NEWS RELEASE

RedHill Biopharma Signs New $1.8 Million Plus Sales Royalties Middle East Deal For Talicia®

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The deal aims to accelerate Talicia's entry into new Middle East markets

Under the terms of the agreement RedHill will receive $500,000 in guaranteed payments, including a $250,000 upfront payment and $250,000 in fixed payments due within 18 months, plus a minimum of $1.3 million in near-term potential milestone payments, as well as tiered royalties up to mid-teens percent on Talicia net sales

Talicia is the only FDA-approved all-in-one, low-dose rifabutin-based therapy to address H. pylori antibiotic resistance. It is the #1 branded U.S. gastroenterologist-prescribed H. pylori therapy [1] and is first-line treatment listed in the American College of Gastroenterology (ACG) Clinical Guidelines [2]

H. pylori, a bacterial infection affecting >50% of the world's adult population [3], and up to almost 80% in parts of the Middle East [4], is a WHO-designated Group 1 carcinogen and key risk factor for gastric cancer [5], which causes around 800,000 deaths globally [6]

Talicia is patent protected through 2042 and received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation

RALEIGH, N.C., Oct. 6, 2025 /PRNewswire/ -- **RedHill Biopharma Ltd.** (NASDAQ: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the licensing of Talicia for new Middle East markets in a

deal worth potentially $1.8 million plus sales royalty payments.

Under the terms of the agreement, RedHill will receive $500,000 in guaranteed payments, including a $250,000 upfront payment and $250,000 in fixed payments due within 18 months. In addition, RedHill may receive a minimum of $1.3 million in near-term potential milestone payments, as well as tiered royalties up to mid-teens percent on Talicia net sales.

"With efficacy of up to 90%, a benign safety profile, zero to minimal resistance to its antibiotic components, and a convenient all-in-one capsule formulation with a simplified, adherence-enhancing dosing schedule[7,8,9], Talicia provides a compelling defense against the risk of gastric cancer through eradication of H. pylori – especially against the backdrop of increased antibiotic resistance to clarithromycin-containing therapies which can result in treatment failure rates of up to 40%[10]," **said Rick Scruggs, RedHill's Chief Commercial Officer**. "RedHill is committed to expanding patient access to Talicia globally and we now have an excellent opportunity for market building in the region, where we know there is a significant medical need for effective H. pylori treatment. Additional geographic expansion efforts are also ongoing to broaden market access and to secure additional non-dilutive ex-US licensing revenue streams."

The need for effective H. pylori treatment, designed to address antibiotic resistance, is clear. There is a high and rising prevalence of H. pylori antibiotic resistance, and leading U.S. H. pylori treatment guidelines are explicit on the need to avoid using clarithromycin as part of any H. pylori treatment regimen without prior susceptibility testing. H. pylori is a key risk factor for gastric cancer, which causes approximately 800,000 deaths a year globally - despite it being known that eradication of H. pylori can lead to a 75% decreased gastric cancer risk[11].

Talicia is the number one branded H. pylori therapy prescribed by U.S. gastroenterologists. It is listed as a first-line option for the treatment of H. pylori infection in the American College of Gastroenterology (ACG) Clinical Guideline, Talicia is the only FDA-approved all-in-one, low-dose rifabutin-based therapy designed to address H. pylori resistance to other antibiotics commonly used in H. pylori therapies.

Talicia is patent protected through 2042 and received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation.

About H. pylori

H. pylori is a bacterial infection that affects approximately 35% of the U.S. adult population[12] (an estimated 1.6 million U.S. patients are treated annually) rising to more than 50% globally[13] and reaching even higher levels of almost 80% in parts of the Middle East. Classified by the World Health Organization (WHO) as a Group 1 carcinogen, H. pylori is the strongest known risk factor for gastric cancer (between 70% to 90% of cases with more than 27,000

Americans diagnosed with gastric cancer annually[14] and approximately 800,000 deaths globally per year), a major risk factor for peptic ulcer disease (90% of cases)[15] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[16]. 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[17].

About Talicia®

Approved by the FDA for the treatment of H. pylori infection in adults in November 2019, Talicia is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (omeprazole). Talicia received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation and is also covered by U.S. patents extending patent protection through 2042 with additional patents and applications pending and granted in various territories worldwide. Talicia is also approved by the United Arab Emirates (UAE) Ministry of Health.

