



NEWS RELEASE

Overall Survival Data from HARMONi-A, Featuring Ivonescimab in Combination with Chemotherapy vs. Chemotherapy in 2L+ Treatment of Patients with EGFRm NSCLC in China, to be Showcased at SITC 2025

2025-10-31

Conducted by Akeso, HARMONi-A Represents the First Statistically Significant OS Benefit Achieved in a Phase III Study by an Ivonescimab-Containing Regimen

MIAMI--(BUSINESS WIRE)-- Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today announced that results from the Phase III HARMONi-A trial, conducted in China and sponsored by our partner, Akeso, Inc. ("Akeso," HKEX Code: 9926.HK), featuring the novel, potential first-in-class investigational bispecific antibody, ivonescimab, will be presented as part of the Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2025) in National Harbor, Maryland (Washington D.C. metro area) on Friday, November 7, 2025 at 11:30am ET.

HARMONi-A evaluated ivonescimab combined with platinum-doublet chemotherapy in patients with epidermal growth factor receptor (EGFR)-mutated, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) who have progressed after treatment with an EGFR tyrosine kinase inhibitor (TKI) against placebo plus platinum-doublet chemotherapy. This is a clinical setting with a patient population where PD-1 monoclonal antibodies have previously been unsuccessful in Phase III global clinical trials. HARMONi-A was the first Phase III

study conducted with ivonescimab and now represents the first statistically significant overall survival (OS) benefit achieved by an ivonescimab regimen over a standard of care regimen.

HARMONi-A was a single region, multi-center, Phase III study conducted in China sponsored by Akeso with data generated and analyzed by Akeso. Via the results of HARMONi-A, this setting was the first of two settings which were approved by the National Medical Products Administration (NMPA), the health authority in China. In China, over 40,000 patients have been treated with ivonescimab in either a clinical or commercial setting.

Separately, Summit is sponsoring the HARMONi study, which is the first multiregional Phase III trial studying ivonescimab. HARMONi is evaluating ivonescimab plus platinum-doublet chemotherapy compared to placebo plus platinum-doublet chemotherapy in patients with EGFR mutated, locally advanced or metastatic non-squamous NSCLC who previously received a third generation EGFR TKI. Based on the results of the multiregional HARMONi study, we plan to submit a Biologics License Application (BLA); ivonescimab has not been approved by any regulatory authority in Summit's license territories, including the United States and Europe.

About the SITC 2025 Presentation

SITC 2025 Presentation

Presentation Title: Final Overall Survival Analysis of HARMONi-A Study Comparing Ivonescimab Plus Chemotherapy to Chemotherapy Alone in Patients With EGFR+ NSCLC Progressed on EGFR-TKI Treatment

Abstract No.: 1348

Session: Clinical Oral Abstract Session 1

Session Date & Time: Friday, November 7, 2025, 11:30am ET

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 in China and Australia, 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. 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 could 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. 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, in addition to side effects and safety profiles associated with these targets.

Ivonescimab was engineered by Akeso Inc. (HKEX Code: 9926.HK) and is currently engaged in multiple Phase III clinical trials. Over 3,000 patients have been treated with ivonescimab in clinical studies globally, and over 40,000 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 early 2025, the Company began enrolling patients in the United States for HARMONi-7. Summit intends to open clinical trial sites in the United States for the Phase III study in CRC by the end of 2025.

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). Enrollment in HARMONi was completed in the second half of 2024, and top-line results were announced in May of 2025, with detailed results provided in September 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 planned 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 for ivonescimab in NSCLC: HARMONi-A, HARMONi-2, and HARMONi-6.

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.smmmtx.com> and follow us 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., 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, 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. 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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Source: Summit Therapeutics