NEWS RELEASE

RedHill Biopharma to Submit FDA-Approved Talicia® for UK Marketing Authorisation

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RedHill plans to submit UK MAA[1] for Talicia for H. pylori infection, using MHRA's[2] new fast-track approval process, referencing FDA approval, with potential UK approval in Q4/25

Listed by ACG[3] Clinical Guideline 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

Talicia is also approved and launched in the UAE[4] and additional countries may accept UK MHRA approvals as a reference for their own marketing approval processes

H. pylori infection is a billion-dollar market opportunity affecting approximately 40% of the UK adult population,[5] a third of the U.S. adult population and over 50% of the global adult population[6]

RALEIGH, N.C., March 18, 2025 /PRNewswire/ -- **RedHill Biopharma Ltd.** (NASDAQ: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced its plan to submit a UK Marketing Authorisation Application (MAA) for Talicia for treatment of helicobacter pylori (H. pylori) infection under the Medicines and Healthcare products Regulatory Agency's (MHRA) International Recognition Procedure (IRP), a fast-track regulatory process for UK drug approvals based on a recognized reference approval. Utilizing the U.S. Food and Drug Administration (FDA) approval of Talicia as reference, potential UK approval could be received as early as

the fourth quarter of 2025.

Talicia, 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, is listed in the American College of Gastroenterology (ACG) Guideline as a first-line treatment option and is the number one branded H. pylori therapy prescribed by U.S. gastroenterologists. Some additional countries may accept UK MHRA approvals as a reference for their own approval processes which could expedite ongoing discussions with prospective territorial commercialization partners for Talicia.

H. pylori infection affects approximately 35% of the U.S. adult population and over 50% of the global adult population[7]. It 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) and a major risk factor for peptic ulcer disease (causing 90% of cases)[8].

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "The American College of Gastroenterology (ACG) Guideline specifically recommends against the use of clarithromycin as part of any H. pylori treatment regimen without prior susceptibility testing. Resistance to both clarithromycin and levofloxacin, estimated at up to 40%, has been rising significantly and is linked to high H. pylori treatment failure rates – with more than one in three patients failing on standard proton pump inhibitor-clarithromycin triple therapy when used in the face of known clarithromycin resistance[9]. Talicia is now the leading prescribed branded H. pylori therapy by U.S. gastroenterologists, with the ACG Guideline listing it as first-line treatment option for H. pylori infection, based on Talicia's proven superior efficacy – up to 90% effective - and safety, zero to minimal rifabutin resistance, and its convenient FDA-approved three-times daily (TID) 'breakfast, lunch, and dinner' dosing, providing for easier adherence.[10,11,12] Almost 40% of the UK population are infected by H. pylori[13, 14] and 18 people are diagnosed with gastric cancer in the UK every day[15], despite confirmed eradication of H. pylori infection leading to a 75% decreased risk of gastric cancer.[16] We are committed to expanding the global access and sales of Talicia following approvals in the U.S. and UAE[4], and planned UK submission, and we are exploring opportunities with potential commercialization partners in this global predicted billion-dollar market."

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.

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[17]. 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 GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 program study in prostate cancer in combination with Bayer's darolutamide; (ii) **RHB-204** with a planned Phase 2 study for Crohn's disease and Phase 3-stage for pulmonary nontuberculous mycobacteria (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** / **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 submission of Talicia® for UK Marketing Authorisation and any approval thereof and 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: the risk that the

Company may not submit a UK MAA for Talicia and if it does that submission may not be successful; the risk that the development of RHB-204 for Crohn's disease may not be completed and if completed may not be successful; the risk that the Company will not benefit from its agreement with Hyloris as currently anticipated; 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 observations from preclinical studies are not indicative or predictive of results in clinical trials; 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 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: R&D

[1] MAA refers to Marketing Authorisation Application
[2] MHRA refers to Medicines and Healthcare products Regulatory Authority
[3] ACG refers to American College of Gastroenterologists
[4] UAE refers to United Arab Emirates
[5] https://gutscharity.org.uk/advice-and-information/conditions/helicobacter-pylori/
[6] Hooi JKY, et al. Global Prevalence of Helicobacter Pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology. 2017;153(2):420–429.
[7] Hooi JKY, et al. Global Prevalence of Helicobacter Pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology. 2017;153(2):420–429.
[8] https://juvisepharmaceuticals.com/our-therapeutic-areas/gastroenterology/
[9] Chey et al. Am J Gastroenterol. 2024.
[10] Resistance rates as determined by in vitro testing of 345 H. pylori isolates collected at baseline from patients enrolled in the Talicia pivotal trial.
[11] 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.
[12] 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).
[13] https://gutscharity.org.uk/wp-content/uploads/2019/01/Guts-UK-Helicobacter-pylori-Leaflet.pdf
[14] Hooi JKY, et al. Global Prevalence of Helicobacter Pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology. 2017;153(2):420–429.
[15] https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/stomach-cancer
[16] 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)
[17] 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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