



## Summit Therapeutics Announces Initial Indications for Clinical Trials for Ivonescimab (SMT112)

*Studies Designed in Alignment with Feedback from FDA*

*Company to Host Q1 Earnings Call on May 11, 2023 at 9:00am ET*

**Menlo Park, California, May 3, 2023** - Summit Therapeutics Inc. (NASDAQ: SMMT) (“Summit,” “we,” or the “Company”) today announced that it has determined its first two indications in non-small cell lung cancer (NSCLC) in which to pursue Phase III clinical trials for its innovative, potential first-in-class bispecific antibody, ivonescimab.

Summit has held multiple meetings with the US Food and Drug Administration (FDA) during the first quarter of 2023 regarding its planned Phase III clinical program and incorporated this feedback accordingly. We plan to initiate clinical studies in the following indications:

- Ivonescimab combined with chemotherapy in patients with epidermal growth factor receptor (EGFR)-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with a third-generation EGFR tyrosine kinase inhibitor (TKI) (“HARMONi”)
- Ivonescimab combined with chemotherapy in first-line metastatic squamous NSCLC patients (“HARMONi-3”)

For the HARMONi trial, Summit intends to dose its first patient during the current quarter (Q2 2023). We intend to dose our first patient in the HARMONi-3 trial in the second half of 2023.

Ivonescimab, known as SMT112 in the United States, Canada, Europe, 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. There is higher expression (presence) of both PD-1 and VEGF in tumor tissue and the tumor microenvironment (TME) as compared to normal, healthy tissue in the body. Ivonescimab’s tetravalent structure enables higher avidity (accumulated strength of multiple binding interactions) with over 10 fold increased binding affinity to PD-1 in the presence of VEGF *in vitro* in tumor cells.<sup>1</sup> This tetravalent structure, the design of the molecule, and bringing these two targets into a single bispecific antibody have the potential to steer ivonescimab to the tumor tissue versus healthy tissue, which are intended to improve side effects and safety concerns associated with these targets and have the potential to focus the antitumor activity of both targets.

Over 750 patients have been dosed with ivonescimab in clinical studies in China and Australia.

“I am immensely proud of the speed and efficiency of our team to enable clinical trials for SMT112,” stated Robert W. Duggan, Chairman & Chief Executive Officer of Summit. “I am particularly enthusiastic about the potential of ivonescimab: this shared enthusiasm is the impetus behind Team Summit’s rapid development to enter into multiple Phase III clinical trials with SMT112. With our confidence in our ability to clinically develop, achieve regulatory approvals, and effectively commercialize a quality product, we believe that we have the

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<sup>1</sup> Zhong *et al*, SITC 2022



opportunity to make a significant difference in the lives of those patients who could benefit from this innovative therapy.”

“Our agreement to in-license ivonescimab from our high-achieving partner, Akeso, went effective this past January,” added Dr. Maky Zanganeh, Co-CEO & President of Summit. “In just over three months’ time, we are preparing to enroll patients in our first Phase III clinical trial, while actively preparing to launch our second Phase III study later this year. The commitment, preparation, diligence, and vision of Team Summit is shining brightly today and reflects the work we have completed to maximize the opportunities for the success of ivonescimab.”

Ivonescimab is an investigational product and is not approved for use by any health authority. Its efficacy and safety for the treatment of any indication have not been established.

### **First Quarter 2023 Earnings Call**

Summit will host an earnings call to announce its first quarter 2023 financial results and provide an operational update for the Company on Thursday, May 11, 2023, before the market opens. Summit will host a live webcast of the earnings conference call at 9:00am ET. It will be accessible through Summit’s website [www.smmtx.com](http://www.smmtx.com). An archived edition of the session will be available on our website.

### **Summit Therapeutics’ Mission Statement**

To build a viable, long-lasting health care organization that assumes full responsibility for designing, developing, trial execution and enrollment, regulatory submission and approval, as well as successful commercialization of patient, physician, caregiver, and societal-friendly medicinal therapy intended to: improve quality of life, increase potential duration of life, and resolve serious medical healthcare needs. To identify and control promising product candidates based on exceptional scientific development and administrative expertise, develop our products in a rapid, cost-efficient manner, and to engage commercialization and/or development partners when appropriate.

We accomplish this by building a team of world class professional scientists and business administrators that apply their experience and knowledge to this mission. Team Summit exists to pose, strategize, and execute a path forward in medicinal therapeutic health care that places Summit in a well-deserved, top market share, leadership position. Team Summit assumes full responsibility for stimulating continuous expansion of knowledge, ability, capability, and well-being for all involved stakeholders and highly-valued shareholders.

### **About Summit Therapeutics**

Summit was founded in 2003 and our shares are listed on the Nasdaq Global Market (symbol ‘SMMT’). We are headquartered in Menlo Park, California, and we have additional offices in Oxford, UK and Cambridge, UK. For more information, please visit <https://www.smmtx.com> and follow us on Twitter @summitplc.

### **About Ivonescimab**

Ivonescimab, known as SMT112 in the United States, Canada, Europe, and Japan (Summit’s license territories), 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 was discovered by Akeso Inc. (HKEX Code: 9926.HK, “Akeso”) and is currently engaged in multiple Phase III clinical trials in China. Summit intends to begin multiple Phase III clinical trials in its license territories in 2023. Over 750 patients have been dosed with ivonescimab in clinical studies in China and Australia.



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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 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 impact of the COVID-19 pandemic on the Company's operations and clinical trials, potential acquisitions 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 results of our evaluation of the underlying data in connection with the development and commercialization activities for SMT112, 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, and global public health crises, including the coronavirus COVID-19 outbreak, 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 SMT112. 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.