Akesobio

康方生物科技(開曼)有限公司

Akeso, Inc.

(Incorporated in the Cayman Islands with limited liability)
(於開曼群島註冊成立的有限公司)
Stock Code 股份代號：9926

2024 Interim Akeso Corporate Presentation

2024.08

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1 Business Highlights

Highlights of Akeso Pipeline Development Progress in 2024 H1

- ✓ **1** blockbuster New Drug Marketing Authorization Applications (NDA) approved by CDE
- ✓ **1** new Supplemental Indication Applications (sNDA) for Marketed Drugs approved by CDE
- ✓ **4** new Supplemental Indication Applications (sNDA) submitted and are under review
- ✓ **7** Phase III clinical trials of **5** products newly initiated (including 3 new products)
- ✓ **3** new drug candidates entered clinical stage

Ivonescimab (PD -1/VEGF)

EGFR TKI progressor nsq-NSCLC

Penpulimab

3L Nasopharyngeal carcinoma

Cadonilimab

• 1L Gastric Cancer

Cadonilimab

• 1L Cervical cancer

Ivonescimab

• 1L PD-L1(+) NSCLC Priority Review

Penpulimab

• 1L Nasopharyngeal carcinoma

Ivonescimab

• 1L Biliary tract cancer
• 1L Pancreatic Cancer

Ivonescimab + Ligufalimab (CD47)

• 1L Head and Neck Squamous Cell Carcinoma

Cadonilimab

• Unresectable NSCLC
• Intermediate stage hepatocellular carcinoma

Cadonilimab + Pulocimab (VEGFR-2)

• in PD-(L) 1 Therapy for 2L Gastric Cancer

Manfidokimab (IL-4Rα)

• Atopic dermatitis

AK135 (IL-1RAP)

AK137 (CD73/LAG3)

AK138D1 (HER3 ADC)

Two First-in-Class bispecific antibodies (cadonilimab and ivonescimab) driving commercial growth

In 1H 2024, total product revenue of Akeso were ~ $132 million USD (RMB 939 million), +24 % over the same period last year

The growth is mainly due to the marketing approval and sales growth of the company's two bispecific antibody products

开坦尼
卡度尼利单抗 Cadonilimab

Cadonilimab's sales in the first half of 2024 were ***~ $100 million USD (RMB 706 million***), ***+ 16.5 %*** from the same period last year

Since the approval from June 29, 2022, the cumulative sales have reached ***$368 million USD (RMB 2.61 billion)***

依达方
依沃西单抗 Ivonescimab

Ivonescimab reached a revenue of ***$15 million USD (RMB 103 million***), since approval in May 24, 2024

In June 2024, Akeso and Summit signed an amended license agreement and confirmed ***~ $11 million USD (RMB 80 million)*** in licensing revenue in 1H 2024

Cadonilimab included in 13 clinical treatment guidelines, covering multiple indications

Included in 13 guidelines and consensus

Covering gynecological tumors, gastric cancer, liver cancer, esophageal cancer, nasopharyngeal cancer, etc.

- First recommendation in CSCO Cervical Cancer Guidelines (2022)(2023)
- For recurrent and metastatic cervical cancer, the only recommendation of the National Health and Medical Commission's Guidelines for the Clinical Application of Immuno-Therapies (2022)
- Gynecological Tumors Immunotherapy Checkpoint Inhibitors Clinical Application Guidelines (2023)
- Chinese Gynecologic Oncology Practice Guidelines, 7th Edition (2023)
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines 2023.V1 : Chinese Edition
- Chinese Expert Consensus (2023) on clinical diagnosis and treatment of gastric adenocarcinoma of cervix

- First-line treatment for gastric cancer (regardless of PD-L1 expression level/status) is included in the CSCO Gastric Cancer Guidelines (2024)
- Gastric cancer is included in the CSCO Guidelines for the Clinical Application of Immune Checkpoint Inhibitors (2024)
- Expert Consensus on gastric cancer immunotherapy based on PD-L1 protein expression level (2023)

- Chinese Guidelines for Radiotherapy of Esophageal Cancer (2023)

- CSCO Nasopharyngeal Carcinoma Gidelines (2024)

- Multidisciplinary Chinese Expert Consensus (2023) on combinational immunotherapy for hepatocellular carcinoma
- Targeted immunotherapy combined with local treatment for advanced hepatocellular carcinoma Chinese Expert Consensus

Ivonescimab approved: reshaping the lung cancer treatment landscape and efficiently achieving commercialization

World First, Landscape Reshaping

‘Immunotherapy+ Anti-angiogenesis’ bsAb

Market approval on May 24, 2024

EGFR TKI resistant non-small cell lung cancer

On May 31, the first batch of new drugs was shipped, bringing new treatment options to patients

5 Guidelines Recommendation + Expert Consensus

- ✓ Included in the first category recommendation of the Chinese Guidelines for the Treatment of Stage IV Primary Lung Cancer (2024)
- ✓ Chinese Anti-Cancer Association Lung Cancer Diagnosis and Treatment Guidelines (2024) first level recommendation (to be released)
- ✓ Expert consensus on immunotherapy for advanced non-small cell lung cancer with positive driver genes (2023)
- ✓ Expert consensus on Third-generation EGFR-TKI progressor treatment (2023)
- ✓ " China Malignant Tumor Discipline Development Report " - Future Prospects for Lung Cancer

Cadonilimab achieving success in first-line Cervical Cancer, and expanding into multiple additional indications

Next generation IO cornerstone therapy: *broad-spectrum, high-efficacy, low-toxicity, and differentiated*

开坦尼 卡度尼利单抗 Cadonilimab

Significant market opportunities and benefiting large patient populations

23+ clinical trials ongoing, covering 16 indications

8 registrational / Phase III clinical studies, 3 of which have obtained positive results, covering major indications of gastric cancer, lung cancer, hepatocellular cancer and cervical cancer

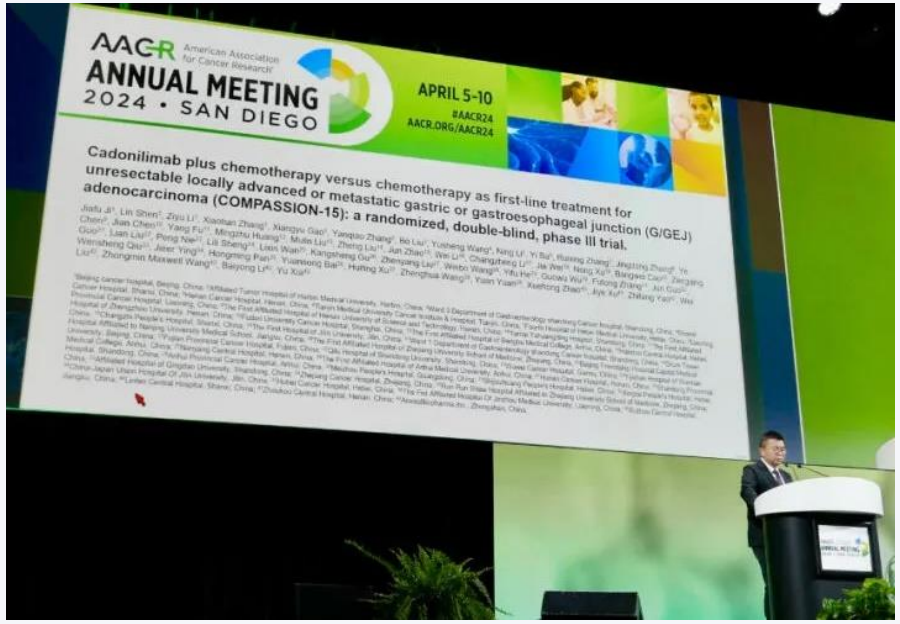
• 2/3L cervical cancer (mono)	Approved for marketing
• 1L cervical cancer (+ chemotherapy ± bevacizumab)	***Achieved PFS and OS dual endpoints, sNDA under review***
• 1L gastric cancer (+ chemotherapy)	***Achieved OS endpoint, sNDA under review***
• PD-(L)1 therapy resistant gastric cancer (+AK109+ chemo)	FPI
• 1L PD-L1(-) non-small cell lung cancer (+ chemotherapy)	Enrollment ongoing
• Concurrent / sequential chemoradiotherapy followed by consolidation therapy in unresectable locally advanced NSCLC (mono)	Initiating
• Postoperative adjuvant therapy for HCC (mono)	Enrollment ongoing
• Intermediate stage HCC (+Lenvatinimab+TACE)	Enrollment ongoing

