UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 13, 2025

Summit Therapeutics Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	001-36866	37-1979717
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

601 Brickell Key Drive, Suite 1000, Miami, FL	33131
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (305) 203-2034

Not applicable
(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 **Results of Operations and Financial Conditions.**

As of December 31, 2024, the preliminary unaudited balance of cash, cash equivalents, and short-term investment of Summit Therapeutics Inc. (the "Company") was no less than $410 million. This included the repayment of outstanding principal and interest totaling $31.8 million from a related party loan that was previously outstanding, as disclosed in the Company's Form 10-Q for the quarter ended September 30, 2024, filed on October 30, 2024. This amount is preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ materially from the amount that will be reflected in the Company's consolidated financial statements for the year ended December 31, 2024.

In accordance with General Instruction B.2 of Form 8-K, the information set forth under Item 2.02 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 **Regulation FD Disclosure.**

On January 13, 2025, the Company intends to present at the 43rd Annual J.P. Morgan Healthcare Conference. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 7.01 as if fully set forth herein.

In accordance with General Instruction B.2 of Form 8-K, the information set forth under Item 7.01 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit Number	**Description**
99.1	Investor Presentation Slides made available on January 13, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

SUMMIT THERAPEUTICS INC.

Date: January 13, 2025

By: /s/ Manmeet Soni

Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)

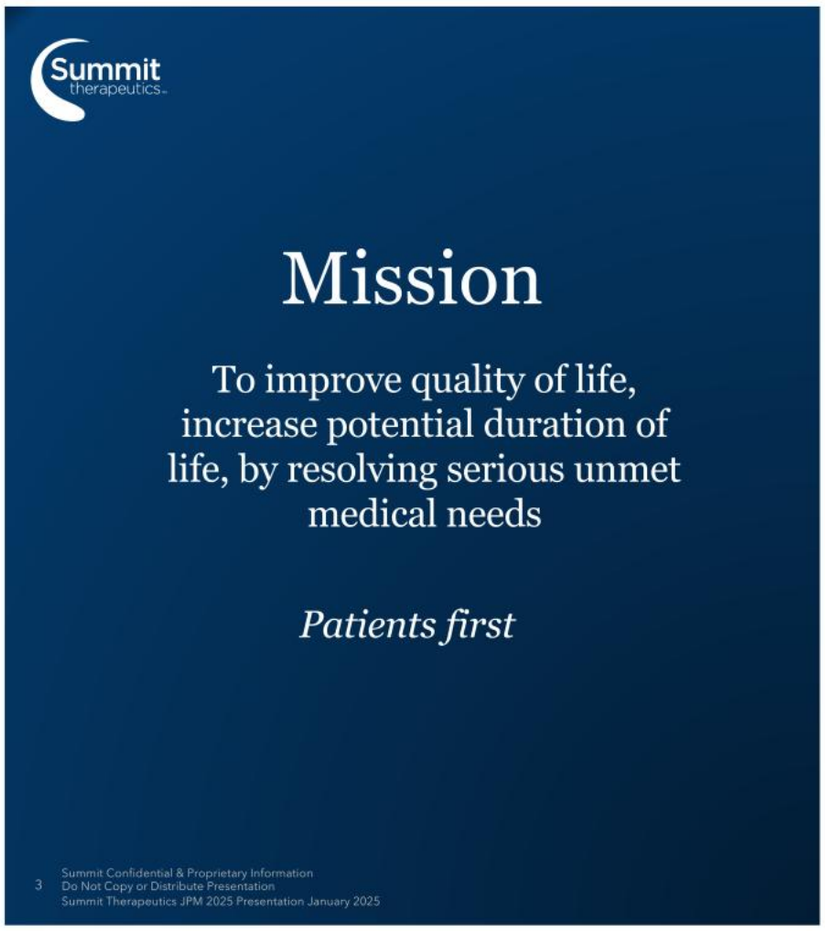
43rd Annual J.P. Morgan Healthcare Conference

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



Cornerstone

High-speed Execution

Leadership in Global Onco
with a Proven Track Recc

Helping patients return
*the **MAGIC of NORMA***

2024 Achievements

2024 Major Achievements

Ivonescimab: 9 Total Phase III Trials

Fully-Enrolled Trials: 3
Enrolling Trials: 4
Imminently Starting Trials: 2

Akesobio

HARMONi-2

Ivonescimab statistically significant and **decisive PFS improvement** vs. **Pembrolizumab**[1]

HARMONi-A

Ivonescimab Approved in China[2]

Summit therapeutics

HARMONi

Completed enrollment in global Phase III trial

HARMONi-7

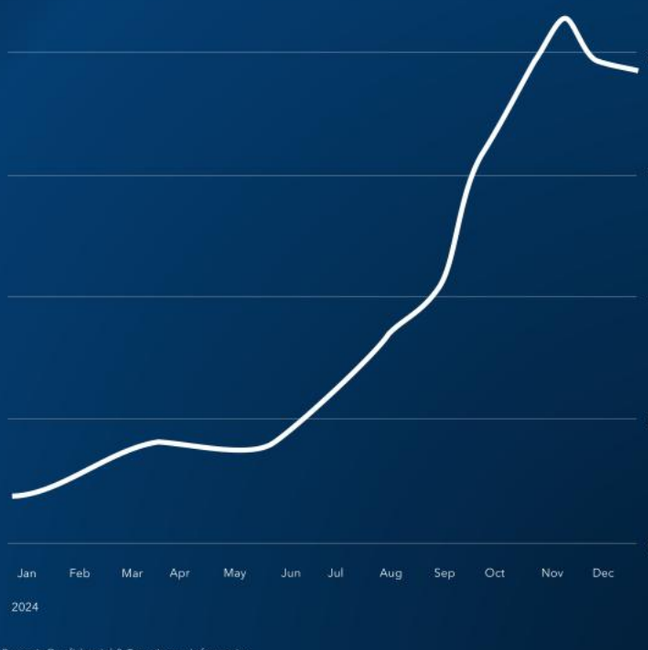
Announced

Enrollment Starting Early 2025

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] HARMONi-2 Study: Ivonescimab vs. Pembrolizumab in PD-L1 positive NSCLC conducted in China, sponsored by Akeso with data generated and analyzed by Akeso, HARMONi-2 ClinicalTrials.gov identifier: NCT05499390; [2]2L+ EGFRm NSCLC after an EGFR TKI therapy based on HARMONi-A study, ClinicalTrials.gov identifier: NCT05184712; HARMONi, ClinicalTrials.gov identifier: NCT06396065; HARMONi-7, ClinicalTrials.gov identifier: NCT06767514

