



## NEWS RELEASE

# RedHill Biopharma and Gaelan Medical Enter Into License Agreement for Talicia® for the United Arab Emirates

1/6/2022

Gaelan Medical to pay RedHill \$2 million upfront plus potential regulatory and sales milestones and tiered royalties on net sales, for the exclusive rights in the United Arab Emirates to Talicia®

Talicia is a U.S. FDA-approved treatment for H. pylori, a bacterial infection that affects more than 50% of the world's adult population representing significant unmet need

RALEIGH, N.C. and TEL-AVIV, Israel, Jan. 6, 2022 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, announced that it has entered into an exclusive license agreement with Gaelan Medical Trade LLC ("Gaelan Medical"), a wholly owned subsidiary of the Ghassan Aboud Group (GAG), for Talicia® (omeprazole magnesium, amoxicillin and rifabutin)<sup>[1]</sup>, an H. pylori therapy, in the United Arab Emirates (UAE).

Under the terms of the agreement, RedHill will receive an upfront payment of \$2 million and is eligible for additional milestone payments as well as tiered royalties up to mid-teens on net sales of Talicia in the UAE. Gaelan Medical will receive the exclusive rights to commercialize Talicia in the UAE, as well as a right of first refusal to

commercialize Talicia in the Gulf Cooperation Council region (Saudi Arabia, Kuwait, Qatar, Bahrain and Oman) for a pre-determined period.

"We are delighted to partner with Gaelen Medical to help bring Talicia to H. pylori patients in the UAE and potentially other territories in the region," **said Dror Ben-Asher, RedHill's CEO**. "This partnership is particularly important given that H. pylori, a major public health concern, impacts up to 84% of the population in the region<sup>[2]</sup> and is one of the strongest risk factors for gastric cancer, leading to a recent regional clinical consensus meeting calling for eradication therapy to be offered to all individuals infected with H. pylori<sup>[3]</sup>. We are seeing rapid growth of Talicia in the U.S. in light of the alarming failure rates of clarithromycin-based therapies and growing physician awareness of the need for highly effective first-line H. pylori therapy. We continue to explore with potential partners the expansion of Talicia's reach into additional ex-U.S. territories."

"H. pylori can cause extensive damage if not properly eradicated first-time and there is considerable need for a therapy like Talicia in the UAE, where 41% of the population<sup>[4]</sup> is affected and have limited options for treatment," **said Ghassan Aboud, Chairman of GAG**. "Talicia would become the first approved combination product in the UAE specifically designed to treat H. pylori, and we are excited to be partnering with RedHill and at the prospect of realizing Talicia's potential to help patients with H. pylori infection in the UAE and potentially other territories in the region."

### **About Talicia®**

Talicia® is the only rifabutin-based therapy approved for the treatment of H. pylori infection and is designed to address the high resistance of H. pylori bacteria seen with other antibiotics. The high rates of H. pylori resistance to clarithromycin have led to significant rates of treatment failure with clarithromycin-based therapies and are a strong public health concern, as highlighted by the ACG, FDA and the World Health Organization (WHO) in recent years.

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 ( $p < 0.0001$ ). Minimal to zero resistance to rifabutin, a key component of Talicia®, was detected in RedHill's pivotal Phase 3 study. Further, in an analysis of data from this study, it was observed that subjects who were confirmed adherent<sup>[5]</sup> to their therapy had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm<sup>[6]</sup>.

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.

### About H. pylori

H. pylori is a bacterial infection that affects approximately 35%<sup>[7]</sup> of the U.S. population, with an estimated two million patients treated annually<sup>[8]</sup>. Worldwide, more than 50% of the population has H. pylori infection, which is classified by the WHO as a Group 1 carcinogen. It remains the strongest known risk factor for gastric cancer<sup>[9]</sup> and a major risk factor for peptic ulcer disease<sup>[10]</sup> and gastric mucosa-associated lymphoid tissue (MALT) lymphoma<sup>[11]</sup>. More than 27,000 Americans are diagnosed with gastric cancer annually<sup>[12]</sup>. Eradication of H. pylori is becoming increasingly difficult, with current therapies failing in approximately 25-40% of patients who remain H. pylori-positive due to high resistance of H. pylori to antibiotics – especially clarithromycin – which is still commonly used in standard combination therapies<sup>[13]</sup>.

### About Gaelan Medical

Gaelan Medical is a part of Ghassan Aboud Group, an international conglomerate that has been engaged in several key business sectors including health care, automotive, hospitality, real estate, retail, catering, logistics, pastoral, trade and distribution and media for more than two decades. Headquartered in the United Arab Emirates, GAG's business operations are complemented by offices in Australia, Belgium, Jordan and Turkey.