Cadonilimab addressing critical unmet need in first-line Gastric Cancer treatment

Significant efficacy in the all comers and PD-L1 low-expression and negative population

AK104-302(COMPASSION-15)

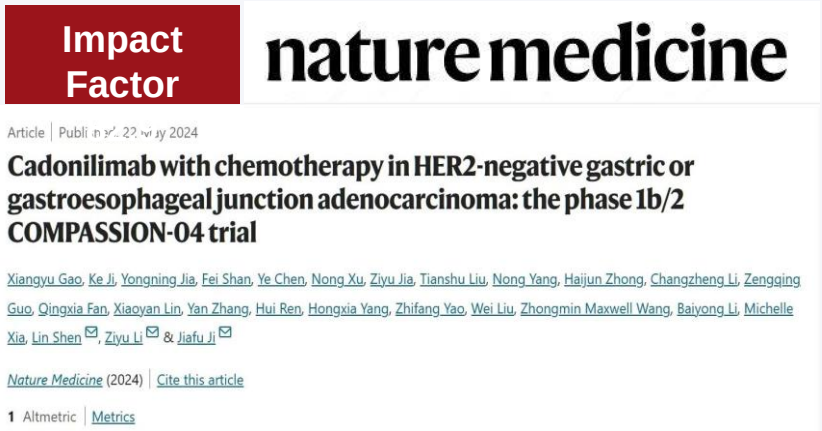
invited as one of the four official AACR press conference themes



Professor JI Jiafu in 2024 AACR Oral Presentation

AK104-201(COMPASSION-04)

published in top international medical journal Nature Medicine



"The combination of cadunolimab and chemotherapy has brought ***revolutionary progress, especially for patients with low PD-L1 expression.*** The success of the bispecific antibody combination regimen as the first-line treatment for advanced gastric cancer is ***unique and unparalleled*** at present ."

–Professor SHEN Lin

The only Phase III study on first-line gastric cancer that benefits the all comers, regardless of PD-L1 expression/status. The significant efficacy of cadonilimab as a first-line treatment for the all comers of advanced gastric cancer, effectively filled ***the clinical gap of the limited efficacy*** of PD-1 monoclonal antibodies in ***PD-L1 low-expression and negative gastric cancer***, and providing an efficient immunotherapy solution for patients with advanced gastric cancer.

Cadonilimab addressing critical unmet need in first-line Cervical Cancer treatment

Significant efficacy in the entire population and PD-L1 low-expression and negative population

AK104-303 (COMPASSION-16) 1L cervival cancer obtained strong positive results

(AK104-303/Compassion-16)
cadonilimab + chemotherapy ± bev vs chemotherapy ± bev first-line treatment for advanced cervical cancer

Phase III results show statistically significant and clinically meaningful benefit
Full data will be released at the top gynecological oncology conference

"Cadonilimab has shown outstanding efficacy in the first-line treatment of all comers of advanced cervical cancer, which has greatly encouraged the physicians.

I am delighted to see that this new drug with a synergistic anti-tumor immuno mechanism that simultaneously targets PD-1 and CTLA-4 has successfully moved from late-line treatment to first-line treatment in the treatment of advanced cervical cancer. I look forward to its early approval for first-line treatment indication, so that it can continue to release its excellent clinical value in a wider range of patient populations."

—Professor WU Xiaohua

The only Phase III study in first-line cervical cancer that benefits all comers, regardless of PD-L1 expression/status.
The significant efficacy of cadonilimab as a first-line treatment for all comers in advanced cervical cancer fulfilled a critical unmet need: the ***limited efficacy of*** PD-1 monoclonal antibodies in ***PD-L1 low-expression and negative cervical cancer.***

Ivonescimab achieves success in lung cancer and expands in both Chinese and Global Markets

New generation of IO cornerstone drugs: broad-spectrum, high-efficacy, low-toxicity, and differentiated

依达方 依沃西单抗 Ivonescimab

Expand and enhance lung cancer markets, expand into additional tumor types, and upgrade existing SoC

Conducted **25+** clinical trials, covering **17** indications

6 Phase III clinical trials in lung cancer, **2** of which have obtained positive results,

3 new Phase III clinical trials initiated, including **6** PD-(L)1 head-to-head Phase III clinical trials

IO therapy market for non-small cell lung cancer (NSCLC) treatment reached

US$ **18.5 billion** in 2022

• **EGFR-TKI progressor NSCLC (+ chemo)**	Approved for marketing in China
• **1L PD-L1(+) NSCLC (** vs Pembro)	PFS endpoint reached with strong positive results, sNDA under priority review
• **1L advanced sq-NSCLC** (+ chemo vs Tislelizumab + chemo)	Enrollment ongoing
• **1L metastatic sq-NSCLC (**+ chemo vs Pembro + chemo)	Enrollment in progress
• …	
• **3rd Gen EGFR-TKI progressor NSCLC (+ chemo)**	Global enrollment ongoing
• **1L metastatic sq-NSCLC (** + chemo vs Pembro + chemo)	Global enrollment ongoing
• …	

Summit therapeutics

• **1L biliary tract cancer (+ chemo vs Durvalumab + chemo)**	Initiated
• **1L head and neck squamous cell carcinoma (+AK117 vs Pembro)**	Initiated
• **1L pancreatic cancer (+ chemotherapy)**	To be initiated soon

AK112-301 data released in ASCO, bringing new treatment options for TKI- resistant patients

Rated by OncoAlert as 2024 ASCO Lung Cancer Top 10

Professor Zhang Li 2024 ASCO Oral Presentation

Top international medical journals Published in JAMA (Journal of the American Medical Association)

JAMA® The Journal of the American Medical Association

Impact Factor 120.7


Research

JAMA | Original Investigation

Ivonescimab Plus Chemotherapy in Non-Small Cell Lung Cancer With *EGFR* Variant
A Randomized Clinical Trial

HARMONi-A Study Investigators

IMPORTANCE For patients with non-small cell lung cancer whose disease progressed while receiving EGFR tyrosine kinase inhibitor (EGFR-TKI) therapy, particularly third-generation TKIs, optimal treatment options remain limited.

OBJECTIVE To compare the efficacy of ivonescimab plus chemotherapy with chemotherapy alone for patients with relapsed advanced or metastatic non-small cell lung cancer with the epidermal growth factor receptor (*EGFR*) variant.

