

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 12, 2026

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: <u>(305) 203-2034</u>		
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, 2025, the preliminary unaudited balance of cash, cash equivalents, and short-term investments of Summit Therapeutics Inc. (the "Company") was approximately \$710 million. 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, 2025.

In accordance with General Instruction B.2 of Form 8-K, the information set forth under Item 2.02 and in Exhibits 99.1 and 99.2 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 12, 2026, the Company intends to present at the 44th 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.

On January 12, 2026, the Company issued a press release announcing the submission of a Biologics License Application to U.S. Food and Drug Administration seeking approval for ivonescimab in combination with chemotherapy in second line or later treatment of patients with epidermal growth factor receptor-mutated locally advanced or metastatic non-squamous non-small cell lung cancer. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

On January 12, 2026, the Company issued a press release announcing a clinical trial collaboration with GSK plc ("GSK") to evaluate ivonescimab in combination with GSK's risvutag rezetecan (also known as GSK'227), GSK's novel investigational B7-H3 targeting antibody drug conjugate (ADC), across multiple solid tumor settings, including small cell lung cancer (SCLC). A copy of the press release is attached as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated by reference herein.

In accordance with General Instruction B.2 of Form 8-K, the information set forth under Item 7.01 and in Exhibits 99.1, 99.2 and 99.3 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Investor Presentation Slides made available on January 12, 2026
99.2	Press release, dated January 12, 2026
99.3	Press release, dated January 12, 2026
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 12, 2026

By:

/s/ Manmeet S. Soni

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



44th Annual J.P. Morgan Healthcare Conference

January 12, 2026

BOB DUGGAN
Chairman & Co-Chief Executive Officer

DR. MAKY ZANGANEH
President & Co-Chief Executive Officer

Forward Looking Statement

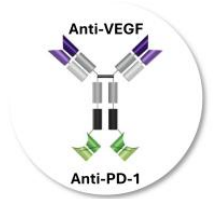
Any statements in this presentation about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, entry into and actions related to the Company's partnership with Akeso Inc., the 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, the expected timing of BLA submissions or FDA decisions, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, the Company's estimates regarding stock-based compensation, 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 Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, industry, or political conditions, including the effects of geopolitical developments, domestic and foreign trade policies, and monetary policies, 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, 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" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study that with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. 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, readers 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 release 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.



US Biologics
License
Application (BLA)
Submitted to the
FDA in the Fourth
Quarter 2025

SUBMITTED!



HARMONI

*Ivonescimab + Chemo vs. Chemo
in 2L+ EGFRm NSCLC*

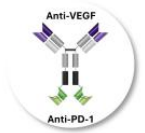
Abbreviations: 2L+ = second-line or later line; Chemo = Chemotherapy; EGFRm = epidermal growth factor receptor mutation-positive; FDA = US Food and Drug Administration; NSCLC = non-small cell lung cancer; PD-1 = programmed cell death protein 1; VEGF = vascular endothelial growth factor; vs. = versus





Ivonescimab

Includes both Summit and Akeso trials



PD-1 x VEGF Class Frontrunner with Multi-Year Lead

Mission: Patients First

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

Proven Track Record

Leadership in global oncology with a proven track record with high-speed and quality execution.

4 Global Phase III Trials

HARMONi HARMONi.3
HARMONi.7 HARMONi-GB

4
Phase III Trials with Positive Results

Positive Phase III Readouts to Date
The only in-class Phase III Readouts

14
Phase III Trials¹

Phase III Trials in Multiple Tumor Types¹

>4K
Trial Patients

Patients Dosed in All Clinical Trials²

2
Chinese Approvals

Indications Approved in China by the NMPA

42
Sponsored Trials

Total Ivonescimab Trials Sponsored by Summit or Akeso²

116
Total Trials

Total Trials Involving Ivonescimab on clinicaltrials.gov²

>60K
Commercial Patients in China

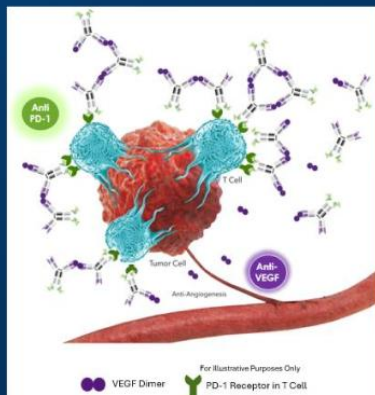
Patients Dosed Commercially in China

Abbreviations: PD-1=programmed cell death protein 1; VEGF=vascular endothelial growth factor; NMPA = National Medical Products Administration (China)
References: 1. Total sponsored (by Summit or Akeso) clinical trials as of January 6, 2026, via clinicaltrials.gov or public announcement; 2. Data on File 56, 57, Summit Therapeutics Inc.



