Summit Therapeutics Inc.

('We,' 'Summit,' or the 'Company')

Summit Therapeutics Reports Financial Results and Operational Progress for the First Quarter Ended March 31, 2021

Cambridge, MA, May 17, 2021 - Summit Therapeutics Inc. (NASDAQ: SMMT) today reports its financial results and provides an update on its operational progress for the first quarter ended March 31, 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 in advance of reviewing this release.

Ridinilazole for *C. difficile* Infection ('CDI')

1. As of May 14, 2021, Summit had enrolled a total of 652 patients into its two ridinilazole Phase 3 Ri-CoDIFy clinical trials; together, both trials have a projected enrollment goal of 1,360 patients. Below is a table outlining the enrollment statistics by calendar quarter since the opening of the trials in February 2019.

Quarter	Number of Patients Enrolled	Cumulative Patients Enrolled
Q1 2019	9	9
Q2 2019	21	30
Q3 2019	43	73
Q4 2019	78	151
Q1 2020	101	252
Q2 2020	73	325
Q3 2020	64	389
Q4 2020	105	494
Q1 2021	109	603
Q2 2021*	*49**	*652**

*Q2 2021 includes quarter-to-date enrollment through May 14, 2021

2. As previously disclosed, Summit is not providing public commentary on the timing of completion of the Phase 3 Ri-CoDIFy clinical trials. The Company plans to publicly update stakeholders quarterly as to enrollment status.
3. The Ri-CoDIFy clinical trials aim to support application for marketing approval of the precision antibiotic ridinilazole in the United States and other territories, with the goal of use as first-line therapy to treat initial infection and reduce recurrence of CDI.
4. BARDA is supporting the Phase 3 clinical trials and regulatory development of ridinilazole with a financial award of potential funding of up to $72.5 million. As of March 31, 2021, an aggregate of $53.9 million had been received.
5. 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 disease. Ridinilazole has, thus far, shown a significant relative sparing of the microbiome compared to the broad-spectrum antibiotics that are the current standard of care for *C. diff* infection treatment today.

Discuva Platform

Enterobacteriaceae

The DDS-04 compound series is a novel class of precision antibiotics with a new mechanism of action that acts via the novel bacterial target, LolCDE. Our lead compound is in late lead optimization with the potential to treat multidrug resistant infections caused by a large group of pathogenic gram-negative bacteria, the Enterobacteriaceae. Because LolCDE has never been a target of existing antibiotics and 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 carbapenem-resistant Enterobacteriaceae (CRE)-caused infections, have limited or failing treatment options through currently available antibiotics.

Corporate Highlights

In March 2021, Summit launched its Ri-CoDIFy 3 study, an additional Phase 3 clinical trial for the study of the use of ridinilazole in adolescents 12 to 17 years of age. The study, which is expected to enroll approximately 40 patients, has an aim to determine the safety of ridinilazole in adolescents as a part of the overall support for our Phase 3 program.

Financial Highlights

1. Cash and cash equivalents on March 31, 2021, of $102.2 million compared to $66.4 million on December 31, 2020. The balance as of March 31, 2021, includes $55 million in proceeds received in connection with a Note Purchase Agreement with Robert W. Duggan, the Company's Chairman, Chief Executive Officer, and majority shareholder.
2. In March 2021, the Company announced a Rights Offering for our existing shareholders to participate in the purchase of additional shares our common stock, which commenced in April 2021 and the associated subscription rights expired on May 10, 2021. Through this Rights Offering, the Company raised $75 million through the issuance and sale of 14,312,976 shares of common stock. Of the $75 million raised through the Rights Offering, $55 million was used to repay an outstanding note payable.
3. The Company's existing cash and cash equivalents and committed external funding are expected to be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2022.
4. Net loss for the three months ended March 31, 2021, of $17.5 million compared to a net loss of $6.1 million for the three months ended March 31, 2020.

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 and 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 homes, and the wider community. Summit estimates that there are approximately 500,000 cases of CDI each year across the United States 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 Urgent Threats by the CDC.

