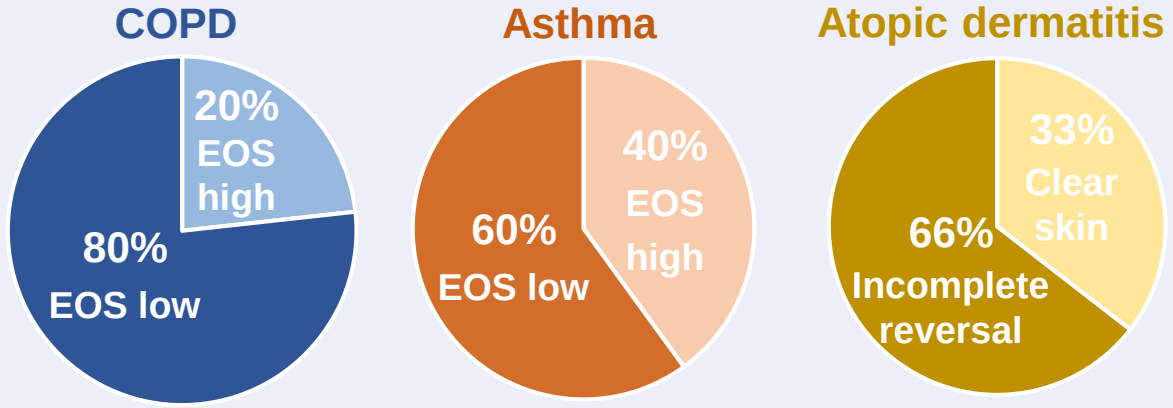
- ✓ Target both IL-4R and ST2, inhibiting multiple cytokines in both Th2 and non-Th2 inflammatory pathways
- ✓ Extended half-life for better patient compliance

- Phase I dose escalation ongoing with good safety profile
- Phase I enrollment expected to complete in 2025 Q3

~USD 8.4bn Chinese COPD market value**

~USD 5bn Chinese atopic dermatitis market value*

Focus on significant unmet medical needs in treatment of respiratory and dermatological autoimmune diseases



- Options for non-eosinophilic COPD and asthma are very limited, yet they account for 60%-80%[1,2] of the market
- Currently approved biologics in atopic dermatitis all target type 2 cytokines, which lead to clear skin only in up to a third of patients[3]

** Data source: Frost & Sullivan's forecast about China's moderate to severe atopic dermatitis drug market in 2030*

*** Data source: Frost & Sullivan's forecast about China's COPD drug market in 2030*

EOS high defined here as ≥300 eosinophil cells per microliter of blood.

1. Lancet Respir Med. 2025 Jan;13(1):47-58. 2. N Engl J Med 2021;384:1800-1809.
3. The Lancet, Volume 405, Issue 10478, 2025, Pages 583-596, ISSN 0140-6736

Discovery Strategies and Therapeutic Platform Development
Focus on Unmet Medical Need

Guided by medical needs and clinical value
Improve R&D success rate for more effective, safer, and accessible innovative therapies

Deep knowledge of disease biology
Prioritize high-potential targets

Select the best drug types and platforms based on molecular mechanisms and treatment approach

Continuously optimize & expand technology platforms

Forward looking investments into broad disease areas, unmet medical needs

- **Oncology**
- **Autoimmune diseases**
- Allergic diseases
- CNS diseases
- Metabolic diseases
- Aging-related diseases
- ……

First-in-class
Best-in-class
Differentiation

- **Multi-specific Ab** — Targeting multiple targets, cell engagers
- **ADC** — Improvements: dual payloads, blood stability
- **Gene therapy** — Tumor vaccines, siRNA, in vivo CAR
- **Targeted drug delivery** — Targeting diseased cells/tissues

“IO 2.0 + ADC” advances into clinical development stage

AK138D1 (HER3 ADC)