Visual Abstract
Supplemental content

Ivonescimabmab combined with chemotherapy bringing new treatment options for TKI - resistant patients :

- **The only clinical study showing significant clinical benefits for patient who progressed on 3rd generation EGFR TKI, which is in line with the current clinical practice**
- **The only clinical study that reached the primary endpoint and OS benefit has shown a positive trend**
- **The only clinical study that PFS hazard ratios won in all subgroups**

The world's first Ph III study showing superiority over Keytruda monotherapy - a better chemo-free option for 1L lung cancer patients

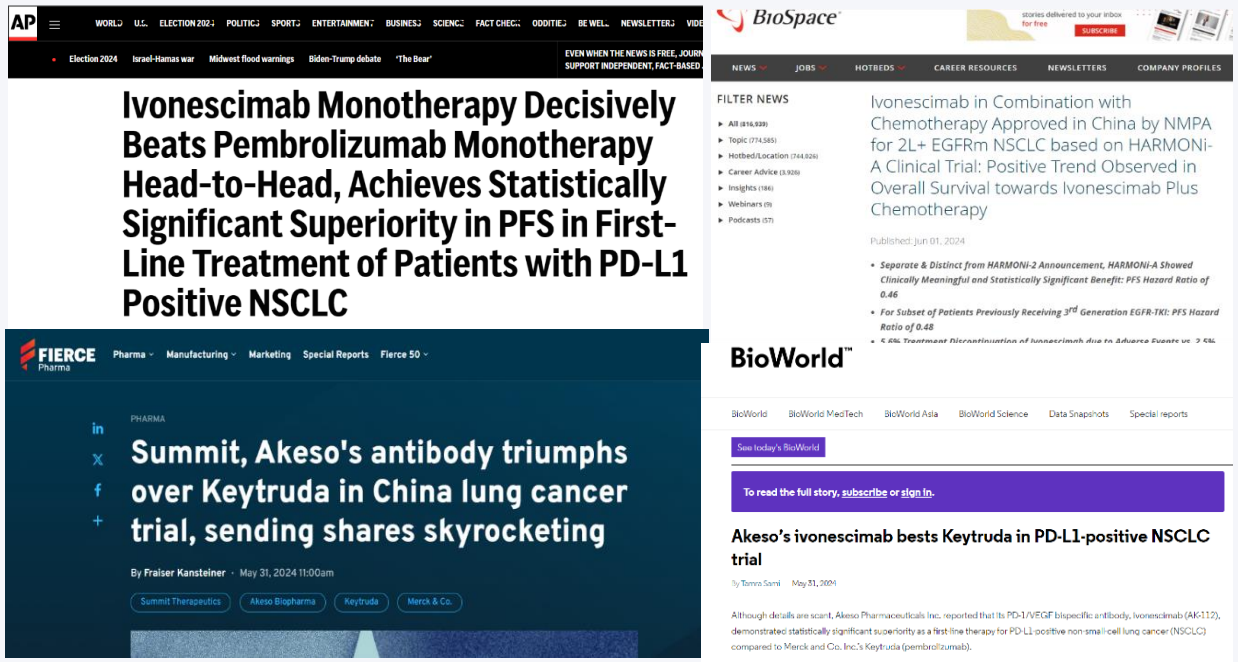
AK112-303 obtained a decisive victory over Keytruda

(AK112-303/HARMONi-2)
Ivonescimab vs Pembrolizumab
First-line treatment for PD-L1(+) NSCLC

The complete data will be presented by
Professor Zhou Caicun,
At the 2024 WCLC Plenary Session
Presidential Symposium Oral Report

IASLC 50 1974–2024
2024 World Conference on Lung Cancer
SEPTEMBER 7-10, 2024 | SAN DIEGO, CA USA

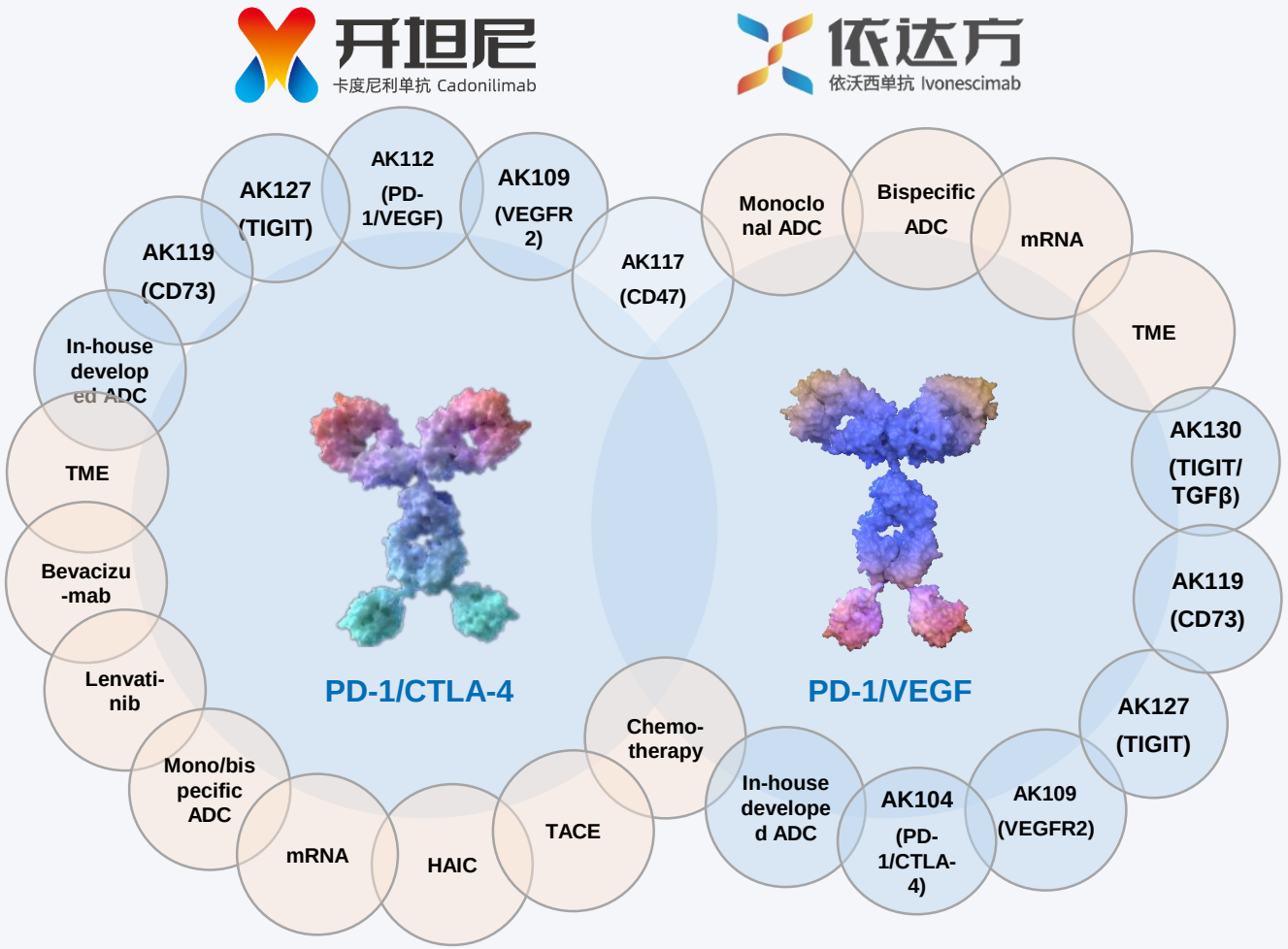
Gaining wide attention from global media



- Strong positive results in phase III with statistical significance and substantial clinical benefit
- Ivonescimab brings a better treatment option of chemo-free therapy for first-line lung cancer patients
- Ivonescimab will become a new Standard of Care in first-line lung cancer treatment

Two I/O bispecifics as cornerstone therapeutics, creating multiple combo options to treat a large number of tumor indications

Two-pronged approach, advancing in parallel
Continuous and productive internal innovation + extensive external collabration



Accelerate internal innovation and combination

- A variety of bispecific antibodies and monoclonal antibodies are already at clinical stage
- **The first self-developed ADC** entered clinical satge
- **In-house developed bispecific ADC** is about to enter clinical stage

Actively expand external collaborations on new anti-tumor mechanisms

- Open combination exploration, especially with **ADC mRNA, TME** , etc.

