

# 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025

BOB DUGGAN, Chairman & CEO DR. MAKY ZANGANEH, CEO & President

# Forward Looking Statement

Any statements in this presentation about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, entry into and actions related to the Company's partnership with Akeso Inc., the Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the results of our evaluation of the underlying data in connection with the development and commercialization activities for ivonescimab, the outcome of discussions with regulatory authorities, including the Food and Drug Administration, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials, the results of such trials, and their success, and global public health crises that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, whether business development opportunities to expand the Company's pipeline of drug candidates, including without limitation, through potential acquisitions of, and/or collaborations with, other entities occur, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of filings that the Company makes with the Securities and Exchange Commission. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, the audience should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this presentation represent the Company's views only as of the date of this presentation and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this presentation.



# Mission

To improve quality of life, increase potential duration of life, by resolving serious unmet medical needs

Patients first

# Cornerstone

**High-speed Execution** 

Leadership in Global Oncology with a Proven Track Record

Helping patients return to the **MAGIC of NORMAL** 

# 2024 Achievements



# 2024 Major Achievements





### Ivonescimab: 9 Total Phase III Trials

Fully-Enrolled Trials: 3

**Enrolling Trials: 4** 

Imminently Starting Trials: 2





Ivonescimab statistically significant and decisive PFS improvement vs. Pembrolizumab<sup>1</sup>



**Ivonescimab**Approved in China<sup>2</sup>



# HARMONI

Completed enrollment in global Phase III trial



Announced

Enrollment Starting
Early 2025

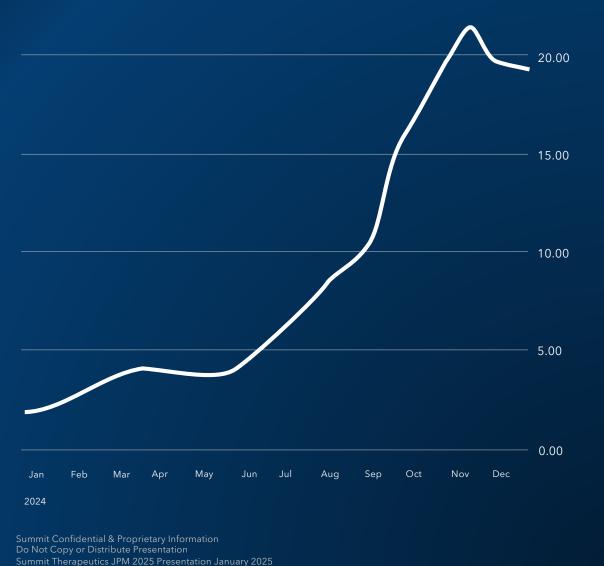








# 2024 Stock Performance 50-Day Moving Avg



## FINANCIAL SUMMARY

SMMT 2024 Stock Performance: + 584%<sup>1</sup>

\$435 Million in Financing in 2024

YE 2024, unaudited cash balance in excess of \$410 Million

Current Debt: \$0

(\$31.8 Million in principal and interest was paid in Q4 2024)





# Ivonescimab



# Cooperative Binding

Simultaneous blocking of PD-1 & VEGF<sup>1-3</sup>

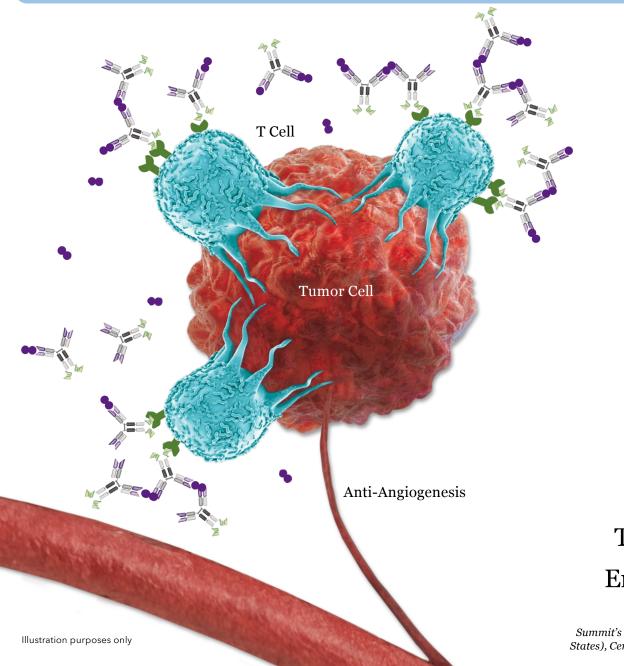
Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA)

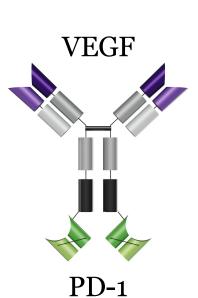
1. Zhao Y. et al., eClinicalMedicine. 2023; 3(62): 102106; 2. Wang L, et al. J Thorac Oncol. 2024 Mar;19(3):465-475; 3. Zhong T, et al. AACR-NCL-EORTC Internationa Conference 2023. Poster #B123, Abstract #35333, Boston, MA, USA. Abbreviation: PD-1, Programmed Cell Death Protein 1; VEGF, vascular endothelial growth facto

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# Ivonescimab Mechanism of Action





VEGF Dimer PD-1 Receptor in T Cell

Enhanced Avidity in Tumor Microenvironment<sup>3</sup> Enhanced Activity of T Cells<sup>3</sup>

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# Ivonescimab





2,300+

Patients treated in clinical trials <sup>1</sup>

9

Phase III announced, ongoing, or completed <sup>2</sup>

14

Publications in 2024 in 7 tumor types <sup>3</sup>

5

Oral Presentations at major medical conferences <sup>3</sup>

1. Data on File. 2024; 2. Akeso's 2024 First Half Interim Results (prnewswire.com, akesobio.com); clinicaltrials.gov 3. Publications available at smmttx.com, Accessed On Jan 04, 2025.

