



Summit Therapeutics plc
(‘Summit’ or the ‘Company’)

Summit Therapeutics Recognises *C. difficile* Awareness Month

- **Company to Highlight Potential of Phase 3 Precision Antibiotic Ridinilazole at the 7th Annual *C. diff.* Conference and Health EXPO**

Oxford, UK, and Cambridge, MA, US, 4 November 2019 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM) recognises *C. difficile* Awareness Month. Each year, more than one million patients in the US and Europe are diagnosed with *C. difficile* infection (‘CDI’), and yet general awareness of CDI is lacking.

“C. difficile is a common, yet largely unknown infection and its Awareness Month provides an opportunity to educate on this illness and bring the focus to the unacceptably high numbers of patients that current CDI treatments fail. The treatment failures are driven by the negative impact of current antibiotic treatments on the healthy bacteria of the gut microbiome,” commented Dr David Roblin, President of R&D of Summit. “By being targeted to C. difficile, our precision antibiotic ridinilazole has the potential to preserve patients’ microbiomes and improve outcomes for patients with CDI.”

As part of its activities for CDI awareness month, Summit will be presenting at the 7th Annual *C. diff.* Conference and Health EXPO in St. Louis, Missouri. The presentation will review data from the Phase 2 clinical trial of ridinilazole compared to vancomycin. In this clinical trial, ridinilazole achieved statistical superiority over vancomycin in the measure of sustained clinical response (‘SCR’), which captured whether patients were cured of CDI and remained cured for 30 days after treatment. In addition, an exploratory endpoint in the trial showed patients treated with ridinilazole had significantly preserved gut microbiomes compared to vancomycin.

Ridinilazole is currently being evaluated in two global Phase 3 clinical trials for superiority over vancomycin in SCR. Data are expected from the trials in the second half of 2021.

For more information on CDI, visit the Peggy Lillis Foundation at www.peggyfoundation.org and www.cdifffoundation.org, and the *C. diff.* Foundation at www.cdifffoundation.org.

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 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, 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.

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.

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 Enterobacteriaceae and are using our proprietary Discuva Platform to expand our pipeline. For more information, visit www.summitplc.com and follow us on Twitter @summitplc.

Contacts

Summit

Glyn Edwards / Richard Pye (UK office)
Michelle Avery (US office)

Tel: 44 (0)1235 443 951
+1 617 225 4455

Cairn Financial Advisers LLP (Nominated Adviser)

Liam Murray / Tony Rawlinson

Tel: +44 (0)20 7213 0880

N+1 Singer (Joint Broker)

Aubrey Powell / Jen Boorer, Corporate Finance
Tom Salvesen, Corporate Broking

Tel: +44 (0)20 7496 3000

Bryan Garnier & Co Limited (Joint Broker)

Phil Walker / Dominic Wilson

Tel: +44 (0)20 7332 2500

MSL Group (US)

Erin Anthoine

Tel: +1 781 684 6652
summit@mslgroup.com

Consilium Strategic Communications (UK)

Mary-Jane Elliott / Sue Stuart / Sukaina Virji
Lindsey Neville

Tel: +44 (0)20 3709 5700
summit@consilium-comms.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 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 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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