NEWS RELEASE

# RedHill Announces Positive MHRA Meeting and Planned UK Marketing Authorisation Application of RHB-102 (BEKINDA®) for Oncology Support

2/16/2023

- UK MHRA scientific advice meeting deems RHB-102 (BEKINDA®) data supportive of submission for approval for chemotherapy and radiotherapy induced nausea and vomiting (CINV/RINV)
- RHB-102 UK Marketing Authorisation Application (MAA) submission planned for 2H/23
- If approved for marketing by the MHRA, RHB-102 could become the first oral 24hr extended-release 5-HT3 antiemetic drug in the UK indicated for the treatment of CINV/RINV

TEL-AVIV, Israel and RALEIGH, N.C., Feb. 16, 2023 /PRNewswire/ -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that following a positive pre-MAA meeting it plans to submit a Marketing Authorisation Application (MAA) to the UK Medicines & Healthcare products Regulatory Agency (MHRA) seeking approval for RHB-102 (Bekinda)[1] for oncology support (management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy, also referred to as CINV and RINV) in adults and children over the age of 12.

"This green light for submission from the UK's MHRA is a major milestone towards potential approval and commercialization of RHB-102 in the UK for treating chemotherapy and radiotherapy induced nausea and vomiting. The MHRA pre-MAA scientific advice meeting evaluated the available RHB-102 clinical and pharmacokinetic data generated to date," **said Gilead Raday, RedHill's Chief Operating Officer and Head of R&D**. "Following the positive

input from the MHRA pre-MAA review team we aim to complete our submission of for marketing authorization application of RHB-102 to the UK regulatory authorities in the second half of this year."

RHB-102 is a proprietary 24-hr bimodal release, once-daily oral tablet formulation of ondansetron, a 5-HT3 antagonist considered the gold standard in the treatment and prevention of CINV/RINV. Between 70-80% of patients undergoing chemotherapy or radiotherapy will experience nausea and/or vomiting. The global CINV/RINV market is estimated to be worth over $10 billion by 2031, with the UK market expected to grow at 6.4% CAGR, accounting for around 20% of the European market[2].

Data to support the submission was generated from several clinical studies including the successful U.S. Phase III GUARD study with RHB-102 24 mg for acute gastroenteritis and gastritis[3].

**About RHB-102 (BEKINDA ® ):**

RHB-102 is a proprietary, bimodal release, once-daily oral pill formulation of the antiemetic drug ondansetron, targeting several gastrointestinal indications. RHB-102 24 mg is intended to provide patients with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet. If approved for marketing by the MHRA, RHB-102 24 mg could become the first oral 24hr extended-release 5-HT3 antiemetic drug in the UK indicated for the treatment of CINV/RINV.

The RHB-102 Phase III GUARD gastroenteritis study results were **published in JAMA Network Open**3. The RHB-102 Phase II IBS-D study results were **published in The American Journal of Gastroenterology**[4].

**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[5], and **Aemcolo®** for the treatment of travelers' diarrhea in adults[6]. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (ABC294640)**, a first-in-class oral broad-acting, host-directed, SK2 selective inhibitor targeting multiple indications, including for pandemic preparedness, with a Phase 2/3 program for hospitalized COVID-19 and a Phase 2 program in oncology and a radiation protection program ongoing; (iii) **RHB-107** (**upamostat**), an oral broad-acting, host-directed serine protease inhibitor with potential for pandemic preparedness, is in late-stage development for treatment of non-hospitalized symptomatic COVID-19, and is targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; and (v) **RHB-102** (**Bekinda)**, with expected 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. More information about the Company is available at **www.redhillbio.com**/ **twitter.com/RedHillBio**.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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 the risk that RHB-102 will not be submitted to the UK's MHRA for approval in CINV/RINV, and if submitted may not be approved and if approved may not be successfully commercialized, as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical 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 preclinical studies or clinical trials (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 and sustain 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, preclinical 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 commercial products 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 events using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other companies and technologies within the Company's industry. 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 March 17, 2022, and the Company's Report on Form 6-K filed with the SEC on November 10, 2022. 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

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[1] BEKINDA® (RHB-102) is an investigational new drug, not available for commercial distribution.

[2] **https://www.factmr.com/report/chemotherapy-induced-nausea-and-vomiting-cinv-treatment-market**

[3] Silverman RA, House SL, Meltzer AC, et al. Bimodal release ondansetron for acute gastroenteritis among adolescents and adults. JAMA Network Open 2019;2(11):e1914988.

[4] Plasse TF, Barton G, Davidson E, et al. Bimodal release ondansetron improves stool consistency and symptomatology in diarrhea-predominant irritable bowel syndrome: a randomized, double-blind trial. Am J Gastroenterol 2020;115:1466-73.

[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**.

[6] 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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