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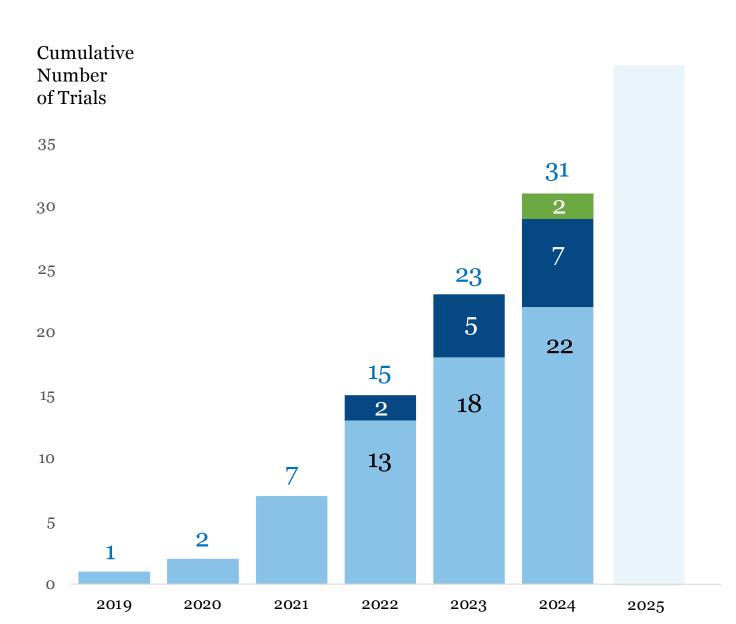
# 31 Ivonescimab Clinical Trials

Announced Phase III

Phase III

Phase I-II

Aspirational



# Ivonescimab Pipeline



Conducted in China Fully Sponsored and Managed by Akeso

#### Phase III

2L+NSCLC: HARMON1.A

1L NSCLC: HARMON1\_2

1L NSCLC: HARMON1-6

1L R/M HNSCC: HARMON 1-HN1

1L Biliary Tract: HARMON 1-GI1

1L Pancreatic: HARMON 1-GI2

#### Phase I-II

**NSCLC Breast** 

Ovarian G/GEJ

SCLC

Hepatocellular Colorectal

Planned and Ongoing Studies Sponsored by Summit Therapeutics\*

#### Phase III

2L+ NSCLC: HARMON1

1L NSCLC: HARMONI-3

1L NSCLC: HARMON17

#### **Expanding CDP**

Further Announcements in 2025 *Not shown in image* 

#### **ISTs**

30+ Approved Trials Being Initiated *Not shown in image* 

> M.D. Anderson **Collaboration Initiated**

\$15 million committed by Summit

\*ISTs, M.D. Anderson collaboration trials not sponsored by Summit. Akeso Phase III clinical trials from Akeso's 2024 First Half Interim Results (prnewswire.com; akesobio.com) and/or clinicaltrials.gov. Abbreviations: ISTs, Investigator sponsored trials; NSCLC, non small cell lung cancer; GI, gastrointestinal; G/GEJ, Gastric / Gastroesophageal Junction; SCLC, small cell lung cancer; HNSCC, Head and neck squamous cell carcinoma; CDP, clinical development plan



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# Ivonescimab Pipeline: NSCLC



Conducted in China Fully Sponsored and Managed by Akeso





Planned and Ongoing Studies Sponsored by Summit Therapeutics

**NSCLC Phase III** 

2L+ EGFRm



Approved in China

# HARMONI

Enrollment complete; Top-line data expected mid-2025

1L

Ivo + chemo

HARMONI-6

Enrolling in China

Ivo monotherapy

Harmoni<sub>-2</sub>

Submitted for approval in China

HARMONI-3

Enrolling globally

HARMONI-7

First patient expected: Early 2025

Abbreviations: EGFRm, epithelial growth factor receptor mutant; NSCLC, non small cell lung cancer; 1L, first-line, 2L+, second-line or later; ivo, ivonescimab; chemo, chemotherapy.



