

## Akeso in 2023 and Beyond

Global Biopharma Innovator with Competitive Advantage in Oncology and beyond

J.P.Morgan 42nd Annual Healthcare Conference, 9 January 2024

Michelle Xia, Ph.D, Founder, Chairwoman & CEO



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## The Akeso Story





Founded in 2012

by a group of top dedicated scientists formerly working at global pharmaceutical companies

- Driven to discover and develop first-in-class and best-in-class medicines



Listed in HKEX since 2020 (09926.HK)

Market Cap: 39B HKD (~ 5B USD) as 29 December 2023

Leading biopharma company in China

## Our Vision is to use the power of science and technology to develop new medicines for global patients



100%

Fully integrated in-house drug discovery, CMC, GMP manufacturing, clinical development and commercialization (bispecific mAb, ADC, bispecific ADC, cell therapy etc.)

- <u>TETRABODY</u>: Our proprietary bispecific mAb technology create the bispecific from asymmetric bivalent form into tetravalent structure
- Developed bispecific mAbs with tetravalent design to achieve efficacy while lower toxicities
- Our global first marketed PD-1 based bispecific mAb proved more powerful than PD-(L)1 mAb for combination therapies

## Akeso Today (at a Glance in Jan 2024)

## Solid Foundation for Continued Growth





3

Commercial drugs in China (1 out-licensed)
World's 1st marketed dual checkpoint blocking bispecific (Cadonilimab)



50+

Innovative assets, covering oncology, immunology, CNS and metabolic diseases



5.39 B (RMB)

(\$800M+)

- Cash balance as 2023.6.30
- Well capitalized and on path to profitability



Q

NDA/sNDA filed (5 new products) Potentially world's 1st marketed checkpoint /angiogenesis bispecific (Ivonescimab)



9

Clinical-stage pipeline



2,800+ Akeso team

- 1100+ R&D
- 650+ manufacturing
- 800+ commercial



6

Bispecific mAbs in clinical stages

- 1 commercial Cadonilimab
- 1 filed for NDA Ivonescimab



120+

**Ongoing clinical trials** 



55.5-acre

- Self-owned R&D and biologics manufacturing sites
- Current biologics production capacity: 54,000L
- Cadonilimab: FIC bispecific mAb targeting on two I/O checkpoint proteins (PD-1 and CTLA-4), approved for marketing in China
- Ivonescimab: FIC bispecific mAb targeting on I/O and angiogenesis proteins (PD-1 and VEGF), filed for marketing approval

## Akeso Innovation Highlights: Leader in Bispecific Antibody Research & Development



> Akeso expanded the bispecific antibody world from asymmetric bivalent form into tetravalent structure, well suited for target enriched situation like the tumor microenvironment (TME)



- ➤ Delivery of Safety and Efficacy:
  Clinical POC with Cadonilimab (PD-1/CTLA-4) and Ivonescimab (PD1/VEGF), e.g.
  - Bleeding risk is significantly reduced with patients treated by ivonescimab vs. bevacizumab
  - Use of ivonescimab in previously impossible indications for VEGF blockers like sq NSCLC

Squamous NSCLC	Ivonescimab (N=122)	Bevacizumab
≥ grade3		
Hemoptysis/pulmonary hemorrhage	<b>1.6</b> % <sup>1</sup>	<b>31%</b> <sup>2</sup>

<sup>1:</sup> Data from clinical trials AK112-201 and AK112-202 2023)

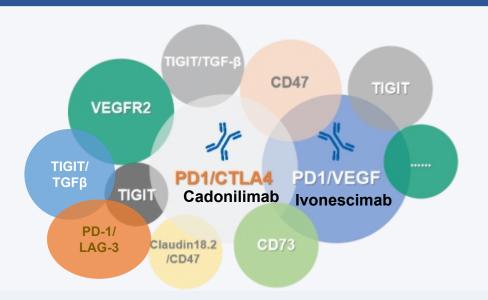
Median follow up: 18.6 months (Data cutoff: June 30,

<sup>2:</sup> Data from bevacizumab label

## Akeso Innovation Highlights: Safe Bispecifics as Cornerstone Drugs to Enable Additional Combination for Deeper Efficacy



## **Tumor Immunotherapy Combinations**



- ✓ With proved safety and efficacy as monotherapy, cadonilimab and ivonescimab, the two cornerstone drugs, serving as foundations of combination therapies, to improve the overall efficacy
- ✓ Complemented by a broad portfolio of products targeting key links in the tumor immune circuit TIGIT, CD47, CD73, VEGFR2, PD-1/LAG3, TIGIT/ TGFβ, Claudin18.2/CD47 ...