+ Immune Check-point Inhibitor
+ Targeted therapy
+ ADC
+ New MOA

Combination with internal innovative products

Combination with external innovative drugs

Ligufalimab (CD47) enters Phase III registrational trial, advancing globally for hematological tumors and solid tumors simultaneously

Expanding addressable tumor types by creating combination therapies with bispecific backbones

Solid tumors: The world's first Phase III registration trial initiated

AK117+ ivonescimab (vs pembrolizumab) 1L PD-L1(+) head and neck squamous cell carcinoma Phase III initiated

The world's first Phase III trial of CD47 in solid tumor

AK117 combined with AK104 or AK112 in solid tumors:
9 clinical trials conducted, covering 7 major indications

AK117+ ivonescimab + chemotherapy
1L colorectal cancer (CRC), Phase II

AK117+ ivonescimab
1L PD-L1(+) head and neck squamous cell carcinoma (HNSCC), Phase II

Hematological tumors: Global multi-center clinical trials in progress

AK117 + AZA
1L MDS **global multi-center Phase II** clinical trial, patient enrollment ongoing

AK117 + Venetoclax (VEN) + AZA
1L unfit AML **China Phase II** clinical trial, **enrollment ongoing**

AK117 + AK129 (PD-1/LAG-3)
China Phase I/II clinical trial for PD-(L)1 resistant r/r cHL **has been initiated**

MDS : high-risk myelodysplastic syndrome ; AML : acute myeloid leukemia
r/r cHL : relapsed or refractory classical Hodgkin lymphoma

Pulocimab (VEGFR2) enters Phase III registration trial, combined with cadonilimab, developing in large IO-resistant indication

Expanding addressable tumor types by creating combination therapies with bispecific backbones

AK109 + AK104 + chemotherapy
The world's first Phase III trial on PD-(L)1 resistant GC/GEJC, enrollment ongoing

AK109 + AK104 ± Docetaxel on PD-(L)1 resistant NSCLC, Phase II ongoing

AK109 + AK104 on PD-(L)1 resistant HCC, Phase II ongoing

2L gastric cancer that progressed on IO therapy
Unmet medical needs

AK109+AK104+chemotherapy
PD-(L)1 resistant GC/GEJC, PhII (N=77)

2024 ASCO ANNUAL MEETING

ORR **48%** / 16% (1)

DCR **96%** / 64% (1)

mPFS **6.8m** / 2.9 (1)

mOS **12.9m** / 7.4 (1)

Data cutoff: February 2024

Phase III trial enrollment ongoing

Note:
1 - RAINBOW , paclitaxel

Ebdarokimab and Ebronucimab NDA under final review

Ebdarokimab (AK101, IL-12/IL-23)

NDA under final review
Submitted in Aug. 2023

Indication:
Moderate to severe plaque psoriasis

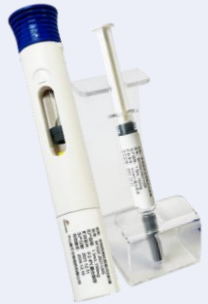
Significant market demand	6.7 million Chinese psoriasis patients $ 9.5 billion USD Chinese market value *
Low dosing frequency	5 doses in the first year , then only 4 doses / year
Significant therapeutic benefit	PASI75 response rate 79.4% ** /67% (1)
Long-term benefits	Long-term efficacy and benefits are stable

Phase III 52- week data will be published at

EADV CONGRESS AMSTERDAM 25-28 SEP 2024

* Data source: Frost & Sullivan, 2017-2030 China Psoriasis Drug Market
** AK101-302 (16- week data) data published in 2023 EADV , N=450
1 – PHONEX 1

Ebronucimab (AK102, PCSK9)



NDA under final review
Submitted in Jun. 2023

Indications:
- Primary hypercholesterolemia and mixed hyperlipidemia
- Heterozygous familial hypercholesterolemia

Significant market demand	110 million Chinese hypercholesterolemia patients $ 1.34 billion USD Chinese market value *
Significant therapeutic benefit	Proportion of people with extremely high and ultra-high cardiovascular risk >80% ** Average LDL-C reduction greater than 65% ** / 58%-63% (2)
Long-term benefits	The lipid-lowering effect is stable, sustainable and safe

Phase III study data was published at

Pharmacological Research

* Estimated PCSK9 Chinese market in 2023, data source: Frost & Sullivan
** AK102-301 Phase III data published in Pharmacological Research , N=722
2– LAPLACE-2, ODYSSEY

Gumokimab (IL-17) pivotal Phase III trial reached endpoints, Manfidokimab (IL-4Rα) pivotal Phase III trial is underway

Gumokimab (AK111, IL-17)

Psoriasis

Focusing on clinical needs and complementing the advantages of Ebdarokimab

- The pivotal Phase III trial has reached the endpoint
- Planning to submit NDA in early 2025

Significant market demand

6.7 million Chinese psoriasis patients
9.5 billion USD Chinese market value *

Ankylosing spondylitis

- Phase III clinical trial enrollment ongoing
- Phase II clinical data will be published at

EADV CONGRESS AMSTERDAM 25-28 SEP 2024

Significant market demand

4 million Chinese patients with ankylosing spondylitis *

* Data source: Frost & Sullivan

Manfidokimab (AK120, IL-4Rα)

Atopic dermatitis

Pivotal Phase III clinical trial enrollment ongoing

Significant market demand

70 million Chinese patients with atopic dermatitis

~ $ 5 billion USD Chinese market value **

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

Deep pipeline of potential First-in-Class and Best-in-Class in-house developed products pipeline

Oncology

Trispecific Antibody
ILT2/IL T4/CSF 1R
HER-3 ADC
Claudin 18.2/ CD47
TIGIT/ TGF-β
CD73
Drebuxelimab
CD47
Ligufalimab
Bispecific ADC-2
ADC-2
IL-1RAP
PD-1/ CD73
PD-1/ LAG3
TIGIT
VEGFR2
Pulocimab
Cell Therapy
Bispecific ADC-1
CD73/ LAG-3
CTLA-4
Quavonlimab
PD-L1
Tagitanlimab


依达方 依沃西单抗 Ivonescimab
PD-1/VEGF


开坦尼 卡度尼利单抗 Cadonilimab
PD-1/CTLA-4


安尼可®
PD-1

普佑恒
PD-1

IND Enabling | Phase I | Phase II | Phase III / Pivotal | NDA/BLA | Commercialized

Neurodegenerative diseases
IL4R/ST2
NGF
IL-4R
Manfidokimab
IL-17
Gumokimab
IL-12/IL-23
Ebdarokimab
PCSK9
Ebronucimab


Autoimmune, Metabolic…etc.

4
marketed products

11+
Potential FIC/BIC BsAb / PcAb / BsAb ADC

22
clinical-stage drug candidates

50+
Innovative assets, covering oncology, immunology and metabolic diseases

Boxed programs are licensed or partnered. Milestone payments, sales royalties, and licensing revenues are expected according to the licensing agreements.