Cooperative Binding

Potentially Drives Synergistic Anti-Tumor Activity



Dual Blockade of PD-1 & VEGF¹

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

5 Summit Proprietary Information - Do Not Copy or Distribute
JPM 2026 Presentation | 1/2026

Increased Avidity in TME

Presence of VEGF-A efficiently enhances the binding affinity to **PD-1** by **several fold**¹ (*in vitro*)

Enhanced Activity of T Cells

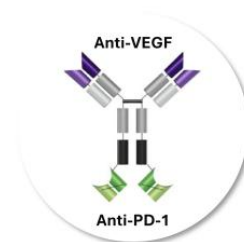
VEGF dimer leads to potential interconnection of ivonescimab molecules which **may increase activity of T cells**¹ (*in vitro*)

Intentional, Potentially Favorable Molecular Profile

Structure may lead to optimized binding in TME¹

Targeting PD-1 may lead to better efficacy profile¹

7 to 10-day half-life could potentially lead to a favorable safety profile.²⁻⁴



Abbreviations: PD-1=programmed cell death protein 1, TME=tumor microenvironment, VEGF=vascular endothelial growth factor
1. Zhong T, et al. Science. 2024;283(3):111722; 2. Zhao Y, et al. eClinicalMedicine. 2023; 3(62): 102106; 3. Wang L, et al. J Thorac Oncol. 2024;19(3):465-475; 4. Data on File 39, Summit Therapeutics Inc.

Ivonescimab Development: Summit + Akeso Pipelines



TUMOR TYPE	STUDY	LINE & INDICATION	REGIMEN	PHASE			STATUS
				1/1b	2	3	
Lung	HARMON ¹ _A	2L advanced EGFR+ NSCLC	Ivonescimab + chemo vs. placebo + chemo	██████████	██████████	██████████	Active, Recruiting Complete
	HARMON ¹ _T	1L metastatic NSCLC	Ivonescimab + chemo vs. pembrolizumab + chemo	██████████	██████████	██████████	Recruiting
	HARMON ¹ _T	1L metastatic PD-L1 high (≥50%) NSCLC	Ivonescimab vs. pembrolizumab	██████████	██████████	██████████	Recruiting
Gastrointestinal	HARMON ¹ _{GT}	1L metastatic CRC	Ivonescimab + chemo vs. bevacizumab + chemo	██████████	██████████	██████████	Recruiting
Lung	HARMON ¹ _A	2L advanced EGFR+ NSCLC	Ivonescimab + chemo vs. placebo + chemo	██████████	██████████	██████████	Active, Recruiting Complete
	HARMON ¹ ₂	1L metastatic NSCLC (all PD-L1 levels)	Ivonescimab vs. pembrolizumab	██████████	██████████	██████████	Active, Recruiting Complete
	HARMON ¹ ₄	1L advanced or metastatic NSCLC	Ivonescimab + chemo vs. tislelizumab + chemo	██████████	██████████	██████████	Active, Recruiting Complete
	HARMON ¹ _{EGV}	2L advanced or metastatic NSCLC progressed on or after PD-L1 therapy	Ivonescimab + docetaxel vs. placebo + docetaxel	██████████	██████████	██████████	Not Yet Recruiting
	HARMON ¹ ₅	Consolidation treatment SCLC not progressed after chemoradiation	Ivonescimab vs. placebo	██████████	██████████	██████████	Recruiting
Breast	AK112-205	Resectable NSCLC	Ivonescimab vs. Ivonescimab + chemo	██████████	██████████	██████████	Active, Recruiting Complete
	AK112-208	1L advanced or metastatic NSCLC	Ivonescimab + cadonilimab ± chemo	██████████	██████████	██████████	Recruiting
Gynecologic	HARMON ¹ _{BC1}	1L inoperable locally advanced/metastatic TNBC	Ivonescimab + nab-paclitaxel vs. placebo + nab-paclitaxel	██████████	██████████	██████████	Recruiting
	AK117-203	1L metastatic TNBC	Ivonescimab + chemo	██████████	██████████	██████████	Recruiting
Head and Neck	AK104-221	2L OC	Ivonescimab ± chemo ± cadonilimab	██████████	██████████	██████████	Recruiting
	AK112-211	1L platinum-sensitive OC	Ivonescimab ± chemo ± olaparib	██████████	██████████	██████████	Recruiting
Gastrointestinal	HARMON ¹ _{HN}	1L recurrent or metastatic HNSCC with PD-L1 positive (CPS ≥1)	Ivonescimab + AK117 vs. placebo + pembrolizumab	██████████	██████████	██████████	Recruiting
	HARMON ¹ _{GH}	1L unresectable locally advanced or metastatic BTC	Ivonescimab + chemo vs. durvalumab + chemo	██████████	██████████	██████████	Active, Recruiting Complete
	HARMON ¹ _{GI2}	1L metastatic PDAC	Ivonescimab + chemo ± AK117 vs. placebo + chemo	██████████	██████████	██████████	Recruiting
Various Cancers	HARMON ¹ _{GI6}	1L metastatic CRC	Ivonescimab + chemo vs. bevacizumab + chemo	██████████	██████████	██████████	Recruiting
	AK112-209	1L advanced HCC	Ivonescimab ± anti-TIGIT antibody ± cadonilimab ± anti-TIGIT/TGF-β vs. sintilimab ± bevacizumab	██████████	██████████	██████████	Recruiting
	AK112-210	1L metastatic PDAC	Ivonescimab ± cadonilimab ± AG vs. AG	██████████	██████████	██████████	Recruiting
	AK119-202	1L or 2L microsatellite stable CRC	Ivonescimab + anti-CD73 mAb ± chemo	██████████	██████████	██████████	Recruiting
	AK130-201	2L advanced BTC	Ivonescimab ± anti-TIGIT/TGF-β or Ivonescimab	██████████	██████████	██████████	Not yet recruiting
Various Cancers	AK117-202	1L or 2L advanced or metastatic NSCLC, GEJ, BTC, PDAC	Ivonescimab + ligufalimab ± chemo	██████████	██████████	██████████	Active, Not Recruiting
	AK127-104	1L advanced malignant tumors	Ivonescimab + anti-TIGIT antibody	██████████	██████████	██████████	Not yet recruiting