2024 Stock Performance
50-Day Moving Avg



FINANCIAL SUMM

SMMT 2024 Stock Perform
+ 584%[1]

$435 Million in Financing i

YE 2024, unaudited cash b
in excess of $410 Milli

Current Debt: $0

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

1. Generated based on data from Yahoo! Finance (http://www.finance.yahoo.com/quote/SMMT - Accessed Janu
2025) based the closing price on the final trading day of 2024 (December 31, 2024, $17.84) and the closing price
final trading day of 2023 (December 29, 2023, $2.61).
Abbreviations: YE, year-end; Avg, average

Ivonescimab

Summit therapeutics

Cooperative Binding

Simultaneous blocking of PD-1 & VEGF[1-3]

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-NCI-EORTC International Conference 2023.Poster #B123,Abstract #35333, Boston, MA, USA. Abbreviations: PD-1, Programmed Cell Death Protein 1; VEGF, vascular endothelial growth factor

Ivonescimab Mechanism of Actio

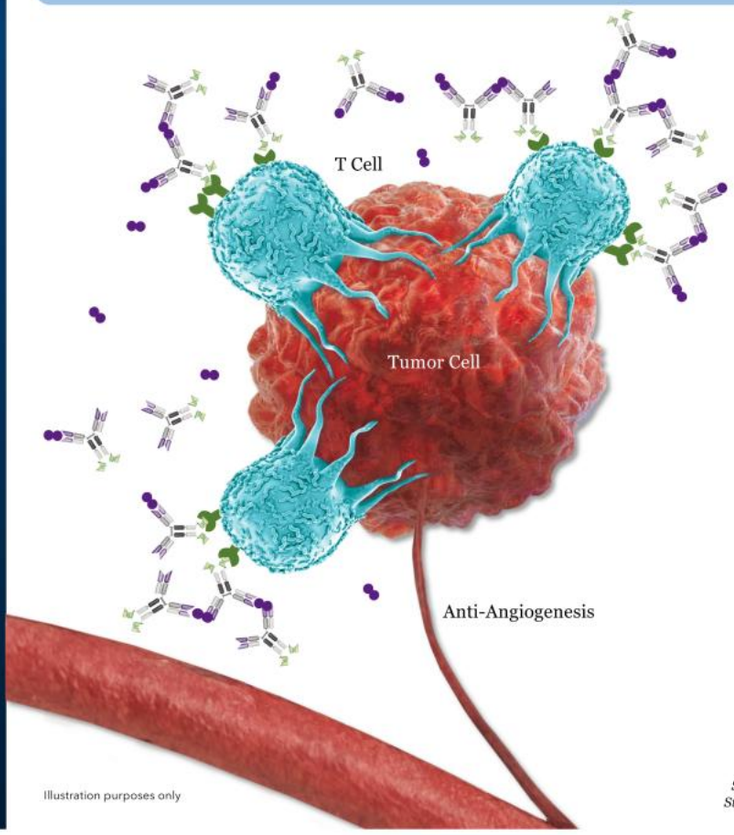


Illustration purposes only

VEGF Dime

VEGF

PD-1

Enhanced Avi
Tumor Microenv

Enhanced Activity

Summit's licensed territory includes North A
States), Central & South America, Europe, Mid

Ivonescimab

Summit therapeutics · Akesobio

2,300+
Patients treated in clinical trials [1]

9
Phase III announced, ongoing, or completed [2]

14
Publications in 2024 in 7 tumor types [3]

5
Oral Presentations at major medical conferences [3]

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.

31 Ivonescimab Clinical Trial

Ivonescimab Pipeline

Akesobio

Conducted in China
Fully Sponsored and Managed by Akeso

Phase III

- *2L+ NSCLC:* HARMONi-A
- *1L NSCLC:* HARMONi-2
- *1L NSCLC:* HARMONi-6
- ***1L R/M HNSCC:*** HARMONi-HN1
- ***1L Biliary Tract:*** HARMONi-GI1
- ***1L Pancreatic:*** HARMONi-GI2

Phase I-II

NSCLC	Breast
Ovarian	Hepatocellular
G/GEJ	Colorectal
SCLC	

Summit therapeutics

Planned and Ongoing Studies
Sponsored by Summit Therapeutics*

Phase III

- *2L+ NSCLC:* HARMONi
- *1L NSCLC:* HARMONi-3
- *1L NSCLC:* HARMONi-7

Expanding CDP

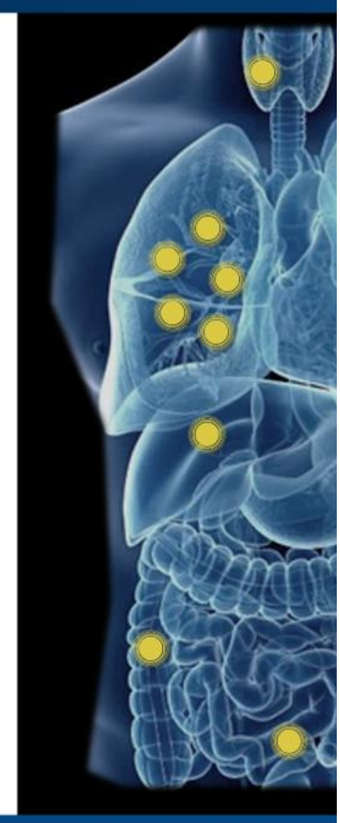
Further Announcements in 2025
Not shown in image

ISTs

30+ Approved Trials Being Initiated
Not shown in image

M.D. Anderson Collaboration Initiated

$15 million committed by Summit



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

*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.

