



## **Summit Therapeutics Partners with Akeso Inc. in Deal for Up to \$5 Billion to In-License Breakthrough Innovative Bispecific Antibody**

*\$500 Million Upfront Payment to Activate the Partnership for Ivonescimab*

**Menlo Park, California, US, and Grand Cayman, Cayman Islands, December 06, 2022** – Summit Therapeutics Inc. (NASDAQ: SMMT) (“Summit,” “we,” or the “Company”) today announced a definitive agreement of its partnership with Akeso Inc. (HKEX Code: 9926.HK, “Akeso”), to in-license its breakthrough bispecific antibody, ivonescimab. Akeso is a pioneer and source originator in developing innovative antibodies. The agreement supports Summit’s mission of developing and commercializing groundbreaking oncology pipeline products aimed at improving the quality of life of patients with serious unmet medical needs. For Akeso, the deal represents an opportunity to introduce its highly innovative antibodies to markets, including the United States, Canada, Europe, and Japan – an important step towards Akeso’s strategic intention of becoming a global biopharma organization.

Ivonescimab, known as AK112 in China and Australia, and also as SMT112 in the United States, Canada, Europe, and Japan, is a novel, potential first-in-class bispecific antibody combining the power of immunotherapy via a blockade of PD-1 with the anti-angiogenesis benefits of an anti-VEGF into a single molecule. Ivonescimab is believed to be the PD-1 / VEGF bispecific antibody that is most advanced in the clinic: there are no known PD-1-based bispecific antibodies approved by the US Food and Drug Administration (“FDA”) or the European Medicines Agency (“EMA”). Akeso has already demonstrated success by commercializing the only PD-1 bispecific approved in China. Its product 开坦尼 (pronounced “Kaitanni”) (cadonilimab), a PD-1 / CTLA-4 bispecific, was approved by the Chinese National Medical Products Administration (“NMPA”) earlier this year for the treatment of relapsed or metastatic cervical cancer patients who progressed on or after platinum-based chemotherapy.

Ivonescimab was engineered to bring two well established oncology targeted mechanisms together. It is our belief that the novel design has the potential to reduce side effects and safety concerns.

“The partnership between Summit Therapeutics and Akeso is a strategically compelling opportunity,” stated Robert W. Duggan, Chairman and Chief Executive Officer of Summit. “It represents bringing together Akeso’s extraordinary team, which has built an innovation engine capable of creating novel bispecific technologies, and the talented members of Team Summit with their proven track record of success of global clinical development, regulatory approvals, and commercialization, particularly in oncology. We believe the potential exists for enormous creation through this partnership. We are extremely encouraged by ivonescimab and the potential for improving the quality and duration of patients’ lives based on clinical data to support this point. Team Summit is honored and enthusiastic to partner with Akeso. Our shared mission and vision is to create a significant difference for the betterment of patient healthcare outcomes around the world.”

“Ivonescimab has demonstrated the potential to deliver superior clinical benefit for patients and tremendous value for investors,” said Dr. Michelle Xia, Co-founder, Chairwoman, CEO, and President of Akeso. “The Akeso team has been dedicated to the development of ivonescimab for the past 8 years, and proudly advanced the molecule to the clinical Phase III stage. The global value of ivonescimab awaits great work from a great team to realize. We are so pleased to partner with the world-class Summit team, who has the track record of successfully bringing over a dozen indications to market for the first-in-class blockbuster drug IMBRUVICA® (ibrutinib). Following intense and in-depth strategic, scientific, and operational discussion on ivonescimab between the Akeso and Summit teams in recent months, we are more confident than ever on a winning path for ivonescimab’s global development.



With this tremendous momentum, we look forward to the swift execution of the clinical development and commercial plan in a global setting for ivonescimab.”

As presented at ASCO 2022, ivonescimab treatment was associated with an overall response rate (ORR) in a Phase II study in patients with non-small cell lung cancer (NSCLC) who have failed EGFR-TKI's of 68.4% and a median Progression-Free Survival (mPFS) time period of 8.2 months when combined with combination chemotherapy (pemetrexed and carboplatin) as compared to historical mPFS of 4.3 months in patients treated with combination chemotherapy (pemetrexed and platinum-based chemotherapy) alone, the current standard of care. In a separate cohort, ivonescimab combined with docetaxel in patients who have failed PD-(L)1 and chemotherapies demonstrated a mPFS of 6.6 months as compared to a historical mPFS of 4.5 months with docetaxel alone, a current standard of care regimen for these patients. The study, which similarly had patients receiving ivonescimab plus chemotherapy as their first line therapy for metastatic disease, was considered to have demonstrated a tolerable safety profile and a low discontinuation rate for adverse events.