Key Features

- Novel cleavable linker with improved plasma stability
- High DAR enables potent cell killing activity and good homogeneity
- Potent cytotoxicity against tumor cells positive for multiple tumor-specific antigens
- Unique CMC process, exploring new ADC R&D directions

Clinical Development

Global
Phase I dose escalation ongoing in AUS

China
Phase I to be initiated

Development Plan

IO 2.0 + ADC
Phase II trials for combination with cadonilimab or ivonescimab in preparation

AK146D1 (Trop2/Nectin4 ADC)

Key Features

- Topoisomerase I inhibitor as payload and novel cleavable linker with improved stability
- Bispecific antibody structure and high DAR deliver stronger antitumor activity, compared with Trop2 ADC or Nectin4 ADC monotherapy

Clinical Development

Global
Phase I dose escalation ongoing in AUS

China
Phase I ongoing

Development Plan

IO 2.0 + ADC 2.0
Phase II trials for combination with cadonilimab or ivonescimab to be initiated

Key Milestones in 2025

Milestones	Assets & Indications		2025H1	2025H2
NDA/sNDA Approval	Ivonescimab	1L PD-L1(+) NSCLC (vs. vs. pembro)	✔	
	Cadonilimab + chemo ± beva	1L CC	✔	
	Ebdarokimab (IL-12/IL-23)	Moderate to severe plaque psoriasis	✔	
	Penpulimab + chemo	1L NPC & 2L+ NPC	✔	
	Penpulimab + Anlotinib	1L HCC		○
Phase III Data Readout / NDA Filing	Ivonescimab + chemo	1L sq-NSCLC (vs. tislelizumab + chemo)	✔	
	Ivonescimab + chemo	NSCLC after 3rd-gen EGFR-TKI progression	✔	
	Penpulimab + Anlotinib	1L advanced HCC	✔	
	Gumokimab (IL-17)	Ankylosing spondylitis *		✔
	Manfidokimab (IL-4R)	Moderate to Severe atopic dermatitis		✔
Phase III Enrollment Complete	Cadonilimab + Pulocimab	PD-(L)1 resistant G/GEJ		○
	Ivonescimab + chemo	1L BTC (vs durvalumab + chemo)		✔
Phase II Enrollment Complete	Ligufalimab + Azacitidine	1L MDS	✔	
	Ligufalimab + Azacitidine + Venetoclax.	1L AML	✔	

global trial/ BLA ✔ completed ○ expect to be completed * **New milestone completed outside the development plan**

Key Milestones in 2025

Milestones	Assets & Indications		2025H1	2025H2
Phase III Initiation	Cadonilimab	Consolidation therapy for NSCLC after CRT	✔	
	Cadonilimab	Perioperative treatment for resectable G/GEJ*		✔
	Cadonilimab	IO resistant HCC*		✔
	Ivonescimab + chemo	1L CRC (vs beva + chemo)	✔	
	Ivonescimab + chemo	PD-(L)1 resistant NSCLC	✔	
	Ivonescimab ± ligufalimab + chemo	1L PDAC	✔	
	Ivonescimab	Consolidation therapy for LS-SCLC*		✔
	Ivonescimab	1L PD-1 TPS≥50%NSCLC	✔	
	Ivonescimab	1L HNSCC	✔	
	Manfidokimab	adolescent AD	✔	
Entry into Phase II	AK129 (PD-1/LAG-3)		✔	
	AK130 (TIGIT/TGF-β)		✔	
	AK131 (PD-1/CD73)		✔	
	AK132 (Claudin18.2/CD47)			○
	AK137 (CD73/LAG3)			○
Entry into Phase I/ IND Application	AK135 (IL-1RAP)		✔	
	AK138D1 (HER3 ADC)		✔	
	AK139 (IL4R/ST2)		✔	
	AK146D1 (Trop2/Nectin4 ADC)		✔	
	AK150 (ILT2/ILT4/CSF1R)			○

global trial/ BLA ✔ completed ○ expect to be completed * **Milestone completed outside the plan**

