



NEWS RELEASE

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

2026-01-12

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--(BUSINESS WIRE)-- 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.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 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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