Summit Therapeutics Inc Reports Financial Results and Operational Progress for the Third Quarter and Nine Months Ended September 30, 2021

Cambridge, Massachusetts, November 15, 2021 - Summit Therapeutics Inc. (NASDAQ: SMMT) ("Summit," "we," or the "Company") today reports its financial results and provides an update on its operational progress for the third quarter and nine months ended September 30, 2021.

Note: A glossary of terms is included at the end of this document in order to allow for the ease of understanding of terms or concepts used throughout this release.

Financial Highlights

- Aggregate cash, accounts receivable, and tax credits receivable on September 30, 2021 totaled $103.9 million as compared to $76.6 million on December 31, 2020. Our cash balance on September 30, 2021 was $80.2 million as compared to $66.4 million on December 31, 2020. Accounts receivable and research and development tax credits receivable on September 30, 2021 were $23.7 million as compared to $10.2 million on December 31, 2020.
- Net loss for the three months ended September 30, 2021 and 2020, was $19.6 million and $17.7 million, respectively. Net loss for the nine months ended September 30, 2021 and 2020, was $61.5 million and $39.2 million, respectively.
- In September 2021, the Company reached the second enrollment milestone under its exclusive license and commercialization agreement with Eurofarma Laboratórios S.A. and billed $1.25 million associated with achieving this milestone, the balance of which was received in November.
- During the three months ended September 30, 2021, the Company received non-dilutive funding of $1.1 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, in support of the Company's Ri-CoDIFy clinical trials and clinical development of ridinilazole. As of September 30, 2021, an aggregate of $55.8 million out of a potential award of $72.5 million has been received from BARDA under contract number HHSO100201700014C. (Remaining potential funding from BARDA has not been included in our previously disclosed aggregate cash and receivables balances, above.)
- During the three months ended September 30, 2021, the Company received non-dilutive funding of $0.2 million from the Trustees of Boston University under the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator ("CARB-X") program, in support of IND-enabling activities for SMT-738. As of September 30, 2021, an aggregate of $0.2 million out of a potential of up to $7.8 million of funding has been received from CARB-X.

Ridinilazole for *C. difficile* Infection (CDI)

Summit's global Phase III clinical trial program for ridinilazole aims to support application for marketing approval of the precision antibiotic in the United States and other territories, with the goal of use of ridinilazole as first-line therapy to treat initial infection and reduce recurrence of *Clostridioides difficile* Infection (CDI). As presented within the American Journal of Physiology – Gastrointestinal and Liver Physiology (August 2020), dysbiosis of the gut microbiota with altered bile acid composition within the microbiome is believed to play a critical role in *C. difficile* infection, including recurrence of the disease. Using data from our Phase II clinical trial, ridinilazole has shown a relative sparing of the microbiome compared to the broad-spectrum antibiotics that are the current standard of

care for *C. diff.* Infection treatment today, as presented at ECCMID 2021. In addition, the use of broad-spectrum antibiotics and a perturbed gut microbiome may be associated with certain other infectious diseases, including COVID-19 (Giovanni, Schneider, Calder, and Fauci, *Journal of Infectious Diseases*, Aug 2021).

As announced in August 2021, the Company combined its Ri-CoDIFy 1 and 2 studies into a single, fully-enrolled clinical trial. Top-line results for this combined trial are expected in Q1 2022. The Ri-CoDIFy 3 clinical trial is currently enrolling adolescent subjects ages 12 to 17 years to evaluate the safety of the investigational drug and how it is metabolized in such patients.

Discuva Platform

SMT-738 for Carbapenem-Resistant Enterobacteriaceae Infections

The DDS-04 compound series is a novel class of precision antibiotics generated from our Discuva Platform with a new mechanism of action that acts via the clinically unexploited bacterial target, LolCDE. SMT-738 is the first molecule of this novel class with the potential to treat multidrug resistant infections caused by a large family of pathogenic Gram-negative bacteria, the Enterobacteriaceae, that include serious human pathogens such as *Escherichia coli* and *Klebsiella pneumoniae*. Combining a novel antibiotic class (SMT-738) with a clinically unexploited target (LolCDE) mitigates the risk of pre-existing resistance, potentially allowing for the effective treatment of Enterobacteriaceae-caused infections that currently have very limited and failing treatment options due to resistance to existing antibiotic classes.

