



Interim Overall Survival Analysis Requested from Chinese Health Authorities Shows a Clinically Meaningful, Positive Trend Favoring Ivonescimab Compared to Pembrolizumab in PD-L1 Positive Advanced NSCLC from HARMONi-2 Study Conducted by Akeso in China

Interim Analysis of HARMONi-2 Shows an Overall Survival Hazard Ratio of 0.777 Favoring Ivonescimab at 39% Data Maturity, Implying a Potential Numerical 22% Reduction in the Risk of Death Compared to Pembrolizumab

Ivonescimab Monotherapy Approved by NMPA in China for Front-Line PD-L1 Positive Advanced NSCLC

Miami, Florida, April 25, 2025 – Summit Therapeutics Inc. (NASDAQ: SMMT) (“Summit,” “we,” or the “Company”) today noted that Akeso, Inc. (Akeso, HKEX Code: 9926.HK) announced that ivonescimab was approved by the Chinese Health Authorities, the National Medical Products Administration (NMPA), for a second indication based on the results of the Phase III clinical trial, HARMONi-2 or AK112-303. HARMONi-2 evaluated monotherapy ivonescimab against monotherapy pembrolizumab in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors have positive PD-L1 expression. HARMONi-2 is a single region, multi-center, Phase III study conducted in China sponsored by Akeso with all relevant data exclusively generated, managed, and analyzed by Akeso.

As a part of the review of the supplemental marketing application submitted by Akeso seeking a label expansion of ivonescimab in China, the NMPA requested that Akeso perform an interim analysis of overall survival (OS).

Akeso announced that the results of this interim overall survival analysis included a clinically meaningful hazard ratio of 0.777. The analysis was conducted at 39% data maturity, with a nominal alpha level of 0.0001.

Last September, for the primary analysis for HARMONi-2, ivonescimab monotherapy demonstrated a statistically significant improvement in the trial’s primary endpoint, progression-free survival (PFS) by Independent Radiologic Review Committee (IRRC), when compared to monotherapy pembrolizumab, achieving a hazard ratio (HR) of 0.51 (95% CI: 0.38, 0.69; $p < 0.0001$). A clinically meaningful benefit was demonstrated across clinical subgroups, including those with PD-L1 low expression, PD-L1 high expression, squamous and non-squamous histologies.

“We are pleased to see that a trial that was designed to test for progression-free survival as the sole primary endpoint demonstrates a clinically meaningful overall survival trend at just 39% data maturity.” added Robert W. Duggan, Chairman and Co-Chief Executive Officer and Dr. Maky Zanganeh, Co-Chief Executive Officer and President of Summit. “The clinically meaningful overall survival trend underscores the opportunity of ivonescimab to represent a potential to be the next generation in PD-1 directed immunotherapy, and potentially make a significant difference in the lives of patients with lung cancer and prospectively other tumors,”

Summit is currently enrolling patients in the HARMONi-7 study. HARMONi-7 is a multiregional Phase III clinical trial sponsored by Summit which is evaluating monotherapy ivonescimab against monotherapy pembrolizumab in patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression. HARMONi-7 is currently enrolling patients globally and is conducted with registrational intent for the United States and other regions within Summit’s license territories.



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 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), 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 2,300 patients have been treated with ivonescimab in clinical studies globally.

Summit has begun its clinical development of ivonescimab in non-small cell lung cancer (NSCLC), commencing enrollment in 2023 in two multi-regional Phase III clinical trials, HARMONi and HARMONi-3, and the Company has begun to activate clinical trial sites in the United States for HARMONi-7.

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 have progressed after treatment with a 3rd generation EGFR TKI (e.g., osimertinib). Enrollment in HARMONi was completed in the second half of 2024, and top-line results are expected to be announced in the middle of this year.

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 and non-squamous NSCLC.

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.

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 non-small cell lung cancer (NSCLC), irrespective of PD-L1 expression.

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 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 Company's anticipated spending and cash runway, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, potential acquisitions, statements about the previously disclosed At-The-Market equity offering program ("ATM Program"), the expected proceeds and uses thereof, and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995.



Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the 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, 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" section of filings that the Company makes with the Securities and Exchange Commission. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ivonescimab. Accordingly, 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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