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# 1L NSCLC Ivonescimab vs. Anti-PD-1 +/- chemo





PD-L1 High, Monotherapy **Ivonescimab** vs **pembrolizumab**<sup>2</sup>

Enrollment starting in early 2025



PD-L1 All-Comers

Ivonescimab + chemo vs

pembrolizumab + chemo¹

Currently enrolling



# Harmoni<sub>2</sub>

PD-L1 Positive, Monotherapy **Ivonescimab** vs **pembrolizumab**<sup>3</sup>

WCLC 2024 Presidential Symposium



Squamous, PD-L1 All-Comers **Ivonescimab** + chemo vs **tislelizumab** (PD-1) + chemo<sup>4</sup>

Currently enrolling



# Patient Population

- Stage IIIB-IV **NSCLC**
- 1L therapy for
- rearrangements

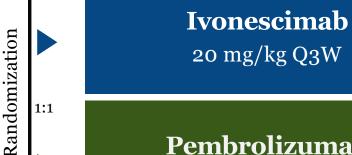


# Monotherapy Ivonescimab vs. Pembrolizumab Randomized, Double-blind, Phase III Study

NCT05499390<sup>a</sup>



- advanced NSCLC
- PD-L1 Positive Expression
- No EGFR mutations or ALK
- ECOG PS o or 1



**Pembrolizumab** 200 mg Q3W

#### **Treatment Until**

- no clinical benefit
- unacceptable toxicity
- 24 months of treatment

#### Stratification

- Clinical stage (IIIB/C vs. IV)
- Histology (SQ vs. non-SQ)

1:1

N = 398

• PD-L1 TPS (≥50% vs. 1-49%)

#### Endpoints

**Primary:** PFS by blind IRRC per RECIST v1.1

Secondary: OS, PFS assessed by INVs, ORR, DoR, TTR, safety

Exploratory: QoL

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

a. Patients were randomized from November 2022 to August 2023. Data cut off: January 29, 2024. Abbreviations: NSCLC, non-small cell lung cancer; EGFR, epidermal growth factor receptor; ALK, anaplastic lymphoma kinase; ECOG PS, Eastern Cooperative Oncology Group performance score; PD-L1, programmed death ligand 1; TPS, tumor proportion score; SQ, squamous cell carcinoma; Q3W, every three weeks; PFS, progression-free survival; IRRC, independent radiology review committee; OS, overall survival; INVs, investigators; ORR, overall response rate; DoR, duration of response; TTR, time to response; QoL, quality of life

Caicun Zhou | HARMONi-2

2024 World Conference on Lung Cancer Presidential Symposium, 9/8/24, San Diego, CA





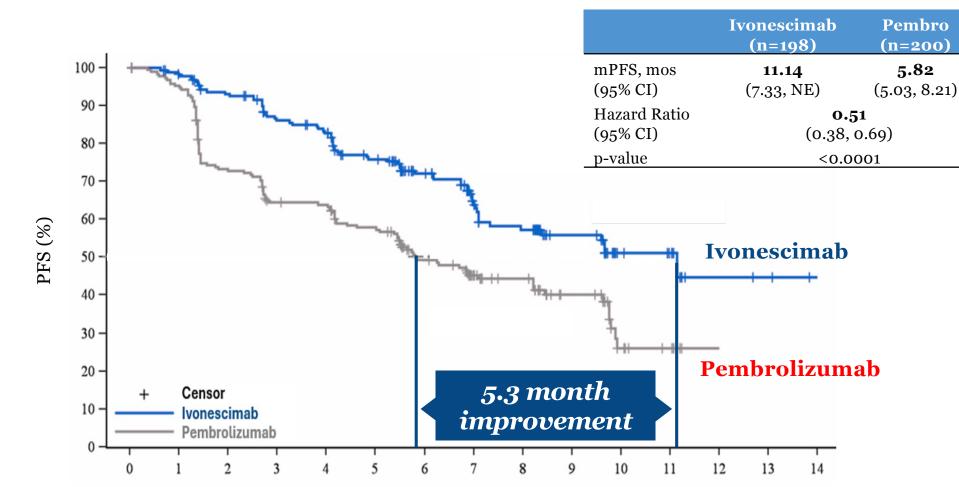
# Ivonescimab showed a

decisive, statistically significant improvement in PFS vs. pembrolizumab

in this Phase III study



# Monotherapy Ivonescimab vs. Pembrolizumab ITT: PD-L1 Positive NSCLC



#### Number at risk (Events)

Ivonescimab	198(0)	189(3)	175(13)	156(26)	148(32)	128(44)	99(50)	68(60)	59(67)	38(68)	14(71)	11(71)	3(72)	2(72)	0(72)
Pembrolizumah	200(0)	187(9)	141(52)	121(69)	119(70)	103(81)	74(95)	53(101)	45(102)	25(106)	9(112)	5(112)	0(112)		

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso. Abbreviations: mPFS, median progression-free survival; PFS, progression free survival; PD-L1, programmed death ligand 1; CI, confidence interval; ITT, intention to treat population; pembro, pembrolizumab.

