NEWS RELEASE

RedHill and Medi-Cal Deal Maintains Talicia® Reimbursement Without Prior Authorization for 15 Million Californians

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Medi-Cal, California's Medicaid healthcare program, and RedHill have renewed their contract to maintain Talicia's first-line position on the Medi-Cal Fee-For-Service (FFS) Contract Drug List (CDL) with no prior authorization and a $0 copay – a major benefit for approximately fifteen million Californian Medi-Cal patients

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The renewed terms reflect both parties' ongoing commitment to improving patient access and outcomes, reinforcing Talicia's role as an essential treatment option, and follow the new American College of Gastroenterology (ACG) Clinical Guideline[1] for H. pylori infection, listing Talicia as an empirically prescribed first-line option

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Talicia's convenient all-in-one three-times daily (TID) formulation offers a simplified patient experience, supporting high rates of H. pylori eradication without the requirement of prior resistance testing, and continues to be the branded H. pylori therapy most prescribed by U.S. gastroenterologists[2]

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H. pylori infection affects approximately 35% of the U.S. adult population[3] and is classified by the World Health Organization (WHO) as a Group 1 carcinogen, being the strongest known risk factor for gastric cancer[4] and a major risk factor for peptic ulcer disease[5]

RALEIGH, N.C. and TEL AVIV, Israel, Oct. 1, 2024 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the renewal of its contract with Medi-Cal, California's Medicaid healthcare program, to maintain Talicia's first-line position on the Medi-Cal Fee-For-Service (FFS) Contract Drug List (CDL) with no prior authorization and a $0 copay, effective October 1, 2024.

"This renewed agreement with Medi-Cal is great news for the approximately 15 million Californian patients who rely on Medi-Cal and represents a clear vote of confidence in the safety and efficacy of Talicia, which has been listed by Medi-Cal since 2021," **said Rick D. Scruggs, President and Chief Commercial Officer of RedHill Biopharma, Inc**. "The continuing access to Talicia further reflects the strength of our collaboration and aligned commitment to improving patient care. This agreement comes in the wake of the publication of the new American College of Gastroenterology (ACG) Clinical Guideline for H. pylori infection, listing Talicia as an empirically prescribed first-line option – a clear scientific validation of Talicia's effective, simple and convenient all-in-one three-times daily (TID) therapeutic approach, supporting high rates of H. pylori eradication without the need for prior resistance testing."

About H. pylori

H. pylori is a bacterial infection that affects approximately 35%[6] of the U.S. population, with an estimated two million patients treated annually3. Worldwide, around 66% of the population has H. pylori infection[7], which is classified by the World Health Organization (WHO) as a Group 1 carcinogen. It 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]. More than 27,000 Americans are diagnosed with gastric cancer annually[11]. 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[12].

About Talicia®

Talicia® is the only low-dose 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. More specifically, the high rates of H. pylori resistance to clarithromycin have led to significant increases in treatment failures with clarithromycin-based therapies and are a strong public health concern, as highlighted by the ACG, FDA and the 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[13] to their therapy had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm[14].

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.

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 gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs **Talicia®**, for the treatment of Helicobacter pylori (H. pylori) infection in adults[15], and **Aemcolo®**, for the treatment of travelers' diarrhea in adults[16]. RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class oral broad-acting, host-directed SPHK2 selective inhibitor with potential for pandemic preparedness, targeting multiple indications with a U.S. government collaboration for development for Acute Radiation Syndrome (ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 program in oncology; (ii) **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, with non-dilutive external funding covering the entirety of the RHB-107 arm of the 300-patient Phase 2 adaptive platform trial, and is also targeting multiple other cancer and inflammatory gastrointestinal diseases; (iii) **RHB-102**, with potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting, positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; and (v) **RHB-204**, a Phase 3-stage program for pulmonary nontuberculous mycobacteria (NTM) disease.

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 effects of Talicia® in the treatment of Helicobacter pylori infection. 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 that acceptance onto the RNCP Product Development Pipeline 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 opaganib for any indication; the risk that observations from preclinical studies are not indicative or predictive of results in clinical trials; the risk that the FDA pre-study requirements will not be met and/or that the Phase 3 study of RHB-107 in COVID-19 outpatients will not be approved to commence or if approved, will not be completed or, should that be the case, that we will not be successful in obtaining alternative non-dilutive development funding for RHB-107; the risk that RHB-107's late-stage development for non-hospitalized COVID-19 will not benefit from the resources redirected from the terminated RHB-204 Phase 3 study, and that the Phase 2/3 COVID-19 study for RHB-107 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 COVID-19 studies for opaganib and RHB-107 are likely to 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 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® and Aemcolo®; (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 8, 2024. 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

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[1] Chey, William D. MD, FACG1; Howden, Colin W. MD, FACG2; Moss, Steven F. MD, FACG3; Morgan, Douglas R. MD, MPH, FACG4; Greer, Katarina B. MD, MSEpi5; Grover, Shilpa MD, MPH6; Shah, Shailja C. MD, MPH7. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. The American Journal of Gastroenterology 119(9):p 1730-1753, September 2024. | DOI: 10.14309/ajg.0000000000002968

[2] IQVIA XPO Data on file

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

[4] 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.

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

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

[7] **https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/helicobacter-pylori**

[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.

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[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.

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

[12] 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.

[13] 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.

[14] 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).

[15] 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**.

[16] Aemcolo® (rifamycin) is indicated for the treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults. For full prescribing information see: **www.Aemcolo.com**.

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