Ivonescimab Pipeline: NSCLC

	Akesobio *Conducted in China* *Fully Sponsored and Managed by Akeso*	Summit therapeutics *Planned and Ongoing Studies* *Sponsored by Summit Therapeutics*
	NSCLC Phase III	NSCLC Phase III
2L+ EGFRm	HARMONi-A *Approved in China*	HARMONi *Enrollment complete; Top-line data expected mid-2025*
1L		
Ivo + chemo	HARMONi-6 *Enrolling in China*	HARMONi-3 *Enrolling globally*
Ivo monotherapy	HARMONi-2 *Submitted for approval in China*	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.

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

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

Summit therapeutics Global

Akesob Chi

HARMONi-7

PD-L1 High, Monotherapy
Ivonescimab vs
pembrolizumab[2]

Enrollment starting in early 2025

HARMONi-3

PD-L1 All-Comers
Ivonescimab + chemo vs
pembrolizumab + chemo[1]

Currently enrolling

HARMO

PD-L1 Positive, M
Ivonescimab vs
pembrolizumal

WCLC 2024
Presidential Symp

HARMO

Squamous, PD-L1
Ivonescimab +
tislelizumab (PI

Currently enrollin

1. HARMONi-3. ClinicalTrials.gov identifier: NCT05899608. Updated May 06, 2024. Accessed May 29, 2024. Study Details | Clinical Study of Ivonescimab for First-line Treatment of Metastatic Squamous NSCLC Patients | ClinicalTrials.gov; 2. HARMONi-
ClinicalTrials.gov identifier: NCT06767514 Updated Jan 10, 2025, Accessed on Jan. 10, 2025, Study Details | Clinical Study of Ivonescimab for First-line Treatment of Metastatic NSCLC Patients With High PD-L1 | ClinicalTrials.gov ; 3. Zhou C, et al. HARM
Presentation. Presented at: World Conference on Lung Cancer Annual Meeting Presidential Symposium. Sep 8, 2024, San Diego, CA; 4. HARMONi-6. ClinicalTrials.gov identifier: NCT05840016. Updated Aug 22, 2023. Accessed on Jan 11, 2025.
https://clinicaltrials.gov/study/NCT05840016?intr=NCT05840016&rank=1. Abbreviations 1L, first-line; 2L+, second-line or later; chemo, chemotherapy; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein 1; PD-L1, programmed c

HARMONi-2

Akeso Sponsored Study

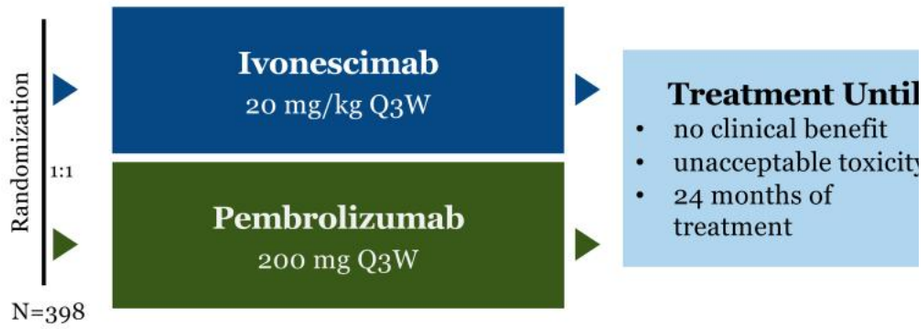
Akesobio

Monotherapy Ivonescimab vs. Pembro

Randomized, Double-blind, Phase

Patient Population

- Stage IIIB-IV NSCLC
- 1L therapy for advanced NSCLC
- PD-L1 Positive Expression
- No *EGFR* mutations or *ALK* rearrangements
- ECOG PS 0 or 1



Stratification

- Clinical stage (IIIB/C vs. IV)
- Histology (SQ vs. non-SQ)
- PD-L1 TPS (≥50% vs. 1-49%)

Endpoints

Primary: PFS by blind IRRC per RECIST v1.1
Secondary: OS, PFS assessed by INVs, ORR, Do
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

HARMONi-2

Akeso Sponsored Study

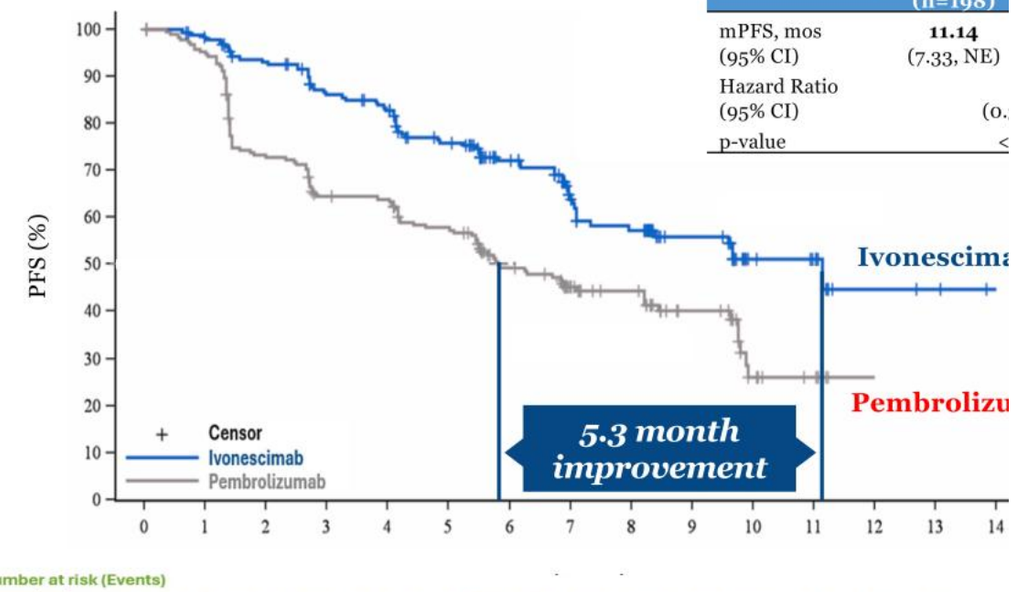
Ivonescimab showed a decisive, statistically significant improvement in PFS vs. pembrolizumab in this Phase III study

