



NEWS RELEASE

Ivonescimab with Chemotherapy Demonstrated a Statistically Significant Overall Survival Benefit Compared to Tislelizumab Plus Chemotherapy in 1L Treatment of Patients with Squamous NSCLC in the HARMONi-6 Study Conducted by Akeso in China

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Ivonescimab Plus Chemotherapy Reduced the Risk of Death by 34% Compared to Tislelizumab Plus Chemotherapy;
Hazard Ratio 0.66

First Regimen to Achieve a Statistically Significant and Clinically Meaningful Overall Survival Benefit over an anti-PD-(L)1 Antibody Combined with Chemotherapy in a Phase III Clinical Trial in 1L NSCLC

Tolerable Safety Profile Consistent with Prior Clinical Trial Results

Simultaneous Publication of Latest Ivonescimab HARMONi-6 Results in The Lancet

Summit Conference Call to Be Held at 7:00 a.m. ET on Monday, June 1, 2026

MIAMI--(BUSINESS WIRE)-- Summit Therapeutics Inc. (NASDAQ: SMMT) today announced positive overall survival (OS) results from the Phase III HARMONi-6 trial, conducted in China and sponsored by Summit's partner Akeso, Inc. (HKEX Code: 9926.HK), will be presented today as part of the Plenary Session at the 2026 American Society of

Clinical Oncology (ASCO) Annual Meeting in Chicago.

The presentation is entitled “Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in previously untreated advanced squamous non-small cell lung cancer: Overall survival results of the phase 3 HARMONi-6 trial.” HARMONi-6 is evaluating ivonescimab in combination with platinum-based chemotherapy compared to tislelizumab, a PD-1 inhibitor, in combination with platinum-based chemotherapy in patients with locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) irrespective of PD-L1 expression. HARMONi-6 is a single region, multi-center, Phase III study conducted in China and sponsored by Akeso, with all relevant data exclusively generated, managed, and analyzed by Akeso. The trial's primary endpoint is progression-free survival (PFS), and OS is a key secondary endpoint.

The trial results will be presented by Dr. Shun Lu, MD, PhD, Chief of Shanghai Lung Cancer Center at Shanghai Chest Hospital, Professor of Medicine at Shanghai Jiaotong University, and associate editor for the Journal of Thoracic Oncology.

In major markets globally, first-line therapy for patients with advanced NSCLC without driver mutations is most commonly a PD-1 inhibitor plus platinum-based chemotherapy. Prior to HARMONi-6, there were no known Phase III clinical trials in advanced NSCLC which have shown a statistically significant and clinically meaningful improvement in OS when compared to PD-(L)1 inhibitor therapy in combination with chemotherapy in a head-to-head setting. Examples of PD-(L)1 inhibitors include pembrolizumab, nivolumab, tislelizumab, and atezolizumab.

Clinically Meaningful Efficacy

In the HARMONi-6 planned interim analysis of OS, ivonescimab in combination with chemotherapy demonstrated a statistically significant improvement when compared to tislelizumab in combination with chemotherapy, with a hazard ratio (HR) of 0.66 (95% CI: 0.50, 0.87; p=0.0017). A clinically meaningful benefit was demonstrated across clinical subgroups, including those with either PD-L1 negative or positive expression. OS rates at 24 months were 64.7% for those patients receiving ivonescimab plus chemotherapy compared to 48.6% for those receiving tislelizumab plus chemotherapy. Median follow-up time of the current data cut was 21.4 months.

HARMONi-6 ITT (n=532): Median Follow-up: 21.36 mos.	Ivonescimab + Chemo (n=266)	Tislelizumab + Chemo (n=266)
Median OS	27.89 mos. (95% CI: 27.89, NE)	23.69 mos. (95% CI: 20.11, NE)
24-Month OS Rates	64.7%	48.6%
OS Stratified HR	0.66 (95% CI: 0.50, 0.87; p= 0.0017)	

mos.: months; NE: not established

HARMONi-6 PD-L1 Subgroup Analyses	Ivonescimab + Chemo vs. Tislelizumab + Chemo
PD-L1 Negative (PD-L1 TPS <1%) OS stratified HR Ivonescimab + Chemo n=105; Tislelizumab + Chemo n=105	0.64 (95% CI: 0.43, 0.96)
PD-L1 Positive (PD-L1 TPS >1%) OS stratified HR Ivonescimab + Chemo n=161; Tislelizumab + Chemo n=161	0.68 (95% CI: 0.46, 0.99)

“For the first time, a Phase III clinical study has demonstrated a statistically significant overall survival benefit in front-line driver-mutation-negative non-small cell lung cancer compared to anti-PD-1 therapy in combination with chemotherapy,” said Dr. Maky Zanganeh, President and Co-Chief Executive Officer of Summit. “While this represents another study where ivonescimab has demonstrated a significant OS benefit, these data represent the answer to the question regarding ivonescimab and its ability to translate PFS benefits into the extension of lives for patients with cancer in the front-line setting compared to immunotherapy-based regimens.”

