



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

Summit Announces BARDA Expands Ridinilazole Award by \$8.8 Million to Include Additional NDA-Enabling Work

- **Total Committed BARDA Funding Increased to \$62.4 Million**
- **Total Award Increased to up to \$72.5 Million**

Oxford, UK, and Cambridge, MA, US, 23 January 2020 – Summit Therapeutics plc (NASDAQ: SMMT, AIM: SUMM), a leader in new mechanism antibiotic innovation, today announces that the Biomedical Advanced Research and Development Authority (‘BARDA’) has expanded its award for the clinical and regulatory development of Summit’s precision antibiotic ridinilazole for the treatment of *C. difficile* infection (‘CDI’) by \$8.8 million. The additional funding is being provided to support a new clinical trial in adolescent patients and brings the total value of the award to up to \$72.5 million. The adolescent clinical trial is expected to support a New Drug Application for ridinilazole and also form part of a package of work with the potential to provide an additional six months market exclusivity for ridinilazole in the US and Europe.

“BARDA’s continued support for ridinilazole is instrumental in helping to bring this potential CDI treatment option to patients, whose current treatment options fail to sustain cures for one third of the population,” said Mr Glyn Edwards, Chief Executive Officer of Summit. “We thank BARDA for its commitment to ridinilazole, innovation and public health.”

The total committed funding from the BARDA award under Contract No. HHS0100201700014C is now \$62.4 million, with one final option of \$10.1 million remaining to be exercised at BARDA’s sole discretion. The final option provides funding support for potential applications for marketing approvals of ridinilazole. The BARDA contract provides for a cost-sharing arrangement with the committed funding drawn down over a specified development period.

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014 (MAR). The person responsible for arranging for the release of this announcement on behalf of the Company is Richard Pye, Vice President, Investor Relations and Corporate Affairs.

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. The vast majority of patients are treated with 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. A study estimated that the total costs attributable to the management of CDI were approximately \$6.3 billion per year in the United States.

About Ridinilazole

Ridinilazole is an investigational oral small molecule new mechanism antibiotic that is designed to selectively kill *C. difficile*, thereby preserving patients’ protective gut microbiome and leading to sustained CDI cures. In a Phase 2 proof of concept trial in CDI patients, ridinilazole showed statistical superiority in sustained clinical response (‘SCR’) rates compared to 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. The gut microbiome is known to be important in protecting against CDI. Ridinilazole 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 infections caused by *C. difficile*, Enterobacteriaceae and *N. gonorrhoeae* 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

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the potential benefits and future operation of the BARDA contract, including any potential future payments thereunder, the clinical and preclinical development of the Company's product candidates, the therapeutic potential of the Company's product candidates, the potential commercialisation of the Company's product candidates, the sufficiency of the Company's cash resources, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability of BARDA to terminate our contract for convenience at any time, the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of filings that the Company makes with the Securities and Exchange Commission, including the Company's Annual Report on Form 20-F for the fiscal year ended 31 January 2019. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-



looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.

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