3

Financial Highlights

2025H1 Financial Highlights

RMB million	2025H1	2024H1	Change %
Revenue[1]	1,411.54	1,055.99	33.67%
Commercial Sales (less distribution cost)	1,401.62	939.43	49.20%
Gross Profit*	1,110.78	889.10	24.93%
R&D	731.24	594.39	
Sales and Market	669.94	515.98	
S&M % **	47.80%	54.93%	
Profit/Loss	(588.28)	(249.35)	
Adjusted EBITDA	(178.33)	(37.4)	

1. **including commercial sales + license income-distribution expense**

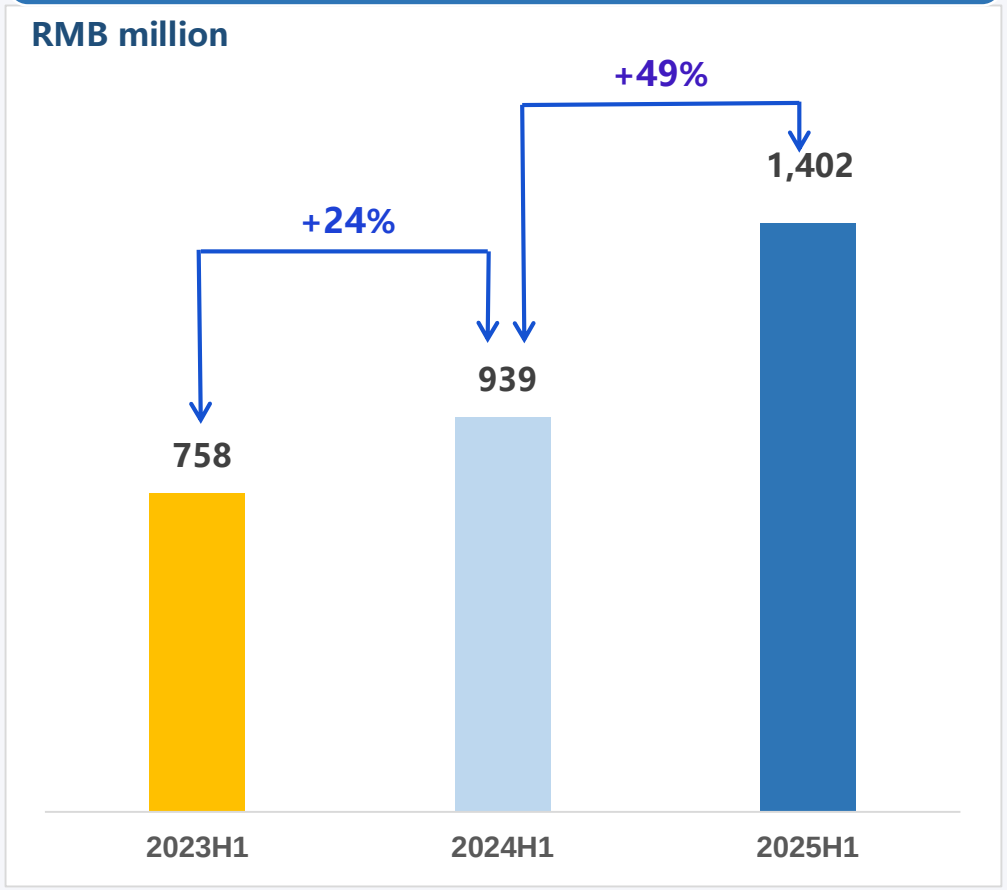
Gross Profit = commercial sales – cost of sales