The HARMONi-6 study **met its primary endpoint** as announced in April 2025, showing a statistically significant and clinically meaningful improvement in PFS. Detailed results for efficacy and safety were presented at the **European Society of Medical Oncology 2025 Congress (ESMO 2025)** last October and published in *The Lancet* simultaneously.

Safety Profile

In this analysis, ivonescimab continued to demonstrate an acceptable and manageable safety profile in the HARMONi-6 study, which was consistent with previous Phase III studies of ivonescimab plus chemotherapy. No additional safety signals were noted in the HARMONi-6 study in this current data cut compared to the previous data cut presented.

Treatment-related serious adverse events occurred in 41.4% of patients receiving ivonescimab in combination with chemotherapy and 34.3% of patients receiving tislelizumab in combination with chemotherapy. Most of the possibly VEGF-related adverse events occurring in the ivonescimab-plus-chemotherapy arm were classified as Grade 1 or 2; Grade 3 or higher hemorrhage events were observed in 2.6% of patients in the ivonescimab-plus-chemotherapy arm compared to 0.8% of patients in the tislelizumab-plus-chemotherapy arm in this study. Treatment-related adverse events (TRAEs) leading to discontinuation in this study occurred in 5.3% of patients receiving ivonescimab plus chemotherapy compared to 4.5% for those receiving tislelizumab plus chemotherapy.

In squamous NSCLC, VEGF-A monoclonal antibodies have had limited clinical development based on historical data demonstrating significant risks of toxicity, including life-threatening hemorrhage and other bleeding complications. The results of this study further validate the unique mechanism of action of ivonescimab, including apparent key differences as compared to historical clinical studies where an anti-PD-1 monoclonal antibody and an anti-VEGF

monoclonal antibody were administered separately.

HARMONi-6 Clinical Trial Results Published in The Lancet

The Lancet simultaneously published these findings in a manuscript titled, "Ivonescimab plus Chemotherapy for Squamous Non-small-cell Lung Cancer."

"A heartfelt congratulations to our partner, Akeso, for their continuing, tremendous efforts to make a significant difference in the lives of patients with cancer," said Robert W. Duggan, Chairman and Co-Chief Executive Officer of Summit. "The decision we made in December 2022 to enter into a partnership specifically with Akeso and accelerate the global clinical development plan of this potentially landscape-changing compound in ivonescimab is further validated with these groundbreaking results for patients facing high unmet medical needs. We look forward to continuing this positive momentum."

Conference Call

Summit will host a conference call and live webcast to discuss recent updates related to ivonescimab, including data released at ASCO, on Monday, June 1, 2026, at 7:00 a.m. ET. Conference call and webcast information is accessible through the company's website, www.smmttx.com. An archived edition of the webcast will be available on the website later in the day on Monday.

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. Summit believes ivonescimab's specifically engineered tetravalent structure (four binding sites) enables higher avidity (accumulated strength of multiple binding interactions) in the TME (Zhong, et al, iScience, 2025). 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, iScience, 2025) 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 70,000 patients when considering those treated in a commercial setting in China, as noted by Akeso.

There are currently 15 Phase III clinical studies that are either announced, ongoing, or have been completed studying ivonescimab, four of which are Summit-sponsored global studies, one of which is a multiregional study sponsored by a cooperative group, and 10 of which are being or have been conducted in China 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, Summit 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 is evaluating 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 third-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, which the FDA accepted for filing in January 2026; the goal Prescription Drug User Fee Act (PDUFA) date is November 14, 2026.

HARMONi-3 is a Phase III clinical trial evaluating 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. The clinical trial is evaluating the two histologies as individual, separately powered cohorts with independent statistical powering.

HARMONi-7 is a Phase III clinical trial evaluating 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.

ILLUMINE is a Phase III study being conducted by GORTEC, a cooperative group dedicated to Head and Neck Oncology, in recurrent / metastatic head and neck squamous cell carcinoma (r/m HNSCC). ILLUMINE is a three-arm Phase III clinical trial designed to evaluate ivonescimab monotherapy, as well as ivonescimab in combination with ligufalimab, Akeso's proprietary anti-CD47 monoclonal antibody, compared to monotherapy pembrolizumab in

patients with PD-L1 positive r/m HNSCC.

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 both the HARMONi-A and HARMONi-6 studies, and 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, triple-negative breast cancer, head and neck squamous cell carcinoma, small cell lung cancer, colorectal cancer, and pancreatic 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.

About Summit Therapeutics Inc.

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 the company's shares are listed on the Nasdaq Global Market (symbol "SMMT"). Summit is headquartered in Miami, Florida, with additional offices in Palo Alto, California, Princeton, New Jersey, Dublin, Ireland, and Oxford, UK.

For more information, please visit <https://www.smmmtx.com> and follow Summit on X @SMMT_TX.

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. and other collaborations, 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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