Akesobio

Monotherapy Ivonescimab vs. Pembro

ITT: PD-L1 Positi

	Ivonescima (n=198)
mPFS, mos (95% CI)	**11.14** (7.33, NE)
Hazard Ratio (95% CI)	(o.
p-value	<



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)
Pembrolizumab	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
Cancer Presidential Sym
9/8/24, San Diego, CA

HARMONi-2

Akeso Sponsored Study

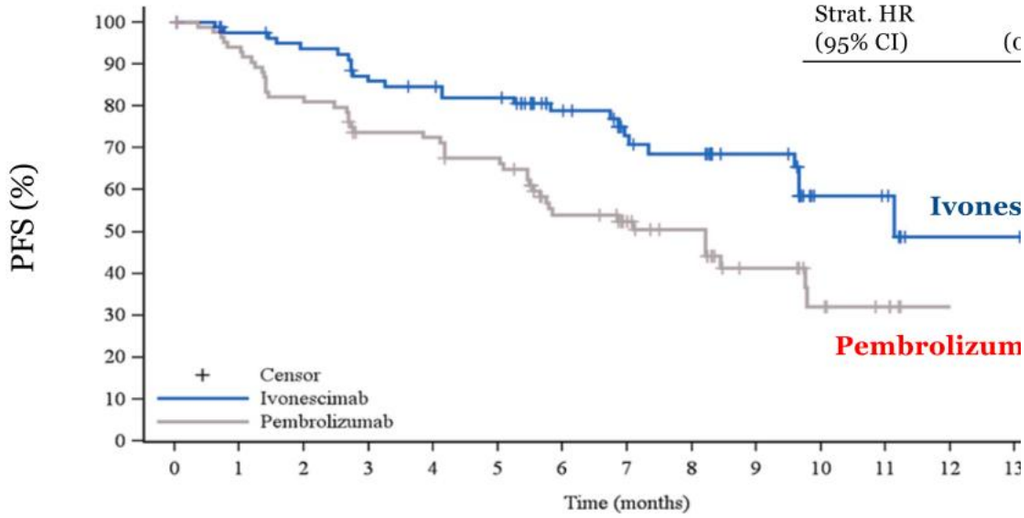
Ivonescimab showed a clinically meaningful improvement in PFS vs. pembrolizumab across major clinical subgroups in this Phase III study

Akesobio

Monotherapy Ivonescimab vs. Pembro

PD-L1 High Expressin

	Ivo (n=8
Strat. HR (95% CI)	(c



Number at risk (Events)

Ivonescimab	83(0)	77(2)	73(5)	66(11)	64(12)	61(14)	45(16)	34(19)	31(21)	23(21)	8(24)	7(24)	1(25)	1(2
Pembrolizumab	85(0)	79(5)	69(15)	59(22)	58(23)	53(27)	37(37)	29(38)	24(39)	12(43)	7(45)	4(45)	0(45)	

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; Strat. HR: stratified hazard ratio; CI, confidence interval; ivo, ivonescimab; pembro, pembrolizumab

Caicun Zhou | HARMONi-2

2024 World Conference
Cancer Presidential Sym
9/8/24, San Diego, CA

HARMONi-2

Akeso Sponsored Study

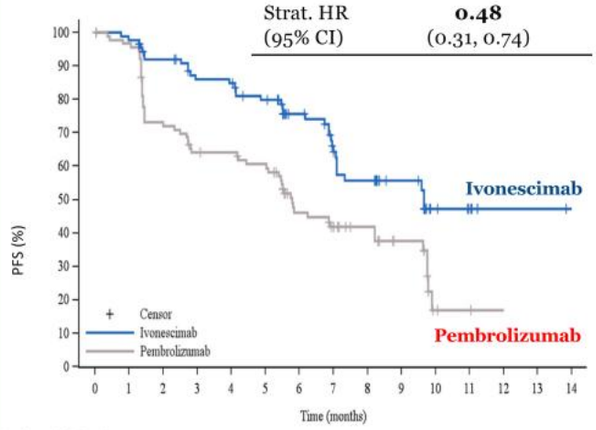
Ivonescimab showed a clinically meaningful improvement in PFS vs. pembrolizumab across major clinical subgroups in this Phase III study

Akesobio

Monotherapy Ivonescimab vs. Pembro
NSCLC by

Squamous

	Ivo (n=90)	Pembro (n=91)
Strat. HR (95% CI)	**0.48** (0.31, 0.74)	

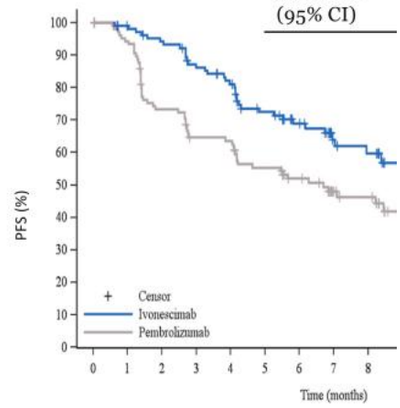


Number at risk (Events)