Sales and Market %: Sales and marketing expenses/Commercial sales× 100%

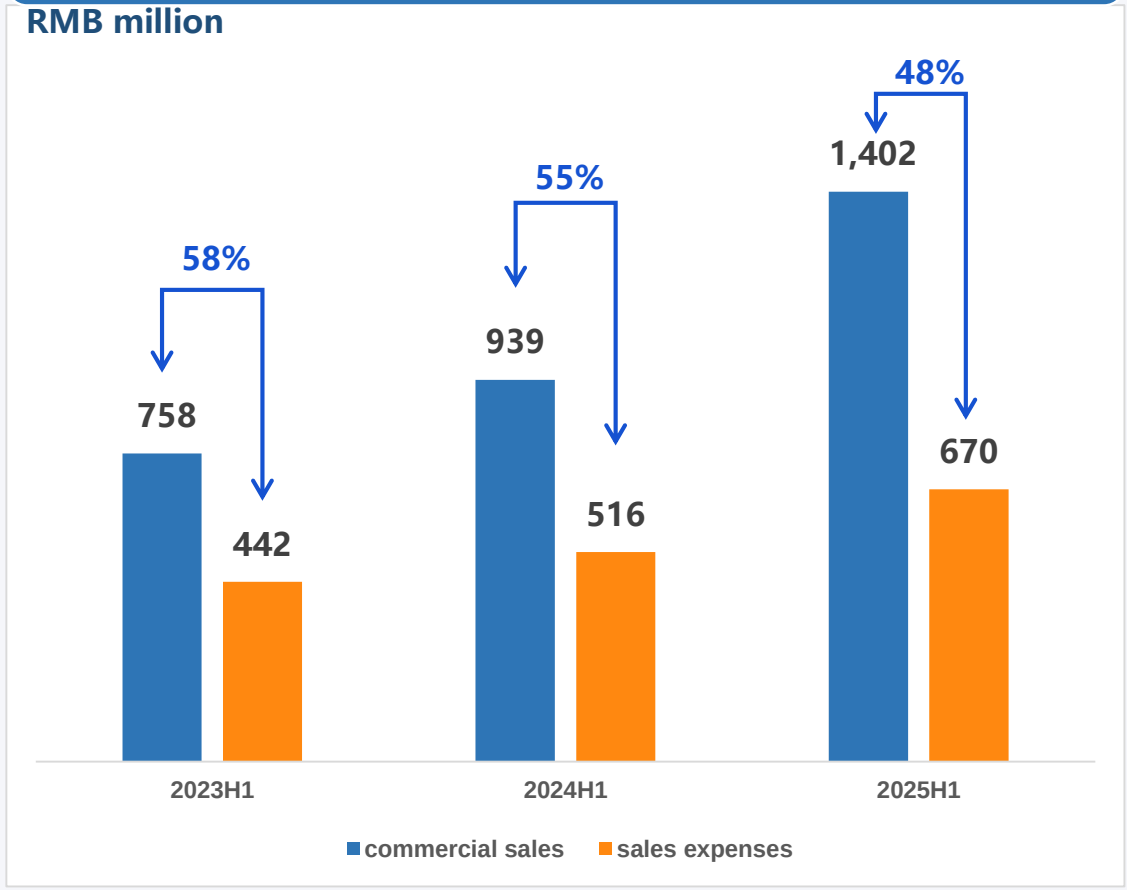
- ✓ 2025H1 Revenue of RMB**1.412** billion. Commercial sales of RMB**1.402** billion, **+49% y-o-y** increase from 2024H1
- ✓ Total of cash and cash equivalent, other short-term financial asset as of 2025.6.30: RMB**7.138** billion
- ✓ **Improvements in Expense Ratios:**
  - ✓ Sales and Marketing: 2025 H1 S&M expenses **decrease to 48%** of Commercial Sales from 55% in 2024H1
  - ✓ R&D: 2025H1 R&D expense **decrease to 52%** of Commercial Sales from 63% in 2024H1
- ✓ Key Expense in 2025 H1 compared to 2024 H1:
  - ✓ Accounting loss in 2025H1 recognized by the Group from its long-term equity investment in Summit Therapeutics was RMB**191.7** million, compared to RMB**32.6** million in 2024H1
  - ✓ R&D expenses increased by RMB137 million in 2025H1 compared to 2024H1 (**23%** YoY increase), mainly attributed to additional Phase III studies and the development of new pipeline and therapeutic platforms
  - ✓ ESOP and RSU expense 2025 H1 was RMB27 million, an increase of RMB22 million over 1H 2024
- ✓ 2025H1 **Adjusted EBITDA** RMB **-178.3**million

