NEWS RELEASE

Joint U.S. Commercialization of RedHill's Talicia® Commences

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The full sales and operational launch of Talicia, under the joint commercialization agreement between Talicia Holdings Inc. (THI), a jointly controlled entity of RedHill and Cumberland has started and is now being rolled out to support accelerated market penetration and expanded reach

Focused on unlocking the full market potential of Talicia, the #1 branded U.S. gastroenterologist-prescribed H. pylori therapy[1], THI and Cumberland will manage the launch and ongoing joint commercialization activities

H. pylori infection affects 35% of the U.S. adult population and an estimated 1.6 million U.S. patients are treated annually[2]. Talicia is the only FDA-approved all-in-one, low-dose rifabutin-based H. pylori therapy addressing antibiotic resistance and is recommended as an empiric first-line H. pylori therapy in the American College of Gastroenterology (ACG) Clinical Guideline[3]

RALEIGH, N.C. and TEL-AVIV, Israel, Feb. 25, 2026 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that the full sales and operational launch of Talicia, under the joint commercialization agreement between Talicia Holdings Inc. ("THI") and Cumberland Pharmaceuticals Inc. (Nasdaq: CPIX), has started and is now being rolled out to support accelerated market penetration and expanded reach. This marks the operational launch of the joint commercialization model previously announced in October 2025, including Cumberland's $4 million strategic investment.

Focused on unlocking the full market potential of Talicia, the #1 branded U.S. gastroenterologist-prescribed H. pylori therapy, THI, a RedHill and Cumberland jointly controlled operating entity (70/30 RedHill/ Cumberland ownership) will manage the launch and ongoing joint commercialization, in coordination with Cumberland.

"H. pylori infection affects 35% of the U.S. adult population and is a leading cause of gastric cancer, responsible for approximately 11,000 related U.S. deaths a year," **said Rick Scruggs, President of THI and RedHill's Chief Commercial Officer.** "Patients should have access to the most effective, clinically differentiated, therapies designed to eradicate H. pylori infection on the first attempt, while mitigating the risk of antibiotic resistance. We are excited to propel Talicia into its next phase of growth in this expanding market. We are integrating key commercial resources and leveraging our combined expertise to balance stronger prescription growth with the delivery of operational efficiencies as we drive to ensure that more patients benefit from this important therapy."

Talicia is the only FDA-approved all-in-one, low-dose rifabutin-based H. pylori therapy designed to address growing antibiotic resistance concerns to other available therapies. It is listed as a first-line H. pylori treatment option in the 2024 American College of Gastroenterology (ACG) Clinical Guideline, which emphasizes using 14-day, "optimized" regimens for the first attempt to maximize cure rates and avoid the need for complex, less-effective salvage therapies[4]. It is patent protected through 2042 and received eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation. Talicia is also the only FDA-approved medication for H. pylori infection with an all-in-one formulation, with the added benefit of simple dosing.

RedHill continues to work towards expanding patient access to Talicia globally. Efforts focused on potential new market entries in the UK and the Middle East, along with work to further broaden market access and secure additional non-dilutive ex-U.S. licensing revenue streams, are ongoing.

About H. pylori

H. pylori is a bacterial infection that affects approximately 35% of the U.S. adult population (an estimated 1.6 million U.S. patients are treated annually) rising to more than 50% globally[4]. 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[5] and approximately 800,000 deaths globally per year), a major risk factor for peptic ulcer disease (90% of cases)[6] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[7]. 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[8].

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.

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[9], with a recent co-commercialization agreement in the U.S. with Cumberland Pharmaceuticals. 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 medical countermeasures including 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); (iii) **RHB-102**, with a planned Phase 2 proof-of-concept study for GLP-1/GIP receptor agonist-associated GI intolerance, positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis, positive results from a U.S. Phase 2 study for IBS-D and potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting. RHB-102 is partnered with Hyloris Pharma (EBR: HYL) for worldwide development and commercialization outside North America; and (iv) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, including COVID-19 and also targeting multiple cancer and inflammatory gastrointestinal diseases.

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

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.

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**.

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 the relationship with Cumberland on the commercialization 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: the risk that co-commercialization of Talicia with Cumberland may not provide the anticipated commercial and operational benefits to RedHill's global Talicia business or to RedHill's financial position, costs or its broader strategic objectives, including accelerating prescriptions, improving operational efficiencies and enabling more patients to benefit from Talicia; the risk regarding the Company's ability to maintain compliance with Nasdaq's listing requirements, including the minimum stockholders' equity requirement; 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: Corporate

[1] IQVIA XPO Data on file

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

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

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

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

[6] 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**

[7] 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.

[8] 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.

[9] 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**.

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