Summit Therapeutics plc
('Summit' or the 'Company')

Summit Doses First Patient in Phase 3 Clinical Trials of Precision Antibiotic Ridinilazole for *C. Difficile* Infection

- **Trials Aim to Show Superiority of Ridinilazole Over Standard of Care Treatment Vancomycin**
- **Health Economic Outcomes Included to Support Commercialisation**

Oxford, UK, and Cambridge, MA, US, 13 February 2019 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM), a leader in new mechanism antibiotic innovation, today announces it has dosed the first patient in the global Phase 3 clinical trials of its precision oral antibiotic, ridinilazole, for *C. difficile* infection ('CDI'). The trials aim to show superiority of ridinilazole over the standard of care, vancomycin, in a measure that combines CDI cure and recurrence called sustained clinical response ('SCR'). Ridinilazole achieved statistical superiority over vancomycin in SCR in a Phase 2 clinical trial.

"Starting our Phase 3 programme is an important milestone for Summit," **commented Mr Glyn Edwards, Chief Executive Officer of Summit.** "*With positive results, we believe ridinilazole could be positioned as the drug of choice in the front-line treatment of CDI, which potentially provides patients with sustained cures and hospitals with compelling cost savings."*

"Ridinilazole is the trail-blazer in our growing pipeline of innovative product candidates targeting serious infectious diseases," **added Dr David Roblin, President of R&D of Summit**. *"Our Phase 3 programme exemplifies our broader strategy of demonstrating significant advantages over current standards of care by gathering a carefully considered package of clinical and economic data to address the needs of physicians, regulators, healthcare providers, payors and, above all, patients."*

The Phase 3 clinical programme comprises two global, randomised, double-blind, active-controlled clinical trials called Ri-CoDIFy 1 and Ri-CoDIFy 2. The trials will be run concurrently with each expected to enrol approximately 680 patients at sites in North America, Latin America, Europe, Australia and Asia. Upon confirmation of a positive CDI toxin test, patients will be randomised to receive either ridinilazole (200mg twice a day) or vancomycin (125mg four times a day) for ten days. The primary endpoint of both clinical trials will test for superiority in SCR, defined as cure at the end of treatment and no recurrence of CDI within 30 days post-treatment. Secondary endpoints include cure at the end of treatment and SCR at 60 days and 90 days post-treatment. Additional endpoints will evaluate the impact of ridinilazole and vancomycin on the gut microbiome, which is known to protect against CDI. The Phase 3 clinical trials also include health economic outcome measures, such as readmission rates and length of hospital stay, to help support the commercialisation of ridinilazole, if approved.

Top-line data from the Phase 3 programme are expected to be reported in the second half of 2021.

The clinical and regulatory development of ridinilazole is being funded in part with Federal funds from the US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority ('BARDA'), under Contract No. HHS0100201700014C. Summit is eligible to receive up to $62 million in funding from BARDA to support the clinical and regulatory development of ridinilazole.

About *C. difficile* Infection
C. difficile infection is a serious healthcare threat in hospitals, long-term care homes and increasingly in the wider community with over one million estimated cases of CDI annually in the United States and Europe. CDI is caused by an infection of the colon by the bacterium *C. difficile*, which produces toxins that cause

inflammation and severe diarrhoea, and in the most serious cases can be fatal. Patients typically develop CDI following the use of broad-spectrum antibiotics that can cause widespread damage to the natural gastrointestinal (gut) flora and allow overgrowth of *C. difficile* bacteria. The vast majority of patients are treated with broad-spectrum antibiotics, which cause further damage to the gut flora and are associated with high rates of recurrent disease. Reducing disease recurrence is the key clinical issue in CDI as repeat episodes are typically more severe and associated with an increase in mortality rates and healthcare costs. The economic impact of CDI is significant with one study estimating annual acute care costs at $4.8 billion in the US.

About Ridinilazole

Ridinilazole is an oral small molecule new mechanism antibiotic that is designed to selectively kill *C. difficile*, thereby preserving patients' protective gut microbiome and leading to sustained CDI cures. In a Phase 2 proof of concept trial in CDI patients, ridinilazole showed statistical superiority in sustained clinical response ('SCR') rates compared to the standard of care, vancomycin. In that trial, SCR was defined as clinical cure at end of treatment and no recurrence of CDI within 30 days of the end of therapy. Ridinilazole was also shown to be highly preserving of the gut microbiome in the Phase 2 proof of concept trial, which was believed to be the reason for the improved clinical outcome for the ridinilazole-treated patients. In addition, ridinilazole preserved the gut microbiome to a greater extent than the marketed narrow-spectrum antibiotic fidaxomicin in an exploratory Phase 2 clinical trial. Ridinilazole has received Qualified Infectious Disease Product ('QIDP') designation and has been granted Fast Track designation by the US Food and Drug Administration. The QIDP incentives are provided through the US GAIN Act and include a potential extension of marketing exclusivity for an additional five years upon FDA approval.

About Summit Therapeutics

Summit Therapeutics is a leader in antibiotic innovation. Our new mechanism antibiotics are designed to become the new standards of care for the benefit of patients and create value for payors and healthcare providers. We are currently developing new mechanism antibiotics for infections caused by *C. difficile, N. gonorrhoeae* and ESKAPE pathogens and are using our proprietary Discuva Platform to expand our pipeline. For more information, visit www.summitplc.com and follow us on Twitter @summitplc.

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014 (MAR). The person responsible for arranging the release of this announcement on behalf of the Company is Richard Pye, Senior Director, Corporate Affairs and Communications.

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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 commercialisation of the Company's product candidates, the sufficiency of the Company's cash resources, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals 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, 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, including the Company's Annual Report on Form 20-F for the fiscal year ended 31 January 2018. 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.

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