Sustained Growth in Sales while Controlling S&M Expenses

Commercial Sales Growth



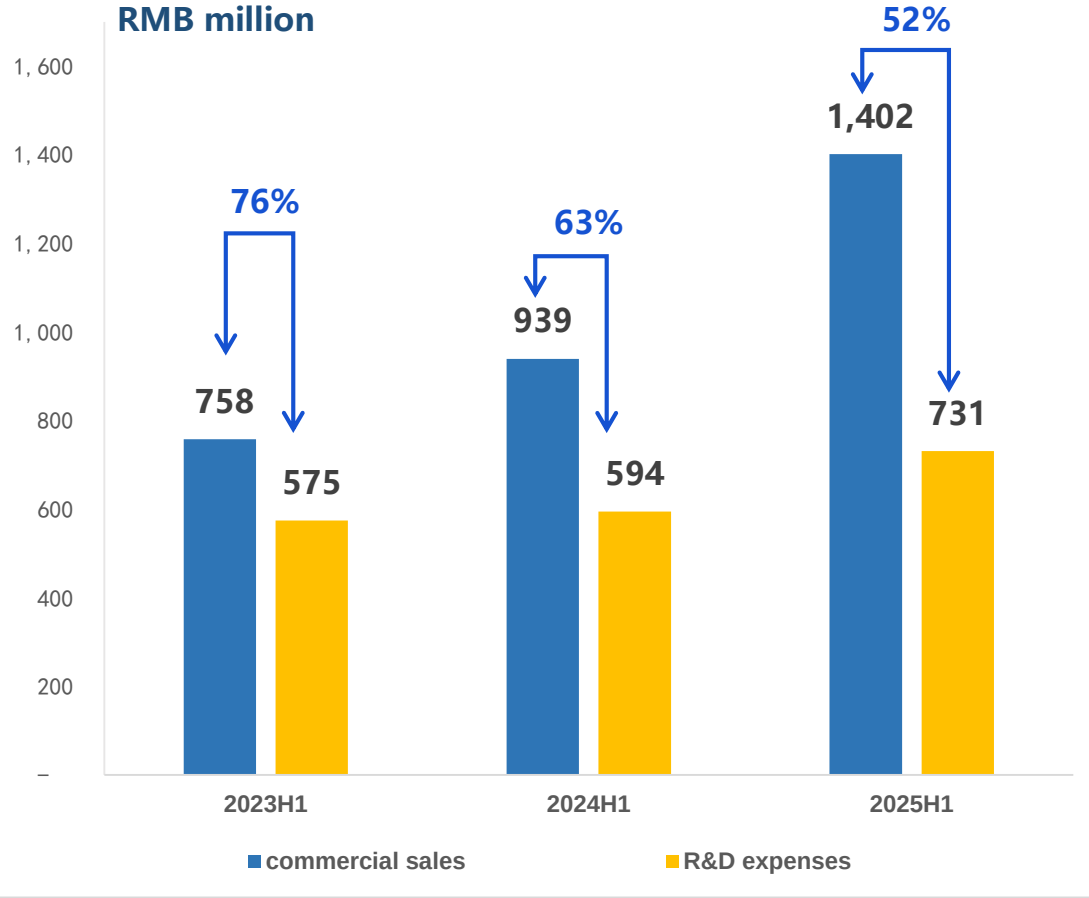
Sales Expenses to Commercial Sales Ratio[1]



