



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

Summit Therapeutics Reports Ridinilazole Significantly Improved Short and Longer-Term Quality of Life Measures in Patients with *C. difficile* Infection Compared to Standard of Care

- **Statistically Significant Improvements in Physical and Mental Health Measures**
- **Benefit of Ridinilazole Treatment Seen as Early as Day Five**
- **Data from Phase 2 Clinical Trial Presented at ID Week 2019**

Oxford, UK, and Cambridge, MA, US, 3 October 2019 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM) today announced that it presented results from the Phase 2 clinical trial of ridinilazole in *C. difficile* infection (‘CDI’) detailing improvements in patient quality of life following antibiotic treatment for CDI. These results were presented in a poster session at ID Week 2019 being held in Washington, DC between 2-6 October.

“CDI is debilitating for patients, both physically and mentally. Our Phase 2 clinical trial documented significant early and longer-term improvements in patient quality of life over the current standard of care,” commented Dr David Roblin, President of R&D of Summit. “These findings suggest the benefits of treatment with ridinilazole goes beyond the clinical benefits seen in the Phase 2 clinical trial, with our precision antibiotic also improving the overall wellbeing of the patient.”

The Phase 2 clinical trial called CoDIFy evaluated ridinilazole compared to vancomycin in 100 patients with CDI. As part of the trial, patients completed the EuroQol 5-Dimension questionnaire three level version (EQ-5D-3L) at baseline, day 5, 10, 12 (test of clinical cure at end of treatment) and 40 (test of sustained clinical response). The EQ-5D-3L is a standard measure of health status which evaluates five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

“The patient is at the centre of our drug development universe. Global regulatory authorities and payors recognise that the value of treatments encompasses more than just clinical results and are placing increasing importance on patient reported outcomes, such as the EQ-5D index, in assessing new therapies,” said Dr Daniel Elger, Chief Commercial Officer. “We are highly encouraged by the early and significant changes seen in the Phase 2 trial for patients on ridinilazole compared to the current standard of care, vancomycin, and look forward to the data from patient reported outcomes in our ongoing Phase 3 clinical trials of ridinilazole.”

Overall, fewer patients treated with ridinilazole than patients treated with vancomycin reported any problems over the time points in four of the five domains: mobility, self-care, usual activities and pain/discomfort. Patients in both arms reported problems with anxiety and depression at baseline, however, the number of patients treated with ridinilazole reporting problems in this measure decreased throughout the timepoints. In contrast, the number of patients treated with vancomycin reporting problems with anxiety and depression increased at Day ten and remained high through the end of the study. By Day 40, patients treated with ridinilazole had improved significantly more than vancomycin in anxiety and depression. As early as Day five, patients treated with ridinilazole reported significant improvements in index scores ($p=0.008$), a measure which combines scores from the five domains, and visual analogue scale (VAS) scores ($p=0.01$), which is a self-reported score of overall health. While both treatment arms showed significant improvements in pain and discomfort with treatment, by Day ten, numerically fewer patients treated with ridinilazole reported issues than those treated with vancomycin. These results, along with the statistical superiority achieved in the primary clinical endpoint of sustained clinical response, support the continued development of ridinilazole.



A copy of the presentation is available in the Publications section of Summit's website, www.summitplc.com.

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 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 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.

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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 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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