NEWS RELEASE

RedHill Announces New USPTO Patent Covering Talicia® Through 2034

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U.S. Patent and Trademark Office (USPTO) issues new patent covering Talicia[1] as an all-in-one treatment of Helicobacter pylori (H. pylori), supporting Talicia protection until February 12, 2034

This new patent adds to the existing strong intellectual property portfolio protecting Talicia, including composition of matter and other patents and FDA-granted data exclusivities granted under the GAIN QIDP designation and section 505(b)(2)

Talicia is the only FDA-approved rifabutin-containing all-in-one therapy for the eradication of H. pylori, providing an optimized antibiotic resistance profile and the leading branded first-line therapy prescribed by U.S. gastroenterologists[2] for H. pylori infection, which affects approximately 35% of the U.S. adult population[3]

TEL AVIV, Israel and RALEIGH, N.C., March 11, 2024 /PRNewswire/ -- RedHill Biopharma Ltd. (NASDAQ: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the issue of a new U.S. patent covering Talicia[1] as an all-in-one fixed-dose combination of amoxicillin, omeprazole and rifabutin and its use for the treatment of helicobacter pylori (H. pylori) infection (Patent No. 11,931,463 to be issued March 19, 2024[4]). Talicia is the leading branded first-line therapy prescribed by U.S. gastroenterologists for H. pylori infection, which affects approximately 35% of the U.S. adult population and this patent is expected to provide protection for Talicia until February 12, 2034.

"Talicia is the only FDA-approved rifabutin-containing all-in-one therapy for the eradication of H. pylori. Its components and formulation are optimized to provide patients with the right medications for successful H. pylori eradication with an optimized resistance profile, which is significant in the face of growing microbial resistance to clarithromycin-based regimens," said **Patricia Anderson, RedHill's Senior Vice President of Regulatory Affairs**. "The granting of this new U.S. patent further adds to the strong intellectual property protecting Talicia, including the recently announced patent for treatment regardless of patient Body Mass Index (BMI), several other composition of matter and other patents, and additional FDA-granted data exclusivities granted under the Generating Antibiotic Incentives Now (GAIN) Act Qualified Infectious Disease Product (QIDP) designation and the approval of Talicia under section 505(b)(2)."

About H. pylori infection

H. pylori is a bacterial infection that affects approximately 35% of the U.S. population, with an estimated two million patients treated annually[5]. Worldwide, more than 50% of the population has H. pylori infection, which is classified by the World Health Organization (WHO) as a Group 1 carcinogen. It remains the strongest known risk factor for gastric cancer[6] and a major risk factor for peptic ulcer disease[7] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[8]. More than 27,000 Americans are diagnosed with gastric cancer annually[9]. 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.

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), approved by the U.S. Food and Drug Administration (FDA) for the treatment of H. pylori infection in adults.

Talicia is the only low-dose rifabutin-based therapy approved for the treatment of H. pylori infection and is designed to address H. pylori's high resistance to 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 American College of Gastroenterology, the FDA and the WHO in recent years.

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[10] to their therapy had response rates of 90.3% in the Talicia arm vs. 64.7% in the active comparator arm[11]. 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 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: IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all of the medicines you take, including prescription or non-prescription medications or herbal supplements before starting Talicia. Talicia may affect the way other medicines work, and other medicines may affect the way Talicia works. Do not start any new medications while taking Talicia without first speaking with your healthcare provider.

- You should not take Talicia if you are known to be sensitive to any of the components of Talicia (omeprazole, amoxicillin, rifabutin), penicillins, proton pump inhibitors or rifamycins.
- You should not take Talicia if you are taking rilpivirine-containing products, delavirdine or voriconazole.

Before you take Talicia, tell your healthcare provider about all of your medical conditions, including if you:

- Are pregnant or plan to become pregnant. Talicia may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during your treatment with Talicia.
- Have severe kidney disease or liver disease.

When taking Talicia, do not crush or chew capsules. Do not take Talicia with alcohol.

Call your healthcare provider immediately if while taking Talicia you develop:

- New rash or other skin changes, muscle or joint pains, swelling of any area of the body, severe flu-like symptoms, difficulty breathing, fever, blood in your urine, increased or decreased urination, drowsiness, confusion, nausea, vomiting, ongoing stomach pain, bloody diarrhea, or if diarrhea continues after therapy is completed, weight gain or changes in your eyesight.

What are the common side effects of Talicia?

- The most common side effects of Talicia are diarrhea, headache, nausea, stomach pain, rash, indigestion, mouth or throat pain, vomiting, and vaginal yeast infection. Call your healthcare professional for medical advice about side effects.
- Tell your healthcare provider if you experience tiredness, weakness, achiness, headaches, dizziness,

depression, increased sensitivity to light, or pain when taking a deep breath.
- Talicia may reduce the effectiveness of oral or other forms of hormonal birth-control. You should use an additional non-hormonal highly effective method of birth control while taking Talicia.
- You may experience a brown-orange discoloration of your urine or tears while taking Talicia.
- The information here is not comprehensive. Talk to your healthcare provider to learn more.

APPROVED USE FOR TALICIA

TALICIA is indicated for the treatment of Helicobacter pylori infection in adults.

Click here for the full Prescribing Information for TALICIA.

You are encouraged to report Adverse Reactions to RedHill Biopharma Inc. at 1-833-ADRHILL (1-833-237-4455) or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

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 adults1, and **Aemcolo®**, for the treatment of travelers' diarrhea in adults[12]. 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** / **twitter.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, including, but not limited to, statements regarding the intended use of net proceeds from the offering, may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words and include statements regarding the risk that the Company will not comply with the listing requirements of the Nasdaq Capital Market ("Nasdaq") to remain listed for trading on Nasdaq, the addition of new revenue generating products, out-licensing of the Company's development pipeline assets, timing of opaganib's development for Acute Radiation Syndrome, non-dilutive development funding from RHB-107 and its inclusion in a key platform study. 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 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 HB-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, 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, as well as risks and uncertainties associated with 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 28, 2023. 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] 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] 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] Patent issued by The United States Patent and Trademark Office (USPTO), the federal agency for granting U.S. patents and registering trademarks.

[5] IQVIA Custom Study for RedHill Biopharma, 2019

[6] 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.

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

[8] 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.

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

[10] 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.

[11] 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).

[12] 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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