Ivonescimab	90(0)	87(2)	79(7)	71(12)	70(13)	63(17)	49(20)	37(27)	32(32)	21(32)	8(35)	5(35)	1(35)	1(35)	0(35)
Pembrolizumab	91(0)	87(3)	65(24)	56(32)	55(32)	51(35)	32(46)	25(49)	20(49)	13(51)	2(56)	1(56)	0(56)		

Non-Squamous

Strat. HR (95% CI)



Number at risk (Events)

Ivonescimab	108(0)	102(1)	96(6)	85(14)	78(19)	65(27)	50(30)	31(33)	27(35)
Pembrolizumab	109(0)	100(6)	76(28)	65(37)	64(38)	52(46)	42(49)	28(52)	25(53)

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; CI, confidence interval; NSCLC, non-small cell lung cancer; ivo, ivonescimab; pembro, pembrolizumab

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

HARMONi-2

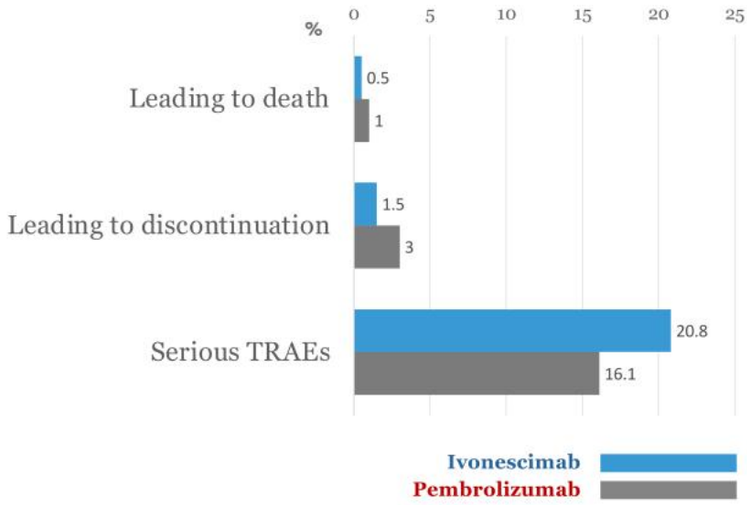
Akeso Sponsored Study

Ivonescimab safety profile was consistent with prior studies and well tolerated, including patients with SQ-NSCLC

Akesobio

Monotherapy Ivonescimab vs. Pembro
Ivonescimab Showed Manageable Safe

Treatment-related Adverse Events



Ivone
exh
simil
to t
pembr
29.
28.1%

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.

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

Monotherapy Ivonescimab vs. Pembro

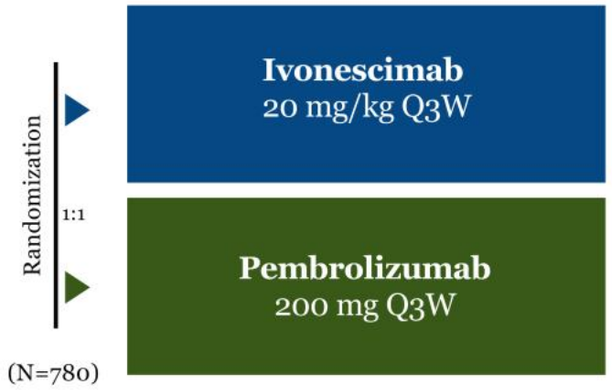
Randomized, Double-blind, Pha
1L NSCLC with PD-L1 High

HARMONi-7

Summit Sponsored Study

Key Inclusion

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



Treatment until

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

Stratification Factors Include Histology

Squamous vs. Non-Squamous

Study Endpoints

Primary endpoints: PFS, OS
Secondary endpoints: ORR, safety and tole

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

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

1. HARMONi-7. ClinicalTrials.gov identifier: NCT06767514 Updated Jan 10, 2025, Accessed on Jan. 10, 2025 Study Details | Clinical Study of Ivonescimab for First-line Treatment of Metastatic NSCLC Patients With High PD-L1 | ClinicalTrials.gov

HARMONi-3

Summit Sponsored Study

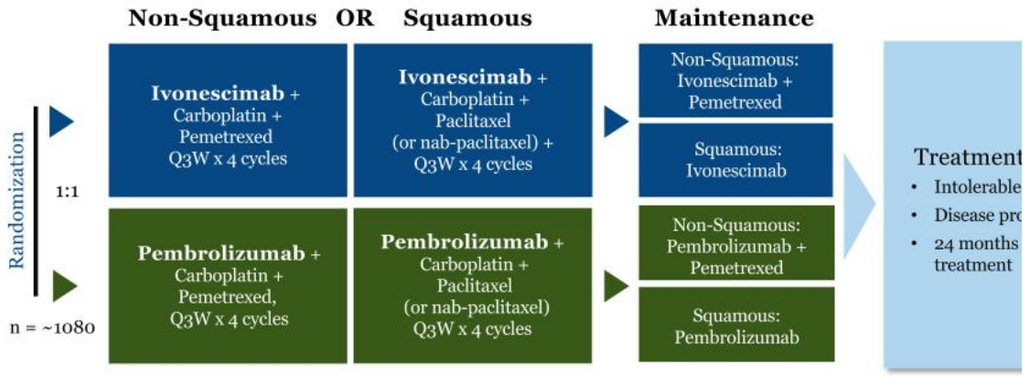
Key Inclusion

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

Ivonescimab + Chemo vs. Pembrolizumab

Randomized, Double-blind, Ph

1L NSCLC: PD-L1



Stratification Factors Include Histology

Squamous vs. Non-Squamous

Study Endpoints

Primary
- OS, PFS by Investigator

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

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

* PFS by BICR is a sensitivity analysis

Abbreviations: NSCLC, non-small cell lung cancer; PD-L1, programmed cell death-ligand; Q3W, every three weeks; PFS, progression free survival; OS, overall survival; ORR, overall response rate; DCR, disease control rate; DOR, duration of response; BICR, blinded independent central review; 1L, first-line.