Caicun Zhou | HARMONi-2 2024 World Conference on Lung Cancer Presidential Symposium, 9/8/24, San Diego, CA





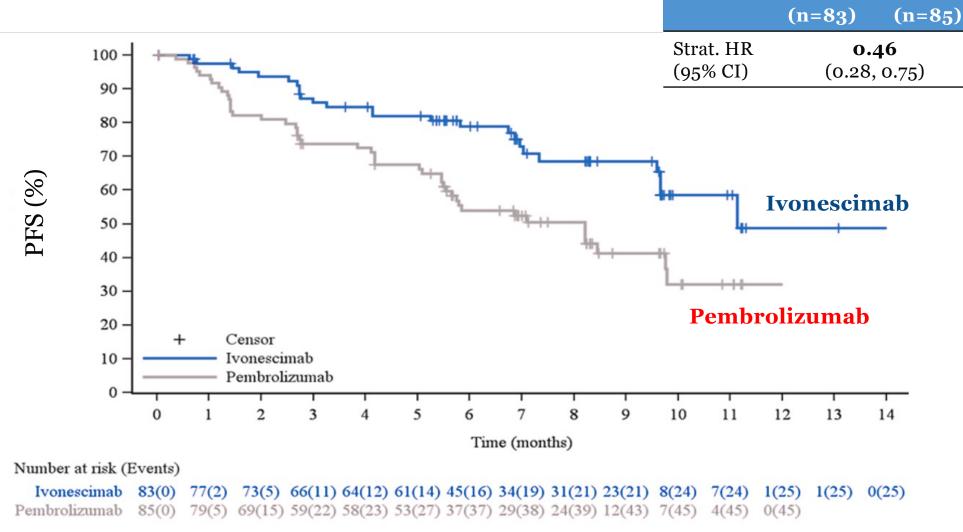
# Ivonescimab showed a

clinically
meaningful
improvement
in PFS vs.
pembrolizumab

across major clinical subgroups in this Phase III study



# Monotherapy Ivonescimab vs. Pembrolizumab PD-L1 High Expressing Tumors



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2024 World Conference on Lung Cancer Presidential Symposium, 9/8/24, San Diego, CA

Caicun Zhou | HARMONi-2



**Pembro** 

Ivo



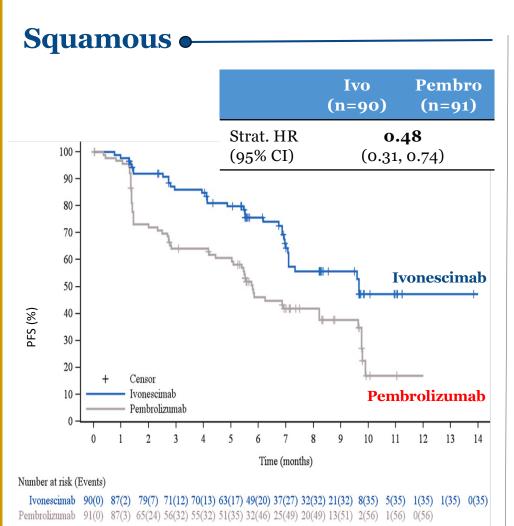
# Ivonescimab showed a

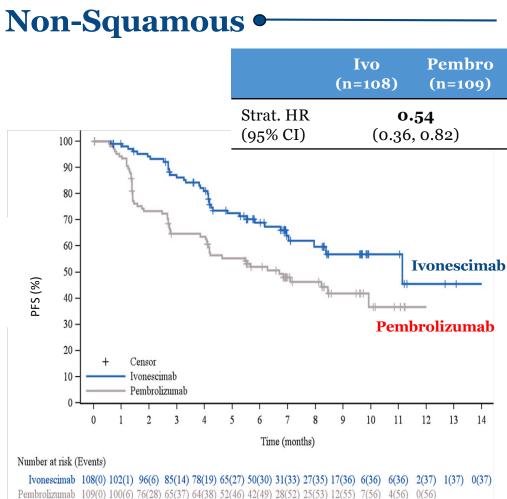
clinically
meaningful
improvement
in PFS vs.
pembrolizumab

across major clinical subgroups in this Phase III study

# Akesobio

# Monotherapy Ivonescimab vs. Pembrolizumab NSCLC by Histology





Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

Abbreviations: PFS, progression-free survival; PD-L1, programmed death ligand 1; TPS, tumor proportion score; strat. HR: stratified hazard ratio; Cl, confidence interval; NSCLC, non-small cell lung cancer; ivo, ivonescimab; pembro, pembrolizumab

Caicun Zhou | HARMONi-2 2024 World Conference on Lung Cancer Presidential Symposium, 9/8/24, San Diego, CA





Ivonescimab safety profile was consistent with prior studies and

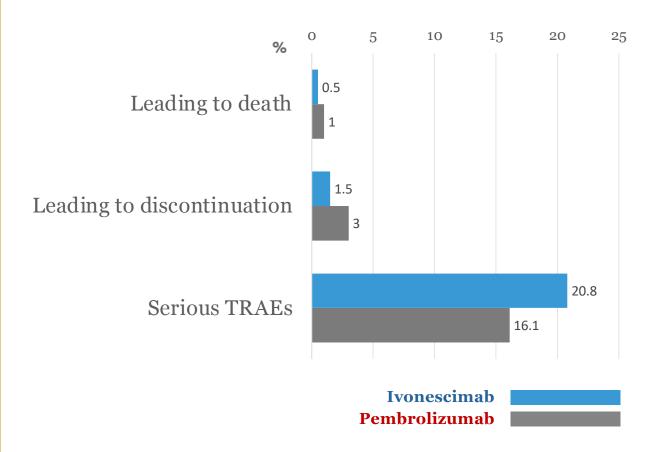
well tolerated,

including patients with SQ-NSCLC

# Akesobio

# Monotherapy Ivonescimab vs. Pembrolizumab Ivonescimab Showed Manageable Safety Profile

### Treatment-related Adverse Events



**Ivonescimab** exhibited

similar irAEs to that of pembrolizumab

29.9% ivo 28.1% pembro

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

Abbreviations: AEs, adverse events; SQ, squamous cell carcinoma; NSCLC, Non-small Cell Lung Cancer, TRAEs, treatment-related adverse events; irAEs, immune related adverse events; ivo. ivonescimab: pembro. pembrolizumab.