## Cadonilimab / Ivonescimab

Cornerstone Bispecific mAbs for Combination Therapies (with new direction, new mechanism, new pipeline etc)









Checkpoint Inhibitor

Targeted Therapy

ADC

New MOA

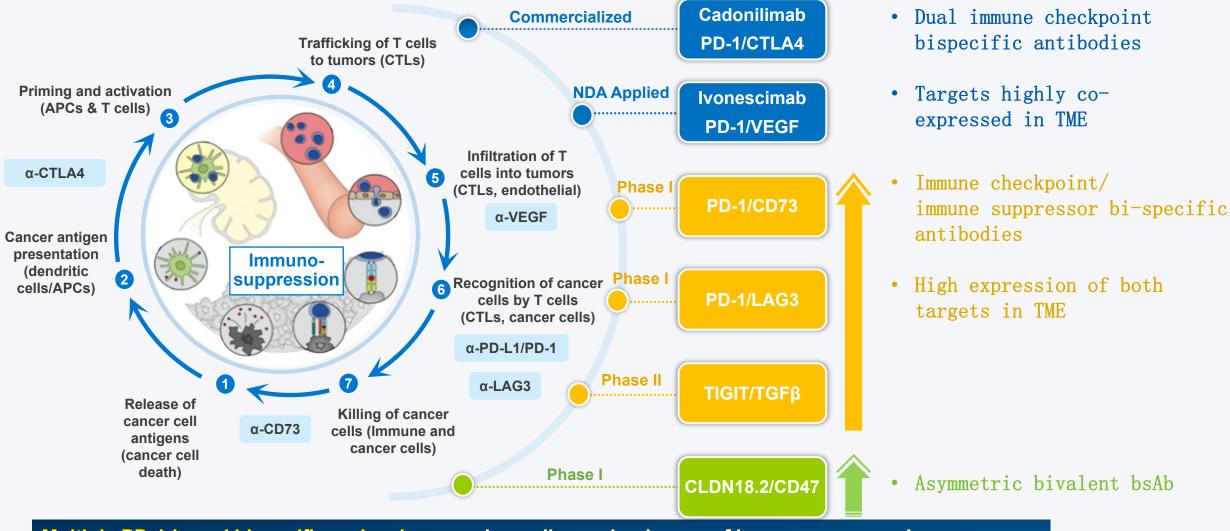
- Multiple Phase Ib/II trials are ongoing at Akeso to evaluate the potentially deeper efficacy through combination with bispecific antibodies
- ☐ Promising efficacy and safety results obtained in the trials, and data planned to be published in 2024

#### e.g.

- Cadonilimab+pulocimab (AK109)+chemo in 2L IO resistant GC/GEJC (AK109-201)
- Cadonilimab+TACE+Lenvatinib in unresectable HCC (AK104-216) ASCO GI (2024)
- Ivonescimab+ligufalimab in 1L PD-1(+) HNSCC (AK117-201)

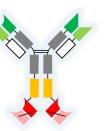
## Akeso Innovation Highlights: Expand & Extend to Deliver Bispecific Technologies to More Patients





Multiple PD-1-based bispecific molecules covering a diverse landscape of immuno-suppression Advanced combo strategies centered around bispecific with targeted or chemotherapy





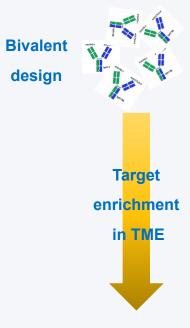
## Cadonilimab

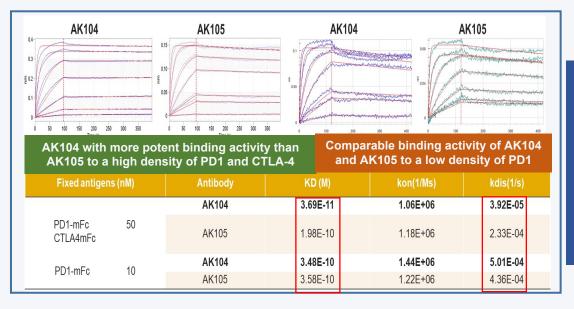
First Marketed Dual Checkpoint Blocking Antibody Targeting PD-1 & CTLA-4