2L+ EGFRm NSCLC

Ivonescimab + Chemo vs. Placebo + Chemo

HARMONi

EGFRm after a 3rd-gen TKI
Ivonescimab + chemo vs.
placebo + chemo[1]

Completed enrollment

Topline data expected mid-2025

HARM

EGFRm after a TK
Ivonescimab + c
placebo + chemo[2]

Positive Phase III
- ASCO 2024 Pres
- *JAMA* Manuscri

Approved indicatio

References: 1 HARMONi. ClinicalTrials.gov Identified: NCT06396065. Accessed December 06, 2024. Study Details | Phase III Study of AK112 for NSCLC Patients | ClinicalTrials.gov. 2. HARMONi-A Study Investigators, Fang W, Zhao Y, Luo Y, et al. JAMA. 2024 May 31; Abbreviations: EGFRm, epidermal growth factor receptor mutation positive; gen, generation; TKI, tyrosine-kinase inhibitor; NSCLC, non-small cell lung cancer; chemo, chemotherapy; ASCO, American Society of Clinical Oncology; *JAMA, Journal of the American Medical Association*

HARMONi-A

Akeso Sponsored Study

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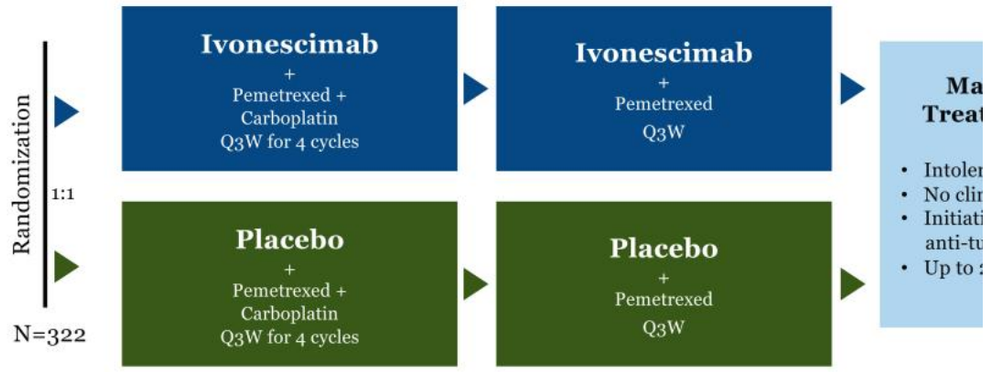
Ivonescimab + Chemo vs. Placebo

Randomized, Double-blind, Ph
2L+ EG

Key Eligibility Criteria

- Stage IIIB-IV NSCLC
- EGFR mutation
- ECOG PS 0 or 1
- Any PD-L1 expression
- Post EGFR-TKI



Stratification Factors

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

Endpoints

- Primary: PFS by BICR
- Secondary: OS, Response rate, DoR, Time t 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.

HARMONi-A Study Investi
Zhao Y, Luo Y, et al. JAMA

HARMONi-A

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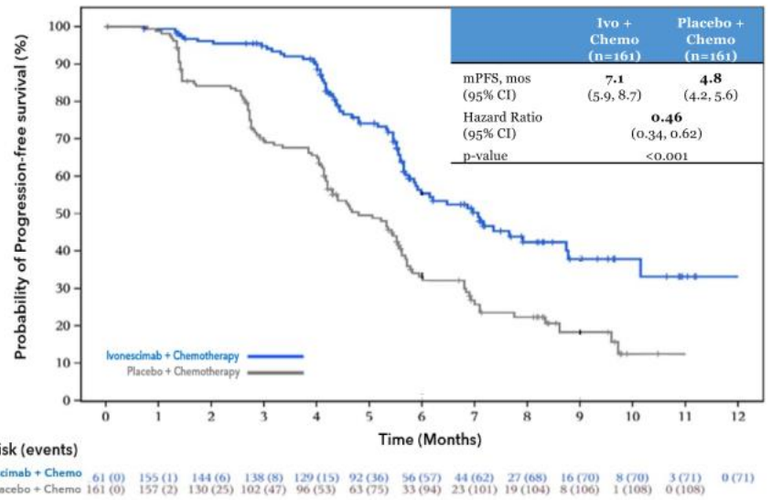
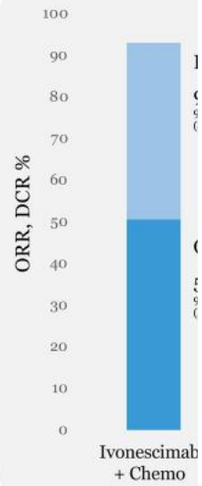
Ivonescimab + Chemo **significantly improved PFS** in patients who progressed on prior EGFR-TKIs in this Phase III study



At risk (events)

Ivonescimab + Chemo	61 (0)	155 (1)	144 (6)	138 (8)	129 (15)	92 (36)	56 (57)	44 (62)	27 (68)	16 (70)	8 (70)	3 (71)	0 (71)
Placebo + Chemo	161 (0)	157 (2)	130 (25)	102 (47)	96 (53)	63 (75)	33 (94)	23 (101)	19 (104)	8 (106)	1 (108)	0 (108)	



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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.

