# Press Release

## RedHill Biopharma Announces U.S. Commercial Launch of Talicia® for *H. pylori* Infection

*Talicia® is the first and only FDA-approved rifabutin-based therapy for treatment of H. pylori infection designed as a first-line option to address the high and growing H. pylori resistance to clarithromycin*

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*Talicia® is targeting an estimated two million U.S. patients treated annually for H. pylori infection*

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*H. pylori infection affects approximately 35% of the U.S. population; it is a Group 1 carcinogen and the strongest known risk factor for gastric cancer*

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*Talicia® is eligible for a total of eight years of U.S. market exclusivity, in addition to patent protection until 2034*

**TEL-AVIV, Israel and RALEIGH, N.C., March 9, 2020 --** RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company focused on gastrointestinal diseases, today announced the U.S. commercial launch of Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[1] delayed-release capsules 10 mg[2]/250 mg/12.5 mg for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. RedHill's expanded U.S. sales force

[1] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: www.talicia.com.

[2] Each delayed-release capsule contains omeprazole 10 mg (equivalent to 10.3 mg omeprazole magnesium), amoxicillin 250 mg and rifabutin 12.5 mg.

will promote Talicia® nationwide to approximately 25,000 gastroenterologists, primary care physicians and other healthcare providers.

"We are delighted to announce the availability of Talicia® in pharmacies nationwide - the first new FDA-approved drug to combat *H. pylori* infection in over a decade," **said Rick Scruggs, Chief Commercial Officer of RedHill.** "Patients who adhered[3] to their therapy in our pivotal Phase 3 trial achieved 90% efficacy[4] while taking Talicia®. Over the past several months we have worked diligently to ensure an optimal launch for Talicia®, including an expansive disease and antibiotic resistance awareness campaign focused on the gastroenterology and primary care provider communities. We are in the process of finalizing agreements with national payers and have put in place patient support programs to ensure patients and physicians have access to Talicia®."

Talicia® is the only rifabutin-based therapy approved for the treatment of *H. pylori* infection and is designed to address the high and growing resistance of *H. pylori* bacteria to clarithromycin-based standard-of-care therapies. The high rates of *H. pylori* resistance to clarithromycin have led to significant rates of treatment failure with clarithromycin-based standard-of-care therapy. No resistance to rifabutin, a key component of Talicia®, was detected in RedHill's pivotal Phase 3 study.

**About Talicia®**

Talicia® is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (PPI) (omeprazole). In November 2019, Talicia® was approved by the U.S. FDA for the treatment of *H. pylori* infection in adults. In the pivotal Phase 3 study, Talicia® demonstrated 84% eradication of *H. pylori* infection in the intent-to-treat (ITT) group vs. 58% in the active comparator arm ($p<0.0001$). Further, in an analysis of data from this study, it was observed that subjects who were confirmed adherent with their therapy had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm[4].

Talicia® is eligible for a total of eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation and is also covered by U.S. patents which extend patent protection until 2034 with additional patents and applications pending and granted in various territories worldwide.

[3] Defined as the PK population which included those subjects in the ITT population who had demonstrated presence of any component of investigational drug at Visit 3 (approx. day 13) or had undetected levels drawn >250 hours after the last dose.

[4] The Pivotal Phase 3 study of Talicia® demonstrated 84% eradication of *H. pylori* infection with Talicia® vs. 58% in the active comparator arm (ITT analysis, $p<0.0001$).

**About *H. pylori***

*H. pylori* bacterial infection affects approximately 35%[5] of the U.S. population, with an estimated two million patients treated annually[6]. Worldwide, more than 50% of the population is affected by *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[7] and a major risk factor for peptic ulcer disease[8] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[9]. More than 27,000 Americans are diagnosed with gastric cancer annually[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[11].

**About RedHill Biopharma Ltd.**

RedHill Biopharma Ltd. (Nasdaq: 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 drugs **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults and **Aemcolo®** for the treatment of travelers' diarrhea[12]. RedHill acquired rights to **Movantik®** for opioid-induced constipation[13], the acquisition remains subject to certain customary closing conditions and regulatory clearances. 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 1/2a 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.

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

[6] IQVIA Custom Study for RedHill Biopharma, 2019

[7] 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.

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

[9] 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.

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

[11] 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; 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.

[12] For full prescribing information see: Aemcolo® (rifamycin): www.Aemcolo.com.

[13] For full prescribing information see: Movantik® (naloxegol) www.Movantik.com.

**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.

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.

*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® and the timing of hiring sales representatives 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® and Aemcolo® and following closing of the acquisition, Movantik®; (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 March 4, 2020. 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.*


**Company contact:**
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

**IR contact (U.S.):**
Timothy McCarthy, CFA, MBA
Managing Director, Relationship Manager
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com