Expand collaboration with SUMMIT to accelerate development, registration and commercialization in various regions around the world

On June 3rd 2024 , Akeso and SUMMIT signed an amended license agreement to expand the licensed territory of ivonescimab

- Akeso will receive an upfront and milestone payments of **$70 million USD,** as well as **royalties** in newly licensed markets and also **supply income** of ivonescimab
- Expanding collaboration with Summit to include **development and commercialization rights in Central and South America, Middle East and Africa**

Further strengthened the cross-regional sharing of clinical data and registraional materials

Will significantly accelerate regulatory registration and commercialization in various regions around the world

Summit therapeutics × THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

On July 25th 2024, Summit and MD Anderson reached a 5-year strategic collaboration

To accelerate the development of SMT112/AK112 for multiple tumor types including RCC, CRC, BC, skin cancer and glioblastoma

2

Core Product Clinical Progress

Cadonilimab's major readout, R&D progress, regulatory affairs and milestones

Data Readout

R&D, Regulatory Affairs

AK104-216
Intermediate HCC, PhII

COMPASSION-15/
AK104-302
1L GC, PhIII

AK104-201
1L GC, PhII

AK109-201
PD-(L)1 resistant GC, PhII

AK104-303
1L CC, PhIII

Q1 2024	Q2 2024	Q3 2024	Q4 2024

FPI AK104-307 1L PD-L1(-) NSCLC recruiting

AK104-303
1L CC Ph3 reached primary endpoint of PFS & OS

FPI AK109-301 PD-(L)1 resistant GC recruiting

FPI AK104-308 intermediate HCC recruiting

AK104-306 HCC adjuvant therapy expect to complete patient enrollment by end 2024

2024.1
1L GC sNDA accepted by CDE

2024.4
1L CC sNDA accepted by CDE

Cadonilimab (COMPASSION-15) potential new treatment in Gastric Cancers

COMPASSION-15: cadonilimab +XELOX 1L G/GEJ (N=610)

Brings safer and more efficacious IO therapy to
All comers of GC
(regardless of PD-L1 expression/status)

sNDA submitted in 2024.1, under review

All comers mOS 15.0m vs 10.8m

HR 0.62 (p < 0.001)

Data cutoff 2023.8, median follow-up 18.69m

Meet unmet medical need
of PD-L1 low expression/negative

1st IO drug to demonstrate survival benefit to patients with PD-L1 low expression/negative

Reshape a New Pattern of Treatment of 1L GC

Significant survival benefit in CPS≥5 subgroup

mOS NR vs 10.6m

HR 0.56(p < 0.001)/0.71(1), 0.71(2)

Significant survival benefit in CPS < 5 subgroup
CPS<5 account for 49.8% of ITT (CPS < 1 ~23%)

mOS 14.8m vs 11.1m

HR 0.7/0.91(1),0.94(2)

Median follow-up 18.69m

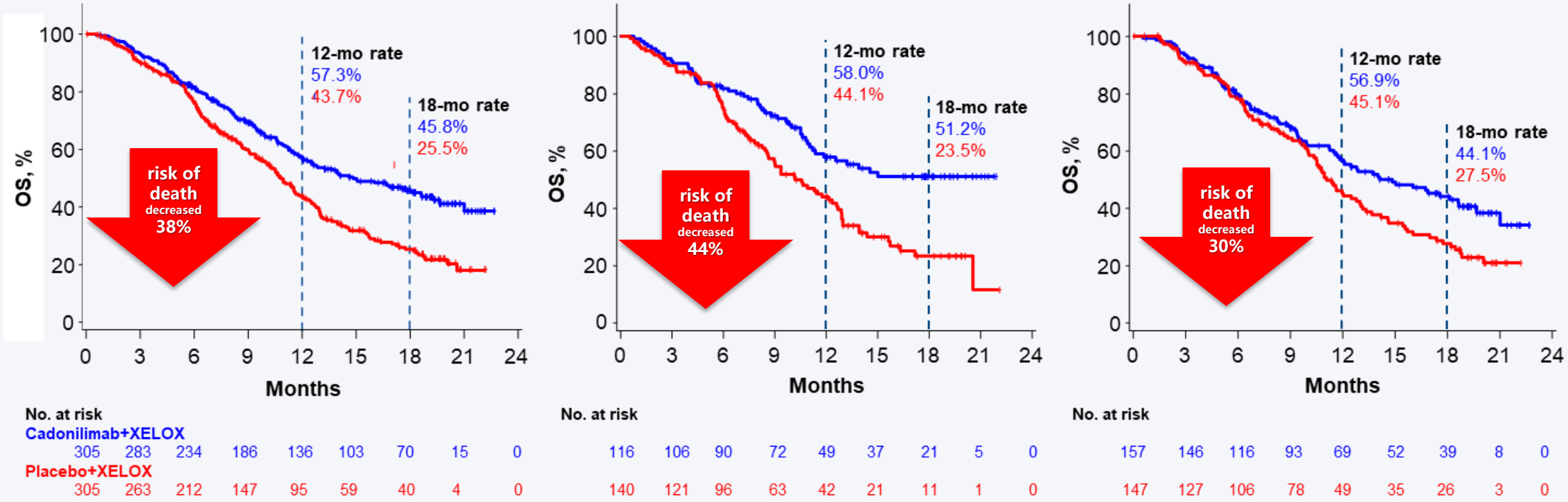
Note:
1 - RATIONALE-305，tislelizumab+chemo; 2 - CheckMate-649，nivolumab+chemo

COMPASSION-15 primary endpoint: OS results showed cadonilimab + chemo decreased death risk by 38% vs chemo

ITT Population	Cadonilimab+XELOX N=305	Placebo+XELOX N=305
Median, mo (95% CI)	15.0 (12.3,19.3)	10.8 (9.8,12.0)
HR (95% CI)	0.62 (0.50-0.78)	
P value	<0.001	

PD-L1 CPS≥5	Cadonilimab+XELOX N=116	Placebo+XELOX N=140
Median, mo (95% CI)	NR# (11.4, NE*)	10.6 (8.6,12.6)
HR (95% CI)	0.56 (0.39-0.80)	
P value	<0.001	

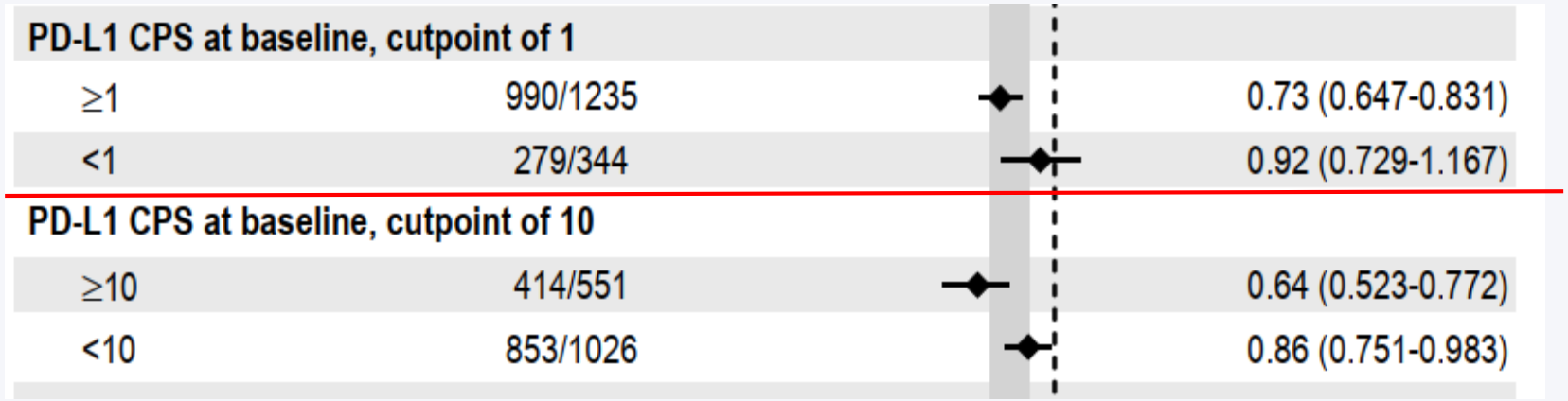
PD-L1 CPS<5	Cadonilimab+XELOX N=157	Placebo+XELOX N=147
Median, mo (95% CI)	14.8 (11.6, 18.6)	11.1 (10.1, 13.0)
HR (95% CI)	0.70 (0.51-0.95)	
P value	0.011	