Ivonescimab has received Breakthrough Therapy Designation status in China from the NMPA for three indications: combination therapy with chemotherapy for NSCLC patients who have failed a previous EGFR-TKI, combination therapy with chemotherapy for NSCLC patients who have failed to respond to a prior PD-(L)1 therapy, and monotherapy as first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression. Ivonescimab is currently being developed in China and Australia in multiple solid tumors, including a Phase III clinical trial in patients with NSCLC that is positive for an epidermal growth factor receptor (EGFR) mutation whose disease has progressed after treatment with an EGFR tyrosine-kinase inhibitor (TKI).

Summit is initiating development activities for SMT112 and will do so first in NSCLC indications. Summit plans to start treating patients in clinical studies by the second quarter of 2023.

The definitive partnership calls for Summit to receive the rights to develop and commercialize ivonescimab (SMT112) in the United States, Canada, Europe, and Japan. Akeso will retain development and commercialization rights for the rest of the regions including China. In exchange for these rights, Summit will make an upfront payment of \$500 million. The total potential deal value is \$5.0 billion, as Akeso will be eligible to receive regulatory and commercial milestones of up to \$4.5 billion. In addition, Akeso will be eligible to receive low double-digit royalties on net sales. In conjunction with the closing of the deal, Dr. Michelle Xia will be appointed to the board of directors of Summit. The deal is subject to customary closing practices, including applicable waiting periods under the Hart-Scott-Rodino (HSR) Act.

“After reviewing a substantial number of opportunities, much of which was focused on potential treatments for solid tumors, we have found the ideal partnership with the potential to change the paradigm for treating patients facing difficult odds with devastating diagnoses,” added Dr. Maky Zanganeh, Co-Chief Executive Officer, President, and a member of Summit's Board of Directors. “Ten years ago, metastatic lung cancer patients rarely survived for more than ten to twelve months from diagnosis. Today, survival can be measured in years. Our goal is to improve the quality of life of a patient facing immeasurable odds while extending the duration of that patient's life. Our focus is always on how we can improve the lives of patients. We sought patient-friendly medicinal therapies through our search to expand our pipeline portfolio, and we are proud to take this meaningful step towards accomplishing this goal. We have significant work to do, but we are steadfastly committed to bringing ivonescimab into the hands of patients who need it most. We are thrilled to reach this agreement with Michelle and the team at Akeso, and we are excited to make this vision a reality. I am proud of Team Summit who have diligently worked these past few months to establish a strong bond with the team at Akeso, and I would like to thank the talented people of Team Akeso for spending so much quality time creating this meaningful partnership.”



## **Announcement of \$500 Million Rights Offering**

In conjunction with today's announcement regarding the definitive agreement related to SMT112, the Company has also announced that the Company's Board of Directors has approved a rights offering available to all holders of record of the Company's common stock, par value \$0.01 (the "Common Stock") as of the close of the market on the record date which will be no earlier than January 23, 2023 (the "Record Date"). The Company intends to distribute to all holders of Common Stock as of the Record Date non-transferable subscription rights to purchase shares of Common Stock at a price per share equal to the lesser of (i) \$1.05, or (ii) the volume weighted-average price of the Common Stock for the five consecutive trading days through and including the expiration date of the offering. Assuming that the rights offering is fully subscribed, the Company will receive gross proceeds of up to \$500 million, less expenses related to the rights offering.

The rights offering will include an over-subscription right to permit each rights holder that exercises its basic subscription rights in full to purchase additional shares of Common Stock that remain unsubscribed at the expiration of the offering. The availability of the over-subscription right will be subject to certain terms and conditions to be set forth in the offering documents.

Mr. Duggan, the beneficial owner of approximately 81% of Summit's Common Stock prior to this rights offering, and Dr. Zanganeh, the beneficial owner of approximately 6.4% of the Company's Common Stock prior to this rights offering, have each indicated that they intend to participate in the rights offering and subscribe for at least the full amount of their basic subscription rights, but have not made any formal binding commitment to participate.