Abbreviations: 1L=first-line; 2L=second-line; AG=albumin-bound paclitaxel plus gemcitabine; BTC=biliary tract cancer; Chemo=chemotherapy; CPS=combined positive score; CRC=colorectal cancer; EGFR=epidermal growth factor receptor mutant positive; GEJ=gastroesophageal junction; HCC=hepatocellular carcinoma; HNSCC=head and neck squamous cell carcinoma; mAb=monoclonal antibody; NSCLC=non-small cell lung cancer; OC=ovarian cancer; PD-L1=programmed cell death-ligand 1; PDAC=pancreatic ductal adenocarcinoma; SCLC=Small Cell Lung Cancer; TIGIT=T cell immunoreceptor with Ig and ITIM domains; TNBC=triple negative breast cancer; vs.=versus. Reference: ClinicalTrials.gov



Ivonescimab Development: Summit Pipeline

TUMOR TYPE	STUDY	LINE & INDICATION	REGIMEN	PHASE				STATUS
				1/1b	2	3	Approved	
Lung	HARMON ¹	2L advanced EGFRm+ NSCLC	ivonescimab + chemo vs. placebo + chemo					Active, Recruiting Complete
	HARMON ^{1,3}	1L metastatic NSCLC	ivonescimab + chemo vs. pembrolizumab + chemo					Recruiting
	HARMON ^{1,7}	1L metastatic PD-L1 high (≥50%) NSCLC	ivonescimab vs. pembrolizumab					Recruiting
Gastrointestinal	HARMON ^{1,GT}	1L metastatic CRC	ivonescimab + chemo vs. bevacizumab + chemo					Recruiting

Phase I and II trials completed by Akeso.

Collaborations

RevMed: Novel RAS(ON)i: NSCLC, PDAC, CRC
GSK: Novel B7-H3: multi-tumor incl. SCLC
More Planned in 2026

RASi

ADC

>60 ISTs Supported¹

15 Currently Enrolling
5 via MD Anderson Collaboration

>46

Ivonescimab Posters,
Publications & Presentations²

Present-time biopharma confidence in ivonescimab is a significant governor in our go-forward clinical development expense



Summit initiating additional set of Phase III studies
Further details coming starting in Q1 2026

References: 1. In Summit license territories, Data on File 55, Summit Therapeutics Inc. Supported + at a minimum, a notification of support communicated to PI; 2. Publications available at summitx.com. Accessed on Jan 6, 2026.
Abbreviations: 1L=first-line; 2L=second-line; ADC=antibody drug conjugate; Chemo=chemotherapy; CRC=colorectal cancer; EGFRm+=epidermal growth factor receptor mutant positive; IST=Investigator Sponsored Trial; NSCLC=non-small-cell lung cancer; PDAC=pancreatic ductal adenocarcinoma; PD-L1=programmed cell death-ligand 1; RAS=renin-angiotensin system; RASi=RAS inhibitor; RAS(ON)i=RAS inhibitor to RAS proteins in ON state (revmed.com/science, Accessed Jan 10, 2026); SCLC=small cell lung cancer; incl.=including; vs.=versus. Reference: ClinicalTrials.gov