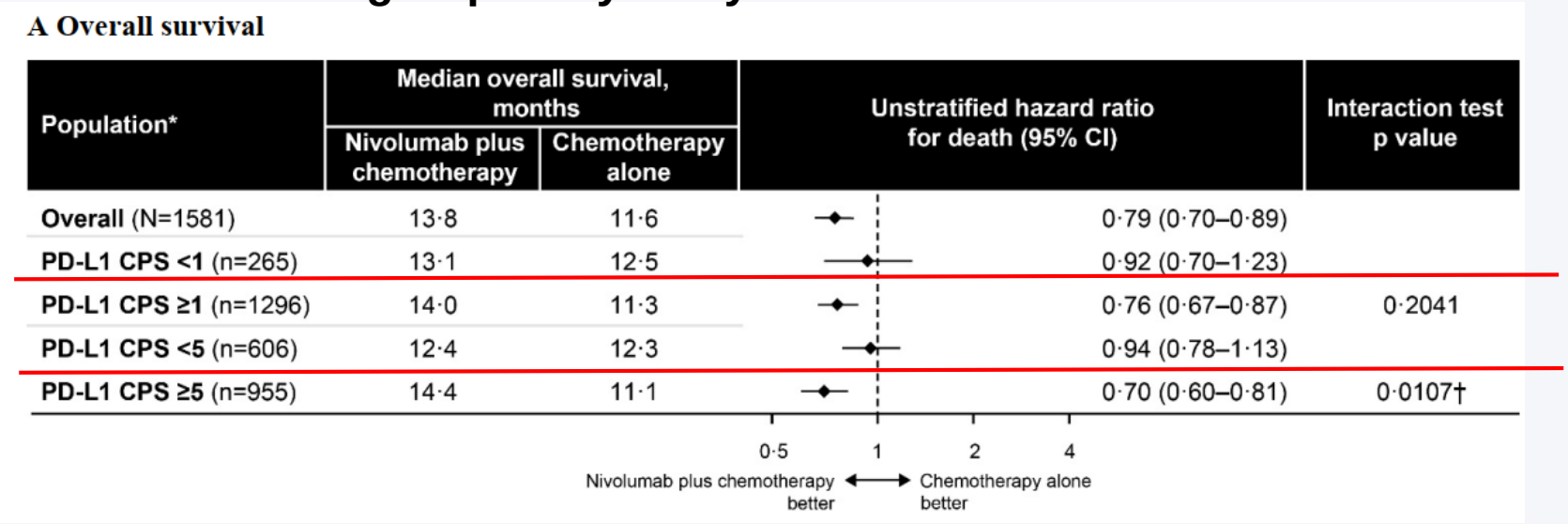
- Cadonilimab plus chemo group demonstrates long-term survival benefits: 12-month OS rate of cadonilimab plus chemo increased 13.6% vs chemo (57.3% vs 43.7%), 18-month OS rate increased 20.3% (45.8% v s 25.5%)

Historic data: No OS benefit observed with PD-L1 negative (CPS<1) or low expression (CPS<5) in CM649 and KN859 trials

OS subgroup analysis by PD-L1 CPS in KN859



OS subgroup analysis by PD-L1 CPS in CM 649



Lancet. 2021;398(10294):27-40.; 2023ESMO VP1-2023.

Cadonilimab reached primary endpoints and demonstrated significant survival benefits in all comers in 1L Cervical Cancer

AK104-303 (COMPASSION-16) 1L CC statistically significant results

(AK104-303/Compassion-16)
cadonilimab+chemo±bev vs chemo±bev
1L advanced cervical cancer

statistically significant and clinically meaningful Phase III results

- 440 participants enrolled
- Primary endpoints: **PFS, OS**
- PD-L1(-) account for 26% of ITT population *(KEYNOTE-826: PD-L1(-) ~11%)*
- **In line with population distribution in real world**

- ✓ Among ITT population, cadonilimab reached primary endpoints of PFS and OS with significant survival benefits in treatment group, and demonstrated superior PFS and OS HR.
- ✓ **The ONLY Ph3 trial showed statistically significant results in 1L CC all comers,** results of PD-L1(-) and all comers are consistent *(vs KEYNOTE-826, PFS HR and OS HR were 0.95 and 0.87 in PD-L1(-) population)*
- ✓ **Positive results observed broadly across subgroups**
  - ✓ with/without bev
  - ✓ with/without CCRT
  - ✓ With/without distant metastasis
- ✓ **Superiority from subgroup without bev treatment** - Patients with cervical cancer often have contraindications to bevacizumab due to long-term toxicity of radiotherapy such as radiation proctitis and radiation cystitis. This problem is solved by cadonilimab.
- ✓ **Meet medical need. Cadonilimab shows good safety profile, and no additional safety signals were identified**

Cadonilimab demonstrates superior efficacy as first-line treatment in all comers of cervical caner, addressing critical unmet medical need in PD-L1 low expression/negative patients. Cadonilimab provides an efficacious IO therapy for advanced cervical cancer.

Ivonescimab's major readout, R&D progress, regulatory affairs and milestones

Data Readout

R&D, Regulatory Affairs

Q1 2024	Q2 2024	Q3 2024	Q4 2024
AK112-201sqNSCLC elcc European Lung Cancer Congress 2024 PRAGUE CZECH REPUBLIC 20-23 MARCH 2024 AK112-201&202 NSCLC with brain metastasis elcc European Lung Cancer Congress 2024 PRAGUE CZECH REPUBLIC 20-23 MARCH 2024	AK112-301 / HARMONi-A 2024 ASCO ANNUAL MEETING JAMA The Journal of the American Medical Association AK117-202 BTC 2024 ASCO ANNUAL MEETING	AK112-303 / HARMONi-2 2024 World Conference on Lung Cancer AK112-205 NSCLC neoadjuvant 2024 World Conference on Lung Cancer	AK112-206 CRC ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE AK117-203 TNBC ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE AK117-201 HNSCC ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

2024.5.31

AK112-303 / HARMONi-2
1L PD-L1(+) NSCLC (vs pembrolizumab) reached primary endpoint of PFS, **statistically significant results**

Summit therapeutics

Expect to complete patient enrollment of HARMONi
3rd EGFR-TKI resistant nsq-NSCLC

AK112-306 1L sqNSCLC (vs tislelizumab+chemo)
Expect to complete patient enrollment in Q4

Ph 3 trials initiated
1L HNSCC, 1L BTC, 1L pancreatic cancer

2024.5.24 依达方® approved by NMPA
EGFR-TKI resistant nsq-NSCLC

2024.8 sNDA accepted by NMPA, fast track
monotherapy(chemo-free) 1L PD-L1(+) NSCLC

AK112-303 results to be published at 2024 WCLC, The potential best 1L chemo-free therapy

AK112-303 / HARMONi-2 : ivonescimab versus pembrolizumab in 1L PD-L1(+) NSCLC (N=398)

The success of the HARMONi-2 study also highlights the great value of the synergistic effect of ivonescimab's MOA of "immuno-oncology + anti-angiogenesis". We are very much looking forward to ivonescimab's entering the first-line treatment of lung cancer and becoming **a new standard of care**, bringing a better **"chemo-free"** treatment option to first-line lung cancer patients.

