

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

Summit Therapeutics to Receive \$1.0 Million Milestone Payment from Eurofarma Milestone Based on Achievement of Patient Enrolment Target in Phase 3

Clinical Trials of Ridinilazole

Oxford, UK, and Cambridge, MA, US, 6 February 2020 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM) today announced that it achieved the first milestone under its license and collaboration agreement with Eurofarma Laboratórios SA ('Eurofarma'). The \$1.0 million milestone payment was triggered by Summit achieving its initial patient enrolment target at trial sites in Latin America in the Phase 3 clinical trials of ridinilazole for *C. difficile* infection ('CDI').

"CDI is a global issue caused largely by broad spectrum antibiotic-induced imbalances in the healthy gut microbiome. By being precisely targeted to C. difficile and therefore preserving the microbiome to protect against CDI recurrence, ridinilazole has the potential to significantly improve patient outcomes through sustaining cures," **said Mr Glyn Edwards, Chairman and CEO of Summit.** "Eurofarma is an ideal partner for us with the necessary expertise to successfully market ridinilazole in Latin America, should it receive approval. We're pleased with the progress we have made in enrolling our Phase 3 clinical trials, and we look forward to the results of the trials expected in the second half of 2021."

The global Phase 3 clinical trials, initiated in February 2019, aim to show superiority of ridinilazole over the standard of care, vancomycin, in sustained clinical response, a measure that encompasses both the initial cure and the key unmet need of reducing recurrences.

Under the terms of its licence and commercialisation agreement with Eurofarma, Summit is entitled to receive a further \$2.75 million upon the achievement of additional staged patient enrolment targets in Latin America in the Phase 3 clinical trials, along with other development, commercial and sales milestones and product supply transfer payments.

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.

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

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. A study estimated that the total costs attributable to the management of CDI were approximately \$6.3 billion per year in the United States.



About Ridinilazole

Ridinilazole is an investigational 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 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. The gut microbiome is known to be important in protecting against CDI. 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,* Enterobacteriaceae and *N. gonorrhoeae* 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 potential benefits and future operation of our license and commercialization agreement with Eurofarma Laboratórios SA, 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 2019. Accordingly, readers should not place undue reliance on forwardlooking 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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