Ivonescimab

Four Phase III Clinical Studies with Positive Results



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

HARMONI-2

PD-L1 Positive, Monotherapy
Ivonescimab vs. pembrolizumab

HARMONI-6

Squamous, PD-L1 All-Comers
Ivonescimab + chemo vs. tislelizumab (PD-1) + chemo

Presented at WCLC 2024
Presidential Symposium¹
*The Lancet*²

Approved indication in China

Awaiting data
maturation for OS

Presented at ESMO 2025
Presidential Symposium³
*The Lancet*⁴

sNDA pending in China

Awaiting data
maturation for OS

2L+ EGFRm NSCLC Ivonescimab + Chemo vs. Placebo + Chemo

HARMONI-A

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

HARMONI

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

Presented at ASCO 2024⁵
OS Update: SITC Nov. 2025⁷
*JAMA*⁶

Approved indication in China

Presented at WCLC 2025
Presidential Symposium⁸

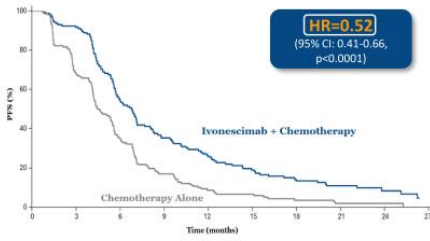
US BLA submitted Q4 2025

References: 1. Wang C, et al. HARMONI-2. Presented at WCLC 2024; 2. Xiong A, et al. *Lancet*. 2025;405(10481):839-849; 3. Lu S, et al. HARMONI-6. Presented at ESMO 2025; 4. Chen Z, et al. *Lancet*. 2025;406(10515):2078-2088; 5. Zhang L, et al. HARMONI-A study. Presented at ASCO 2024; 6. Fang W, et al. *JAMA*. 2024;332(7):561-570; 7. Zhang L, et al. Final OS Analysis: HARMONI-A. Presented at SITC 2025; 8. Goldman J, et al. HARMONI. Presented at WCLC 2025. Abbreviations: 1L=first-line; 2L=second-line; ASCO=American Society of Clinical Oncology; chemo=chemotherapy; EGFRm=epidermal growth factor receptor mutation; ESMO=European Society for Medical Oncology; gen=generation; JAMA=The Journal of the American Medical Association; NSCLC=non-small cell lung cancer; OS=overall survival; PD-1=programmed cell death protein 1; PD-L1=programmed cell death-ligand 1; SITC=The Society for Immunotherapy of Cancer; sNDA=Supplemental New Drug Application (for marketing authorization); TKI=tyrosine kinase inhibitor; VEGF=vascular endothelial growth factor; vs.=versus; WCLC=World Conference on Lung Cancer.



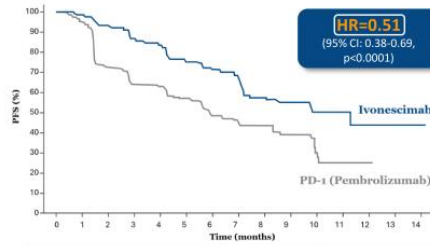
Three Settings: Four Phase III Studies with Positive Results

Summit Therapeutics HARMONI (2L+, EGFR+)



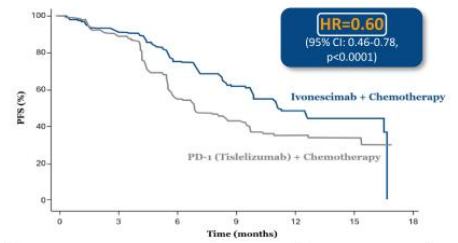
HARMONI	Ivonescimab + chemo (N=218)	Placebo + chemo (N=218)
TRAEs	207 (95.0%)	203 (93.1%)
Serious TRAEs	61 (28.0%)	33 (15.1%)
TRAEs Leading to Discontinuation	16 (7.3%)	11 (5.0%)
TRAEs Leading to Death	4 (1.8%)	5 (2.3%)

Akesobio HARMONI-2 (1L, PD-L1+)



HARMONI-2	Ivonescimab (N=197)	PD-1 (pembrolizumab) (N=199)
TRAEs	177 (89.8%)	163 (81.9%)
Serious TRAEs	41 (20.8%)	32 (16.1%)
TRAEs Leading to Discontinuation	3 (1.5%)	6 (3.0%)
TRAEs Leading to Death	1 (0.5%)	2 (1.0%)

