



## **Summit Therapeutics Announces Clinical Trial Collaboration with Pfizer to Evaluate Ivonescimab in Combination with Pfizer Antibody Drug Conjugates (ADCs)**

*Summit and Pfizer Seek to Accelerate Development Opportunities of Ivonescimab and Vedotin-based ADCs*

*Pfizer to Contribute Multiple ADCs to Evaluate with Ivonescimab in Unique Solid Tumor Settings*

*Clinical Trials Expected to Start in the Middle of This Year*

**Miami, Florida – February 24, 2025** – Summit Therapeutics Inc. (NASDAQ: SMMT) today announced a clinical trial collaboration with Pfizer Inc. (NYSE: PFE) to evaluate ivonescimab, a novel, investigational PD-1 / VEGF bispecific antibody, in combination with several of Pfizer’s antibody drug conjugates (ADCs) across multiple solid tumor settings.

“Rapidly developing novel mechanisms that go beyond what is currently available to patients and physicians is what we believe will make the most significant impact for those facing the greatest challenges from cancer today,” noted Bob Duggan and Dr. Maky Zanganeh, Summit’s Co-CEOs. “As we seek to accelerate the development of our potentially transformative ivonescimab across non-small cell lung cancer and other solid tumor settings, this collaboration will allow us to quickly advance beyond our promising late-stage development plan to evaluate ivonescimab in combination with some of the most innovative ADCs from Pfizer.”

The goal of the collaboration is to evaluate ivonescimab, in combination with several unique Pfizer ADCs across multiple solid tumor settings to accelerate the advancement of potentially landscape-changing combinations, which seek to improve the standards of care for patients facing serious unmet needs. Each study intends to evaluate ivonescimab plus one of Pfizer’s vedotin ADCs in individual, distinct solid tumor settings to determine the safety profile and potential anti-tumor activity of the combinations.

"We are excited to partner with Summit Therapeutics to explore the clinical synergy of our therapies," said Megan O'Meara, M.D., Head, Oncology Early Stage Development, Pfizer. "Together, we are advancing the exploration of our ADCs in rational, differentiated combinations with a bispecific antibody designed to address the unique complexities of tumor biology. This collaboration represents the next wave of investigational targeted combinations with the potential to transform treatment options for people living with cancer."

Under the terms of the agreement, Summit will provide ivonescimab for use in the proposed studies, and Pfizer will be responsible for conducting the operations of the studies. The studies will be overseen by both Summit and Pfizer. Both parties retain their respective rights to their products. The studies combining ivonescimab with Pfizer’s vedotin ADCs are planned to begin in the middle of this year. Further details on the clinical trials will be announced at a later 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 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 when in the presence of both PD-1 and 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 (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 designed to evaluate ivonescimab combined with chemotherapy compared to pembrolizumab combined with chemotherapy in patients with first-line metastatic 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 two single-region (China), randomized Phase III clinical trials for ivonescimab in NSCLC, HARMONi-A and HARMONi-2.

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.

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 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, 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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