Presented by Dr. Li Zhang, ASCO 2024

HARMONi-A

Akeso Sponsored Study

HARMONi-A safety profile generally

well tolerated,

without unexpected AEs and low rate of treatment discontinuation

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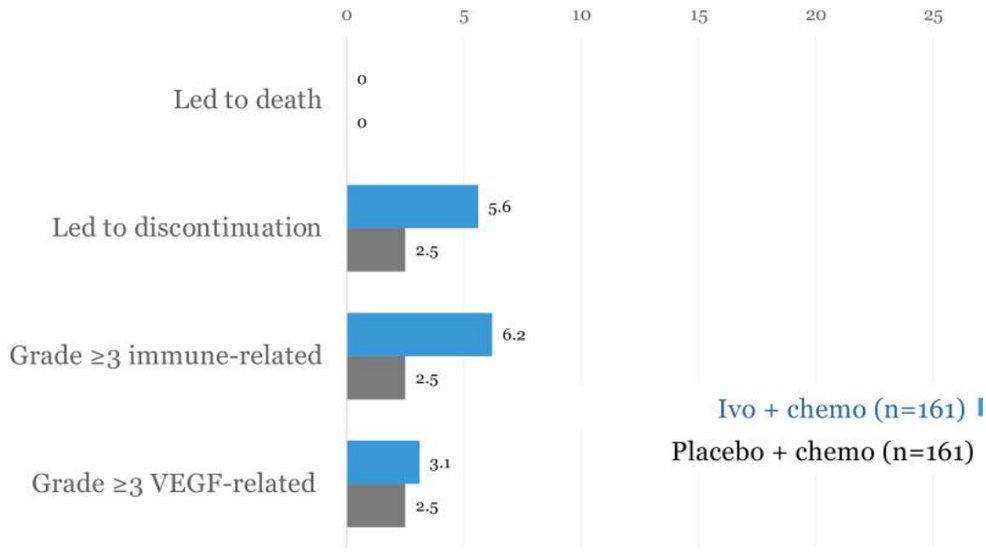
Ivonescimab + Chemo vs. Placebo

2L+ EG

Treatment-related Adverse Eve



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References: HARMONi-A Study Investigators, Fang W, Zhao Y, Luo Y, et al. JAMA [supplemental appendix]. 2024 May 31
Abbreviations: VEGF, Vascular endothelial growth factor; AEs, adverse events; chemo, chemotherapy; ivo, ivonescimab; 2L+, second-line or later.

Presented by Dr. Li Zhang, ASCO 2024

HARMONi

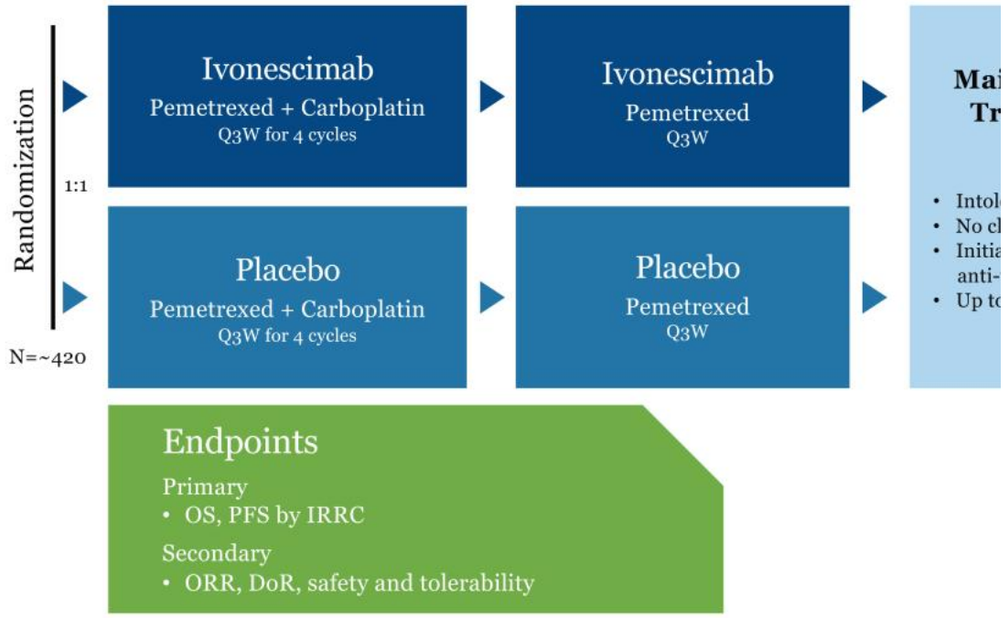
Summit Sponsored Study

Locally advanced or metastatic non-squamous NSCLC

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

Ivonescimab + Chemo vs. Placebo

Randomized, Double-blind, Ph
2L+ EG



Endpoints

Primary
- OS, PFS by IRRC

Secondary
- ORR, DoR, safety and tolerability

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References: 1. HARMONi-Phase III Study of AK112 for NSCLC Patients. ClinicalTrials.gov identifier: NCT06396065.. Accessed January 10, 2025.. Abbreviations: NSCLC, non-small cell lung cancer; EGFR, epidermal grow TKI, tyrosine kinase inhibitor; PD-L1, programmed death-ligand; OS, overall survival; PFS, progression free survival; IRRC, independent radiologic review committee; Q3W, every 3 weeks; DoR, duration of response; 2L+,