## **Key Inclusion**

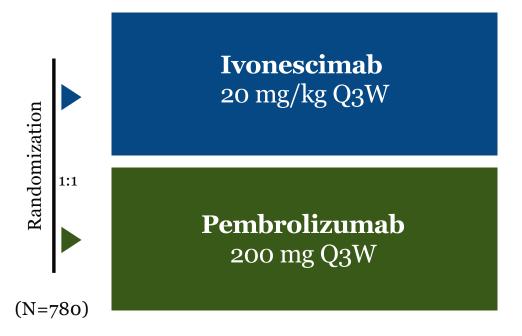
- 1L squamous or non-squamous metastatic NSCLC
- PD-L1 high expression
- No activating genomic alterations

Abbreviations: NSCLC, non-small cell lung cancer; PD-L1, programmed cell death-ligand 1; Q3W, every three weeks; PFS, progression free survival; OS, overall survival: ORR, overall response rate: 1L, first-line

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# Monotherapy Ivonescimab vs. Pembrolizumab

Randomized, Double-blind, Phase III Study 1L NSCLC with PD-L1 High Expression NCT06767514<sup>1</sup>



#### **Treatment until**

- Intolerable toxicity,
- Disease progression,
- 24 months of treatment

Safety and Survival Follow-up

Stratification Factors
Include Histology

Squamous vs. Non-Squamous

Study Endpoints

Primary and points: Pl

Primary endpoints: PFS, OS

Secondary endpoints: ORR, safety and tolerability





## **Key Inclusion**

- 1L squamous or non-squamous metastatic NSCLC
- Regardless of PD-L1 expression
- No activating genomic alterations

## Ivonescimab + Chemo vs. Pembrolizumab + Chemo

Randomized, Double-blind, Phase III Study 1L NSCLC: PD-L1 All-Comers\*

NCT05899608

#### Non-Squamous OR Squamous

Ivonescimab + Carboplatin + Pemetrexed Q3W x 4 cycles 1:1

Randomization

 $n = \sim 1080$ 

**Paclitaxel** (or nab-paclitaxel) + Q3W x 4 cycles

Ivonescimab +

Carboplatin +

Pembrolizumab + Carboplatin + Paclitaxel (or nab-paclitaxel) Q3W x 4 cycles

#### Maintenance

Non-Squamous: Ivonescimab + Pemetrexed

> Squamous: Ivonescimab

Non-Squamous: Pembrolizumab + Pemetrexed

Squamous: Pembrolizumab

- Intolerable toxicity,

### Treatment Until:

- Disease progression,
- · 24 months of treatment

### **Stratification Factors** Include Histology

Pembrolizumab +

Carboplatin +

Pemetrexed.

Q3W x 4 cycles

Squamous vs. Non-Squamous

#### Study Endpoints

#### Primary

• OS, PFS by Investigator

#### Secondary

- ORR, DCR, DOR, safety and tolerability
- PFS by BICR\*



Safety and Survival Follow-up

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA).



# 2L+ EGFRm NSCLC

Ivonescimab + Chemo vs. Placebo + Chemo

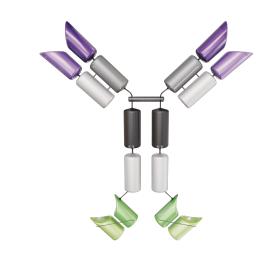


# HARMON<sup>1</sup>

EGFRm after a 3rd-gen TKI **Ivonescimab** + chemo vs. placebo + chemo<sup>1</sup>

Completed enrollment

Topline data expected mid-2025



# HARMONI<sub>-A</sub>

EGFRm after a TKI **Ivonescimab** + chemo vs.

placebo + chemo<sup>2</sup>

#### Positive Phase III Study:

- ASCO 2024 Presentation
- JAMA Manuscript

Approved indication in China



## Key Eligibility Criteria

- Stage IIIB-IV **NSCLC**
- EGFR mutation
- ECOG PS o or 1
- Any PD-L1 expression



## Ivonescimab + Chemo vs. Placebo + Chemo

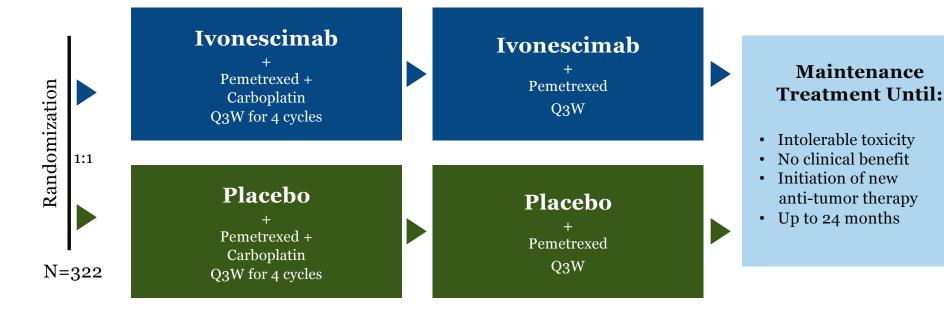
Randomized, Double-blind, Phase III Study 2L+ EGFRm NSCLC