Akesobio HARMONI-6 (1L, squamous)



HARMONI-6	Ivonescimab + chemo (N=266)	PD-1 (tislelizumab) + chemo (N=265)
TRAEs	264 (99.2%)	261 (98.5%)
Serious TRAEs	86 (32.3%)	80 (30.2%)
TRAEs Leading to Discontinuation	9 (3.4%)	11 (4.2%)
TRAEs Leading to Death	8 (3.0%)	10 (3.8%)

Goldman et al WCLC 2025

Xiong A et al Lancet 2025; 402:839-49

Chen Z et al Lancet 2025; 406:2078-2088

Ivonescimab demonstrated statistically significant and clinically meaningful PFS benefit in patients with NSCLC in Ph III studies
Regulatory approvals in China based on HARMONI-A and HARMONI-2; HARMONI-6 currently under regulatory review in China



Ivonescimab Milestones Achieved

2024

HARMONI_A 

▶ **Data, PFS, iOS: Ph3 2L+ EGFRm NSCLC (China)^{4,5}**
NMPA Approval: 2L+ EGFRm NSCLC (China)

HARMONI₃ 

Trial Amendment: Ph3 1L NSCLC: Initiation of Non-Squamous Portion in Addition to Enrolling Patients with Squamous NSCLC (Global)³

HARMONI₂ 

▶ **Data, PFS: Ph3 1L NSCLC PD-L1+ (China)¹**

HARMONI₇ 

FPI: Ph3 1L NSCLC PD-L1 High (Global)²

2025

HARMONI₂ 

▶ **Data, iOS: Ph3 1L NSCLC PD-L1+ (China)^{6,7}**
NMPA Approval: 1L NSCLC PD-1+ (China)

HARMONI₆ 

▶ **Data, PFS: Ph3 1L NSCLC SQ (China) @ ESMO^{8,9}**

HARMONI 

▶ **Data, PFS & OS: Ph3 2L+ EGFRm NSCLC (Global) @ WCLC¹⁰**
FDA Submission: 2L+ EGFRm NSCLC (US)

HARMONI_A 

▶ **Data, OS: Ph3 2L+ EGFRm NSCLC (China) @ SITC¹¹**

HARMONI_{GB} 

FPI: Ph3 1L CRC (Global)

References: 1. Wang C, et al. HARMONI-3. Presented at WCLC 2024; 2. Passaro A, et al. HARMONI-7 TP. Presented at EACC 2025; 3. Zhang J, et al. HARMONI-3 TP; 4. Zhang L, et al. HARMONI-A study. Presented at ASCO 2024; 5. Fang W, et al. JAMA. 2024;332(7):561-570; 6. Xiong A, et al. Lancet. 2025;405(10481):839-849; 7. Summit Press Release April 25, 2025; 8. Lu S, et al. HARMONI-6. Presented at ESMO 2025; 9. Chen Z, et al. Lancet. 2025;406(10151):2078-2088; 10. Goldman J, et al. HARMONI. Presented at WCLC 2025; 11. Zhang L, et al. Final OS Analysis: HARMONI-A. Presented at SITC 2025.

Potential for positive results from China studies to translate to the west?



HARMONI_i Summit
Ivonescimab + Chemo vs. Chemo in 2L+ EGFRm NSCLC¹

Potential for positive PFS data to translate to positive OS data?



HARMONI_A Akesobio
Ivonescimab + Chemo vs. Chemo in 2L+ EGFRm NSCLC²

Strong OS Trends, HR < 0.80^{1,3}

HARMONI_i Summit **HARMONI**₂ Akesobio

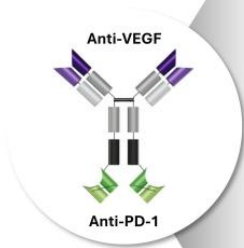
Potential for positive monotherapy results to be sustained with addition of chemotherapy?