TALICIA: INDICATION AND IMPORTANT SAFETY INFORMATION

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.

Drug-induced enterocolitis syndrome (DIES) has been reported with use of amoxicillin, a component of Talicia.

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 (≥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 **www.Talicia.com**.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on U.S. development and commercialization of drugs for gastrointestinal diseases, infectious diseases and oncology. RedHill promotes the FDA approved gastrointestinal drug **Talicia®,** for the treatment of Helicobacter pylori (H. pylori) infection in adults[18]. RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anti-inflammatory, antiviral, and anticancer activity, targeting multiple indications with U.S. government and academic collaborations for development for radiation and chemical exposure indications such as GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 study in prostate cancer in

combination with darolutamide; (ii) **RHB-204**, a next-generation optimized formulation of RHB-104, with a planned Phase 2 study for Crohn's disease (based on RHB-104's positive Phase 3 Crohn's disease study results) and Phase 3-stage for pulmonary nontuberculous mycobacteria (NTM) disease; (iii) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, is in late-stage development as a treatment for non-hospitalized symptomatic COVID-19 and is also targeting multiple other cancer and inflammatory gastrointestinal diseases; and (iv) **RHB-102**, with potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting, positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis and positive results from a U.S. Phase 2 study for IBS-D. RHB-102 is partnered with Hyloris Pharma (EBR: HYL) for worldwide development and commercialization outside North America.

More information about the Company is available at **www.redhillbio.com** / **X.com/RedHillBio**.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and may discuss investment opportunities, stock analysis, financial performance, investor relations, and market trends. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words, and include, among others, statements regarding the potential impact of Talicia. 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: market and other conditions; the Company's ability to maintain compliance with the Nasdaq Capital Market's listing requirements; the risk that the addition of new revenue generating products or out-licensing transactions will not occur; the risk of current uncertainty regarding U.S. government research and development funding and that the U.S. government is under no obligation to continue to support development of our products and can cease such support at any time; the risk that acceptance onto the RNCP Product Development Pipeline or other governmental and non-governmental development programs will not guarantee ongoing development or that any such development will not be completed or successful; the risk that the FDA does not agree with the Company's proposed development plans for its programs; the risk that the Company's development programs and studies may not be successful and, even if successful, such studies and results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional studies may be required; the risk that the Company will not successfully commercialize its products; as well as risks 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 any necessary commercial companion diagnostics; (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®; (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 April 10, 2025. 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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Category: Commercial

[1] IQVIA XPO Data on file

[2] Chey W, Howden C, Moss S, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori infection. Am J Gastroenterol. 2024;119:1730-53.

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

[4] Sharara AI, Alsohaibani FI, Alsaegh A, Al Ejji K, Al Awadhi S, Malfertheiner P, Karam SA, Al-Taweel T. First regional consensus on the management of Helicobacter pylori infection in the Middle East. World J Gastroenterol 2025; 31(27): 107138 [PMID: **40741103** DOI: **10.3748/wjg.v31.i27.107138**]

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

[6] Ilic M, Ilic I. Epidemiology of stomach cancer. World J Gastroenterol. 2022 Mar 28;28(12):1187-1203. doi: 10.3748/wjg.v28.i12.1187. PMID: 35431510; PMCID: PMC8968487.

[7] Resistance rates as determined by in vitro testing of 345 H. pylori isolates collected at baseline from patients enrolled in the Talicia pivotal trial

[8] 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.

[9] 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).

[10] Chey et al. Am J Gastroenterol. 2024

[11] Kumar S, et al. Risk Factors and Incidence of Gastric Cancer After Detection of Helicobacter pylori Infection: A Large Cohort Study. Gastroenterology. 2020;158(3)

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

[13] Hooi JKY, et al. Global Prevalence of Helicobacter Pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology. 2017;153(2):420–429.

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

[15] Malfertheiner, P., Camargo, M.C., El-Omar, E. et al. Helicobacter pylori infection. Nat Rev Dis Primers 9, 19 (2023). **https://doi.org/10.1038/s41572-023-00431-8**

[16] 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.

[17] 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.

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

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