



Summit Therapeutics Inc.

(‘Summit’ or the ‘Company’)

Summit Therapeutics Announces Preclinical Candidate and Associated CARB-X Funding Support for the Treatment of Infections Caused by Carbapenem-Resistant Enterobacteriaceae, a CDC Urgent Threat and WHO Critical Priority

Cambridge, MA, May 18, 2021 - Summit Therapeutics Inc. (NASDAQ: SMMT) announced today that it has selected a new preclinical candidate, SMT026738 (“SMT-738”), for development in the fight against multidrug resistant infections, specifically carbapenem-resistant Enterobacteriaceae (CRE) infections. Simultaneously, Summit has received an award from CARB-X to progress this candidate through preclinical development and Phase 1a clinical trials. The award commits initial funding of up to \$4.1 million, with the possibility of up to another \$3.7 million based on the achievement of future milestones.

SMT-738 is the first of a novel class of precision antibiotics with a new mechanism of action that acts via the bacterial target, LolCDE. SMT-738 has 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.

“Our mission at Summit is to create patient- and societal-friendly medicinal therapies that improve the quality and duration of patients’ lives, while resolving serious unmet needs,” said Robert W. Duggan, Executive Chairman and Chief Executive Officer of Summit. “SMT-738 has the potential to save the lives of patients with as yet untreatable infections through a novel drug class with a low propensity for resistance development. We are excited and optimistic to take on the real challenge of antibiotic resistance and are grateful to CARB-X for partnering with us in support of this important mission.”

SMT-738 was discovered using Summit’s proprietary technology, our Discuva Platform, as a part of the DDS-04 series, and we retain worldwide clinical development and commercial rights to the compound. We expect to begin Phase 1 studies in 2023.

“With the growing threat of antibiotic resistance, particularly with respect to CRE infections, SMT-738 is clearly differentiated from all agents, including the beta-lactamase inhibitors, that are currently used to treat such infections,” adds David Powell, Ph.D., Summit’s Chief Scientific Officer. “By leveraging the transposon libraries of bacteria within our Discuva Platform, we have identified the target to be the clinically unexploited LolCDE complex, an essential lipid transport system in Gram-negative bacteria. SMT-738 has potent *in vitro* activity against clinical CRE isolates including difficult to treat metallo-beta-lactamase carrying strains encoding the New Delhi Metallo-beta-lactamase (NDM). Having encountered no existing resistance in clinical isolates to the novel chemistry of SMT-738, the ability of our drug molecule to reset the clock against growing resistance is critical in our collective fight against these pathogens causing an urgent public health threat.”

Carbapenem-resistant Enterobacteriaceae are considered an Urgent Threat by the US Centers for Disease Control and Prevention (CDC) and a Critical Priority by the World Health Organization (WHO) for which new treatments are urgently needed.



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 existing antibiotics. The most difficult to treat among them are the carbapenem-resistant Enterobacteriaceae, which are classified as an Urgent Threat by the US Centers for Disease Control and Prevention (CDC).

About SMT-738

SMT-738 is a novel, first-in-class, new mechanism, precision antibiotic targeting Enterobacteriaceae. SMT-738 is a small molecule antibiotic that 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, have limited or failing treatment options through currently available antibiotics. SMT-738 has successfully completed preliminary repeat dose toxicology studies.

About CARB-X

CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator) is a global non-profit partnership dedicated to supporting early development antibacterial R&D to address the rising threat of drug-resistant bacteria. CARB-X is led by Boston University and funding is provided by the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the US Department of Health and Human Services; the Wellcome Trust, a global charity based in the UK working to improve health globally; Germany's Federal Ministry of Education and Research (BMBF); the UK Department of Health and Social Care's Global Antimicrobial Resistance Innovation Fund (GAMRIF); the Bill & Melinda Gates Foundation, and with in-kind support from National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH) within the US Department of Health and Human Services. CARB-X is investing up to US\$480 million from 2016-2022 to support innovative antibiotics and other therapeutics, vaccines and rapid diagnostics. CARB-X focuses exclusively on high priority drug-resistant bacteria, especially Gram-negatives. CARB-X is headquartered at Boston University School of Law. For more information, visit <https://carb-x.org/>. Follow us on Twitter @CARB_X.

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 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 disease, initially focusing on *Clostridioides difficile* infections (CDI). The overriding objective of Summit Therapeutics is to create value for patients, hospital caregivers, and community-based 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. SMT-738, the second candidate within Summit's portfolio of products, 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 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. 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.