HARMONI₆ Akesobio
Ivonescimab + Chemo vs. Tislelizumab + Chemo in 1L NSCLC^{4,5}

References: 1. Goldman J, et al. HARMONI. Presented at WCLC 2025.; 2. Zhang L, et al. Final OS Analysis: HARMONI-A. Presented at SITC 2025.; 3. Summit Press Release, April 23, 2025.; 4. Lu S, et al. HARMONI-6. Presented at ESMO 2025.; 5. Chen Z, et al. Lancet. 2025;406(10515):2078-2088.
Abbreviations: 1L=first-line; 2L=second-line; Chemo=chemotherapy; EGFRm=epidermal growth factor receptor mutant positive; NSCLC=non-small-cell lung cancer; HR=hazard ratio; OS=overall survival; PFS=progression-free survival; vs.=versus. Reference: ClinicalTrials.gov

Shaping the Path to Become a Commercial Entity



1Q26

Further details beginning this quarter on new global Phase IIIs

1H26

HARMONI-3 SQ: Completion of enrollment expected

2H26

HARMONI-3 SQ: PFS, interim OS data readout expected
HARMONI-3 nSQ: Completion of enrollment expected
HARMONI: BLA Decision in 2L+ EGFRm NSCLC expected

1H27

HARMONI-3 nSQ: PFS data readout expected

Abbreviations: 2L=second line; BLA=Biologics License Application; EGFRm=epidermal growth factor receptor mutant positive; NSCLC=non-small-cell lung cancer; nSQ=non-squamous; OS=overall survival; PD-1=programmed cell death protein 1; PD-L1=programmed cell death-ligand 1; PFS=progression-free survival; SQ=squamous; VEGF=vascular endothelial growth factor.

Strong Balance Sheet to Kick Off 2026

~\$710M

Unaudited Cash

as of 12/31/2025

\$0

No Debt

as of 12/31/2025

Platform Opportunity



1. KEYTRUDA® USPL, OPDIVO® USPL, LISTAVO® USPL, IMFINZI® USPL, BAVENCIO® USPL, HEMPERLI® USPL, TECENTRIQ® USPL, ZYNYZ® USPL, AVASTIN® USPL, CYRAMZA® USPL, LENVIMA® USPL, INLYTA® USPL, SUTENTY® USPL. 2. TD Cowen and IQVIA, estimates. 3. Sifel report, estimate; compilation of Form 10-K and 20-F as filed with the US SEC. 4. MRK 2024 Form 10-K, as filed with the US SEC. 5. TD Cowen and IQVIA, estimate. Abbreviations: EGFRm=epidermal growth factor receptor mutation; NSCLC=non-small-cell lung cancer; PD-1=programmed cell death protein 1; PD-L1=programmed cell death-ligand 1; TNBC=triple-negative breast cancer; VEGF=vascular endothelial growth factor





Bob Duggan

Chairman & Co-Chief Executive Officer



Dr. Maky Zanganeh

President & Co-Chief Executive Officer



Manmeet Soni

Chief Operating Officer & Chief Financial Officer



Dave Gancarz

Chief Business & Strategy Officer



Dr. Allen Yang

Chief R&D Officer



Dr. Fong Chow

Chief Biometrics Officer



Dr. Urte Gayko

Chief Regulatory, Pharmacovigilance & Quality Officer



Dr. Jack West

VP, Medical Affairs and Thoracic Oncology Expert





Summit Therapeutics Announces Submission of Biologics License Application (BLA) to U.S. FDA Seeking Approval for Ivonescimab in Combination with Chemotherapy in 2L+ Treatment of Patients with EGFRm NSCLC

Significant Unmet Need Remains in this Setting

Over 14,000 Patients are Eligible for 2L+ Treatment in This Setting in the United States Each Year

Summit Enters 2026 with Approximately \$710 Million in Cash

Miami, Florida, January 12, 2026 – Summit Therapeutics Inc. (NASDAQ: SMMT) (“Summit,” “we,” or the “Company”) today announced that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval for ivonescimab, the novel, first-in-class investigational bispecific antibody, in combination with chemotherapy in second-line or later treatment of patients with epidermal growth factor receptor (EGFR)-mutated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC). The BLA submission was based on the overall results of the global Phase III HARMONi trial. The BLA was submitted during the fourth quarter of 2025.

“This BLA submission, the first for ivonescimab, marks a critical milestone for Summit, our global clinical development plan, and the many patients with EGFRm NSCLC in need of better therapeutics options,” stated Robert W. Duggan and Dr. Maky Zanganeh, Co-Chief Executive Officers of Summit. “As we continue to support and expand ivonescimab’s rapid development via our growing set of global Phase III trials and clinical collaborations, we look forward to the potential first U.S. approval for ivonescimab in this difficult to treat setting.”

HARMONi evaluated ivonescimab plus platinum-doublet chemotherapy compared to placebo plus platinum-doublet chemotherapy in patients with EGFR-mutated, locally advanced or metastatic NSCLC who have progressed after treatment with a 3rd generation EGFR tyrosine kinase inhibitor (TKI). This is a clinical setting with a patient population where PD-1 monoclonal antibodies have previously been unsuccessful in Phase III global clinical trials in showing either a progression-free survival (PFS) or overall survival (OS) benefit, the two primary endpoints of this clinical study.