Corporate Highlights

- In July, the Company presented breakthrough research data from its Phase II clinical trials for ridinilazole. Topics included evidence from Phase II trial sample data evidencing ridinilazole's preservation of the gut microbiome, potential benefits for the control of antimicrobial resistance related to the minimal impact of ridinilazole on the gut resistome, and a novel mechanism of action for ridinilazole. These topics were displayed in the form of three ePosters at the prestigious ECCMID 2021 conference, one of which was an ECCMID-designated Top Rated ePoster. These posters can be found on our corporate website, www.summittxinc.com/publications.
- On August 11, the Company announced that, based on a thorough review of the design and enrollment status of two ongoing blinded Phase III Ri-CoDIFy trials, it will combine its two blinded pivotal Phase III clinical trials evaluating ridinilazole versus vancomycin into a single study.
- On October 7, Kenneth A. Clark, a prominent advisor to biotechnology and biopharmaceutical companies, was appointed to the Company’s Board of Directors. Mr. Clark is a partner at Wilson Sonsini Goodrich & Rosati (WSGR). He has previously served as a board member for privately-held and publicly-traded companies, including Pharmacyclics, Inc., where Mr. Clark advised on two significant transactions, highlighted by Pharmacyclics’ $21 billion acquisition by AbbVie, one of the largest bio/pharma acquisitions of its kind. He received his undergraduate degree from Vanderbilt University and earned his juris doctorate from the University of Texas School of Law.

- On November 3, Dr. Urte Gayko, a seasoned regulatory and clinical development executive, was appointed to the Company's Board of Directors. Dr. Gayko is the Senior Vice President of Drug Development & Regulator Affairs at Nektar Therapeutics; she was previously the Global Head of Regulatory Affairs and Pharmacovigilance at Pharmacyclics, Inc. Dr. Gayko has over 20 years of experience in regulatory affairs and clinical development ranging from pre-commercial entities to large biopharmaceutical companies, including Amgen and AbbVie. Dr. Gayko performed her PhD research in molecular and cellular biology at Harvard University.
- Throughout the first three quarters of 2021, we have continued to build supporting layers to our team to fit the expansive vision of our company going forward. In doing so, we have appointed several individuals to positions of senior leadership, continuing to enhance the strong existing core leadership team and positioning the Company well for our strategic goals in the coming years. Leaders who have joined in Q3 and the beginning of Q4 comprise Heads of departments including, but not limited to, Marketing, Clinical Pharmacology & DMPK, Clinical Development, Information Technology, Market Access, and our General Counsel. Each of these leaders brings substantial experience and are respected leaders within their fields.

About *C. difficile* Infection

Clostridioides difficile, or *C. difficile,* infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon, severe watery diarrhea, painful abdominal cramping, nausea, fever, and dehydration. CDI can also result in more serious disease complications, including bowel perforation, sepsis, and death. CDI is a contagious infectious disease that represents a serious healthcare issue in hospitals, long-term care facilities, and the wider community. Summit estimates that there are approximately 500,000 cases of CDI each year across the United States with acute care costs exceeding $5.4 billion in the US based on a meta-analysis published in the *Journal of Global Health*, June 2019.

About Enterobacteriaceae

Enterobacteriaceae are a family of bacteria responsible for serious infections across a number of conditions including bloodstream infections, urinary tract infections, and hospital-acquired pneumonias. Multidrug resistant Enterobacteriaceae are resistant to treatment by most or occasionally all existent antibiotics. The most difficult to treat among them are the carbapenem-resistant Enterobacteriaceae (CRE), which are classified as an Urgent Threat by the US Centers for Disease Control and Prevention (CDC).

