



Summit Therapeutics plc

(‘Summit’, the ‘Company’ or the ‘Group’)

Summit Therapeutics Reports Financial Results and Operational Progress for the First Quarter and Three Months Ended March 31, 2020

Oxford, UK, and Cambridge, MA, US, June 2, 2020 - Summit Therapeutics plc (NASDAQ: SMMT) today reports its financial results and provides an update on its operational conditions for the first quarter and three months ended March 31, 2020.

Ridinilazole for *C. difficile* Infection (‘CDI’)

- As of May 31, 2020, the Company had enrolled a total of 291 patients into its Phase 3 Ri-CoDIFy clinical trials. Below is a table outlining the enrollment statistics by calendar quarter and for this past April and May since the opening of the trials in February 2019.

Quarter	Number of patients enrolled	Cumulative Patients Enrolled
Q1 2019	9	9
Q2 2019	21	30
Q3 2019	43	73
Q4 2019	78	151
Q1 2020	101	252
April 2020	16	268
May 2020	23	291

- Due to the uncertainties surrounding COVID-19, Summit Therapeutics is withdrawing public commentary on the timing of completion of the Phase 3 Ri-CoDIFy clinical trials. The Company will be updating stakeholders quarterly as to enrollment status.
- The Ri-CoDIFy clinical trials aim to support registration of the precision antibiotic ridinilazole in the US and other territories resulting in its intended adoption as a first-line treatment for CDI by:
 - testing for superiority over the current standard of care, vancomycin, in the primary endpoint of sustained clinical response at 30 days after treatment has ended;
 - generating health economic data to support ridinilazole's commercial launch, when as and if approved by regulatory authorities; and
 - undertaking microbiome analysis that aims to show ridinilazole's impact on the gut microbiome.
- BARDA is supporting the Phase 3 clinical and regulatory development of ridinilazole with a financial award of potential funding of up to \$72.5 million. As of March 31, 2020, an aggregate of \$42.4 million had been received.

Discuva Platform

Enterobacteriaceae

- DDS-04 compound series is a new class of precision antibiotics in lead optimisation that acts *via* the novel bacterial target LolCDE with the potential to treat infections caused by the Gram-negative bacteria, Enterobacteriaceae.



Gonorrhoea

- DDS-01 compound series is a new class of precision antibiotics in lead optimization against *Neisseria gonorrhoeae*, and is supported by an award of up to \$5.7 million from CARB-X.

Corporate Highlights

- Mr. Robert W. Duggan was appointed as Chief Executive Officer, Dr. Elaine Stracker was appointed Interim Chief Operating Officer and Dr. Ventzislav Stefanov was appointed Executive Vice President and President of Discuva, the Company's discovery engine employing 14 people, in April 2020. Mr. Glyn Edwards stepped down as Chief Executive Officer in April 2020, and he remains on the board as a Non-Executive Director.
- Dr. David Powell was promoted to Chief Scientific Officer and Ms. Divya Chari was appointed as Head of Global Clinical Operations in March 2020. Ms. Laura Trespidi was promoted to SVP, CMC and Supply Chain in February 2020.

COVID-19

- In light of the ongoing COVID-19 pandemic, Summit's employees continue to work remotely, enabling the majority of day to day business operations to continue. Summit's own laboratory facilities have begun to reopen to resume work on key projects; site access by staff is being monitored closely and is limited to ensure the safety of Summit researchers. There continues to be a negative impact on patient enrollment into the Ri-CoDIFy clinical trials.

Financial Highlights

- Cash and cash equivalents at March 31, 2020, of \$55.3 million (£44.4 million) compared to \$60.3 million (£48.4 million) at December 31, 2019.
- Loss for the three months ended March 31, 2020, of \$6.1 million (£4.9 million) compared to a loss of \$6.9 million (£5.3 million) for the three months ended March 31, 2019. Excluding the impact of exchange rate changes, the loss for the three months ended March 31, 2020, would be \$9.3 million (£7.5 million) compared to a loss of \$6.2 million (£4.7 million) for the three months ended March 31, 2019.