——Dr. ZHOU Caicun

Phase III results show statistically significance and substantial clinical benefit

Baseline

- PD-L1 TPS 1-49% accounted for 57.8%
- PD-L1 TPS ≥ 50% accounted for 42.2%
- **Consistent with real-world patients' expression level distribution**

All subgroups showed strong positive results

- Squamous / non-squamous cell carcinoma, **excellent data in squamous cell carcinoma**
- With / without liver metastasis
- With / without brain metastasis

Significantly extended PFS

- **Significantly prolonged PFS** compared to pembro, **HR significantly better than expected**
- In both patient group of PD-L1 TPS 1-49% and PD-L1 TPS ≥ 50% , **the PFS benefit** of ivonescimab **was significan and HR are better than expected**

Good safety

The overall safety profile was good, no additional safety signals were identified.

sNDA was submitted in July 2024
Under Priority Review

AK112-301 results published at 2024 ASCO

AK112-301 / HARMONi-A: ivonescimab + chemo EGFR-TKI resistant nsq-NSCLC (N=322)

2024 ASCO ANNUAL MEETING

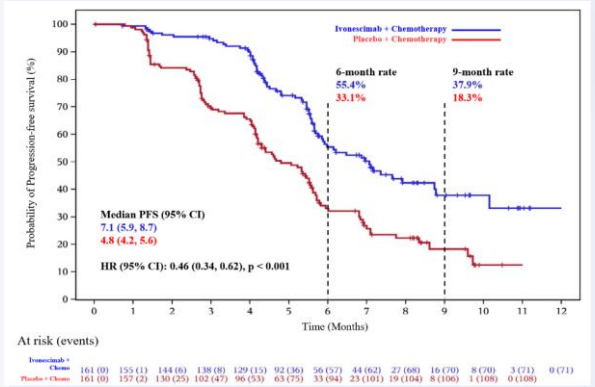
The results of HARMONi-A study was reported at the world's top oncology academic annual meeting, published in international authoritative journals, and promoting the approval of the local new drugs. These achievements demonstrate the strong strength of the "Chinese scholars + local new drugs" combination, and also show the international academic community's recognition of the domestically developed first-in-class bi-specific.

—— Dr. ZHANG Li, ASCO Press Conference

JAMA® The Journal of the American Medical Association

Baseline

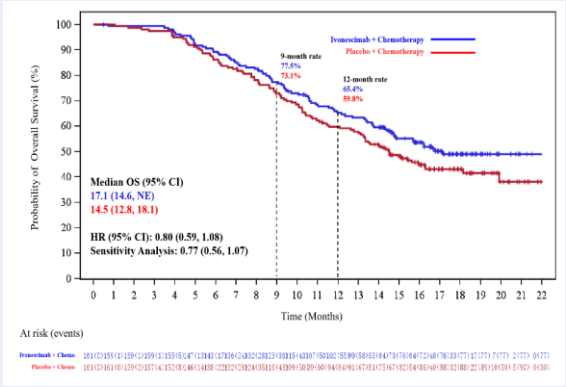
The proportion of patients who have used the third- generation EGFR-TKI is ~85%



Significantly prolonged PFS

- mPFS 7.1m vs 4.8m , HR 0.46
- Subgroup treated with 3rd gen TKI HR 0.48
- Subgroup with brain metastases HR 0.40

Data cutoff: 2023.3, median follow-up 7.89m



Significant OS benefit trend

- Under 52% data maturity, the OS curves separate
- Ivonescimab group showed a clear trend of extending OS, mOS 17.1m vs 14.5m
- HR 0.8 / HR 0.77 (1)

Data cutoff: 2023.12.31

Good safety

The incidence of TRAEs of Ivonescimab group was comparable to the control group (chemo)
The incidence of grade ≥ 3 irAEs was 6.2% and 2.5%, respectively.
The incidence of ≥ grade 3 VEGF target-related adverse events was only 3.1% and 2.5%

1. Patients who received new immune checkpoint inhibitors were treated as censored, the adjusted analysis data

Phase II data of ivonescimab for BTC were presented at 2024 ASCO, Phase III trial has been initiated

ivonescimab + chemo
1L advanced BTC (N=22)

2024 ASCO ANNUAL MEETING

A potential better treatment option for first-line treatment of advanced biliary tract cancer (BTC)

Significant anti-tumor activity

ORR **63.6%** /26.7% [1], 29% [2]

ORR in patients with gallbladder cancer **77.8%**

DCR **100%** / 85.3% [1], 75% [2]

mPFS **8.5m** / 7.2 [1], 6.5 [2]

mOS **16.8m** / 12.8 [1], 12.7 [2]

Strong safety

There were no TRAEs leading to death or treatment discontinuation

Data cutoff: 2024.1, median follow-up: 13.8 months

Note:
1. TOPAZ-1;
2. KEYNOTE-966

Currently, the first-line treatment for advanced BTC is PD-(L)1 combined with chemotherapy.

Survival benefit are still limited, Unmet medical needs with gallbladder cancer patients remain significant

1L Advanced biliary tract cancer

ivonescimab + chemotherapy

(vs durvalumab + chemotherapy)

Phase III trial has been initiated

Ivonescimab + AK117 Phase III trial initiated, Phase II results to be published at 2024 ESMO

Ivonescimab has shown positive results in Phase II clinical trials for multiple indications

ivonescimab + AK117
1L PD-L1(+) HNSCC

Phase II results to be published

BARCELONA 2024 ESMO congress
BARCELONA SPAIN
13-17 SEPTEMBER 2024

PhIII trial initiated
Global 1st PhIII clinical trial of AK117+IO combination therapy (vs pembrolizumab)

ivonescimab + chemo
1L TNBC

Phase II results to be published

BARCELONA 2024 ESMO congress
BARCELONA SPAIN
13-17 SEPTEMBER 2024

ivonescimab ± AK117 + chemo
1L CRC

Phase II results to be published

BARCELONA 2024 ESMO congress
BARCELONA SPAIN
13-17 SEPTEMBER 2024

3

Financial Highlights

2024H1 Financial Highlights

RMB Million	2024H1	2023H1	2022H1
Revenue	1024.74	3676.86	163.14
Net product sales	939.43	757.87	163.14
License income[1]	85.32	2,918.99	-
Cost of sales*	(81.57)	(77.18)	(28.11)
Product gross profit	889.10	717.47	269.08
R&D expenses	(594.39)	(574.67)	(595.38)
Selling and marketing expenses	(515.98)	(442.16)	(149.5)
Selling expense %***	*54.9%*	*58.3%*	*92%*
(Loss)/Profit for the Period	(249.35)	2,489.54	(691.88)

