Press Release

RedHill Biopharma Launches *H. pylori* Disease State Awareness Field Campaign Ahead of Talicia® Launch

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RedHill is on track to launch Talicia® in the U.S. in the first quarter of 2020 for the treatment of H. pylori infection in adults

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RedHill to sponsor H. pylori medical education event at the Pri-Med South Conference scheduled for February 6-9, 2020

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RedHill to sponsor the No Stomach for Cancer (NSFC) Spotlight on Stomach Cancer Symposium in May 2020

TEL-AVIV, Israel and RALEIGH, N.C., January 27, 2020 RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases, today announced it has launched a nationwide *H. pylori* disease state educational field campaign led by its sales force, ahead of the planned U.S. launch of Talicia®[1] later this quarter.

H. pylori infection is a highly prevalent and increasingly resistant Group 1 carcinogen. RedHill's disease state educational field campaign is intended to provide healthcare professionals with a greater awareness of the risks related to *H. pylori* infection and the high and growing resistance of the *H. pylori* bacterium to standard-of-care antibiotics, which has led to a 25-40% failure rate of current therapies[2]. The campaign is primarily being carried out by RedHill's field sales force, which has grown

[1] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: http://bit.ly/2CozHNH.

[2] Malfertheiner P. et al. Management of *Helicobacter pylori* infection - the Maastricht IV/ Florence Consensus Report, Gut 2012;61:646-664; O'Connor A. et al. Treatment of *Helicobacter pylori* Infection 2015, Helicobacter 20 (S1) 54-61;

over the past several months and is expected to include 140 representatives within the coming weeks. It is estimated that *H. pylori* resistance to clarithromycin more than doubled between 2009-2013[3]. The campaign aims to raise awareness among the main physicians who treat the disease, which include gastroenterologists, primary care and other healthcare providers. This educational effort is further supported by RedHill's medical affairs, thought leader liaisons and marketing teams.

"Ahead of the planned U.S. commercial launch of Talicia later this quarter, we are excited to offer an educational resource to healthcare professionals to gain a greater understanding of the risks and causes of treatment failure and the importance of diagnosis and eradication of *H. pylori*," **said Rick D. Scruggs, RedHill's Chief Operating Officer, U.S. Operations.** "Our market access team has been working to establish coverage for Talicia ahead of its commercial launch, to allow more patients to benefit from this new treatment. Talicia's story has been met with a positive response, which has led to formulary placement discussions with several major payers. We look forward to offering patients and physicians a new treatment option."

RedHill continues to support a number of prevention and awareness initiatives for stomach cancer and will sponsor the No Stomach for Cancer (NSFC) Spotlight on Stomach Cancer Symposium that will take place on May 2, 2020, at the Duke University Cancer Institute in Durham, N.C.

RedHill will also sponsor an educational program at the Pri-Med South Conference on February 6-9, 2020, in Fort Lauderdale, FL, where Professor Colin W. Howden, M.D., a leading KOL on *H. pylori*, will speak about evolving strategies for the eradication of *H. pylori* infection.

"*H. pylori* infection is a highly prevalent Group 1 carcinogen and the strongest risk factor for peptic ulcer disease and non-cardia gastric cancer. More than 27,500 Americans are diagnosed with gastric cancer each year, and more than 11,000 die from the disease annually[4]. As a recent publication[5] has shown, eradication of *H. pylori* reduces the risk of gastric cancer. Despite the risks associated with *H. pylori* infection, there has been a lack of advances in treatment options over the past decade and treatment has become increasingly difficult due to growing bacterial resistance to antibiotics used in current therapies," **said June S. Almenoff, M.D., Ph.D., RedHill's Chief Scientific Officer**. "Treatment of *H. pylori* infection may decrease the risk of gastric cancer if eradication is successful. We believe it is imperative to raise awareness among healthcare professionals and patients on the importance of diagnosis and the risks associated with lack of treatment and failed eradication."

Venerito M. et al. Meta-analysis of bismuth quadruple therapy versus clarithromycin triple therapy for empiric primary treatment of *Helicobacter pylori* infection. Digestion 2013;88(1):33-45.