Phase II Studies Conducted in China

Akeso Sponsored

Promising Phase II Data: CRC, TNBC, HNSCC, Early-Stage 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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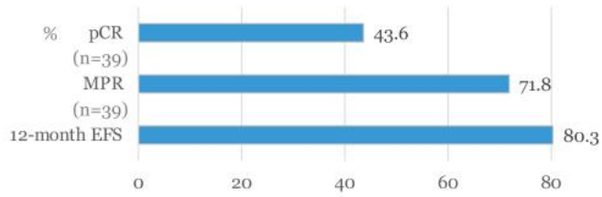
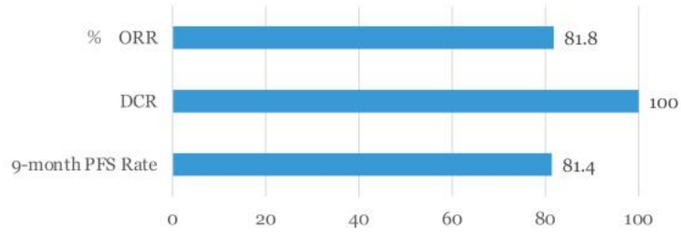
Ivonescimab in Phase II Studies in Variou

Perioperative Resectable NSCLC[1]



1L MSS Colorectal Cancer (CRC)[2]



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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, Early-Stage 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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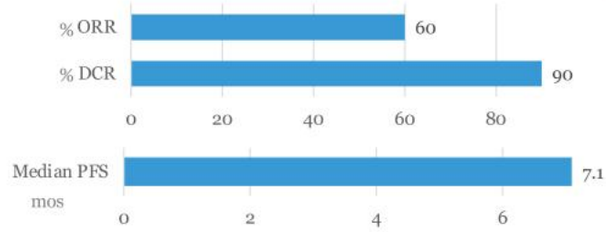
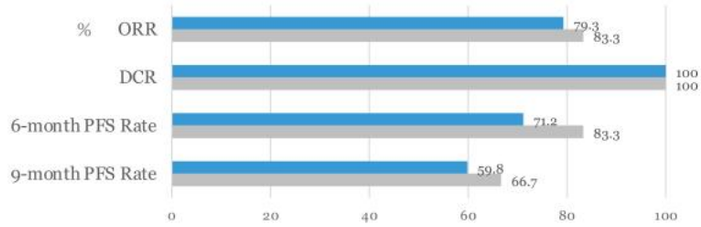
Ivonescimab in Phase II Studies in Variou

1L PD-L1 Positive R/M Head and Neck (HNSCC)[1]



1L Triple Negative Breast Cancer (TNBC)[2]



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

Ivonescimab Catalysts in 2025-2026

Summit therapeutics Global

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First Global Clinical Trial Results in Mid-2025

Expanding our Global Clinical Development Plan[2]

Way Beyond NSCLC

Investigator Sponsored Trials Activating[3]

NSCLC and Way Beyond

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Enrollment Cor

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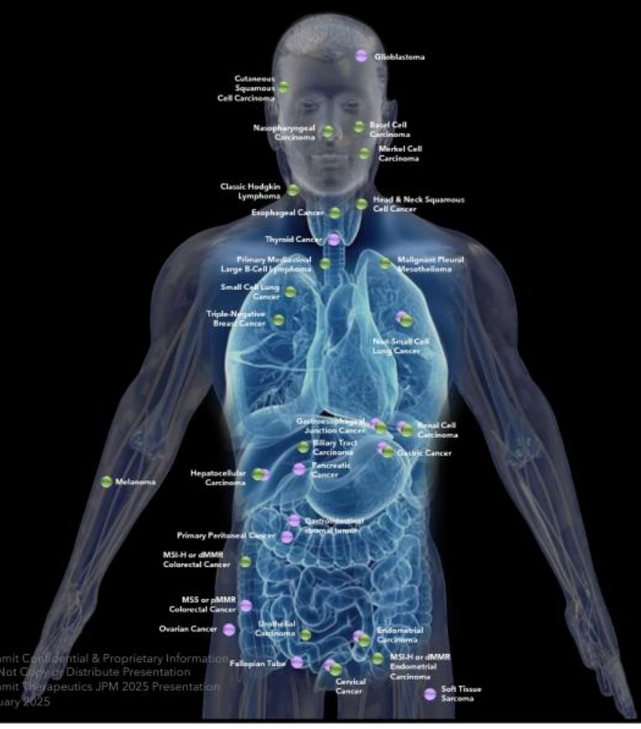
Phase III Clinic

NSCLC and Wa

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

References: 1. HARMONi-6 (AK112-306) enrollment expected to be completed by the end of 2024 or shortly thereafter per Akeso 2024 Interim Corporate Deck (https://www.akesobio.com/media/2287/2024-interim-corporate-deck.pdf, accessed January 11, 2025). 2. S
ended September 30, 2024, filed October 30, 2024, page 28. 3. https://clinicaltrials.gov/search?term=ivonescimab, Accessed January 12, 2025. 4. Akeso published the record for AK112-308 in first-line locally advanced or metastatic triple negative breast cancer on clinic
(https://clinicaltrials.gov/study/NCT06767527; Accessed January 12, 2025) indicating a study start date of January 2025. This is in addition to the planned Phase III study in first line pancreatic cancer referenced in Akeso's 2024 Interim Report (akesobio.com; accessed Ja

Ivonescimab Opportunity
Goes *Beyond* Checkpoint Inhibitors (CPI)



$90B+ 2028 Estim
CPI TAM[2]

$20B+ NSCLC *CPI* T

50+ Approved Indications fo
PD-(L)1 & VEGF Therapies[1]

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

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authority other than China's National Medical Products Administration (NMPA)

1. Data from cancer.gov updated 2024. 2. IQVIA MIDAS Disease, Dec 2023; IQVIA Institute Apr 2024. 3. TD Cowen; Investors Guide to Immuno-Oncology; Sept 6, 2023; Abbreviations: PD-(L)1, programmed cell death-(ligand) 1; PD-1, programmed cell death protein 1; VEGF, vascular endothelial growth factor; TAM, Total Addressable Market; Ph, phase; Ivo, ivonescimab.; CPI, checkpoint inhibitor


Summit
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FOR THE BETTER
TOGETHER