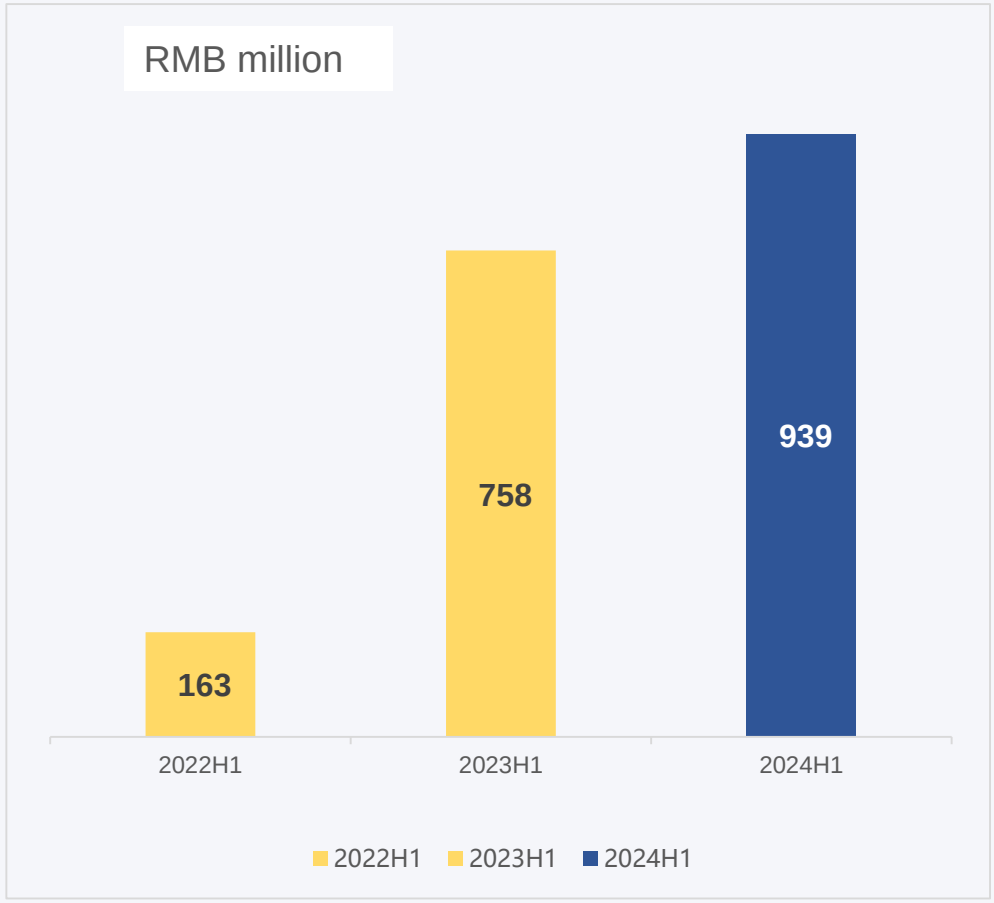
- ✓ **2024H1,** Revenue was RMB**1.02**billion
- ✓ Net product sales ~RMB**939**million, YoY **+24.0%** increase compared to RMB758 million in 2023H1
- ✓ 2024.3.28 successfully raised ~RMB**1.06billion**[2] through placement
- ✓ **Strong cash position** as of date of 2024.6.30, cash and cash equivalents, short-term financial assets and deposits totaled RMB**5.7**billion
- ✓ **2024H1**, EBITDA was RMB**-124**million

Note1: On June 3, 2024, the Company entered into an amendment to the license agreement with SUMMIT to expand the license territory of ivonescimab. Pursuant to this amendment to the license agreement, we recognized license income of approximately RMB80.0 million during the Reporting Period.
Cost of sales*: raw materials, direct labour, depreciation of equipment and buildings and manufacturing overhead related to the production of products
Selling expense %***: Selling and marketing expenses/net product sales×100%

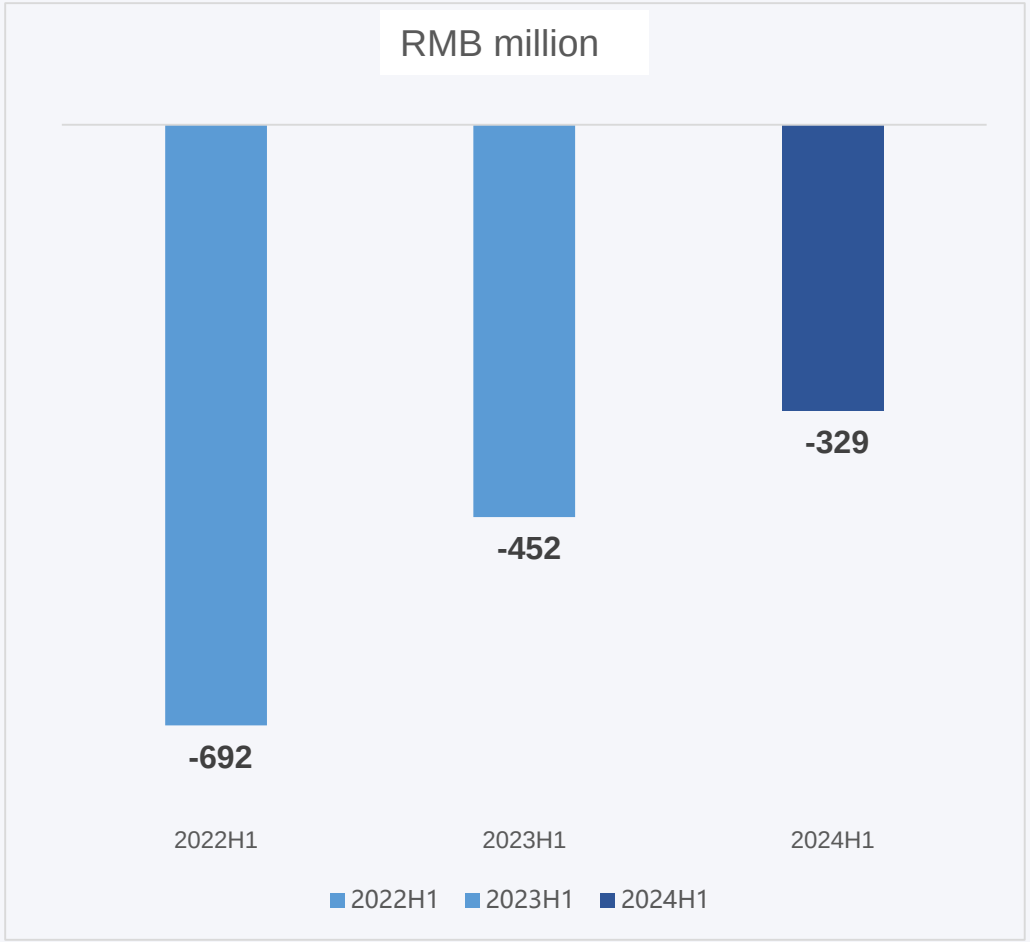
Note 2: calculated by FX rate of RMB/HKD 0.91

Strong growth of operating income, operating loss continue to narrow

Product sales increased strongly



Net operating loss* continued to narrow



*=net income-license income from BD + provision for investment losses by equity-accounting-method - other income and gains from foreign exchange differences of BD

Akeso Investment Thesis

- Recently approved ivonescimab is the world's best-in-class I/O therapy for the treatment of lung cancer, and expected to be SOC for certain types of lung cancer treatment in the near future
- Akeso oncology program is anchored by two commercially available bispecific antibody treatments: ivonescimab and cadonilimab, covering the most critical mechanisms in solid tumor treatment
- Akeso's deep pipeline of internally developed antibodies enable us to create a broad set of cancer combination therapies using wholly owned assets
- Our world class CMC and manufacturing creates a dependable and cost competitive stream of therapeutic products for patients in China and around the world
- We have a strong balance sheet, rapidly growing revenue and efficient operating expenditure. This enables the company to continue to innovate and develop best-in-class antibody therapeutics.

Akesobio

Q&A

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