About Summit Therapeutics

The overriding objective of Summit Therapeutics is to create value for patients, hospital caregivers, and community-based healthcare providers, as well as healthcare payers around the world. We seek to create value by developing drugs with high therapeutic efficacy - curing the cause or effect of the patient's condition with minimal or zero disease recurrence or antimicrobial resistance, for the longest extent possible - and minimizing the trauma caused to the patient and healthcare ecosystem by minimizing serious side effects, disease recurrence, and inaccessibility to our treatments as a result of financial or other barriers. Summit Therapeutics, empowered by its Discuva Platform, the Company's innovative antibiotic discovery engine, and supported by BARDA and CARB-X funding, intends to be the leader in patient-friendly and paradigm-shifting treatments for infectious diseases and other significant unmet medical needs while being an ally to physicians. Our new mechanism pipeline product candidates are designed with the goal to become the patient-friendly, new-era standard of care, by working in harmony with the human microbiome to treat prospective patients suffering from infectious diseases, initially focusing on *Clostridioides difficile* infection (CDI). Currently, Summit's lead product candidate, ridinilazole, is a novel, first-in-class drug engaged in a global Phase III trial program versus vancomycin, for use as first-line therapy for the treatment of initial and recurrent *Clostridioides difficile* infection, and to show superiority in sustained clinical

response. Commercialization of ridinilazole is subject to regulatory approvals. SMT-738, the second candidate within Summit's portfolio, is currently in the IND-enabling phase for the treatment of multidrug resistant infections, specifically those caused by carbapenem-resistant Enterobacteriaceae (CRE).

For more information, please visit https://www.summittxinc.com and follow us on Twitter @summitplc. For more information on the Company's Discuva Platform, please visit https://www.summittxinc.com/our-science/discuva-platform.

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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, 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 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 uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, 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, 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 ridinilazole. 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 1,309	$ 181	$ 1,558	$ 675
Operating expenses:				
Research and development	19,943	13,726	62,245	40,210
General and administrative	5,662	6,846	15,831	16,192
Impairment of intangible assets	—	859	—	859
Total operating expenses	25,605	21,431	78,076	57,261
Other operating income	4,810	4,309	16,379	14,949
Operating loss	(19,486)	(16,941)	(60,139)	(41,637)
Other (expense) income, net	(113)	(858)	(1,364)	2,289
Loss before income tax	(19,599)	(17,799)	(61,503)	(39,348)
Income tax benefit	—	56	—	192
Net loss	$ (19,599)	$ (17,743)	$ (61,503)	$ (39,156)
Basic and diluted loss per share	$ (0.20)	$ (0.26)	$ (0.68)	$ (0.58)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(863)	2,326	352	(2,350)
Comprehensive loss	$ (20,462)	$ (15,417)	$ (61,151)	$ (41,506)

CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(Unaudited)
In thousands

	September 30, 2021	December 31, 2020
Cash	$ 80,248	$ 66,417
Total assets	128,673	102,498
Total liabilities	26,375	23,045
Total stockholders' equity	102,298	79,453

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

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (63,408)	$ (40,140)
Net cash used in investing activities	(186)	(371)
Net cash provided by financing activities	76,655	3
Effect of exchange rate changes on cash	770	(2,064)
Increase (decrease) in cash	$ 13,831	$ (42,572)

Appendix: Glossary of Critical Terms Contained Herein

Antibiotic resistance genes – Genes known to be involved in bacterial resistance; such genes may include for example beta-lactamases which can inactivate various beta-lactam antibiotics.