[3] Shiota S, Reddy R, Alsarraj A, et al. Antibiotic resistance of Helicobacter pylori among male United States veterans. Clin Gastroenterol Hepatol. 2015;13:1616-1624.

[4] National Cancer Institute, Surveillance, Epidemiology, and End Results Program (SEER)

[5] Kumar S et al. Risk Factors and Incidence of Gastric Cancer After Detection of *Helicobacter pylori* Infection: A Large Cohort Study. Gastroenterology 2019; doi: 10.1053/j.gastro.2019.10.019.

About *H. Pylori*

H. pylori bacterial infection affects approximately 35% of the U.S. population[6], with an estimated two million patients treated annually[7]. *H. pylori* infection, which is classified by the World Health Organization (WHO) as a Group 1 carcinogen, remains the strongest known risk factor for gastric cancer[8] and a major risk factor for peptic ulcer disease[9] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[10]. Eradication of *H. pylori* is becoming increasingly difficult, with current standard-of-care therapies failing in approximately 25-40% of patients who remain *H. pylori*-positive due to growing resistance of *H. pylori* to antibiotics commonly used in standard combination therapies[2]. It is estimated that *H. pylori* resistance to clarithromycin more than doubled between 2009-2013[3].

About Talicia® (omeprazole magnesium, amoxicillin and rifabutin)

INDICATION AND USAGE

Talicia is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of *Helicobacter pylori* infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Talicia and other antibacterial drugs, Talicia should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

Talicia contains omeprazole, a proton pump inhibitor (PPI), amoxicillin a penicillin-class antibacterial and rifabutin, a rifamycin antibacterial. It is contraindicated in patients with known hypersensitivity to any of these medications, any other components of the formulation, any other beta-lactams or any other rifamycin.

Talicia is contraindicated in patients receiving rilpivirine-containing products.

Talicia is contraindicated in patients receiving delavirdine or voriconazole.

Serious and occasionally fatal hypersensitivity reactions have been reported with omeprazole, amoxicillin and rifabutin.

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[6] Hooi JKY et al. Global Prevalence of *Helicobacter pylori Infection*: Systematic Review and Meta-Analysis. Gastroenterology 2017; 153:420-429.

[7] IQVIA Custom Study for RedHill Biopharma, 2019

[8] Lamb A et al. Role of the *Helicobacter pylori*-Induced inflammatory response in the development of gastric cancer. J Cell Biochem 2013;114.3:491-497.

[9] NIH – Helicobacter pylori and Cancer, September 2013.

[10] Hu Q et al. Gastric mucosa-associated lymphoid tissue lymphoma and Helicobacter pylori infection: a review of current diagnosis and management. Biomarker research 2016;4.1:15.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.

Talicia may cause fetal harm. Talicia is not recommended for use in pregnancy.

Talicia may reduce the efficacy of hormonal contraceptives. An additional non-hormonal method of contraception is recommended when taking Talicia.

Talicia should not be used in patients with hepatic impairment or severe renal impairment.

Acute Interstitial Nephritis has been observed in patients taking PPIs and penicillins.

Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs. These events have occurred as both new onset and exacerbation of existing autoimmune disease.

The most common adverse reactions (≥1%) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

To report SUSPECTED ADVERSE REACTIONS, contact RedHill Biopharma INC. at 1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full prescribing information for Talicia® is available at http://bit.ly/2CozHNH.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases. RedHill promotes the gastrointestinal drug **Aemcolo®** in the U.S. and is planning to launch **Talicia®** in the U.S. for the treatment of *Helicobacter pylori (H. pylori)* infection in adults. RedHill's key clinical late-stage development programs include: (i) **RHB-104,** with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102** (**Bekinda®**), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **ABC294640 (Yeliva®),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106,** an encapsulated bowel preparation, and (vi) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at www.redhillbio.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the

Company's control and cannot be predicted or quantified, and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks related to the timing for the launch of Talicia® as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its therapeutic candidates and its FDA-approved products; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia®; (v) the Company's ability to successfully commercialize and promote Talicia®, Aemcolo®, and Mytesi®; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on February 26, 2019, as amended on May 15, 2019. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise unless required by law.

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