Press Release

RedHill Biopharma Announces Publication of RHB-102 Gastroenteritis Phase 3 Study Results in JAMA

TEL-AVIV, Israel and RALEIGH, N.C., Nov.12, 2019 RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases, today announced the publication of results from the Company's Phase 3 study with RHB-102 (Bekinda®)[1] in acute gastroenteritis (the GUARD study) in the *Journal of the American Medical Association* (*JAMA*) *Network Open*.

The article[2], entitled "Bimodal Release Ondansetron for Acute Gastroenteritis Among Adolescents and Adults" became available online as an open-access article on November 8, 2019, *JAMA Netw Open.* 2019;2(11):e1914988. doi:10.1001/jamanetworkopen.2019.14988

The article describes the positive results from the first Phase 3 study with RHB-102 (Bekinda) in acute gastroenteritis. The double-blind, placebo-controlled, parallel-group randomized trial treated subjects ages 12 years and older who presented with frequent vomiting resulting from acute gastroenteritis. The clinical study was conducted in 21 emergency and urgent care departments in the United States.

The GUARD study met its primary endpoint, prevention of further vomiting for at least 24 hours among adolescents and adults with gastroenteritis-related emesis without the usage of intravenous hydration or rescue medication. Further, the results demonstrated that RHB-102 (Bekinda) is well tolerated and can be safely administered to patients with acute gastroenteritis. The authors conclude that orally-administered RHB-102 (Bekinda) is an effective antiemetic among adolescents and adults

[1] RHB-102 (Bekinda®) is an investigational new drug, not available for commercial distribution. Bekinda® is a proposed tradename and is subject to FDA review and approval.

[2] The article was authored by: Robert Silverman, MD, MS; Stacey House, MD, PhD; Andrew Meltzer, MD; Barry Hahn, MD; Luis Lovato, MD; Jahn Avarello, MD; Joseph Miller, MD, MS; Ira Kalfus, MD; Reza Fathi, PhD; Gilead Raday, MSc; Terry Plasse, MD and Eric Yan, PhD.

with moderate to severe vomiting from acute gastroenteritis and that it may decrease the need for intravenous hydration, or medication and emergency department care to manage acute gastroenteritis.

RHB-102 (Bekinda) is a proprietary, oral, bimodal-release (24 hours), once-daily pill formulation of ondansetron, a drug that prevents vomiting by blocking certain effects of serotonin. Acute gastroenteritis and gastritis are inflammations of the gastrointestinal tract, most commonly caused by a viral infection. Symptoms of gastroenteritis include nausea, vomiting, diarrhea, and abdominal pain. The GUARD study was designed to determine if Bekinda can prevent the need for intravenous (IV) hydration or IV drugs by relieving the vomiting. Bekinda is unique in that it releases drug quickly after administration for fast symptom relief and has a slow-acting matrix that allows the preparation to have a therapeutic effect for up to 24 hours.

RedHill is currently working toward a confirmatory Phase 3 study to support a potential New Drug Application (NDA) for RHB-102 (Bekinda) for the treatment of acute gastroenteritis and gastritis.

RedHill is also developing RHB-102 (Bekinda) in a different dosage for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) and is currently finalizing the design of two pivotal Phase 3 studies for IBS-D.

About RHB-102 (Bekinda®):
RHB-102 (Bekinda) is a proprietary, bimodal extended-release (24 hours) oral tablet formulation of, ondansetron, covered by several issued and pending patents. A positive first Phase 3 clinical study with RHB-102 (Bekinda) for the treatment of acute gastroenteritis and gastritis successfully met its primary endpoint. A positive Phase 2 study with RHB-102 (Bekinda) for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D), presented at the Digestive Diseases Week (DDW) meeting in 2018, also successfully met its primary endpoint.

About RedHill Biopharma Ltd.
RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S., **Donnatal®**, **EnteraGam®**, and **Mytesi®**, and is planning to launch **Aemcolo®** and **Talicia®** in the U.S.[3] In November 2019, the FDA approved Talicia® for marketing in the U.S. for the treatment of *Helicobacter pylori (H. pylori)* infection in adults. RedHill's key clinical late-stage development programs include: (i) **RHB-104,** with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102** (**Bekinda®**)**,** with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study

[3] For full prescribing information see: Aemcolo®: www.Aemcolo.com; Mytesi®: www.Mytesi.com; EnteraGam® https://bit.ly/2N3q7DW; Talicia®: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213004lbl.pdf.

for IBS-D; (iv) **ABC294640 (Yeliva®),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at www.redhillbio.com.

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, without limitation, risks related to the commencement or the timing of a confirmatory Phase 3 study for RHB-102 (Bekinda) for acute gastroenteritis and gastritis and two pivotal Phase 3 studies for RHB-102 (Bekinda) for IBS-D, 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 therapeutic candidates; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number 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®, Aemcolo®, Donnatal®, EnteraGam® and Mytesi®; (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, 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 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 February 26, 2019, as amended on May 15, 2019. 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.

Company contact:
Adi Frish
Senior VP of Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):
Timothy McCarthy, CFA, MBA
Managing Director, Relationship Manager
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com