The Company intends to register the rights offering with the Securities and Exchange Commission (the "SEC") by filing a prospectus on Form S-1. When available, a copy of the prospectus supplement may be obtained at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).

This press release does not constitute an offer to sell or the solicitation of an offer to buy these securities, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. The rights offering will be made pursuant to a registration statement on Form S-1 containing the detailed terms of the rights offering to be filed with the SEC. Any offer will be made only by means of a prospectus forming part of the registration statement.

## **Issuance of \$520 Million Promissory Note**

In conjunction with this agreement, Mr. Duggan and Dr. Zanganeh entered into a Note Purchase Agreement pursuant to which the Company was loaned \$520 million in exchange for the issuance by the Company of unsecured promissory notes in the amount of \$520 million.

Pursuant to the Note Purchase Agreement, the Company has issued to Mr. Duggan and Dr. Zanganeh unsecured promissory notes in the amount of \$400 million and \$20 million, respectively (the "February Notes"), which will mature and become due on February 15, 2023 (the "February Maturity Date") and an unsecured promissory note to Mr. Duggan in the amount of \$100 million (the "September Note" and together with the February Notes, the "Notes"), which will mature and become due on September 15, 2023 (the "September Maturity Date" and together with the February Maturity Date, the "Maturity Dates"). The Maturity Dates may be extended one or more times at the Company's election, but in no event to a date later than September 6, 2024. The Notes accrue interest at a rate of 7.5%.



Interest will be prepaid on the Notes for the period through February 15, 2023; such prepaid interest will be paid in shares of the Company's common stock. If the Company exercises its right to extend the term of the Notes, interest will accrue on the outstanding principal balance at the interest rate equal to the then US prime interest rate plus 50 basis points as adjusted monthly. After the three months immediately following the applicable Maturity Dates, interest will accrue at the then US prime interest rate plus 300 basis points, as adjusted monthly. At the Company's election, the Notes are extendable to no later than September 6, 2024. If the Company consummates a public offering, then the February Notes will be prepaid by an amount equal to the lesser of the net amount raised by the Company in the public offering or the outstanding principal of the February Notes. The prepayment would not be required prior to May 15, 2023.

The Company may prepay any portion of the Notes at its option without penalty. It is anticipated that the February Notes will be repaid in connection with the consummation of the anticipated rights offering.

The Notes issued has not been registered under the Securities and Exchange Act of 1933, as amended, and may not be offered or sold absent registration or an applicable exemption from registration requirements.

The Company expects to use the funds raised to support the following activities:

- Payment of the upfront obligation associated with the aforementioned partnership agreement;
- Activities to support clinical development and regulatory approval for SMT112;
- Pursue business development opportunities to expand our pipeline of drug candidates; and
- General corporate purposes.

#### **41st Annual J.P. Morgan Annual Healthcare Conference**

Summit will present alongside Akeso at the 41<sup>st</sup> Annual J.P. Morgan Healthcare Conference, which will include additional details related to this transaction. The presentation will be available afterwards through Summit's website at <https://www.summittxinc.com>.

#### **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, and 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.summittxinc.com> and follow us on Twitter @summitplc.

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**About Akeso Inc.**

Akeso (HKEX: 09926) is a commercial-stage biopharmaceutical company committed to the discovery, development, manufacturing and commercialization of innovative medicines with high unmet medical needs worldwide. Founded in 2012, the company has established a comprehensive in-house drug development platform (ACE Platform) and know-how, including R&D, clinical development, CMC (Chemistry, Manufacturing, and Controls), and commercialization capabilities. With fully integrated multi-functional platform, Akeso is internally working on a robust pipeline of over 30 innovative assets in the fields of cancer, autoimmune disease, inflammation, metabolic disease, and other major therapeutic areas. 17 assets have entered into clinical stage. Leveraging its in-house developed bispecific platform technology ("Tetrabody technology"), Akeso has advanced four potential first-in-class bispecific antibody drugs into market or clinical development, including cadonilimab (PD-1 / CTLA-4), ivonescimab (PD-1 / VEGF), PD-1 / LAG-3, and TIGIT / TGF-Beta bispecific antibodies. In June 2022, cadonilimab was approved by the NMPA and became the first commercialized PD-1 based bispecific drug globally. Another Akeso internally discovered and developed oncology product, penpulimab (a PD-1 antibody), was granted marketing approval in China in August 2021. Akeso is listed on the Main Board of the Stock Exchange of Hong Kong Limited.

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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.