Bile acids – a collection of steroid-based gut metabolites, the balance of the amount of and types of bile acids in the gut microbiome are believed to play an important role in the development of or prevention of an initial and potential recurrent instance of *C. difficile* Infection.[i]

Bloodstream infections – an infectious disease defined by the presence of viable bacterial or fungal microorganisms in the bloodstream that elicit or have elicited an inflammatory response.[ii]

Carbapenem-Resistant Enterobacteriaceae (CRE) – Enterobacteriaceae that are resistant to carbapenems, a type of antibiotic used to treat some of the most resistant forms of gram-negative bacteria. This resistance means that there are fewer options available to treat infections caused by these bacteria, as CRE do not respond to commonly used antibiotics. In many cases, including infections such as urinary tract infections caused by CRE germs, more complex treatments are required. Instead of taking oral antibiotics at home, patients with these infections might require hospitalization and intravenous (IV) antibiotics. Occasionally CRE are resistant to all available antibiotics. CRE are a threat to public health.[iii]

Clostridia – a class of bacteria that exist within a healthy gut microbiome that likely plays a largely crucial role in microbiome homeostasis by interacting with the other resident microbe populations and providing specific and essential functions to the overall microbiome. While most groups of Clostridia have a commensal, or co-existing, relationship with the rest of the gut microbiome, some Clostridia can be pathogenic, when larger concentrations of the bacteria exist, such as *Clostridioides difficile* bacteria.[iv]

***Clostridioides difficile* (*C. difficile* or *C. diff.*)** – a germ (bacterium) that can cause severe diarrhea and colitis (an inflammation of the colon). *C. difficile* can live naturally in the intestines (gut) of humans and not cause any problem. Sometimes changes in the gut microbiome lead the bacteria to grow and produce toxins from which illness can develop.[v]

***C. diff.* Infection (CDI)** – a bacterial infection of the colon that produces toxins causing inflammation of the colon and severe watery diarrhea, very painful and persistent abdominal cramping, nausea, fever, and dehydration. CDI can also result in more serious disease complications, including bowel perforation (a tear in the gastrointestinal tract), sepsis, and death. Most cases of *C. diff.* infection occur while a person is taking antibiotics or not long after a person has finished taking antibiotics. CDI is an insidious and debilitating disease that necessitates patient isolation because of its contagious nature, making it able to be passed from one person to another either in a hospital or long-term care facility setting or in the community.[vi]

DDS-04 – a series of new mechanism antibiotics targeting Enterobacteriaceae. DDS-04 acts via LolCDE, an essential bacterial complex responsible for the transport of lipoproteins from the inner to outer membrane in gram-negative bacteria. Because this complex has not been a previous target of existing antimicrobials, bacterial resistance does not yet exist to this targeted approach, potentially allowing for the treatment of highly-resistant Enterobacteriaceae-caused infections. Some of these infections, particularly in a subset of CRE-caused infections, do not have effective treatments through currently available antibiotics.[vii]

Discuva Platform – Summit Therapeutics' proprietary platform that enables the identification of novel antimicrobials to expand Summit's pipeline of investigational drugs. The Discuva Platform focuses on identifying new antibiotics against bacteria where increasing resistance has limited treatment via existing antibiotics currently on the market.[viii]

Enterobacteriaceae – a large family of different types of bacteria (germs) that commonly cause infections both in healthcare settings, such as hospitals and long-term care facilities, and in communities. Examples of germs in the Enterobacteriaceae family include *Escherichia coli* (commonly known as *E. coli*) and *Klebsiella pneumoniae*. Enterobacteriaceae are frequent carriers of resistance genes to many of the currently available antibiotics used to treat bacterial infections. Because they are bacteria, Enterobacteriaceae can be passed from person to person.[ix]

Escherichia coli (E. coli) – a type of Enterobacteriaceae found in the environment, foods, and intestines of people and animals. *E. coli* are a large and diverse group of bacteria. Although most strains of *E. coli* are harmless, others can make a person sick. Some kinds of *E. coli* can cause diarrhea, while others cause urinary tract infections, bloodstream infections, respiratory illness and pneumonia, and other illnesses.[x]

Gastrointestinal tract – a series of hollow organs joined in a long, twisting tube from the mouth to the anus. These organs also include the esophagus, stomach, small intestine, and large intestine.[xi]

Gut microbiome – within the human gastrointestinal tract, the gut microbiome is a collection of microbiota, consisting of trillions of microorganisms that inhabit the gut. The gut microbiota is considered an important partner to human cell systems, interacting extensively with other organs in the body to influence a wide range of functions from digestion to immunity. The balance of the different types of cells and microorganisms within the microbiome is considered to be important in the microbiome's ability to properly play its role within the human body. Disruption in the balance of microorganisms within the gut microbiome (known as dysbiosis) is believed to impact the gut microbiome's role in keeping a person healthy and free of certain conditions or diseases.[xii xiii]

Gut microbiota – the trillions of microorganisms, including symbiotic and pathogenic microorganisms, that inhabit the gut. Examples of these microorganisms include bacteria, fungi, viruses, protists, and archaea.

