Summit Therapeutics plc

("Summit" or "the Company")

POSITIVE RESULTS FROM SUMMIT'S PHASE 2 CoDIFy TRIAL HIGHLIGHT POTENTIAL OF RIDINILAZOLE IN THE TREATMENT OF *C. DIFFICILE* INFECTION

- **Data Presented in Poster Session at 26th ECCMID Conference**

Oxford, UK, 11 April 2016 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM), the drug discovery and development company advancing therapies for Duchenne muscular dystrophy and *Clostridium difficile* infection ('CDI'), announces the presentation today of major findings from the Phase 2 CoDIFy trial highlighting the potential of ridinilazole in the treatment of CDI at the 26th European Congress of Clinical Microbiology and Infectious Diseases ('ECCMID'). These findings include a markedly reduced recurrence rate and a statistically superior rate of sustained clinical response ('SCR') in patients with CDI receiving ridinilazole compared with those receiving the standard of care, vancomycin. Ridinilazole is a novel class antibiotic with the potential for broad use across the CDI disease spectrum.

"Preventing disease recurrence is a major unmet need in CDI, both for newly diagnosed patients who are receiving initial treatment and for patients who are receiving treatment for recurrent disease," **said Dale Gerding, MD, Research Physician, Hines Veterans Affairs Hospital, Professor of Medicine, Loyola University Stritch School of Medicine, and an author on the presentation. "***In this context, it is very encouraging to see such a marked reduction in recurrences with ridinilazole in the Phase 2 trial."*

Glyn Edwards, CEO of Summit, added*: "Ridinilazole's narrow spectrum of activity appeared to substantially reduce damage to the gut microbiome in the Phase 2 clinical trial, allowing patients to maintain or rebuild their natural defences against recurrence of CDI. The wealth of data we have reported on the compound to date, including the positive efficacy results presented today at ECCMID, suggest that ridinilazole could become a truly differentiated product with potential for broad use in CDI, including front-line treatment."*

Key efficacy findings from the trial presented at ECCMID were:

- Statistical superiority in SCR with rates of 66.7% for ridinilazole compared to 42.4% for vancomycin
- Marked reduction in recurrence with rates of 14.3% for ridinilazole compared to 34.8% for vancomycin
- Cure rates at the end of treatment of 77.8% for ridinilazole and 69.7% for vancomycin

The primary analysis was conducted on the modified intent-to-treat ('mITT') population that comprised subjects with CDI confirmed by the presence of free toxin in faeces. These results were consistent across the intent to treat ('ITT') and per protocol ('PP') groups. Ridinilazole was generally well-tolerated and the overall adverse event profiles of ridinilazole and vancomycin were comparable.

The poster, entitled "Ridinilazole for Clostridium difficile infections: safety and efficacy compared with vancomycin from the CoDIFy Phase 2 clinical trial," was presented by Professor Mark H. Wilcox, Consultant Microbiologist & Head of Microbiology at the Leeds Teaching Hospitals NHS Trust, Professor of Medical Microbiology at the University of Leeds, and Public Health England's Lead on *C. difficile* in England. Other authors on the poster were RJ Vickers, GS Tillotson, R Nathan, S Hazan, C Lucasti, J Pullman, J Deck, B Maliakkal, Y Pesant, B Yacyshyn and DN Gerding.

A copy of the poster is available from Summit's website: www.summitplc.com/publications.

About CoDIFy

CoDIFy was a double blind, randomized, active controlled, multi-centre, Phase 2 clinical trial that evaluated the efficacy of ridinilazole against vancomycin in a total of 100 patients. Half of the patients received

ridinilazole for ten days (200 mg, twice a day), and the remaining half received vancomycin for ten days (125 mg, four times a day). The results of the trial showed ridinilazole achieved statistical superiority in SCR with rates of 66.7% compared to 42.4% for vancomycin. SCR is defined as cure at the end of therapy and no recurrent disease 30 days post end of therapy. In preliminary analysis of the gut microbiome, ridinilazole was found to be highly preserving of the gut microbiome. Ridinilazole treated patients in CoDIFy exhibited no further damage to their microbiome during therapy with a proportion of patients showing initial evidence of recovery of key bacterial groups with roles in protecting from CDI. In contrast, vancomycin treated patients suffered substantial damage to their gut microbiome during treatment and this persisted in many patients during the 30-day post treatment period.

Notes to Editors

About *C. difficile* Infection

C. difficile infection is a serious healthcare threat in hospitals, long-term care homes and increasingly the wider community with between 450,000 and 700,000 cases of CDI in the US annually. It is caused by an infection of the colon by the bacterium *C. difficile*, which produces toxins that cause inflammation, 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, and these cause further damage to the gut flora and are associated with high rates of recurrent disease. Recurrent disease is the key clinical issue 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 (previously known as SMT19969) is an orally administered small molecule antibiotic that Summit is developing specifically for the treatment of CDI. In preclinical efficacy studies, ridinilazole exhibited a narrow spectrum of activity and had a potent bactericidal effect against all clinical isolates of *C. difficile* tested. 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 this 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 has received Qualified Infectious Disease Product ('QIDP') designation and has been granted Fast Track status by the US Food and Drug Administration. The QIDP incentives are provided through the US GAIN Act and include an extension of marketing exclusivity for an additional five years upon FDA approval.

About Summit Therapeutics

Summit is a biopharmaceutical company focused on the discovery, development and commercialisation of novel medicines for indications for which there are no existing or only inadequate therapies. Summit is conducting clinical programs focused on the genetic disease Duchenne muscular dystrophy and the infectious disease *C. difficile* infection. Further information is available at www.summitplc.com and Summit can be followed on Twitter (@summitplc).

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