About *C. difficile* Infection

Clostridioides difficile, or *C. difficile*, infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon and severe diarrhea. CDI can also result in more serious disease complications, including pseudomembranous colitis, bowel perforation, toxic megacolon and sepsis. CDI represents a serious healthcare issue in hospitals, long-term care homes and in the wider community. Summit estimates there are over one million cases of CDI each year in the United States and Europe, based on an epidemiology report on CDI that was published in 2015 by Decision Resources, a healthcare research and consulting company. Recurrence rates of up to 25% have been reported following treatment with the current standard of care, vancomycin. The vicious cycle of recurrence continues further, with patients who have one recurrence being at increased risk for another. The Healthcare Cost and Utilization Project, a family of databases developed through a federal-state-industry partnership, sponsored by the Agency for Healthcare Research and Quality of the US Department of Health and Human Services, reported an approximate 3.5-fold increase in hospital stays associated with CDI between 2000 and 2008. The economic impact of CDI is significant. A study



published in 2016 in *BMC Infectious Diseases* estimated that the total costs attributable to the management of CDI were approximately \$6.3 billion per year.

About Enterobacteriaceae

Enterobacteriaceae are a family of bacteria responsible for severe and often deadly infections. They account for a significant number of cases across a number of conditions including bloodstream infections, urinary tract infections and hospital-acquired pneumonias. Summit estimates that there are more than one million infections in the United States annually caused by Enterobacteriaceae across these three conditions based on data published in 2018 in the *Journal of Antimicrobial Chemotherapy*, 2016 in the *Journal of Molecular Science*, 2014 in the National Healthcare Safety Network, 2014 and 2018 in the *New England Journal of Medicine*, 2015 in *Nature Reviews Microbiology*, 2012 in *World Journal of Urology* and 2014 in *PLOS One*. Mechanisms of antibiotic resistance to Enterobacteriaceae are listed as both urgent and serious threats by the CDC.

About Gonorrhea

There is an urgent unmet need for the development of new antibiotics against gonorrhea, which is a sexually transmitted infection caused by an overgrowth of the bacteria *Neisseria gonorrhoeae* (*N. gonorrhoeae*). *N. gonorrhoeae* can cause infection of the genitals, throat, and eyes. Untreated infections may spread to the rest of the body, especially the joints, and in women may cause pelvic inflammatory disease and possible infertility. It is estimated by the WHO that there are approximately 78 million new cases of gonorrhea globally per year. *N. gonorrhoeae* has consistently developed resistance to each class of antibiotics recommended for the treatment of gonorrhea infections, and there is now only one treatment that is recommended by the CDC, a combination of the cephalosporin antibiotic ceftriaxone and the macrolide antibiotic azithromycin. The WHO ranks gonorrhea as a "high" priority for research and development while the CDC states that additional treatment options are urgently needed.

About Summit Therapeutics

Summit Therapeutics, led by its Discuva Platform, the Company's discovery engine, is a leader in antibiotic innovation. Our new mechanism antibiotics are designed to become the patient-friendly new era standard of care for those suffering from infectious disease, subject to regulatory approvals, and create value for payors and healthcare providers. In the present time, we are developing new mechanism antibiotics to treat 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. For more information on the Company's Discuva Platform, visit <https://www.summitplc.com/our-science/discuva-platform>.

For more information:

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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 or CARB-X 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 of the Discuva Platform, the potential commercialization 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, the impact of the COVID-19 pandemic 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 or CARB-X to terminate the 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 preclinical studies and clinical trials and the results of such preclinical studies and clinical 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, legal, regulatory, political and economic risks arising from or relating to global public health crises that reduce economic activity (including the recent coronavirus COVID-19 outbreak) and the enrollment in and completion of clinical trials, laws and regulations affecting government contracts, 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 Transition Report on Form 20-F for the eleven months ended December 31, 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.

The financial information in the Company's financial statements has been prepared assuming the Company will continue on a going concern basis. Based on management's forecasts, the Company's existing cash and cash equivalents, anticipated payments from BARDA under its contract for the development of ridinilazole, anticipated payments from CARB-X under its contract for the development of its gonorrhea antibiotic program, and anticipated milestone payments from its license and commercialization agreement with Eurofarma are expected to be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements through January 31, 2021. The Company will need to raise additional funding in order to support, beyond this date, its planned research and development efforts, its preparatory commercialization related activities should ridinilazole receive marketing approval, as well as to support activities associated with operating as a public company in the United States. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition, and may cast and raise significant doubt on the Company's ability to continue as a going concern.