Based upon standard review timelines, if the application is accepted as submitted, we anticipate a decision from the agency by the fourth quarter of 2026.

Update Regarding Current Financial Position

As of December 31, 2025, the company’s preliminary unaudited balance of cash, cash equivalents, and short-term investments was approximately \$710 million. This amount is preliminary and is subject to completion of financial closing procedures. As a result, this amount may differ from the amount that will be reflected in the Company’s consolidated financial statements for the year ended December 31, 2025.

About Ivonescimab

Ivonescimab, known as SMT112 in Summit’s license territories, North America, South America, Europe, the Middle East, Africa, and Japan, and as AK112 outside of Summit’s license territories, is a novel, potential first-in-class



investigational bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. By design, ivonescimab displays unique cooperative binding to each of its intended targets with multifold higher affinity to PD-1 when in the presence of VEGF.

This is intended to differentiate ivonescimab as there is potentially higher expression (presence) of both PD-1 and VEGF in tumor tissue and the tumor microenvironment (TME) as compared to normal tissue in the body. We believe ivonescimab's specifically engineered tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the TME (Zhong, et al, SITC, 2023). This tetravalent structure, the intentional novel design of the molecule, and bringing these two targets into a single bispecific antibody with cooperative binding qualities have the potential to direct ivonescimab to the tumor tissue versus healthy tissue. The intent of this design, together with a half-life of 6 to 7 days after the first dose (Zhong, et al, SITC, 2023) increasing to approximately 10 days at steady state dosing, is to improve upon previously established efficacy thresholds, side effects, and safety profiles associated with prior approved drugs to these targets.

Ivonescimab was engineered by Akeso Inc. (HKEX Code: 9926.HK) and is currently utilized in multiple Phase III clinical trials. Over 4,000 patients have been treated with ivonescimab in clinical studies globally, and over 60,000 patients when considering those treated in a commercial setting in China, as noted by Akeso.

Summit began its clinical development of ivonescimab in NSCLC, commencing enrollment in 2023 in two multiregional Phase III clinical trials, HARMONi and HARMONi-3. In 2025, the Company began enrolling patients in HARMONi-7. Summit expanded its Phase III clinical development program into CRC in the fourth quarter of 2025 by initiating enrollment in HARMONi-GI3.

HARMONi is a Phase III clinical trial which intends to evaluate ivonescimab combined with chemotherapy compared to placebo plus chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a 3rd generation EGFR TKI (e.g., osimertinib). Detailed results of the study were provided in September 2025, and a Biologics License Application (BLA) was submitted to the United States Food and Drug Administration (FDA) for marketing authorization in the fourth quarter of 2025.

HARMONi-3 is a Phase III clinical trial, which is intended to evaluate ivonescimab combined with chemotherapy compared to pembrolizumab combined with chemotherapy in patients with first-line metastatic, squamous or non-squamous NSCLC, irrespective of PD-L1 expression.

HARMONi-7 is a Phase III clinical trial which is intended to evaluate ivonescimab monotherapy compared to pembrolizumab monotherapy in patients with first-line metastatic NSCLC whose tumors have high PD-L1 expression.

HARMONi-GI3 is a Phase III clinical trial evaluating ivonescimab in combination with chemotherapy compared with bevacizumab plus chemotherapy in patients with first-line unresectable metastatic CRC.

In addition, Akeso has recently had positive read-outs in three single-region (China), randomized Phase III clinical trials, HARMONi-A, HARMONi-2, and HARMONi-6, for ivonescimab in NSCLC, including a statistically significant overall survival benefit in HARMONi-A with a manageable safety profile in each study.

HARMONi-A was a Phase III clinical trial which evaluated ivonescimab combined with chemotherapy compared to placebo plus chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with an EGFR TKI.

HARMONi-2 is a Phase III clinical trial evaluating monotherapy ivonescimab against monotherapy pembrolizumab in patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression.



HARMONI-6 is a Phase III clinical trial evaluating ivonescimab in combination with platinum-based chemotherapy compared with tislelizumab, an anti-PD-1 antibody, in combination with platinum-based chemotherapy in patients with locally advanced or metastatic squamous NSCLC, irrespective of PD-L1 expression.

Akeso is actively conducting multiple Phase III clinical studies in settings outside of NSCLC, including biliary tract cancer, colorectal cancer, breast cancer, pancreatic cancer, small cell lung cancer, and head and neck cancer.

