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

Phase 2 Clinical Data Published Showing Summit's Ridinilazole Preserved the Gut Microbiome of Patients with *C. difficile* infection

- **Microbiome Damage with Current Treatments May Lead to Disease Recurrence**
- **Ridinilazole Reduced Recurrence Rates by 59% versus Standard of Care Vancomycin**

Oxford, UK, and Cambridge, MA, US, 2 August 2018 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM) announces today the publication in the journal *PLOS ONE* of microbiome analyses highlighting ridinilazole as a precision antibiotic in development for the treatment of *C. difficile* infection ('CDI').

The clinical management of CDI is stymied by poor sustained cures due to high recurrence rates after initial infection. The microbiome is known to play an important role in protecting against initial CDI and the onset of recurrent disease. Thus, preserving the microbiome could help to address the key unmet need in CDI. In a double-blind Phase 2 clinical trial, ridinilazole was highly preserving of patients' microbiomes compared to patients treated with the broad-spectrum standard of care antibiotic vancomycin. With this microbiome preservation, ridinilazole treatment resulted in a 59% reduction in recurrence compared to vancomycin (14.3% vs. 34.8%, respectively). Ridinilazole also demonstrated clinical and statistical superiority over vancomycin in sustained clinical response, which captures whether patients have been cured and remain free from disease recurrence 30 days after completing treatment.

"These results show how the precision action of ridinilazole against C. difficile, and its corresponding lack of impact on the broader microbiome, led to greatly increased rates of sustained cures through decreased disease recurrence. Better prevention of recurrence is the next frontier in CDI therapy, with potential to reduce both patient morbidity and healthcare costs, which escalate further when initial treatment fails," **commented Dr David Roblin, President of R&D at Summit.** *"Ridinilazole exemplifies Summit's strategy of developing new mechanism antibiotics we believe may have the potential to become new standards of care for serious bacterial infections."*

The results published today from the CoDIFy Phase 2 clinical trial highlighted how ridinilazole had significantly less impact on the microbiome assessed at a range of timepoints as compared to vancomycin. In contrast, vancomycin treatment resulted in microbiome-wide changes that persisted beyond the end of treatment. Significant differences were also observed in microbiome health as measured by 'alpha diversity'. Ridinilazole-treated patients had no significant changes while a significant loss in alpha diversity was seen in vancomycin-treated patients ($p > 0.0001$). The microbiome analyses were conducted in collaboration with Tufts Medical Center.

The publication is available here: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0199810.

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. Phase 3 clinical trials are expected to initiate Q1 2019.

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. Existing CDI treatments are

predominantly 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 antibiotic that Summit is developing for the treatment of CDI. In preclinical efficacy studies, ridinilazole exhibited a targeted spectrum of activity that combined a potent bactericidal effect against all clinical isolates of *C. difficile* tested with minimal impact on other bacteria that are typically found in the gut microbiome. 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 and Breakthrough Therapy designation by the US Food and Drug Administration. The QIDP incentives are provided through the US GAIN Act and include an 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 C. difficile infection and gonorrhoea and are using our proprietary Discuva Platform to expand our pipeline. For more information, visit www.summitplc.com and follow us on 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, 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, 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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