NCT05184712a

Maintenance



- Post EGFR-TKI



#### **Stratification Factors**

- Exposure to 3<sup>rd</sup> gen EGFR-TKI before (yes vs no)
- Brain metastases (yes vs no)

#### **Endpoints**

- Primary: PFS by BICR
- Secondary: OS, Response rate, DoR, Time to response, Safety

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

a. Double-blind, placebo-controlled, randomized, phase 3 trial at 55 sites in China enrolled participants from January 2022 to November 2022; a total of 322 eligible patients were enrolled. ClinicalTrials.gov, NCT05184712; Abbreviations: ECOG, Eastern Cooperative Oncology Group; EGFR+, epidermal growth factor receptor positive; gen, generation; IV, intravenous; IRRC, independent radiologic review committee; NSCLC, non-small cell lung cancer; 2L+, second-line or later; PD-L1, programmed cell death-ligand 1; PS, performance status; Q3W, every 3 weeks; TKI, tyrosine-kinase inhibitor; PFS, progression free survival; OS, overall survival; DOR, duration of response. BICR, blinded independent central review.





## Ivonescimab + Chemo

significantly improved PFS in patients

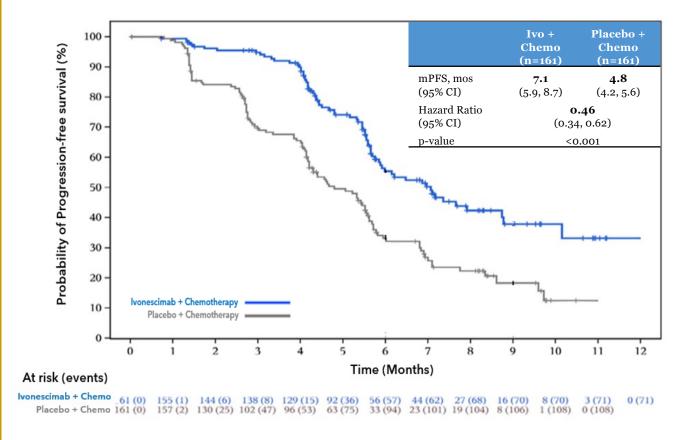
who progressed on prior EGFR-TKIs in this Phase III study

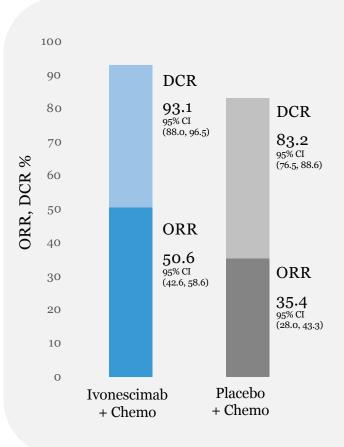


# Ivonescimab + Chemo vs. Placebo + Chemo

2L+ EGFRm NSCLC







Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

Data cutoff: Mar 10, 2023. Median (IQR) follow-up: 7.1 (5.4-9.0) months for ivonescimab and 8.2 (5.5-9.5) months for placebo; HR and P-value were stratified by previous 3rd Gen EGFR-TKI use (yes vs. no) and presence of brain metastases (yes vs. no), and were calculated with stratified Cox model and log rank test. The two-sided P-value boundary is 0.024 as calculated using Lan-Demets spending function with O'Brien-Fleming approximation. Zhang Li, et al. Ivonescimab combined with chemotherapy in patients with EGFR-mutant non-squamous non-small cell lung cancer who progressed on EGFR-TKIs treatment: a randomized, double-blind, multi-center, phase 3 trial (HARMONI-A study). Presentation at ASCO Annual Meeting; May 31, 2024. Chicago, IL, US.; HARMONi-A Study Investigators, Zhang L, Fang W, Zhao Y, et al. JAMA. 2024 May 31.; Abbreviations: CI, confidence interval; CR, complete response; DCR, disease control rate; DoR, duration of response; IRRC, independent radiologic review committee; ivo, ivonescimab; chemo, chemotherapy; PFS, progression-free survival; EGFRm, epidermal growth factor receptor mutation; TKI, tyrosine-kinase inhibitor: ORR, overall response rate: 2L+, second-line or later.







