



NEWS RELEASE

# Multiple Ivonescimab Data Sets from Phase III Studies in Advanced NSCLC Patient Populations to be Featured at ELCC 2026

2026-03-27

Three Poster Presentations Will Feature Updated Ivonescimab Data, including Intracranial Anti-Tumor Activity from the Global HARMONi Phase III Study

MIAMI--(BUSINESS WIRE)-- Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today announced that data for its novel, potential first-in-class investigational bispecific antibody, ivonescimab, will be presented at the 2026 European Lung Cancer Congress (ELCC 2026) in Copenhagen, Denmark. Three posters featuring updated ivonescimab data will be displayed on Friday, March 27 from 1:00 to 2:00 pm Central European Time. Data for HARMONi was generated and analyzed by Summit and for HARMONi-2 by our collaboration and licensing partner, Akeso Inc. (HKEX Code: 9926.HK).

The first poster, "Intracranial Efficacy of Ivonescimab Plus Chemotherapy in Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor (TKI)-Resistant, EGFR-Mutated Non-Small Cell Lung Cancer (NSCLC) in the HARMONi Study" includes outcome data from patients with and without asymptomatic brain metastases at baseline enrolled in HARMONi (NCT06396065). These patients received either ivonescimab delivered in combination with chemotherapy, or chemotherapy alone in this global Phase III trial for patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with an EGFR TKI. Ivonescimab plus chemotherapy demonstrated an improvement in intracranial progression free survival (PFS) in patients with

baseline brain metastases of 10.1 months compared to 6.5 months for chemotherapy (HR 0.53 (0.33-0.84); nominal p=0.0068). In patients who did not have baseline CNS metastases, the addition of ivonescimab also showed an improvement in intracranial PFS over control arm with 15.7 months compared to 11.6 months (HR 0.72 (0.55-0.94); nominal p=0.0172). No new safety signals were identified across baseline brain metastasis subgroups.

The second poster, "Health-Related Quality of Life in Patients Previously Treated with an EGFR-TKI from HARMONi: A Phase 3 Trial of Ivonescimab vs Placebo Plus Chemotherapy" includes data from patients enrolled in HARMONi (NCT06396065). These patients received either ivonescimab delivered in combination with chemotherapy, or chemotherapy alone in this global Phase III trial for patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with an EGFR TKI.

The third poster, "Health-Related Quality of Life with Ivonescimab Versus Pembrolizumab for PD-L1 Positive, NSCLC (HARMONi-2): a Randomised, Double-Blind, Phase 3 Study in China" includes data from patients enrolled in HARMONi-2 or AK112-303 (NCT05499390). These patients received either ivonescimab delivered as monotherapy, or pembrolizumab delivered as monotherapy in this Phase III study conducted exclusively in China for patients with locally advanced or metastatic NSCLC whose tumors have positive PD-L1 expression with all data collected and analyzed by Akeso.

## About the ELCC 2026 Posters

Poster Title: Intracranial Efficacy of Ivonescimab Plus Chemotherapy in EGFR TKI-Resistant, EGFR-Mutated NSCLC in the HARMONi Study

ELCC Presentation No.: 15P

Session Date & Time: Friday, March 27, 1:00 to 2:00pm CET

Poster Title: Health-Related Quality of Life in Patients Previously Treated with an EGFR-TKI from HARMONi: A Phase 3 Trial of Ivonescimab vs Placebo Plus Chemotherapy

ELCC Presentation No.: 20P

Session Date & Time: Friday, March 27, 1:00 to 2:00pm CET

Poster Title: Health-Related Quality of Life with Ivonescimab Versus Pembrolizumab for PD-L1 Positive, NSCLC (HARMONi-2): A Randomised, Double-Blind, Phase 3 Study in China

ELCC Presentation No.: 107P

Session Date & Time: Friday, March 27, 1:00 to 2:00pm CET

## 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, 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 60,000 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 ten 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, 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, 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, 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.

Also including Summit's license territories, a Phase III study is planned to be 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 which is intended 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 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, 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. Ivonescimab was granted Fast Track designation by the US 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 Palo Alto, California, Princeton, New Jersey, Dublin, Ireland, and Oxford, UK.

For more information, please visit <https://www.smmtx.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.

Summit Therapeutics and the Summit Therapeutics logo are registered trademarks of Summit Therapeutics Inc. and/or its affiliates. Copyright 2026, Summit Therapeutics Inc. All Rights Reserved.

#### Contact Summit Investor Relations:

Dave Gancarz

Chief Business & Strategy Officer

Nathan LiaBraaten

Senior Director, Investor Relations

[investors@smmmtx.com](mailto:investors@smmmtx.com)

[media@smmmtx.com](mailto:media@smmmtx.com)

Source: Summit Therapeutics