About Summit Therapeutics
Summit Therapeutics, empowered by its Discuva Platform, the Company's innovative antibiotic discovery engine, supported by BARDA and CARB-X funding, intends to be the leader in patient-friendly and paradigm-shifting innovation while being an ally to physicians. Our new mechanism antibiotics are designed 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 disease, initially focusing on *Clostridioides difficile* infections (CDI). The overriding objective of Summit Therapeutics is to create value for patients, hospital infectious disease caregivers, and community-based infectious disease 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 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. Currently, Summit's lead product candidate, ridinilazole, is engaged in two pivotal global Phase 3 trials, Ri-CoDIFy 1 & 2, each enrolling approximately 680 patients vs. the standard of care (vancomycin) for the treatment and reduction of recurrence of *C. difficile* infections in addition to an adolescent trial, Ri-CoDIFy 3. Commercialization of ridinilazole for the treatment and the reduction of recurrence of CDI is subject to regulatory approvals.

For more information, please visit 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.

Contact Summit Investor Relations:
Dave Gancarz
Vice President, Investor Relations & Corporate Strategy
david.gancarz@summitplc.com

General Inquiries:
investors@summitplc.com

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. 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 share and per share data

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Licensing agreements	$ 192	$ 324
Total revenue	192	324
Operating expenses:		
Research and development	18,379	12,912
General and administrative	4,185	3,572
Total operating expenses	22,564	16,484
Other operating income	5,449	6,820
Loss from operations	(16,923)	(9,340)
Other income (expense), net	(565)	3,261
Loss before income tax	(17,488)	(6,079)
Income tax expense	—	(55)
Net loss	$ (17,488)	$ (6,134)
Basic and diluted loss per share	$ (0.21)	$ (0.09)
Other comprehensive income / (loss):		
Foreign currency translation adjustment	675	(4,624)
Total comprehensive loss	$ (16,813)	$ (10,758)

CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(Unaudited)
In thousands

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 102,194	$ 66,417
Total assets	140,794	102,498
Total liabilities	76,389	23,045
Total stockholders' equity	64,405	79,453

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

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (20,669)	$ (4,959)
Net cash used in investing activities	(39)	(194)
Net cash provided by financing activities	55,897	3
Effect of exchange rates in cash and cash equivalents	588	(3,749)
Net increase / (decrease) in cash and cash equivalents	$ 35,777	$ (8,899)

Appendix: Glossary of Critical Terms Contained Herein

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 infection of *Clostridioides difficile*.[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]

***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.[iv]

***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.[v]

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.[vi]

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.[vii]

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.[viii]

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.[ix]

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.[x]

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 its role in keeping a person healthy and free of certain conditions or diseases.[xi] [xii]

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.[xiii]

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.[xiv]

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.[xv]

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.[xvi]

Vancomycin – an antibiotic that is used to treat CDI when taken by mouth.

[i] Qian, X, *et. al.* Ridinilazole, a narrow spectrum antibiotic for treatment of *Clostridioides difficile* infection, enhances preservation of microbiota-dependent bile acids. *Am J Physiol Gasterintest Liver Physiol* 319: G227-G237, 2020.

[ii] Viscoli C. Bloodstream Infections: The peak of the iceberg. *Virulence*. 7(3):248-251, 2016.

[iii] United States Centers for Disease Control and Prevention. https://www.cdc.gov/hai/organisms/cre/index.html. Accessed February 2021.

[iv] Virginia Department of Health. https://www.vdh.virginia.gov/epidemiology/epidemiology-fact-sheets/clostridiodes-difficile/. Accessed February 2021.

[v] United States Centers for Disease Control and Prevention. https://www.cdc.gov/cdiff/what-is.html. Accessed February 2021.

[vi] Summit Therapeutics, Inc. https://www.summittxinc.com/our-programmes/enterobacteriaceae/. Accessed February 2021.

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

[viii] United States Centers for Disease Control and Prevention. https://www.cdc.gov/hai/organisms/ESBL.html. Accessed February 2021.

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

[x] US National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/digestive-diseases/digestive-system-how-it-works. Accessed February 2021.

[xi] Cani PD. Human gut microbiome: hopes, threats and promises. British Medical Journal (BMJ) *Gut* 67**:**1716-1725, 2018.

[xii] Qian, X, *et. al.* Ridinilazole, a narrow spectrum antibiotic for treatment of *Clostridioides difficile* infection, enhances preservation of microbiota-dependent bile acids. *Am J Physiol Gasterintest Liver Physiol* 319: G227-G237, 2020.

[xiii] Shebl E, Gulick PG. Nosocomial Pneumonia. StatPearls. Updated 2020 Jul 21.

[xiv] United States Centers for Disease Control and Prevention. https://www.cdc.gov/hai/organisms/klebsiella/klebsiella.html. Accessed February 2021.

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

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