Press Release

RedHill Biopharma to Present New Phase 3 Data on RHB-105 and RHB-104 at the American College of Gastroenterology 2019 Annual Meeting

TEL-AVIV, Israel and RALEIGH, N.C., October 28, 2019 RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases, today announced that two oral presentations and two posters on two of the Company's leading drug candidates, RHB-105[1] (Talicia®, *H. pylori* infection) and RHB-104 (Crohn's disease) will be presented at the American College of Gastroenterology (ACG) 2019 Annual Scientific Meeting, being held October 25-30, in San Antonio, Texas. In addition to the four presentations at ACG, RedHill will be sponsoring an *H. pylori* Disease State educational presentation in the Exhibitor Theater and will have a booth (#426) located in the Exhibit Hall.

"RedHill is committed to developing promising treatments for unmet medical needs and to improving treatment paradigms across the gastrointestinal field. We look forward to sharing exciting new data with the gastroenterology community at ACG 2019 from our Phase 3 studies with RHB-105 for the eradication of *H. pylori* and RHB-104 for treating Crohn's disease," **said Gilead Raday, Chief Operating Officer**. "Additionally, we congratulate Professor David Graham, M.D. and Kristina Hulten, Ph.D. for being granted awards by the ACG Abstract Selection Committee for their presentations on RHB-105."

RedHill investigators will share key findings from the ERADICATE Hp2 randomized, double-blind, active comparator Phase 3 study with RHB-105 (Talicia) for the eradication of *H. pylori* infection and from the MAP U.S. randomized, double-blind, placebo-controlled Phase 3 study with RHB-104 in moderately to severely active Crohn's disease.

[1] RHB-105 (Talicia®), RHB-102 (Bekinda®), and Yeliva® (opaganib, ABC294640) are investigational new drugs, not available for commercial distribution. Talicia®, Bekinda®, and Yeliva® are proposed tradenames and are subject to FDA review and approval.

Details for oral presentations

Rifabutin (RHB-105) Based Triple Therapy for Helicobacter pylori (HP) Infection Eradication: Results of Pivotal Phase 3 Multi-Center Study (ERADICATE Hp2)[2]

Presenter: Professor David Graham, M.D., MACG of Baylor College of Medicine
Date: 9:50 a.m. CDT on Wednesday, October 30, 2019
Location: Oral Plenary Session #63
Subject: The abstract discusses the positive Phase 3 ERADICATE Hp2 study results, concluding that RHB-105 (Talicia) was found to be safe, effective and well-tolerated in *H. pylori* eradication, and not affected by clarithromycin or metronidazole resistance.
Note: The abstract was granted the Category Award Winner (stomach) by the ACG Abstract Selection Committee.

RHB-104, a Fixed-Dose, Oral Antibiotic Combination Against Mycobacterium avium paratuberculosis (MAP) Infection, is Effective in Moderate to Severe Active Crohn's Disease[3]

Presenter: Professor David Graham, M.D., MACG of Baylor College of Medicine
Date: 9 a.m. CDT on Wednesday, October 30, 2019
Location: Oral Plenary Session #58
Subject: The abstract discusses the efficacy and safety results from the MAP US study, concluding that RHB-104 demonstrated meaningful improvement in efficacy and biomarkers of active inflammation, with exposure-response for each drug component, early onset of response and benefit in patients with and without concomitant anti-TNF or immunosuppressant therapy.

Details for poster presentations:

Clinical Safety of RHB-105: A Novel Rifabutin Based Triple Therapy for the Treatment of Helicobacter Pylori Infection[4]

Presenter: Ira Kalfus, M.D. of RedHill Biopharma
Date: 1 p.m. – 2:15 p.m. CDT on Tuesday, October 29, 2019
Location: Exhibit Halls 3&4, poster #P2660
Subject: The poster abstract discusses the positive Phase 3 ERADICATE Hp2 study results, concluding that RHB-105 (Talicia) is effective in *H. pylori* eradication.

National and Regional U.S. Antibiotic Resistance to Helicobacter pylori Identified from a Phase 3 Clinical Trial of Treating Naïve Patients in the United States[5]

[2] Authored by Prof. David Y. Graham, M.D, MACG, Dr. Yamil A Canaan M.D., Dr. James L. Maher M.D, Greg Weiner, Ph.D., and Ira N. Kalfus, M.D.
[3] Authored by David Graham, M.D., MACG of Baylor College of Medicine.
[4] Authored by Ira N. Kalfus M.D, Dr. Jeff Bullock, M.D., June Almenoff M.D., PhD, FACP, Patricia Anderson, and David Graham, M.D., MACG.
[5] Authored by Kristina G Hulten, Ph.D., Prof. David Y. Graham, M.D., MACG, Aida Bibliowicz Gottlieb MSc, MBA, and Ira N. Kalfus, M.D

