



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

## **Summit Recognises *C. difficile* Awareness Month**

**Oxford, UK, and Cambridge, MA, US, 1 November 2018** – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM), a leader in new mechanism antibiotic innovation, recognises *C. difficile* Awareness Month, which highlights the common, but largely unknown *C. difficile* infection (CDI) throughout the month of November. *C. difficile* infects over one million patients in the US and Europe each year, causing inflammation and severe diarrhoea that can be fatal. Summit is developing the Phase 3-ready precision antibiotic ridinilazole to address both the initial infection and importantly the key unmet need of reducing recurrence of CDI.

As part of CDI Awareness Month, Summit is presenting on ridinilazole and its Phase 3 clinical trial plans at the 6<sup>th</sup> Annual International *C. diff* Conference and Health Expo taking place 8-9 November 2018 in Philadelphia, PA.

*“We lose over 40 patients a day to CDI in the US. The current standard of care fails to fully address the major burden CDI places on patients, their families and healthcare systems, and new treatment options are desperately needed,” said Nancy C. Caralla, Founding President and Executive Director of the C Diff Foundation. “The biggest need in CDI is reducing recurrence of the disease, as with each CDI episode, we see increasing severity, morbidity and mortality. A targeted therapy used upfront could help to reduce recurrence and provide a better overall outcome for patients. We are excited to see Summit’s ridinilazole advancing into Phase 3 clinical trials.”*

*“The landscape of infectious diseases is shifting towards precision medicine – using a specific drug for a specific infection. CDI is a textbook example whereby broad-spectrum antibiotics exacerbate the problem both in causing the initial disease and in driving recurrence,” said Dr David Roblin, President of R&D of Summit. “We believe ridinilazole has the potential to significantly improve the CDI landscape as a front-line treatment and look forward to initiating our planned Phase 3 clinical trials in the first quarter of 2019.”*

The US Centers for Disease Control and Prevention lists *C. difficile* as an urgent public health threat that requires aggressive action. Most cases of CDI are directly related to prior antibiotic use for unrelated infections, which damages the gut microbiome that could otherwise protect against CDI. The current standard of care, vancomycin, is a broad-spectrum antibiotic, meaning that it indiscriminately kills bacteria, including the protective bacteria in the gut microbiome, and leaves patients susceptible to CDI recurrence. Ridinilazole is designed to selectively kill *C. difficile* and preserve the protective gut microbiome to reduce CDI recurrence and sustain cures. These characteristics were observed in a Phase 2 clinical trial where ridinilazole demonstrated statistical superiority over vancomycin in sustained clinical response.

### **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 a 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, an orally administered small molecule, 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 *C. difficile* infection and gonorrhoea and are using our proprietary Discuva Platform to expand our pipeline. For more information, visit [www.summitplc.com](http://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 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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