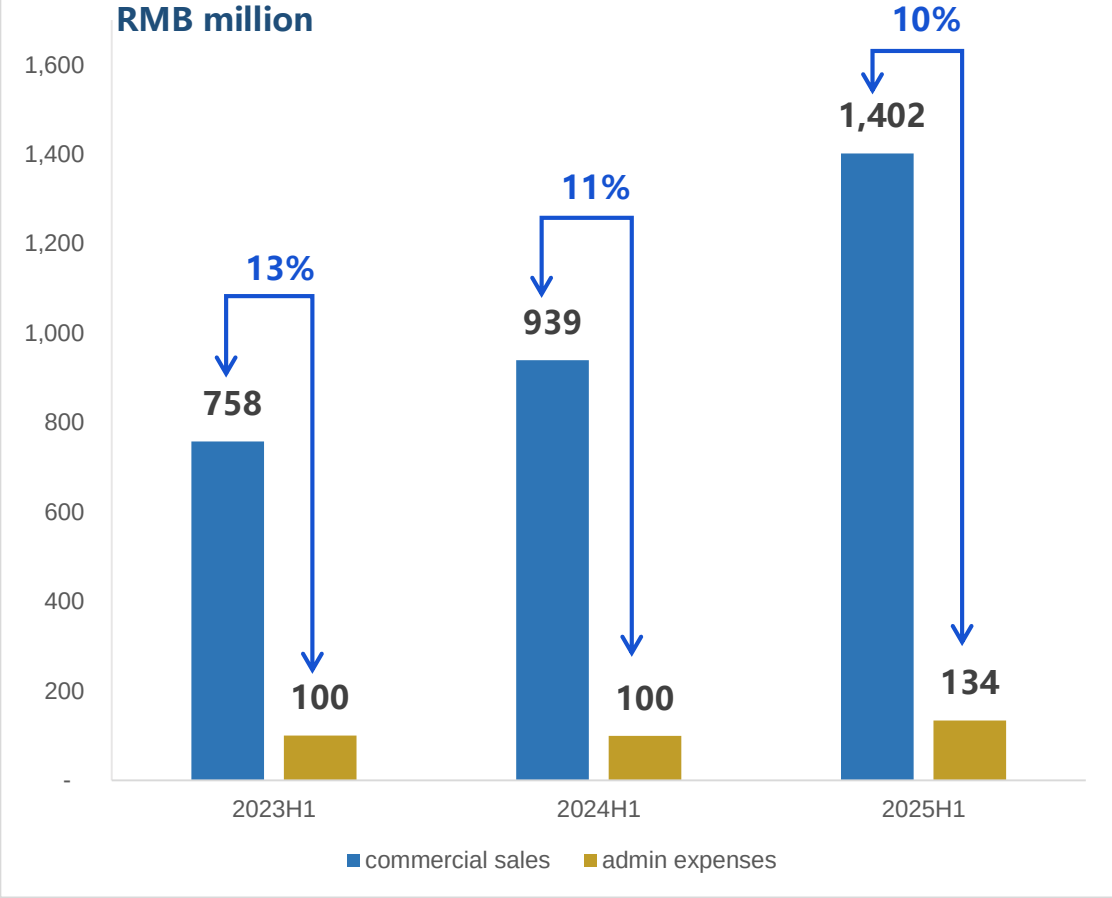
1. Sales Expenses to Commercial Sales ratio：Sales Expense / Commercial Sales × 100%

Steady Decline of Expense Ratios

R&D Expenses to Commercial Sales Ratio[1]



G&A Expenses to Commercial Sales Ratio[2]



1. R&D Expenses to Commercial Sales ratio：R&D Expense / Commercial Sales × 100%
2. G&A expenses to Commercial Sales ratio：G&A expenses / Commercial Sales × 100%

Akesobio

Q&A

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