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

Summit Highlights Phase 3-Ready Precision Antibiotic Ridinilazole at IDWeek 2018

- ***Ridinilazole in Development to Treat C. difficile Infection and Reduce Recurrent Disease***

Oxford, UK, and Cambridge, MA, US, 3 October 2018 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM), a leader in new mechanism antibiotic innovation, is highlighting ridinilazole's potential as a front-line treatment for *C. difficile* infection ('CDI') in a series of oral and poster presentations at the infectious disease conference IDWeek 2018 in San Francisco, CA. Ridinilazole is the Company's most advanced new mechanism antibiotic, which is expected to enter Phase 3 clinical trials in the first quarter of 2019.

As are being outlined at IDWeek, the Phase 3 clinical trials of ridinilazole are designed not only to evaluate ridinilazole in the treatment of CDI but also to show its impact on reducing disease recurrence and in preserving the gut microbiome, important determinants of public health impact. The effectiveness of ridinilazole in the treatment of CDI and CDI recurrence will be evaluated by measuring sustained clinical response ('SCR'), which is the primary endpoint for both of the two planned Phase 3 clinical trials.

"We believe that to have success in antibiotics, we need to be bold and think differently. This is highlighted by our Phase 3 clinical trial design for ridinilazole that aims to show superiority of ridinilazole over vancomycin, the current standard of care. The primary endpoint will measure how ridinilazole can treat CDI and reduce recurrent CDI, the major unmet need in this disease. Finally, we are incorporating health economic outcomes measures that we believe will help support premium pricing," **commented Dr David Roblin, President of R&D of Summit.** *"If the Phase 3 clinical trial results are positive, we believe these measures would differentiate ridinilazole in CDI and support its front-line use."*

A summary of the information being presented at IDWeek includes:

- Ridinilazole achieving statistical superiority over vancomycin in the primary endpoint of SCR in a Phase 2 clinical trial called CoDIFy; this superiority was driven by a large reduction in CDI recurrence.
- Ridinilazole significantly preserved the gut microbiome of patients with CDI in CoDIFy, which Summit believes led to the reduction in recurrent CDI.
- The design of the ridinilazole Phase 3 clinical trials called Ri-CoDIFy which will use the same primary endpoint of SCR.
- Ridinilazole's activity is targeted to the site of infection. Preclinical studies and Phase 1 and 2 clinical trials of ridinilazole have shown negligible systemic exposure and levels of drug in the colon and/or faeces significantly above the minimum inhibitory concentration.
- A good safety profile with ridinilazole, being generally well tolerated in prior clinical trials and non-clinical studies.
- Ridinilazole was significantly more potent against over 500 recent clinical isolates of *C. difficile* than vancomycin and metronidazole, another commonly used CDI treatment, regardless of ribotype or antibiotic resistance profile.
- Diagnostics are important for selective antibiotics, such as ridinilazole, to ensure patients are treated with the right drug for their infection. As was used in CoDIFy, a test for the toxins produced by *C. difficile* will also be used in the Phase 3 clinical trials to confirm that patients have CDI.

Copies of the presentations are available under 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. 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 and follow us on Twitter @summitplc.

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Summit Forward-looking Statements

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