UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 29, 2026

Summit Therapeutics Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	001-36866	37-1979717
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

601 Brickell Key Drive, Suite 1000, Miami, FL	33131
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (305) 203-2034

Not applicable
(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 **Other Events.**

On January 29, 2026, Summit Therapeutics Inc. (the "Company") issued a press release announcing that the U.S. Food & Drug Administration ("FDA") has accepted for filing the Company's Biologics License Application seeking approval for ivonescimab in combination with chemotherapy in patients with epidermal growth factor receptor-mutated locally advanced or metastatic non-squamous non-small cell lung cancer post-tyrosine kinase inhibitor therapy. The FDA provided a Prescription Drug User Fee Act goal action date of November 14, 2026.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated January 29, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

SUMMIT THERAPEUTICS INC.

Date: January 29, 2026

By: /s/ Manmeet S. Soni

Chief Operating Officer, Chief Financial Officer and Director
(Principal Financial Officer)

Summit Therapeutics Announces U.S. FDA Acceptance of Biologics License Application (BLA) Seeking Approval for Ivonescimab in Combination with Chemotherapy in Treatment of Patients with EGFRm NSCLC Post-TKI Therapy

BLA Filing Based on HARMONi Global Phase III Study Results

PDUFA Goal Action Date of November 14, 2026

Significant Unmet Need Remains; Over 14,000 U.S. Patients Eligible for Treatment Each Year in This Setting

Miami, Florida, January 29, 2026 – Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today announced that the U.S. Food & Drug Administration (FDA) has accepted for filing Summit's Biologics License Application (BLA) seeking approval for ivonescimab in combination with chemotherapy in patients with epidermal growth factor receptor (EGFR)-mutated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) post-tyrosine kinase inhibitor (TKI) therapy. The FDA provided a Prescription Drug User Fee Act (PDUFA) goal action date of November 14, 2026.

The BLA was submitted based on the overall results of the Phase III HARMONi trial, which evaluated ivonescimab plus platinum-doublet chemotherapy compared to placebo plus platinum-doublet chemotherapy in patients with EGFR-mutated, locally advanced or metastatic NSCLC who were previously treated with a 3rd generation EGFR TKI.

The FDA has noted that they intend to perform a complete review of the accepted and filed application in accordance with draft guidance, *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications*.[1] This includes planned mid-cycle and wrap-up meetings, and, subject to major deficiencies not being identified during the FDA's review, proposed labeling, prior to the PDUFA date.

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

[1] The most recent version of this draft guidance can be found on the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm

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 14 Phase III clinical studies that are either ongoing or have been completed studying ivonescimab, ten of which are being conducted in China by Akeso and four of which are Summit-sponsored global studies. 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; 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.

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.smmttx.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 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.