NEWS RELEASE

RedHill Biopharma Secures Allowance of Key Chinese Patent Application for Proprietary COVID-19 Treatment, RHB-107

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Strong Use of Composition-of-Matter Coverage: Patent protects the molecular structure of RHB-107, providing market exclusivity beyond method-of-use claims

COVID-19 Therapeutic Use: Includes coverage for treatment of SARS-CoV-2, including wild-type and emerging variants

This patent grant enhances RedHill's strategic positioning in the global COVID-19 therapeutic space, a market still expected to be worth more than $3 billion in 2025[1], and expands its patent footprint in Asia, a key pharmaceutical market

RHB-107 successfully met the primary endpoint of safety and tolerability, delivering promising reduction in hospitalization efficacy results in a U.S. Phase 2 COVID-19 study[2]. Additional clinical data expected from the externally non-dilutive funded PROTECT study, supported by the U.S. Department of Defense

RHB-107 is a novel, patient-friendly oral, once-daily, host-directed potential broad-acting antiviral expected to act independently of viral spike protein mutations[3]

RALEIGH, N.C. and TEL-AVIV, Israel, April 28, 2025 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that the China National Intellectual Property Administration ("CNIPA") has formally allowed a critical use of composition-of-matter patent for RedHill's proprietary investigational compound RHB-107 (upamostat), a potential oral treatment for COVID-19 (patent application No. 202311591091.6).

"This newly allowed Chinese patent application is a significant success, enhancing RedHill's strategic positioning in the global COVID-19 therapeutic space – a market still expected to be worth more than three billion dollars in 2025. It provides broad and robust protection of the use of RHB-107, including its structure in oral formulations targeting SARS-CoV-2 infections, including both wild-type and naturally occurring variants and expanding its patent footprint in Asia, a key pharmaceutical market," **said Guy Goldberg, RedHill's Chief Business Officer**. "It underscores the uniqueness of our antiviral candidate and further strengthens our global intellectual property portfolio as we advance development of a much-needed oral candidate for early, community-based (non-hospitalized) treatment of COVID-19, which still represents a considerable threat to vulnerable patients. As a novel, potentially broad-acting, host-directed antiviral that is expected to act independently of viral spike protein mutations, RHB-107, if approved, could provide a much-needed additional option for use in the early COVID-19 treatment space, alongside Pfizer's Paxlovid."

Data from RHB-107's U.S. Phase 2 study, **published in the International Journal of Infectious Diseases**, showed a 100% reduction in hospitalization due to COVID-19, with zero patients (0/41) on the RHB-107 arms versus 15% (3/20) hospitalized for COVID-19 on the placebo-controlled arm (nominal p-value=0.0317). The study also showed an approximately 88% reduction in reported new severe COVID-19 symptoms after treatment initiation, with new severe COVID-19 symptoms reported by only 2.4% of the RHB-107 treated group (1/41) compared to 20% (4/20) of patients in the placebo-controlled arm (nominal p-value=0.036). Further post-hoc analysis showed faster recovery periods from severe COVID-19 symptoms with a median of 3 days to recovery with RHB-107 compared to 8 days with placebo. Additional clinical data is expected from the externally non-dilutive funded PROTECT study, supported by the U.S. Department of Defense.

About RHB-107 (upamostat)

RHB-107 is a proprietary, first-in-class, once-daily orally administered investigational antiviral, that targets human serine proteases involved in preparing the spike protein for viral entry into target cells. Because it is host-cell targeted, RHB-107 is expected to also be effective against emerging viral variants with mutations in the spike protein. RHB-107 is well tolerated; in the initial COVID-19 study, among 41 patients only one reported a drug-related adverse reaction (a mild, self-limited, rash).

In addition, RHB-107 inhibits several proteases targeting cancer and inflammatory gastrointestinal disease. RHB-

107 has undergone several Phase 1 studies and two Phase 2 studies, demonstrating its clinical safety profile in approximately 200 patients[4].

RedHill acquired the exclusive worldwide rights to RHB-107, excluding China, Hong Kong, Taiwan and Macao, from Germany's Heidelberg Pharma AG (FSE: HPHA) (formerly WILEX AG) for all indications.

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[5], 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 the CNIPA does not grant the patent in a timely manner or at all; 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.

Category: R&D

[1] **https://www.cognitivemarketresearch.com/covid-19-therapeutics-market-report**
[2] A randomized, placebo-controlled pilot study of upamostat, a host-directed serine protease inhibitor, for outpatient treatment of COVID-19 Plasse, Terry F et al. International Journal of Infectious Diseases, Volume 128, 148 – 156.
[3] Preliminary data from a recent in vitro study.
[4] **https://www.ijidonline.com/article/S1201-9712**(22)00638-5/fulltext.
[5] 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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