Ghassan Aboud Group believes that productivity, innovation and transformation require community engagement and ensures that its exclusive portfolio operates in a corporate conscious and a responsible manner making people the number one priority behind its vision "Being at the forefront of excellence".

Gaelan Medical, the UAE based healthcare and beauty distribution business follows a mission of care and cure and is dedicated to support healthcare providers with world-class solutions to better serve communities across the GCC region. Gaelan Medical, with its experienced management team, caters to diverse healthcare needs including, pharmaceuticals, medical consumables, medical equipment, and beauty products. The company's flexibility and strong financial capabilities of its parent company GAG makes it the preferred partner-of-choice and one stop solution for the region.

### About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: [RDHL](#)) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs, **Movantik**® for opioid-induced constipation in adults<sup>[14]</sup>, **Talicia**® for the treatment of Helicobacter pylori (H. pylori) infection in adults, and **Aemcolo**® for the treatment of travelers' diarrhea in adults<sup>[15]</sup>. RedHill's key clinical late-stage development

programs include: (i) **RHB-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (ABC294640)**, a first-in-class, oral SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and Phase 2 studies for prostate cancer and cholangiocarcinoma ongoing; (iii) **RHB-107 (upamostat)**, an oral serine protease inhibitor in a U.S. Phase 2/3 study as treatment for symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (v) **RHB-102**, with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at [www.redhillbio.com](http://www.redhillbio.com) / <https://twitter.com/RedHillBio>.

### 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

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.

Severe cutaneous adverse reactions (SCAR) (e.g. Stevens-Johnson syndrome (SJS), Toxic epidermal necrolysis (TEN)) have been reported with rifabutin, amoxicillin, and omeprazole. Additionally, drug reaction with eosinophilia and

systemic symptoms (DRESS) has been reported with rifabutin.

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

*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.

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 ( $\geq 1\%$ ) 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](http://www.fda.gov/medwatch).

Full prescribing information for Talicia is available at [www.Talicia.com](http://www.Talicia.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, including without limitation the risk that the Company will not succeed to expand Talicia's reach to additional ex-U.S. territories; as well as other risk and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number and type 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 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, pre-clinical 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 18, 2021. 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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**Company contact:**

Adi Frish

Chief Corporate & Business Development Officer

RedHill Biopharma

+972-54-6543-112

**[adi@redhillbio.com](mailto:adi@redhillbio.com)**

**Media Contacts:**

U.S.: Bryan Gibbs, Finn Partners

+1 212 529 2236

**[bryan.gibbs@finnpartners.com](mailto:bryan.gibbs@finnpartners.com)**

UK: Amber Fennell, Consilium  
+44 (0) 7739 658 783  
**fennell@consilium-comms.com**

[1] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) delayed-release capsules 10 mg/250 mg/12.5 mg is indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. For full prescribing information see: **[www.Talicia.com](http://www.Talicia.com)**.

[2] Hussein NR. *Helicobacter pylori* and gastric cancer in the Middle East: a new enigma? *World J Gastroenterol*. 2010;16(26):3226-3234. doi:10.3748/wjg.v16.i26.3226

Hooi JKY, Lai WY, Ng WK, Suen MMY, Underwood FE, Tanyingoh D, et al. Global prevalence of *Helicobacter pylori* infection: systematic review and meta-analysis. *Gastroenterology*. 2017 Aug 1;153(2):420–9.

[3] Liou J, Malfertheiner P, Lee Y Asian Pacific Alliance on *Helicobacter* and Microbiota (APAHAM), et al Screening and eradication of *Helicobacter pylori* for gastric cancer prevention: the Taipei global consensus. *Gut* 2020;69:2093-2112.

[4] Khoder G, Muhammad JS, Mahmoud I, Soliman SSM, Burucoa C. Prevalence of *Helicobacter pylori* and Its Associated Factors among Healthy Asymptomatic Residents in the United Arab Emirates. *Pathogens*. 2019;8(2):44. Published 2019 Apr 1. doi:10.3390/pathogens8020044

[5] 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.

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

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

[8] IQVIA Custom Study for RedHill Biopharma, 2019

[9] 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.

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

[11] 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.

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

[13] 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.

[14] Full prescribing information for Movantik® (naloxegol) is available at: [www.Movantik.com](http://www.Movantik.com).

[15] Full prescribing information for Aemcolo® (rifamycin) is available at: [www.Aemcolo.com](http://www.Aemcolo.com).

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