## HARMONi-A safety profile generally

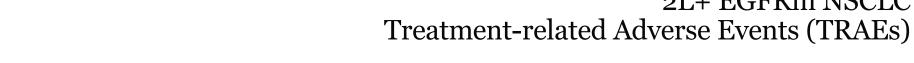
well tolerated,

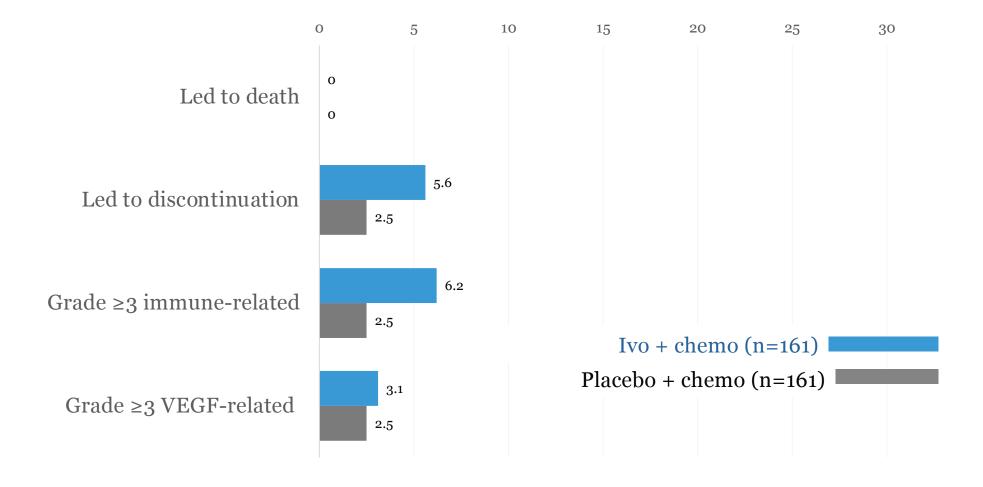
without unexpected AEs and low rate of treatment discontinuation



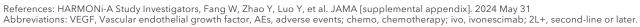
## Ivonescimab + Chemo vs. Placebo + Chemo

2L+ EGFRm NSCLC





Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.





Presented by

ASCO 2024

Dr. Li Zhang, MD

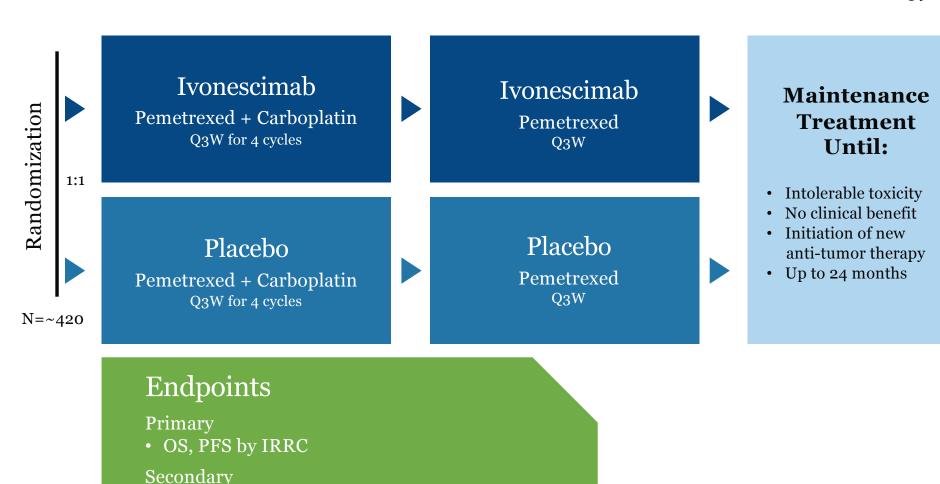


# Locally advanced or metastatic non-squamous NSCLC

- Stage IIIB-IV NSCLC
- EGFR mutation
- Progressed after a 3<sup>rd</sup> generation EGFR-TKI
- Regardless of PD-L1 expression

### Ivonescimab + Chemo vs. Placebo + Chemo

Randomized, Double-blind, Phase III Study 2L+ EGFRm NSCLC NCT06396065<sup>1</sup>



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• ORR, DoR, safety and tolerability

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## Phase II Studies Conducted in China

Akeso Sponsored

Promising
Phase II Data:
CRC, TNBC,
HNSCC, EarlyStage NSCLC

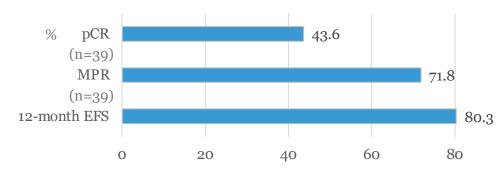
Abbreviations: CRC, colorectal cancer; HNSCC, head and neck squamous cell carcinoma; MSS, microsatellite stable; CRC, colorectal cancer; NSCLC, non small cell lung cancer; pCR, pathological complete response; MPR, major pathological response; TRAEs, treatment-related adverse events; DCR, disease control rate; PFS, progression free survival; ORR, overall response rate; Ivo, ivonescimab; Chemo, chemotherapy; EFS, event free survival; mFU, median follow-up time; mos, months.

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# Ivonescimab in Phase II Studies in Various Settings

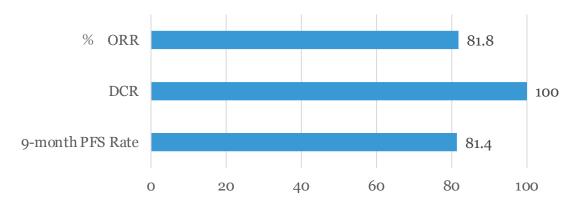
# Perioperative Resectable NSCLC<sup>1</sup>



No TRAEs led to cancelled / delayed surgery or wound healing complications. Overall rate of Serious TRAEs was 2%

Ivo + Chemo n=49 mFU: 8.9 mos.

