NEWS RELEASE

# RedHill Announces New Opaganib Chinese Patent Against Ebola Virus Valid Through 2035

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The new Chinese patent for opaganib as a therapy for inhibition of single-stranded RNA virus replication (notably Ebola Disease Virus) is valid through 2035 and adds to opaganib's strong global intellectual property portfolio across multiple indications

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U.S. Army studies suggest that opaganib may be the first host-directed molecule to show activity in vivo in Ebola virus disease, delivering a statistically significant increase in survival; separately, opaganib demonstrated robust synergistic effect in vitro when combined with remdesivir (Veklury®; Gilead Sciences, Inc.), improving viral inhibition while maintaining cell viability

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A host-directed and potentially broad acting twice-daily oral, small molecule, opaganib is in development for multiple indications, including COVID-19, acute respiratory distress syndrome, oncology and two U.S. government-sponsored countermeasures programs for Acute Radiation Syndrome and Sulfur Mustard exposure. It has a demonstrated safety and efficacy profile, and is well-suited to counter nuclear / chemical exposure and viral pandemic scenarios, being viral mutation-resistant, and easy to administer and distribute

TEL-AVIV, Israel and RALEIGH, N.C., May 6, 2024 /PRNewswire/ -- RedHill Biopharma Ltd. (NASDAQ: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the issue of a new Chinese patent Notice of Allowance covering opaganib[1] as a therapyg for inhibition of single-stranded RNA virus replication (notably Ebola Disease Virus) from the Chinese National Intellectual Property Administration (CNIPA), valid through 2035 (Chinese Patent Application No.: 202110229970.9 issued April 29, 2024).

"This new patent adds to the existing intellectual property portfolio protecting opaganib across multiple indications and represents the first China patent in the Ebola patent family," **said Guy Goldberg, RedHill's Chief Business Officer**. "U.S. Army studies suggest that opaganib may be the first host-directed molecule to show activity in vivo in Ebola virus disease, delivering a statistically significant increase in survival. Targeting multiple indications, including selection by two U.S. government countermeasures programs for Acute Radiation Syndrome and Sulfur Mustard exposure, oral opaganib, has a demonstrated safety and efficacy profile and is well-suited to viral pandemic scenarios, being viral mutation-resistant, and easy to administer and distribute."

**About Ebola virus disease:**

According to the Centers for Disease Control and Prevention (CDC), Ebola disease is a rare and often deadly illness, caused by infection by one of a group of four viruses, known as ebolaviruses, that are found primarily in sub-Saharan Africa and are known as: Zaire, Sudan, Taï Forest (formerly Côte d'Ivoire) and Bundibugyo. Transmission of the disease is mostly through contact with an infected animal (bat or nonhuman primate) or a sick or dead person infected with an ebolavirus. The course of the illness typically progresses from "dry" symptoms initially (such as fever, aches and pains, and fatigue), and then progresses to "wet" symptoms (such as diarrhea, vomiting and unexplained hemorrhaging, bleeding or bruising) as the person becomes sicker. There are currently only two FDA-approved therapies to treat EVD caused by the Ebola virus, species Zaire ebolavirus, in adults and children; Inmazeb™ (atoltivimab/maftivimab/odesivimab, Regeneron Pharmaceuticals, Inc), a combination of three monoclonal antibodies and Ebanga™ (ansuvimab-zykl, **Ridgeback Biotherapeutics, LP**), a single monoclonal antibody. Both are intravenously infused direct acting monoclonal antibody antivirals that bind to glycoproteins on the Ebola virus's surface to prevent the virus from entering a person's cells. There is an urgent need for host-directed small molecule therapies that may be effective against multiple strains of ebolavirus, less likely to be impacted by viral mutation, and that are easy to store, distribute and administer, especially in areas where healthcare services and infrastructures may be sub-optimal.

**About Opaganib (ABC294640)**

Opaganib, a proprietary investigational host-directed and potentially broad-acting drug, is a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anticancer, anti-inflammatory and antiviral activity, targeting multiple potential diseases, including gastrointestinal acute radiation syndrome (GI-ARS), COVID-

19, other viruses as part of pandemic preparedness, and cholangiocarcinoma (bile duct cancer).

Opaganib's host-directed action is thought to work through the inhibition of multiple pathways, the induction of autophagy and apoptosis, and disruption of viral replication, through simultaneous inhibition of three sphingolipid-metabolizing enzymes in human cells (SPHK2, DES1 and GCS).

Opaganib was selected by the U.S. government's Radiation and Nuclear Countermeasures Program (RNCP), led by the National Institute of Allergy and Infectious Diseases, part of the HHS National Institutes of Health, for the nuclear medical countermeasures product development pipeline as a potential treatment for Acute Radiation Syndrome (ARS).

Opaganib has demonstrated antiviral activity against SARS-CoV-2, multiple variants, and several other viruses, such as Influenza A and Ebola. Opaganib delivered a statistically significant increase in survival time when given at 150 mg/kg twice a day (BID) in a United States Army Medical Research Institute of Infectious Diseases (USAMRIID) in vivo Ebola virus study, making it the first host-directed molecule to show activity in Ebola virus disease. Opaganib also recently demonstrated a distinct synergistic effect when combined individually with remdesivir (Veklury®, Gilead Sciences Inc.), significantly improving potency while maintaining cell viability, in a U.S. Army-funded and conducted in vitro Ebola virus study.

Being host-targeted, and based on data accumulated to date, opaganib is expected to maintain effect against emerging viral variants. In prespecified analyses of Phase 2/3 clinical data in hospitalized patients with moderate to severe COVID-19, oral opaganib demonstrated improved viral RNA clearance, faster time to recovery and significant mortality reduction in key patient subpopulations versus placebo on top of standard of care. Opaganib has demonstrated its safety and tolerability profile in more than 470 people in multiple clinical studies and expanded access use. Data from the opaganib global Phase 2/3 study was published in **medRxiv**.

Opaganib has received Orphan Drug designation from the FDA for the treatment of cholangiocarcinoma and has undergone studies in advanced cholangiocarcinoma (Phase 2a) and prostate cancer. Opaganib also has a Phase 1 chemoradiotherapy study protocol ready for FDA-IND submission.

Opaganib has also shown positive preclinical results in renal fibrosis, and has the potential to target multiple oncology, radioprotection, viral, inflammatory, and gastrointestinal indications.

**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[2], and **Aemcolo®**, for the treatment of travelers' diarrhea in adults[3]. 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**.

[1] Opaganib is an investigational new drug, not available for commercial distribution.
[2] 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**.
[3] 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**.

**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 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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