



NEWS RELEASE

RedHill-Supported Medscape H. Pylori Educational Program to Launch at Major Gastroenterology Congress

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RedHill supports an independent medical education grant that includes a new two-part H. Pylori Continuing Medical Education (CME) program, developed by Medscape aimed at advancing clinical knowledge and improving patient outcomes

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The first part of the program, led by a faculty of William Chey, MD, Vivian Asamoah, MD and Shailja Shah, MD, MPH, will take place May 6 during a major U.S. gastroenterology meeting

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H. pylori is classified by the World Health Organization (WHO) as a Group 1 carcinogen, being the strongest known risk factor for gastric cancer^[1] and a major risk factor for peptic ulcer disease^[2]. With almost half the global population infected by H. pylori^[3], its treatment represents a billion-dollar market opportunity^[4]

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Listed by the American College of Gastroenterology (ACG) Clinical Guideline^[5] as a first-line option, Talicia® is the

leading branded H. pylori therapy prescribed by U.S. gastroenterologists, and the only FDA-approved all-in-one, low-dose rifabutin-based therapy designed to address H. pylori resistance to other antibiotics

RALEIGH, N.C., May 2, 2025 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced its support of an independent medical education grant that includes a new two-part H. Pylori CME program, developed by Medscape and designed to advance clinical knowledge and improve patient outcomes. The first part of the program, a livestreamed event entitled "Let's Get Social About H. pylori Management" led by William Chey, MD, Vivian Asamoah, MD and Shailja Shah, MD, MPH, will take place on May 6 during a major gastroenterology meeting.

RedHill also announces that it will be attending Digestive Diseases Week (DDW) in San Diego and will be available at booth 5312.

Kel Sheldon, PhD, BCMAS, RedHill's Director, Medical Affairs, said: "We are proud to announce that RedHill is supporting a Medscape CME educational program to help meet the need for healthcare professional education on H. pylori infection and treatment options. RedHill believes in the critical need to effectively treat H. pylori at the first attempt amid increasing global concern of rising antibiotic resistance, particularly within the macrolide class of anti-infectives. H. pylori is estimated to be carried by around 50% of the global population and it is the strongest known risk factor for gastric cancer and a major risk factor for peptic ulcer disease. This CME program is targeted to help thousands of specialists, primary care providers, nurses, and advanced practice providers, by providing education on guideline-driven H. pylori management, designed to advance clinical knowledge and improve patient outcomes in H. pylori diagnosis and treatment."

The 2-part Medscape CME program consists of:

Part 1: Let's Get Social About H. pylori Management

Faculty: William Chey, MD; Vivian Asamoah, MD; Shailja Shah, MD, MPH

Date/Time: May 6, 2025, at 12 PM ET / 9 AM PT

Link to Event: Youtube - <https://www.youtube.com/watch?v=2w4mVj3Wq7I>

LinkedIn - <https://www.linkedin.com/events/7320172841423761409/>

Facebook - <https://www.facebook.com/events/1396855524656365>

Overview: A 30-minute expert panel livestream (0.5 CME Credits) on Medscape's social media channels (YouTube,

LinkedIn, Facebook, X), focusing on antibiotic resistance, guideline-directed therapies, and patient adherence in H. pylori management. The event will remain available on-demand post-livestream to support those gastroenterology professionals unable to attend the live event.

Part 2: Expert Roundtable: Overcoming Challenges in H. pylori Diagnosis and Treatment

Faculty: Colin Howden, MD; William Chey, MD; Shailja Shah, MD, MPH

Date/Time: June 2025 (TBD)

Overview: A 30-minute interactive, case-based online discussion (0.5 CME Credits), with Q&A, focusing on antibiotic resistance, adherence to new guidelines, and optimizing patient care pathways, in order to help clinicians translate key guideline updates into clinical practice.

H. pylori infection affects around 50% of the global adult population and is classified, by the World Health Organization (WHO), as a Group 1 carcinogen and the strongest known risk factor for gastric cancer (causing between 70% to 90% of cases)[6] and a major risk factor for peptic ulcer disease (causing 90% of cases)[7].

Talicia, the only FDA-approved all-in-one, low-dose rifabutin-based therapy designed to address H. pylori resistance to other antibiotics, is the leading branded H. pylori therapy prescribed by U.S. gastroenterologists and is listed by ACG Clinical Guideline as an empiric first-line option. Talicia is also launched in the United Arab Emirates (UAE) and the Company recently announced its plan to submit a Marketing Authorisation Application (MAA) for Talicia in the UK, which if approved may be accepted by some additional countries as a reference for their own approval processes, which could expedite ongoing discussions with prospective territorial commercialization partners for Talicia.

About H. pylori

H. pylori is a bacterial infection that affects approximately 35% of the U.S. population^[8], with an estimated two million patients treated annually. Worldwide, around 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 and a major risk factor for peptic ulcer disease and gastric mucosa-associated lymphoid tissue (MALT) lymphoma^[9]. More than 27,000 Americans are diagnosed with gastric cancer annually^[10]. 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^[11].

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 has received 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 is also approved by the United Arab Emirates (UAE) Ministry of Health and was launched there by Ghassan Aboud Group (GAG) in August 2024.

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 ($\geq 1\%$) 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. 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^[12], with submission planned for marketing authorization in other territories. 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 anticancer, anti-inflammatory and antiviral activity, targeting multiple indications with U.S. Government and academic collaborations for development for radiation and chemical exposure indications such as Gastrointestinal-Acute Radiation Syndrome (GI-ARS), a Phase 2 study in prostate cancer in combination with Bayer's darolutamide and a Phase 2/3 program for hospitalized COVID-19 patients; (ii) **RHB-204**, an all-in-one, fixed-dose, orally administered, combination antibiotic therapy with a planned Phase 2 study for Crohn's disease and Phase 3-stage for pulmonary nontuberculous mycobacterial (NTM) disease; (iii) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (iv) **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 (v) **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. 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 / twitter.com/RedHillBio.

Forward Looking Statement

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. 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 regain and 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 of market and other conditions and 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

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[12] 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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