## Design of Tetravalent Bispecific Antibody to Deliver Better Efficacy and Safety – Cadonilimab (AK104)



## Globally First Approved tetravalent bispecific antibody



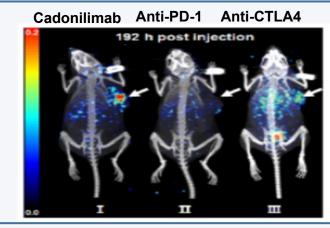


- PD-1 and CTLA-4 featured high level co-expression in tumor (TILs and nodes), and low single expression in peripheral normal tissue
- Tetravalent design allows higher avidity binding in target enriched TME, as supported by the binding assays

(AK105: anti-PD-1 antibody penpulimab)



Cadonilimab (AK104)



Cadonilimab shows stronger tumor retention compared to anti-PD-1 or anti-CTLA-4 antibody in the radioisotope labeling study

Published on mAbs, 2023, VOL. 15, NO. 1, 2180794

## **Cadonilimab Global Clinical Trials**



Field	Treatment	Indications		Phasel	Phase II	Phase III	NDA submission/ Approval
	Mono	2L/3L Cervical Cancer	3				Approved in 2022
Cervical	+ chemotherapy ± bevacizum	ab 1L Cervical cancer				Primary endpoint met	
cancer	Mono	Neoadjuvant therapy for cervical cancer					
	+ XELOX chemotherapy	1L GC/GE					NDA submitted
Gastric cancer	+AK109 (VEGFR2)+ chemotherapy	2L GC/GEJ (PD-1/L1 relapse/refractory)					
Cancer	+AK117+chemotherapy	1L GC/GEJ					
	±AK117+ chemotherapy	Neoadjuvant therapy for GC/GEJ					
	Mono	Adjuvant therapy for HCC				Enrollment ongoing	
Hepatocellular	+ Lenvatinib	1L HCC					
carcinoma	+ Lenvatinib+TACE	intermediate unresectable HCC					
	+AK109	2L HCC (PD-1/L1 relapse/refractory)					
	+ Chemotherapy	1L PD-L1 negative NSCLC				Enrollment ongoing	
	+ Chiauranib	≥2L SCLC					
Lung cancer	+ Docetaxel	2L r/r NSCLC					
	+AK109±docetaxel	2L NSCLC (PD-1/L1 relapse/refractory)					
	+AK112 ± chemotherapy	advanced non-small cell lung cancer					
ESCC*	± AK117+ chemotherapy	1L ESCC					
Pancreatic cancer	+ Chemotherapy	1L PDAC					
	+AK117 (CD47)	advanced solid tumor	3				
Others	+AK119 (CD73)	advanced solid tumor	3			Selective disclos	ure of ongoing clinical trials
	+AK127 (TIGIT)	advanced solid tumor	3			*ESCC: esophag	eal squamous cell carcinoma





2,500+ Patients Treated with Cadonilimab across all trials to date
22+ Clinical Trials with 5 Phase III/Pivotal

## **Candolimab Phase III Trials – Expected Short-Term Catalysts**



AK104-307

First Patient In

1L PD-L1(-) NSCLC Ph III\*\*

Participate in Major Medical Conferences

AK104-302 (1L GC/GEJC) and AK104-303 (1L CC) Data Readout

Q1 2024 Q2 2024 Q3 2024 Q4 2024





AK104-306

**Last Patient In** 

Adjuvant HCC Ph III



Approved in China for 2/3L recurrent and metastatic cervical cancer to the market in June 2022

Cumulative sales of the first 12 months (2022H2 - 2023H1):
 1.15B RMB (\$165M)

<sup>\*</sup>NDA Filing with the CDE for Marketing Approval in China

<sup>\*\*</sup>Head-to-Head vs. Tislelizumab





# Potential FIC PD-1/ VEGF Bispecific Antibody

NDA submitted

Tetravalent Bispecific Antibody to Deliver Better Efficacy and Safety – Ivonescimab (AK112)

