

# Summit Therapeutics Reports Financial Results and Operational Progress for the Second Quarter and Six Months Ended June 30, 2023

Promising Updated Phase II Data Presented at ASCO 2023 for Ivonescimab

First US Patient Treated in Ivonescimab Phase III Clinical Trial with the First Patient in Ivonescimab's Second Phase III Clinical Trial Planned for the Second Half of 2023

**Menio Park, California, August 9, 2023** - Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today reports its financial results and provides an update on operational progress for the second quarter and six months ended June 30, 2023.

### **Operational & Corporate Updates**

- Our operational progress with ivonescimab (SMT112), an innovative, potentially first-in-class 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:
  - Summit is actively engaged in development activities for SMT112. In just over six months since we closed our in-licensing transaction for ivonescimab, Summit has:
    - Held multiple meetings with the US Food & Drug Administration (FDA) regarding its
      planned Phase III clinical program and incorporated this feedback accordingly, and
    - Begun its clinical development in non-small cell lung cancer (NSCLC) 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" trial)
      - Ivonescimab combined with chemotherapy in first-line metastatic squamous NSCLC patients ("HARMONi-3" trial)
  - In May 2023, the first patient in Summit's license territories was treated in the Phase III HARMONi clinical trial.
    - Summit intends to dose patients in the HARMONi-3 trial during the second half of 2023.
  - In June 2023, promising Phase II data from AK112-201, a study of Chinese subjects conducted and analyzed by our partners, Akeso, was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. In addition to encouraging data in multiple indications within NSCLC, a portion of the updated data presented at ASCO supports Summit's HARMONi-3 clinical trial in first-line metastatic squamous NSCLC: Phase II data in 63 treatment-naive, squamous NSCLC patients treated with ivonescimab plus chemotherapy with a median follow-up time of 13.3 months experienced:



- Median progression-free survival (PFS) of 11.0 months (95% CI: 9.5 to 16.8 months)
- Overall response rate (ORR) of 67% (95% CI: 53% to 78%) with a median duration of response of 15 months
- Median overall survival (OS) was not reached; although estimated 9-month OS was 93.2%
- Grade <u>></u>3 treatment-related adverse events (TRAEs) was 41%; the most frequent TRAEs were anemia, decreased neutrophil counts, and alopecia
- Recapping our Collaboration and License Agreement with Akeso Inc. (Akeso) for ivonescimab (SMT112):
  - On December 5, 2022, Summit and Akeso entered into a Collaboration and License Agreement for ivonescimab.
    - The Collaboration and License Agreement with Akeso closed on January 17, 2023 after going effective following customary waiting periods.
  - Summit received the rights to develop and commercialize ivonescimab (SMT112) in the United States, Canada, Europe, and Japan. Akeso retained development and commercialization rights for the rest of the world, including China.
  - In exchange for these rights, Summit committed to an upfront payment of \$500 million, which was paid in two installments.
    - The first installment worth \$300 million was paid in January in conjunction with the closing of the transaction. Of the \$300 million paid to Akeso by Summit, Akeso opted, in accordance with the Collaboration and License Agreement, to receive 10 million shares in lieu of a cash payment of \$25.1 million; the remaining \$274.9 million was paid by Summit to Akeso in cash.
    - The second installment of \$200 million was paid on March 6, 2023 in cash.
  - Going forward, Akeso will be eligible to receive regulatory and commercial milestones of up to \$4.5 billion. In addition, Akeso will receive low double-digit royalties on net sales in the Summit territories.
  - Akeso has a rich and diversified antibody drug pipeline with over 30 internally discovered drug candidates in various stages of development, including six bispecific antibodies. Akeso has taken part in over 80 clinical trials for 17 drug candidates, including 14 pivotal trials. Akeso has two drugs approved for oncology indications in China: a PD-1 inhibitor and a novel PD-1 / CTLA-4 bispecific antibody. Akeso has over 2,400 employees.