FINANCIAL STATEMENTS

Condensed Consolidated Statement of Comprehensive Income (unaudited)

For the three months ended March 31, 2020

	Note	Three months ended March 31, \$000s	Three months ended March 31, £000s	Three months ended March 31, £000s
Revenue		315	253	375
Other operating income		5,096	4,092	4,574
Operating expenses				
Research and development		(12,143)	(9,750)	(8,693)
General and administration		(651)	(523)	(2,367)
Total operating expenses		(12,794)	(10,273)	(11,060)
Operating (loss)		(7,383)	(5,928)	(6,111)
Finance income		1	1	2
Finance costs		(65)	(52)	(60)
(Loss) before income tax		(7,447)	(5,979)	(6,169)
Income tax		1,298	1,042	831
(Loss) for the period		(6,149)	(4,937)	(5,338)
Other comprehensive (loss) / income				
<i>Items that may be reclassified subsequently to profit or loss</i>				
Exchange differences on translating foreign operations		16	13	(6)
Total comprehensive (loss) for the period		(6,133)	(4,924)	(5,344)
Basic and diluted (loss) per ordinary share from operations		(2) cents	(1) pence	(3) pence

Condensed Consolidated Statement of Financial Position (unaudited)

As at March 31, 2020

	March 31, 2020 \$000s	March 31, 2020 £000s	December 31, 2019 £000s
ASSETS			
Non-current assets			
Goodwill	2,259	1,814	1,814
Intangible assets	12,292	9,870	9,950
Property, plant and equipment	1,305	1,048	1,167
	15,856	12,732	12,931
Current assets			
Trade and other receivables	12,179	9,780	8,116
Current tax receivable	6,080	4,882	3,659
Cash and cash equivalents	55,296	44,400	48,417
	73,555	59,062	60,192
Total assets	89,411	71,794	73,123
LIABILITIES			
Non-current liabilities			
Lease liabilities	(374)	(300)	(320)
Deferred revenue	(1,039)	(834)	(374)
Provisions for other liabilities and charges	(2,633)	(2,114)	(2,050)
Deferred tax liability	(2,127)	(1,708)	(1,560)
	(6,173)	(4,956)	(4,304)
Current liabilities			
Trade and other payables	(12,645)	(10,154)	(8,020)
Lease liabilities	(418)	(336)	(358)
Deferred revenue	(2,156)	(1,731)	(1,136)
Contingent consideration	(100)	(80)	(80)
	(15,319)	(12,301)	(9,594)
Total liabilities	(21,492)	(17,257)	(13,898)
Net assets	67,919	54,537	59,225
EQUITY			
Share capital	4,187	3,362	3,359
Share premium account	160,794	129,110	129,110
Share-based payment reserve	1,825	1,465	1,299
Merger reserve	3,770	3,027	3,027
Special reserve	24,899	19,993	19,993
Currency translation reserve	85	69	56
Accumulated losses reserve	(127,641)	(102,489)	(97,619)
Total equity	67,919	54,537	59,225



Condensed Consolidated Statement of Cash Flows (unaudited)