Presenter: Associate Professor Kristina Hulten, Ph.D. of Baylor College of Medicine
Date: 1 p.m. – 2:15 p.m. CDT on Tuesday, October 29, 2019
Location: Exhibit Halls 3&4, poster #P2670
Subject: The poster abstract discusses the increasing resistance of *H. pylori* bacteria to standard-of-care antibiotics and the resistance data collected in the ERADICATE Hp2 study, concluding that emerging resistance patterns support the use of RHB-105 (Talicia) for *H. pylori* eradication.
Note: The poster abstract was granted the Presidential Poster Award by the ACG Abstract Selection Committee.

Exhibitor Theatre:

Current State of Helicobacter pylori Disease, Antibiotic Resistance, and Research
RedHill is sponsoring an educational program focusing on the current state of *Helicobacter pylori* disease, antibiotic resistance, and research.

Presenter: Professor William Chey, M.D. of University of Michigan
Date: 1:40 p.m. – 2:15 p.m. CDT Tuesday, October 29, 2019
Location: Exhibit Hall Theater

In addition to the four presentations, RedHill will be sponsoring an *H. pylori* Disease State educational presentation in the Exhibitor Theater. Furthermore, RedHill will have a booth (#426) at the conference located in the Exhibit Hall, where representatives will be available to discuss the Company's current commercially available products.

About RHB-105 (Talicia®)
The U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for RHB-105 for priority review with a target Prescription Drug User Fee Act (PDUFA) action date of November 2, 2019. RHB-105 is an investigational new drug designed to address the increasing resistance of *H. pylori* bacteria to the antibiotics commonly used in current standard-of-care therapies and the imperative need for new treatments[6]. RHB-105 is a novel and proprietary fixed-dose, all-in-one oral capsule combination of two antibiotics, rifabutin, and amoxicillin, and a proton pump inhibitor (PPI), omeprazole. RHB-105 has been investigated in two positive Phase 3 studies in the U.S. for the treatment of *H. pylori*. The confirmatory Phase 3 study of RHB-105 successfully met its primary endpoint, with results demonstrating 84% eradication of *H. pylori* infection with Talicia vs. 58% in the active comparator arm ($p<0.0001$). In this study, RHB-105 achieved 90.3% efficacy in the eradication of *H. pylori* infection vs. 64.7% of the active comparator arm ($p<0.0001$) in the protocol defined PK population that demonstrated adherence based on measurable blood levels.[7] No resistance to rifabutin, a key component of RHB-105, was detected in the study. If approved, RHB-105 would

[6] World Health Organization, Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics, February 2017.
[7] PK population 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.

be eligible for a total of eight years of U.S. market exclusivity with its Qualified Infectious Disease Product (QIDP) designation, in addition to patent protection extending until at least 2034.

About RHB-104

RHB-104 is a proprietary, orally-administered antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties, with positive results from a first Phase 3 study (MAP US). A randomized, double-blind, placebo-controlled first Phase 3 study with RHB-104 for Crohn's disease successfully met both its primary endpoint and key secondary endpoints and presented the benefit of RHB-104, including as an add-on therapy to standard-of-care treatments for Crohn's disease, such as anti-TNFs. RHB-104 was developed based on the hypothesis that Crohn's disease is caused by *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. The development of RHB-104 is consistent with the growing awareness of the possibility that a bacterially-induced dysregulated immune system may contribute to the pathogenesis of various autoimmune diseases of unknown etiology.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.[8]: **Aemcolo® (rifamycin)** - a prescription drug for the treatment of travelers' diarrhea caused by non-invasive E. coli strains; **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi®** - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy. RedHill's key clinical late-stage development programs include: (i) **RHB-105 (Talicia®)** for the treatment and eradication of *Helicobacter pylori* infection with a U.S. NDA submitted and accepted for priority review with a target PDUFA action date of November 2, 2019; (ii) **RHB-104,** with positive results from a first Phase 3 study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iv) **RHB-102** (**Bekinda®**)**,** with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (v) **Yeliva® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory, and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; and (vii) **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.

[8] For full prescribing information see: Aemcolo®: www.Aemcolo.com; Mytesi®: www.Mytesi.com; EnteraGam® https://bit.ly/2N3q7DW.

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 occurrence or timing of the RHB-105 (Talicia®) PDUFA action date, risks related to the commencement or timing of our clinical trials with RHB-104, RHB-204, RHB-102 (Bekinda®) and Yeliva®(ABC294640), risks related to meetings scheduled with the FDA, including with regard to RHB-104 for Crohn's disease, 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; (v) the Company's ability to successfully commercialize and promote 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 and 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.

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