#### **Financial Highlights**

- Aggregate cash, cash-equivalents, short-term investments, and receivables on June 30, 2023 totaled \$220.1 million as compared to \$654.7 million on December 31, 2022.
  - Our cash, cash-equivalents and short-term investments on June 30, 2023 was \$215.0 million as compared to \$648.6 million on December 31, 2022. Accounts receivable and research and development tax credits receivable on June 30, 2023 were \$5.1 million as compared to \$6.1 million on December 31, 2022.
  - Our short-term investments consist of U.S. treasury securities.
  - Our notes payable balance at June 30, 2023 was \$100.0 million, which is due in September 2024.
  - Based on our current cash and investments position, we believe that we have sufficient capital resources to fund our operating costs and working capital needs, including our planned clinical trials for ivonescimab, for at least twelve months following the issuance of our Q2 financial statements filed on Form 10-Q.
- Net loss for the three and six months ended June 30, 2023 was \$14.7 million and \$557.1 million, respectively. Net loss for the three and six months ended June 30, 2022 was \$16.8 million and \$38.2 million, respectively.
  - The net loss for the six months ended June 30, 2023 includes one-time in-process research and development expenses associated with the in-licensing of ivonescimab from Akeso of \$520.9 million.
- Operating cash outflow for the six months ended June 30, 2023 and 2022 was \$42.4 million and \$38.2 million, respectively.

#### Second Quarter 2023 Earnings Call

Summit will host an earnings call this morning, Wednesday, August 9, 2023, at 9:00am ET. A live webcast and instructions for joining the call are accessible through Summit's website www.smmttx.com. An archived edition of the webcast will be available on our website after the call.

#### **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 administrational 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 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) and is currently engaged in multiple Phase III clinical trials in China. Summit has begun its clinical development of ivonescimab in NSCLC, enrolling the first patient in its license territory in 2023, with multiple Phase III clinical trials intended to be initiated in 2023. Over 825 patients have been treated with ivonescimab in clinical studies in China and Australia, with enrollment beginning recently in the United States.

#### **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.

For more information, please visit https://www.smmttx.com and follow us on X (formerly Twitter) @summitplc.

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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.



## SUMMIT THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

#### In thousands, except per share data

		nths Ended e 30.	Six Months Ended June 30.		
	2023	2022	2023	2022	
Revenue	\$	\$ 235	\$	\$ 485	
Operating expenses:					
Research and development	9,451	9,008	19,334	29,564	
In-process research and development			520,915		
General and administrative	6,316	6,933	13,256	13,592	
Total operating expenses	15,767	15,941	553,505	43,156	
Other operating (expense) income, net	(27)	3,014	557	7,821	
Operating loss	(15,794)	(12,692)	(552,948)	(34,850)	
Other income (expense), net	1,077	(4,079)	(4,145)	(3,318)	
Net loss	\$ (14,717)	\$ (16,771)	<u>\$ (557,093)</u>	\$ (38,168)	
Basic and diluted loss per share	\$ (0.02)	\$ (0.12)	\$ (1.03)	\$ (0.27)	
Comprehensive loss:					
Net loss	\$ (14,717)	\$ (16,771)	\$ (557,093)	\$ (38,168)	
Other comprehensive (loss) income:					
Foreign currency translation adjustments	(76)	789	(128)	(971)	
Reclassification of cumulative currency translation gain to other (expense) income, net	—	—	(419)	—	
Net changes related to short-term investments	(965)		3		
Comprehensive loss	\$ (15,758)	\$ (15,982)	<u>\$ (557,637)</u>	\$ (39,139)	



#### CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION (Unaudited) In thousands

	June 30, 2023		December 31, 2022	
Cash, Restricted Cash, Short-term Investments	\$	215,014	\$	648,607
Total assets	\$	237,372	\$	664,168
Total liabilities	\$	117,773	\$	537,514
Total stockholders' equity	\$	119,599	\$	126,654

#### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS INFORMATION (Unaudited) In thousands

	Six Months Er 2023			nded June 30, 2022	
Net cash used in operating activities Net cash used in investing activities	\$	(42,404) (644,856)	\$	(38,218) (654)	
Net cash provided by financing activities Effect of exchange rate changes on cash		80,032 737		25,187 (771)	
(Decrease) increase in cash and cash equivalents	\$	(606,491)	\$	(14,456)	