## **Partnership with Aligned Mission**

## - Licensing of Ivonescimab to Summit Therapeutics









\$500M

Upfront received

\$5B

**Total milestones** 

Low double - digit

Royalties of net sales

- \$ \$500M upfront was received in full
- 2 global Ph III studies initiated

Record-breaking licensing volume for innovative drugs originated in China

依达方® Ivonescimab (PD-1/VEGF, AK112/SMT-112)

- Exclusive licensing of development & commercialization to Summit in US, Canada, Europe, and Japan
- Accelerating the process to bring ivonescimab to patients around the world

## **Ivonescimab Global Oncology Clinical Trials**

Indication

**Histology/Population** 

Advanced or Metastatic

EGFRm+ 2L+









Trial

Harmon<sup>1</sup>













These ivonescimab clinical trials are being conducted in China and/or Australia and are fully sponsored and managed by Akeso.

HARMONI 3 NSCLC	Squamous 1L Metastatic	Combo ivonescimab + chemo vs. pembro + chemo		
Indication	Regimen		Phase I Phase II	Phase III
NSCLC: 2L EGFRm+	Randomized: Combo (chemo) v	s. chemo		
NSCLC: 1L PD-L1 TPS>1%	Randomized: Monotherapy vs.	pembro (PD-1)		
NSCLC: 1L Squamous	Randomized: Combo (chemo) vs. tislelizumab (PD-1) + chemo			
NSCLC: 1L Squamous	Randomized: Combo (chemo) v	s. pembro (PD-1) + chemo		
Advanced Solid Tumors	Monotherapy			
NSCLC	Combo (chemo)			
NSCLC	Monotherapy			
GYN Tumors	Monotherapy			
Ovarian Cancer	Combination (PARPi)			
NSCLC	Monotherapy & Combo (chemo)			
CRC	Combo (CD47 + chemo)			
HCC	Monotherapy			
NSCLC	Combo (PD-1 / CTLA-4 bsAb + chemo)			
HNSCC	Combo (CD47)			
Advanced Solid Tumors**	Combo (CD47, CD47 + chemo, chemo)			
TNBC	Comb (chemo, CD47 + chemo)			
NSCLC	Combo (CD73 + chemo)			
Advanced Solid Tumors	Monotherapy			
ES-SCLC	Combo (chemo)			

Regimen

chemo

Combo ivonescimab +

chemo vs. placebo +

NSCLC: Non-Small-cell Long Cancer, EGFRm+: Epidermal Growth Factor Receptor mutant positives, Combination, Chemo: Chemotherapy, pembro: pembrolizomab, CRC. Colorectal Cancer, HCC: Hepatocellular Carcinoma, HNSCC: Head & Neck Squamous Cell Carcinoma, BTC: Biliary Tract Cancer, TNBC: Triple Negative Breast Cancer, ES-SCLC: Extensive Stage Small Cell Lung Cancer, PD-1: Programmed Cell Death Protein(Id BARBittoo) WADP Protein(Id BARBITTO) WADP P



1,600+ **Patients** treated with ivonescimab across all trials to date

19+ **Clinical Trials** With 4 Phase III

Same Subset Patient Population



Phase III

## Ivonescimab NDA Filed in China, Global Phase III Trials Initiated





Ivonescimab (PD-1/VEGF, AK112/SMT-112)





### AK112-301

EGFR-TKI progressor of locally advanced or metastatic nsqNSCLC

- ✓ 1st indication in China
- NDA accepted by CDE in August 2023 under priority review

### AK112-303

✓ 1L PD-L1+ NSCLC (mono vs. pembrolizumab) enrollment completed

### AK112-306

 ✓ 1L locally advanced or metastatic sq-NSCLC enrollment ongoing

(AK112+chemo vs. tislelizumab +chemo)





3<sup>rd</sup> gen EGFR-TKI progressor of locally advanced or metastatic nsqNSCLC global Phase III:

- ✓ Enrollment ongoing in US and Europe
- ✓ Enrollment completed for Chinese part (AK112-301)

### HARMONi-3/AK112-3003

1L metastatic sq-NSCLC global Phase III:

✓ Enrollment ongoing globally (SMT-112+chemo *vs. pembrolizumab*+chemo)