For the three months ended March 31, 2020

	Three months ended March 31, 2020 \$000s	Three months ended March 31, 2020 £000s	Three months ended March 31, £000s
Cash flows from operating activities			
Loss before income tax	(7,447)	(5,979)	(6,169)
	(7,447)	(5,979)	(6,169)
Adjusted for:			
Loss on recognition of contingent consideration payable	—	—	(2)
Finance income	(1)	(1)	(2)
Finance costs	65	52	60
Foreign exchange (gain) / loss	(3,429)	(2,753)	691
Depreciation	178	143	150
Amortization of intangible fixed assets	259	208	207
Loss on disposal of assets	—	—	26
Share-based payment	290	233	260
Adjusted loss from operations before changes in working capital	(10,085)	(8,097)	(4,779)
Increase in prepayments and other receivables	(1,537)	(1,235)	(30)
Increase / (decrease) in deferred revenue	1,315	1,055	(1,025)
Increase / (decrease) in trade and other payables	1,967	1,579	(2,270)
Cash used in operations	(8,340)	(6,698)	(8,104)
Contingent consideration paid	—	—	2
Taxation (paid) / received	(5)	(4)	1
Net cash used in operating activities	(8,345)	(6,702)	(8,101)
Investing activities			
Purchase of property, plant and equipment	(30)	(24)	(64)
Purchase of intangible assets	(159)	(128)	—
Interest received	1	1	2
Net cash used in investing activities	(188)	(151)	(62)
Financing activities			
Proceeds from issue of share capital	—	—	19,648
Transaction costs on share capital issued	—	—	(455)
Proceeds from exercise of share options	4	3	—
Repayment of lease liabilities	(51)	(42)	(80)
Repayment of lease interest	(7)	(6)	(9)
Net cash (used in) / generated from financing activities	(54)	(45)	19,104
(Decrease) / increase in cash and cash equivalents	(8,587)	(6,898)	10,941
Effect of exchange rates in cash and cash equivalents	3,584	2,881	(617)
Cash and cash equivalents at beginning of the period	60,299	48,417	9,521
Cash and cash equivalents at end of the period	55,296	44,400	19,845

Condensed Consolidated Statement of Changes in Equity (unaudited)

Three months ended March 31, 2020

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Special reserve £000s	Currency translation reserve £000s	Accumulated losses reserve £000s	Total £000s
At January 1, 2020	3,359	129,110	1,299	3,027	19,993	56	(97,619)	59,225
Loss for the period	—	—	—	—	—	—	(4,937)	(4,937)
Currency translation adjustment	—	—	—	—	—	13	—	13
Total comprehensive loss for the period	—	—	—	—	—	13	(4,937)	(4,924)
Share options exercised	3	—	—	—	—	—	—	3
Equity based compensation expense	—	—	233	—	—	—	—	233
Share-based payment reserve transfer	—	—	(67)	—	—	—	67	—
At March 31, 2020	3,362	129,110	1,465	3,027	19,993	69	(102,489)	54,537

Year ended December 31, 2019

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Special reserve £000s	Currency translation reserve £000s	Accumulated losses reserve £000s	Total £000s
At January 1, 2019	823	74,394	1,119	3,027	19,993	65	(74,217)	25,204
Profit for the year	—	—	—	—	—	—	(23,904)	(23,904)
Currency translation adjustment	—	—	—	—	—	(9)	—	(9)
Total comprehensive profit for the period	—	—	—	—	—	(9)	(23,904)	(23,913)
New share capital issued	2,535	55,872	—	—	—	—	—	58,407
Transaction costs on share capital issued	—	(1,156)	—	—	—	—	—	(1,156)
Share options exercised	1	—	—	—	—	—	—	1
Equity based compensation expense	—	—	682	—	—	—	—	682
Share-based payment reserve transfer	—	—	(502)	—	—	—	502	—
At December 31, 2019	3,359	129,110	1,299	3,027	19,993	56	(97,619)	59,225

Three months ended March 31, 2019

Group	Share capital £000s	Share premium account £000s	Share-based payment reserve £000s	Merger reserve £000s	Special reserve £000s	Currency translation reserve £000s	Accumulated losses reserve £000s	Total £000s
At January 1, 2019	823	74,394	1,119	3,027	19,993	65	(74,217)	25,204
Loss for the period	—	—	—	—	—	—	(5,338)	(5,338)
Currency translation adjustment	—	—	—	—	—	(6)	—	(6)
Total comprehensive profit for the period	—	—	—	—	—	(6)	(5,338)	(5,344)
New share capital issued	781	18,867	—	—	—	—	—	19,648
Transaction costs on share capital issued	—	(456)	—	—	—	—	—	(456)
Equity based compensation expense	—	—	260	—	—	—	—	260
Share-based payment reserve transfer	—	—	(418)	—	—	—	418	—
At March 31, 2019	1,604	92,805	961	3,027	19,993	59	(79,137)	39,312