Gut resistome – within the human gastrointestinal tract, the diversity and dynamics of the antibiotic resistance genes that are harbored by the gut microbiota. Examples of the gut resistome include genes associated with resistance to carbapenem antibiotics.[xiv]

Hospital-acquired pneumonia (HAP) – pneumonia that occurs 48 hours or more after a patient has been admitted to a hospital and was not present and incubating at the time of admission. Ventilator-associated pneumonia (VAP) is a significant sub-set of HAP, often occurring in intensive care units (ICUs) with a patient on a ventilator. Common pathogens of HAP and VAP include Enterobacteriaceae and *Pseudomonas* species. Due to the presence of the bacteria in a hospital, these bacteria may be resistant to different antibiotics, potentially causing the resulting infection to be more difficult to treat.[xv]

Klebsiella pneumoniae – a type of Enterobacteriaceae that can cause different types of healthcare-associated infections, including pneumonia, bloodstream infections, wound or surgical site infections, and meningitis. Increasingly, *Klebsiella* bacteria have developed resistance to antibiotics, most recently to the class of antibiotics known as carbapenems. *Klebsiella* bacteria are normally found in the human intestines (where they do not cause disease). In healthcare settings, *Klebsiella* infections commonly occur among sick patients who are receiving treatment for other conditions. Patients whose care requires devices like ventilators (breathing machines) or intravenous (vein) catheters, and patients who are receiving long courses of certain antibiotics are most at risk for *Klebsiella* infections. Healthy people typically do not develop *Klebsiella* infections.[xvi]

Sepsis – the body's extreme response to an infection and a life-threatening medical emergency. Sepsis occurs when an existing infection triggers a chain reaction throughout a person's body via the bloodstream. Without timely treatment, sepsis can rapidly lead to tissue damage, multi-organ failure, and death. Almost any type of infection can lead to sepsis. Infections that lead to sepsis most often start in the lung, urinary tract, skin, or gastrointestinal tract. Sepsis is a condition and is not contagious; however, the underlying cause of the infection (e.g., bacteria) can be spread from person to person. Bacterial infections cause most cases of sepsis.[xvii]

Shotgun metagenomic analysis – shotgun metagenomic sequencing sequences all genomic DNA present in a sample. This allows a more accurate taxonomic annotation of the microbiota compared to other techniques such as 16S rRNA amplicon sequencing as well as antibiotic resistance gene profiling and metabolic function profiling.

Urinary tract infections (UTI) – common infections that happen when bacteria, often from the skin or rectum, enter the urethra, and infect the urinary tract. The infections can affect several parts of the urinary tract, but the most common type is a bladder infection. Kidney infections are another type of UTI and can be more serious than bladder infections. UTIs are usually caused by bacteria and are treated with antibiotics. People who have had multiple UTIs requiring multiple courses of antibiotics are at increased risk of developing antibiotic-resistant infections that can become increasing complex to treat.[xviii]

Vancomycin – an antibiotic that is used to treat CDI

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[viii] Summit Therapeutics, Inc. https://www.summittxinc.com/our-science/discuva-platform/. Accessed February 2021.

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[xvii] United States Centers for Disease Control and Prevention. https://www.cdc.gov/sepsis/index.html. Accessed February 2021.

[xviii] United States Centers for Disease Control and Prevention. https://www.cdc.gov/antibiotic-use/community/for-patients/common-illnesses/uti.html. Accessed February 2021.