Summit Corporation plc

('Summit' or 'the Company')

SUMMIT PRESENTS NEW PRECLINICAL AND CLINICAL DATA ON SELECTIVE *C. DIFFICILE* ANTIBIOTIC SMT19969 AT ICAAC 2013

Oxford, UK, 11 September 2013 – Summit (AIM: SUMM), a drug discovery and development company advancing therapies for Duchenne Muscular Dystrophy and *C. difficile* infection ('CDI'), reports further positive data on SMT19969, its novel and selective antibiotic for the treatment of CDI, at the 53rd annual Interscience Conference on Antimicrobial Agents and Chemotherapy ('ICAAC 2013') meeting held in Denver, Colorado, USA, September 10-13, 2013.

The data presented includes in-depth results from a Phase 1 clinical trial and additional preclinical studies that have recently been completed. These data are detailed in five poster presentations from Summit and two key collaborators, Dr Ellie Goldstein (R M Alden Research Laboratory, California, USA) and Professor Mark Wilcox (Leeds Teaching Hospitals and University of Leeds, Leeds UK). Summit was also selected to highlight these results in a podium presentation by an expert panel from the American Society of Microbiology.

"These new data presented at ICAAC 2013 further validates the promise of SMT19969 as a novel and highly targeted antibiotic for the treatment of this serious infectious disease," **commented Glyn Edwards, Chief Executive Officer of Summit.** "These results demonstrate that SMT19969 selectively kills all *C. difficile* strains tested, is highly sparing of healthy gut flora and shows no reduction in activity when used in combination with other antibiotics. *This profile is encouraging for treating CDI and significantly reducing rates of recurrent disease and we look forward to advancing SMT19969 into Phase 2 clinical trials in H1 2014."*

Results from Phase 1 Clinical Trial (Posters F-626 & K-167)

Top-line data from a double blind, placebo controlled Phase 1 clinical trial in 56 healthy volunteers were reported in April 2013. Full analysis of the trial data is being presented at ICAAC 2013 showed:

- SMT19969 is safe and well tolerated at all doses tested.
- SMT19969 is highly sparing of natural gut flora in all subjects who received repeat doses of drug for ten days at the expected therapeutic dose or above. The major bacteria groups were largely unchanged with the exception of total Clostridia, which were reduced during treatment.
- Minimal systemic exposure. SMT19969 retained in the GI tract, the site of infection, following oral dosing.
- Minimal drug metabolism with >97% of SMT19969 excreted unchanged in faeces.
- Faecal concentrations of drug were ~1000x above those required for antibiotic activity levels (MIC levels) after administration at the expected therapeutic dose.

Results from Preclinical Efficacy Studies (Posters F-624 & F-631b)

New, comprehensive preclinical studies evaluating the potency and selectivity of SMT19969 have been completed. In summary, the results show SMT19969:

- Has a highly targeted spectrum of activity after screening against a panel of 50 *C. difficile* clinical isolates, and over 500 bacteria that are natural members of gut flora.
- Demonstrates enhanced activity compared to current CDI treatments against emerging, endemic and hyper-virulent *C. difficile* clinical isolates from the US. This included *C. difficile* strains displaying emerging resistance towards vancomycin, the current standard of care. These data compliment earlier studies that showed SMT19969 was highly potent against *C. difficile* clinical isolates from the UK.
- Displays superior selectivity compared to current CDI treatments, with minimal antibiotic effect against a panel of over 500 Gram positive and Gram negative bacteria that are found in gut flora.

The Effect of Combined Use with Common Antibiotics (Poster F-625)
This *in vitro* study evaluated the potential impact of dosing SMT19969 in conjunction with other antibiotics. In summary the results showed:

- Concomitant use of antibiotics will not diminish the potency of SMT19969 with no change in activity observed when tested in combination with other commonly used antibiotics. This is an important result as a significant proportion of CDI patients receive other antibiotics to treat persistent or new infections.

Copies of the presentations will be available shortly from the 'Programmes' section of Summit's website, www.summitplc.com.

The development of SMT19969 is being supported through to completion of a Phase 2 clinical trial by a Translational Award from the Wellcome Trust.

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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 that is 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 SMT19969
SMT19969 is a novel, oral small molecule antibiotic that is being specifically developed for the treatment of CDI. Results from non-clinical efficacy studies show that SMT19969 combines potent 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 against recurrent disease. SMT19969 was safe and well tolerated in a Phase 1 clinical trial in healthy volunteers and it is expected to advance into a Phase 2 patient trial in H1 2014.

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).

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