## 1L MSS Colorectal Cancer (CRC)<sup>2</sup>



No TRAEs led to discontinuation. Overall rate of Serious TRAEs was 22.7%

Ivo + Chemo n=22

mFU: 9.0 mos.

Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

- 1. 2024 IASLC World Conference on Lung Cancer Annual Meeting
- 2. 2024 European Society of Medical Oncology Annual Meeting



## Phase II Studies Conducted in China

Akeso Sponsored

# Promising Phase II Data: CRC, TNBC, HNSCC, EarlyStage NSCLC

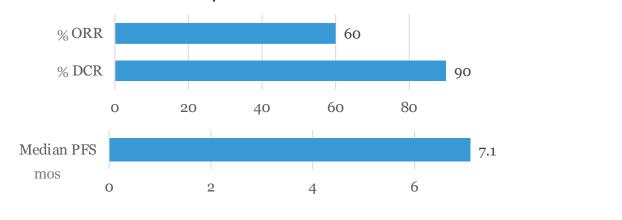
Abbreviations: TNBC, triple-negative breast cancer; R/M, recurrent / metastatic; HNSCC, head and neck squamous cell carcinoma; NSCLC, non small cell lung cancer; TRAEs, treatment-related adverse events; DCR, disease control rate; PFS, progression free survival; ORR, overall response rate; Ivo, ivonescimab; Chemo, chemotherapy; PD-L1, programmed cell death-ligand; EFS, event free survival; CPS, combined positive score; mFU, median follow-up time; mos, months. Note: AK117 is Akeso's proprietary anti-CD47 (cluster of differentiation 47) antibody that is not approved by any regulatory authority and for which Summit does not have any license or ownership rights.

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# Ivonescimab in Phase II Studies in Various Settings

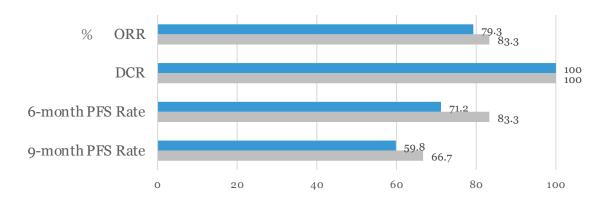
## 1L PD-L1 Positive R/M Head and Neck (HNSCC)<sup>1</sup>



No TRAEs led to discontinuation. Overall rate of Serious TRAEs was 5%

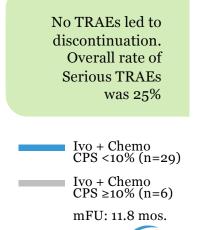
Ivo + CD47 (AK117) n=20 mFU: 4.1 mos.

## 1L Triple Negative Breast Cancer (TNBC)<sup>2</sup>



Ivonescimab is an investigational therapy not presently approved by any regulatory authority other than China's National Medical Products Administration (NMPA). Data generated and analyzed by Akeso.

- 1. 2024 European Society of Medical Oncology Annual Meeting
- 2. 2024 San Antonio Breast Cancer Symposium







# Ivonescimab Catalysts in 2025-2026





First Global Clinical Trial Results in Mid-2025

**Expanding our Global Clinical Development Plan**<sup>2</sup>

Way Beyond NSCLC

Investigator Sponsored
Trials Activating<sup>3</sup>

NSCLC and Way Beyond





Enrollment Completion<sup>1</sup>

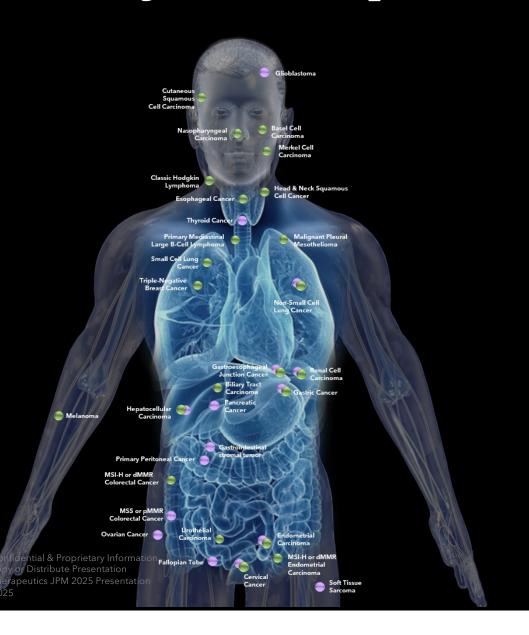
Clinical Trial Data Readouts

NSCLC and Way Beyond

Initiation of Additional Phase III Clinical Trials<sup>4</sup>

NSCLC and Way Beyond

# Ivonescimab Opportunity Goes *Beyond* Checkpoint Inhibitors (CPI)





2028 Estimated *CPI* TAM<sup>2</sup>

\$20B+

NSCLC CPI TAM<sup>2,3</sup>

# 50+ Approved Indications for PD-(L)1 & VEGF Therapies<sup>1</sup>

- Approved Anti-VEGF Therapies
- Approved Anti PD-(L)1 Therapies
- Approved Anti PD-(L)1 & Anti-VEGF Therapies

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