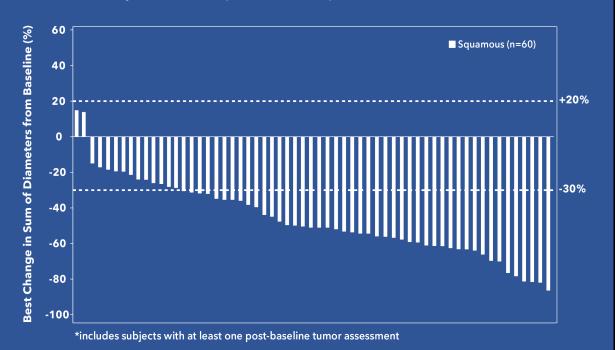


## 1L Adv/Metastatic Squamous NSCLC<sup>1,2</sup>





Median follow up 21.0 months (DCO: 10/10/23)



Percent Changes from Baseline in Target Lesions Sum of Diameters (N=60) Presentation exclusively for purposes of evaluating the landscape for ivonescimab

AK112-201 includes 10 mg/kg dosing (16%) and 20 mg/kg dosing (84%) of ivonescimab

	AK112-201	
	Cohort 1: SQ only; ivonescimab + chemo Phase II, N=63	
ORR†	67%	
DCR†	95%	
mDOR†	12.8m	
<b>mPFS</b> [95% CI]	<b>11.1m</b> [9.5 – 16.3]	

Established Standard of Care

	KEYNOTE-407  China Extension <sup>3</sup> pembrolizumab +  chemo; randomized  Phase III, N=65	KEYNOTE-407  Global <sup>4</sup> pembrolizumab +  chemo; randomized  Phase III, N=278
ORR†	80%	63%
DCR†	91%	86%
mDOR	7.1m	8.8m
<b>mPFS</b> [95% CI]	<b>8.3m</b> [6.2 – 10.5]	<b>8.0m</b> [6.3 – 8.4]

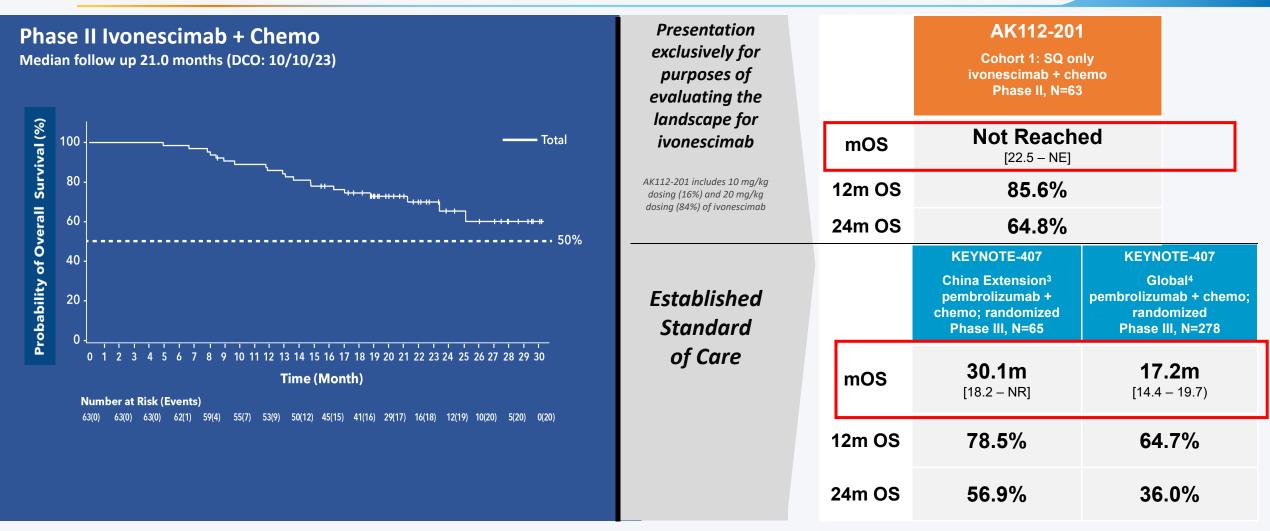
ORR: Overall Response Rate, mDOR: median Duration of Response, mPFS: median Progression Free Survival, DCO: data cutoff, NSCLC: Non-small Cell Lung Cancer, 1L: First Line, CI: Confidence Interval, SQ: Squamous, mFU: median follow-up, chemo: chemotherapy, m: month