Ivonescimab is an investigational therapy that is not approved by any regulatory authority in Summit's license territories, including the United States and Europe. Ivonescimab was initially approved for marketing authorization in China in May 2024. Ivonescimab was granted Fast Track designation by the US Food & Drug Administration (FDA) for the HARMONI clinical trial setting.

About Summit Therapeutics

Summit Therapeutics Inc. is a biopharmaceutical oncology company focused on the discovery, development, and commercialization of patient-, physician-, caregiver- and societal-friendly medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs.

Summit was founded in 2003 and our shares are listed on the Nasdaq Global Market (symbol "SMMT"). We are headquartered in Miami, Florida, and we have additional offices in Menlo Park, California, and Oxford, UK.

For more information, please visit <https://www.smmtx.com> and follow us on X [@SMMT_TX](#).

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Summit Forward-looking Statements

Any statements in this press release 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 intended use of the net proceeds from the private placements, 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, the expected timing of BLA submissions or FDA decisions, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, the Company's estimates regarding stock-based compensation, 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 Company's ability to sell shares of our common stock under the ATM Program, the conditions affecting the capital markets, general economic, industry, or political conditions, including the effects of geopolitical



developments, domestic and foreign trade policies, and monetary policies, 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, 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" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study that with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. 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, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release 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 press release.

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Summit Therapeutics Announces Clinical Trial Collaboration with GSK to Evaluate Ivonescimab in Combination with GSK's B7-H3 Antibody Drug Conjugate (ADC)

Summit to Advance Development Opportunities of Ivonescimab with GSK's Novel B7-H3 risvutatug rezetecan

Multiple Solid Tumor Settings to Be Pursued with Clinical Trials Expected to Start in Mid-2026

Miami, Florida, January 12, 2026 – Summit Therapeutics Inc. (NASDAQ: SMMT) today announced it has entered into a clinical trial collaboration with GSK plc ("GSK", LSE/NYSE: GSK) to evaluate ivonescimab, a novel, investigational PD-1 / VEGF bispecific antibody, in combination with risvutatug rezetecan (also known as GSK'227), GSK's novel investigational B7-H3 targeting antibody drug conjugate (ADC), across multiple solid tumor settings, including small cell lung cancer (SCLC).

"We believe exploring new mechanisms and combinations with the potential to surpass current options for patients and physicians will have the most profound impact on those battling the toughest cancer challenges today," stated Robert W. Duggan and Dr. Maky Zanganeh, Co-Chief Executive Officers of Summit. "With the goal of accelerating development of ivonescimab in multiple solid tumors, this collaboration enables us to swiftly advance ivonescimab and expand Summit's combination strategy."

The intent of this agreement is to investigate the combination potential of ivonescimab and risvutatug rezetecan in multiple solid tumor environments to determine the safety profile and potential anti-tumor effects.

Under the terms of the agreement, Summit will supply ivonescimab for the planned study, while GSK will manage the day-to-day clinical operations of the study. Each party will maintain rights to their respective products, and the agreement is mutually non-exclusive. The study is expected to begin dosing patients in mid-2026.

About risvutatug rezetecan

Risvutatug rezetecan, also known as GSK'227, is a novel investigational B7-H3-targeted antibody-drug conjugate composed of a fully human anti-B7-H3 monoclonal antibody covalently linked to a topoisomerase inhibitor payload. GSK acquired exclusive worldwide rights (excluding China's mainland, Hong Kong, Macau, and Taiwan) from Hansoh Pharma to progress clinical development and commercialisation of risvutatug rezetecan. GSK's global phase III trial for risvutatug rezetecan in relapsed ES-SCLC began in August 2025.

About Ivonescimab

Ivonescimab, known as SMT112 in Summit's license territories, North America, South America, Europe, the Middle East, Africa, and Japan, and as AK112 outside of Summit's license territories, is a novel, potential first-in-class investigational bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. By design, ivonescimab displays unique cooperative binding to each of its intended targets with multifold higher affinity to PD-1 when in the presence of VEGF.

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About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at [gsk.com](https://www.gsk.com).

About Summit Therapeutics

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Summit was founded in 2003 and our shares are listed on the Nasdaq Global Market (symbol "SMMT"). We are headquartered in Miami, Florida, and we have additional offices in Menlo Park, California, and Oxford, UK.

For more information, please visit <https://www.smmtx.com> and follow us on X [@SMMT_TX](https://twitter.com/SMMT_TX).

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Summit Forward-looking Statements

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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, 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" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of filings that the Company makes with the Securities and Exchange Commission. Summit defines a "positive study" as a clinical study that with one or more prespecified primary endpoints in which one of those endpoints achieves a statistically significant benefit according to the protocol or statistical analysis plan. 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, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release 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 press release.

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