Summit Therapeutics plc

("Summit" or "the Company")

SUMMIT THERAPEUTICS GRANTED KEY EUROPEAN PATENT FOR NOVEL ANTIBIOTIC RIDINILAZOLE FOR TREATMENT OF *C. DIFFICILE* INFECTION

Oxford, UK, 19 January 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 that the European Patent Office ('EPO') has granted a key patent covering the novel antibiotic, ridinilazole, and that the opposition period has expired with the patent having faced no challenge. The patent covers the use of ridinilazole for the treatment of infections caused by the bacterium *Clostridium difficile*.

"This is a key patent protecting the use of ridinilazole for the treatment of CDI and its grant and emergence from the period of opposition means this patent is now effective in Europe, in addition to the other major commercial markets including the United States and Japan," **commented Glyn Edwards, Chief Executive Officer of Summit**. *"The robust patent portfolio for ridinilazole, together with the strong Phase 2 clinical data showing statistical superiority over vancomycin, the current standard of care, further strengthens the potential commercial value of this novel product candidate in the treatment of CDI."*

The patent (European patent number EP2373631) is entitled "Antibacterial Compounds" and will provide a period of exclusivity for the use of ridinilazole in the treatment of CDI through until 1st December 2029, with the possibility of patent term extension through to 1st June 2035 subject to the obtaining of Supplementary Protection Certificates and a paediatric investigation plan on marketing approval. The patent has also been validated in all available contracting countries to the European Patent Convention, and so is now in force in over 30 European states including the United Kingdom, Germany, France, Spain, Italy, Switzerland and Norway. Patent protection has previously been granted for ridinilazole for the treatment of CDI in other countries including the United States, Australia, New Zealand, Japan, Russia and China, in addition to other territories.

Ridinilazole is a novel class small molecule antibiotic that Summit is developing for the treatment of CDI. Top-line results from a Phase 2 proof of concept trial reported in late 2015 showed that ridinilazole was statistically superior to vancomycin, the current standard of care, in the endpoint of sustained clinical response ('SCR'). SCR was measured as cure at the end of treatment and no recurrence of CDI within 30 days of the end of treatment.

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 (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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