<sup>†</sup> Includes subjects with at least one post-baseline tumor assessment, ORR based on confirmed BOR; N=60 evaluable for response

<sup>1.</sup> Zhang L, et al., ASCO 2023 poster #9087; 2. Data on File, Akeso Inc; 3. Cheng et. al. JTO Clin Res Rep (2021); 4. Paz-Ares, et. al. Journal of Thoracic Onc (2020)

## 1L Adv/Metastatic Squamous NSCLC<sup>1,2</sup>





OS: overall survival, DCO: data cutoff NSCLC: Non-small Cell Lung Cancer, 1L: First Line, CI: Confidence Interval, SQ: Squamous, pembro: pembrolizumab, chemo: chemotherapy, NE: Not Established, NR Not Reached, TRAEs: Treatment Related Adverse Events

1. Zhang L, et al., ASCO 2023 poster #9087; 2. Data on File, Akeso Inc; 3. Cheng, et. al. JTO Clin Res Rep (2021); 4. Novello, et. al. J Clin Oncol 41, no. 11 (2023)

## Ivonescimab Phase III Trials – Expected Short-Term Catalysts





Participate in Major Medical Conferences





Q1 2024 Q2 2024 Q3 2024 Q4 2024



AK112-303

Interim Analysis
Randomized
Phase III Trial vs.
Pembrolizumab



AK112-301 CDE Decision Expected\* & Topline Data



**Last Patient In** 

1L sq-NSCLC Phase III
Trial vs.
Tislelizumab+chemo





Same Subset Patient Population

\*NDA Filing by Akeso with the CDE for Marketing Approval in China, 2023



## Ligufalimab

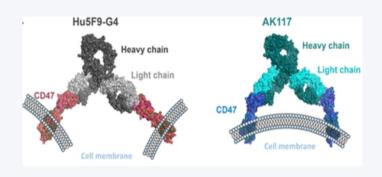
Potential FIC anti-CD47 mAb

## Ligufalimab (AK117): Most Advanced CD47 mAb without RBC Hemagglutination - Provides Foundation for Superior Safety



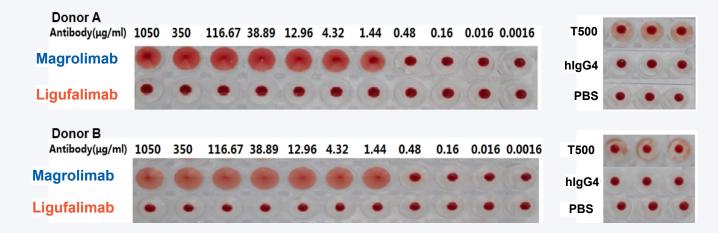
### Ligufalimab (AK117) is a human IgG4 antibody targeting CD47 with an excellent safety profile

## Unique binding stereoselectivity of AK117 avoids transcellular binding



Structure analysis results were published on Journal for ImmunoTherapy of Cancer 2022;10:e005517

## Eliminated Hemagglutination of Human RBC



- Ligufalimab does not induce hemagglutination of human RBC up to 1,050 μg/mL
- Magrolimab triggers hemagglutination at as low as 1.44 μg/mL

## Ligufalimab Favorable Safety Profile in Dose Escalation Phase



- Ligufalimab showed superior safety in Phase I clinical studies [Australia (AK117-101, FIH) and China (AK117-102)]
- No severe hematologic toxicities or severe hemoglobin drop observed at up to 45 mg/kg in solid tumor or lymphoma
- Complete elimination of RBC hemagglutination, and no need for priming dose

Solid Tumor/Lymphoma	Ligufalimab ≥20mg/kg (TEAE)				
Solid Tumor/Lymphoma	20mg/kg (13)	30mg/kg (21)	45mg/kg (17)	Total (51)	
Hemagglutination	0	0	0	0	
Anemia	23% (3/13)	14% (3/21)	41% (7/17)	25% (13/51)	
Thrombocytopenia	8% (1/13)	10% (2/21)	12% (2/17)	10% (5/51)	
Hyperbilirubinemia	8% (1/13)	0	6% (1/17)	4% (2/51)	
Headache	38% (5/13)	0	6% (1/17)	12% (6/51)	
Fatigue	0	10% (2/21)	6% (1/17)	6% (3/51)	
Fever	15% (2/13)	14% (3/21)	6% (1/17)	12% (6/51)	
Infusion-related reaction	0	0	0	0	

