

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

SUMMIT ANNOUNCES FDA CLEARANCE OF IND APPLICATION FOR PHASE 2 STUDY OF SMT19969 TO TREAT C. DIFFICILE INFECTION

- **Initiation of the Phase 2 trial expected during H1 2014**
- **£1.9m milestone payment from Wellcome Trust received**

Oxford, UK, 18 March 2014 – Summit (AIM: SUMM), a drug discovery and development company advancing therapies for Duchenne Muscular Dystrophy and *C. difficile* infection (‘CDI’), announces clearance by the US Food and Drug Administration (‘FDA’) of its Investigational New Drug application (‘IND’) to initiate a Phase 2 proof of concept study of the novel antibiotic SMT19969 for the treatment of CDI. The submission of this application has resulted in a £1.9m milestone payment to Summit by the Wellcome Trust, proceeds of which will support the study. This payment is part of a £4.0m Translational Award from the Wellcome Trust for the development of SMT19969.

“SMT19969 has demonstrated high selectivity for only clostridia in a Phase 1 study of healthy volunteers,” **commented Glyn Edwards, Chief Executive Officer of Summit.** “If this profile is replicated in future studies, SMT19969 could potentially offer a differentiated and more beneficial option to current CDI treatments, which continue to undermine the natural balance of the gut flora and lead to recurrent disease. We are excited about initiating a Phase 2 proof of concept clinical trial with the continued support of the Wellcome Trust.”

The Phase 2 study, named CoDiFy, will be a double blind, active controlled trial comparing the efficacy of SMT19969 to vancomycin (the current standard of care) in CDI patients through assessment of both initial cure rates and absence of recurrent CDI within 30 days of the end of treatment. The Phase 2 trial will recruit 100 patients with CDI and enrolment is expected to commence during H1 2014 at sites in the US and Canada.

SMT19969 is a novel, oral small molecule antibiotic that is being developed specifically for the treatment of CDI. Results from non-clinical efficacy studies show that SMT19969 combines potent bactericidal activity against *C. difficile* with exceptionally high levels of antibacterial selectivity. This targeted antibiotic has displayed efficacy in two key disease models while showing complete protection from recurrent disease. A Phase 1 trial conducted in healthy volunteers showed SMT19969 to be safe and well tolerated at all doses tested. In addition, a significant reduction in total clostridia but not in other bacterial groups was reported which demonstrated that SMT19969 was highly sparing of gut flora.

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Notes to Editors

About C. difficile Infection

C. difficile infection (‘CDI’) is a serious healthcare threat in hospitals, long-term care homes and increasingly the wider community. It is a serious illness caused by infection of the colon by the bacteria *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 disrupt the normal gastrointestinal (gut) flora and so allow *C. difficile* to flourish. Existing CDI antibiotics cause further damage to the gut flora and are associated with recurrent disease. This is the key clinical issue as repeat episodes are typically more severe and associated with an increase in mortality rates and healthcare costs.

About the Wellcome Trust

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. It supports the brightest minds in biomedical research and the medical humanities. The Trust’s breadth of support includes public engagement, education and the

application of research to improve health. It is independent of both political and commercial interests.
www.wellcome.ac.uk

About Summit

Summit is an Oxford, UK based drug discovery and development Company targeting high-value areas of unmet medical need including Duchenne Muscular Dystrophy and *C. difficile* infection. Summit is listed on the AIM market of the London Stock Exchange and trades under the ticker symbol SUMM. Further information is available at www.summitplc.com and follow Summit on Twitter ([@summitplc](https://twitter.com/summitplc)).

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Forward Looking Statements

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