Data cutoff: Aug. 25, 2023

Data pooled from 2 trials: AK117-101 (with monotherapy and cadonilimab combination for advanced solid tumors in Australia), AK117-102 (monotherapy in advanced solid tumors and lymphomas in China)

## Ligufalimab with Potential Best-In-Class Safety Profile and Superior Efficacy



A CD47 blocking antibody without RBC hemagglutination

No priming dose needed; minimal anemia in patients treated; no DLT up to 45 mg/kg

Good safety profile demonstrated in both mono and in combo with bispecific mAb and chemo

Combo with azacitidine showed promising efficacy in 1L HR-MDS and 1L unfit AML

Combo with bispecific I/O mAb and chemo showed promising efficacy signals in advanced solid tumors

Global development planned, including studies in both hematologic and solid tumors:

- Combination with azacitidine for 1L HR-MDS and 1L unfit AML
- Combination with cadonilimab or ivonescimab ± chemo, for advanced solid tumors e.g. HNSCC, GC, pancreatic, TNBC etc.

## Ebdarokimab (IL-12/IL-23) NDA Filed in August 2023



1st IL-12/IL-23 blocking medicine developed in China filed for market approval

Ebdarokimab
IL-12/IL-23, AK101
NDA accepted by CDE in Aug 2023

- Ebdarokimab targets both IL-12&IL-23
- Indication filed: Moderate-to-severe psoriasis

**Excellent safety and efficacy results Sustained benefits over long time use** 

Phase III results published at 2023 EADV



Key results	Ebdarokimab
PASI75(%)	79%*
sPGA0/1(%)	64%*

\*: Clinical trial results of AK101-201, AK101-301, AK101-302 and AK101-303 published at 2023 EADV

Competitive advantage
Convenient dosing regimen:

Only 4 times dosing per year (5 times in the 1st year)

Huge unmet medical needs in China



**6.70** million
Psoriasis patients in China



\$9.5 billion USD

Market size expected in 2030

CAGR up to 27%

Source: Frost & Sullivan, 2017-2030 (Estimated) China Psoriasis Drug Market

## Ebronucimab (PCSK9) NDA Filed in June 2023





Two indications filed

**Excellent safety and efficacy results Sustained benefits over long time use** 

Competitive advantage

3 Dosing regimens
All show significant reduction
from baseline

LDL-C level significantly lowered



65+%\*

In each cycle

Q6W Higher compliance

\*: Clinical trial results of AK102-201, AK102-301, AK102-302 and AK102-303

Huge unmet medical needs in China

patients



110 million

Hypercholesterolemia



\$1.34 billion PCSK9 market

Source: 2023-2030 (Estimated) China PCSK9 Market , Frost & Sullivan

Primary hypercholesterolemia

hypercholesterolemia (HeFH)

and mixed hyperlipidemia

**Heterozygous familial** 

## **Key Near-Term (2024 – Early 2025) Milestones**



### **NDA/sNDA** Approval

#### Ivonescimab + chemo

EGFR-TKI progressed nsq-NSCLC

#### **Ebronucimab (PCSK9)**

- Hypercholesterolemia
- Heterozygous familial hypercholesterolemia

#### Ebdarokimab (IL-12/IL-23)

Moderate-to-severe psoriasis

#### Penpulimab + chemo

• 1L NPC

### **NDA/sNDA Submission**

#### **Ivonescimab**

• 1L PD-L1 (+) NSCLC, vs. pembrolizumab

#### Cadonilimab + chemo

1L GC/GEJC

#### Cadonilimab + chemo ± bevacizumab

1L Cervical Cancer

#### **Gumokimab (IL-17)**

Moderate-to-severe psoriasis

### **Phase III Data Readouts**

#### Cadonilimab + chemo

1L GC/GEJC

#### Cadonilimab + chemo ± bevacizumab

1L Cervical Cancer

#### **Ivonescimab**

• 1L PD-L1 (+) NSCLC, vs. pembrolizumab

#### Ivonescimab + chemo

2L+ EGFR-TKI progressed nsq-NSCLC

#### **Gumokimab (IL-17)**

Moderate-to-severe psoriasis

### **Phase III Enrolment Completion**

#### Cadonilimab

Adjuvant therapy for HCC

#### Ivonescimab + chemo

- 1L sq-NSCLC, vs. tislelizumab + chemo
- 2L+ 3rd gen EGFR-TKI progressed nsq-NSCLC



### **Gumokimab (IL-17)**

Ankylosing spondylitis

#### **Potential Phase III Initiation**

#### Cadonilimab

· 2 Phase III trials

#### **Ivonescimab**

2 Phase III trials

#### Manfidokimab (IL-4R)

1 Phase III trial

#### **POC Readouts**

Cadonilimab combo studies

Ivonescimab combo studies

Ligufalimab combo studies

**AK127 (TIGIT) combo studies** 

AK109 (VEGFR2) combo studies

And more...

### **Pipeline Advancement**

### Pipeline advancing to Phase II

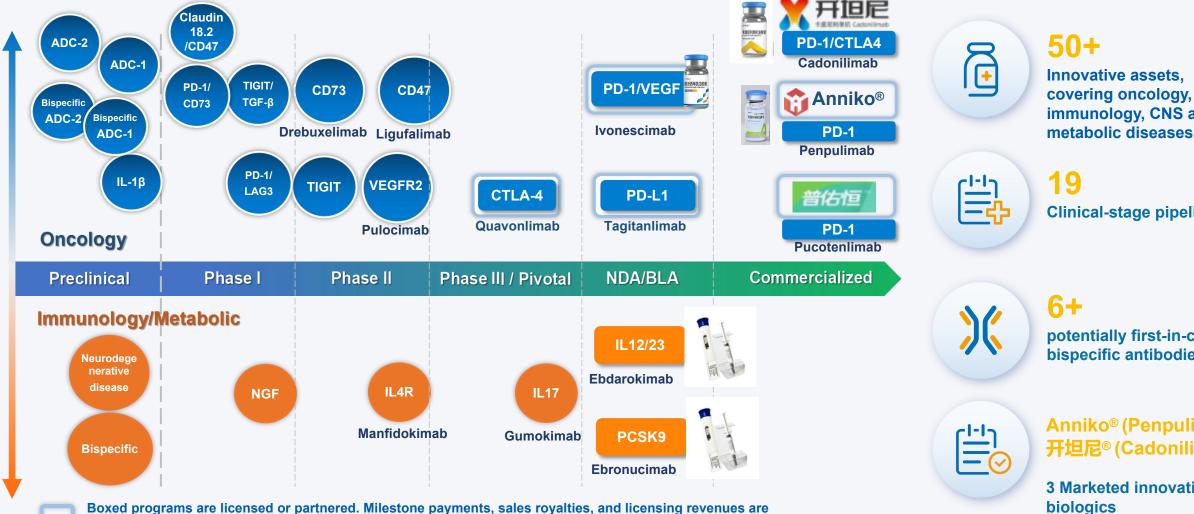
- AK129 (PD-1/LAG3)
- AK130 (TIGIT/TGFβ)

#### First-in-human assets

- ADC
- Neurodegenerative diseases
- TME macrophage modulator And more ...

## Akeso Pipeline with 3 Marketed Drugs and 80+ IND Clearances





Innovative assets. covering oncology, immunology, CNS and

Clinical-stage pipeline

potentially first-in-class bispecific antibodies

Anniko® (Penpulimab) 开坦尼® (Cadonilimab)

3 Marketed innovative biologics

expected according to the licensing agreements.

## Clinical Studies and Commercialization Supported by In-House cGMP Manufacturing Facilities



**Zhongshan National Health Park** 

3,500L
Running capacity



The first central integrated control biopharmaceutical flexible factory based on GE Healthcare FlexFactory™ in South China

Zhongshan Cuiheng - Akeso Bay Science & Technology Park

14,500L Running capacity

4x10,000L

Stainless Steel Tank Under validation

(will be operated in 2024)







Hongkong

54,000L operating capacity

160,000L total planning capacity



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