Press Release

RedHill Biopharma Provides H2/2019 R&D Update

TEL-AVIV, Israel and RALEIGH, N.C., September 26, 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 provided a periodic R&D update.

RHB-105 (Talicia®)[1] - *H. pylori* Infection

The New Drug Application (NDA) for RHB-105 (Talicia) is under priority review by the U.S. Food and Drug Administration (FDA), with an assigned target Prescription Drug User Fee Act (PDUFA) action date of November 2, 2019.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

In light of positive data received from the ongoing non-clinical program with RHB-204, RedHill plans to initiate pivotal Phase 3 study activities with RHB-204 for the treatment of pulmonary NTM infections in the fourth quarter of 2019, subject to additional input from the FDA. The study is intended to assess the efficacy and safety of RHB-204 and potentially support its approval as the first stand-alone, first-line treatment for Mycobacterium avium complex (MAC) disease, the most common cause of pulmonary NTM infections[2].

RHB-104 - Crohn's Disease

Following positive top-line results from the Phase 3 study with RHB-104 (MAP US study), the last patient enrolled in the open-label extension Phase 3 study with RHB-104 in Crohn's disease (MAP US2 study) has recently completed their participation in the study. A total of 30 subjects completed 52 weeks of treatment with RHB-104 in the MAP US2 study, with top-line results expected in the

[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.

[2] Wassilew N et al. Pulmonary disease caused by non-tuberculous mycobacteria. Respiration 91.5 (2016): 386-402

fourth quarter of 2019. Following additional regulatory guidance from the FDA on the path for potential approval of RHB-104, RedHill has intensified its collaborations with leading laboratories in the field of detection of *Mycobacterium avium paratuberculosis* (MAP) bacteria in Crohn's disease patients, including Baylor College of Medicine and the University of Central Florida's (UCF) College of Medicine. As previously announced, additional FDA guidance on RHB-104's potential path to approval is expected in the coming months.

RHB-102 (Bekinda®)[1] - Acute Gastroenteritis & Gastritis and Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

In addition to the intended adult labeling of Bekinda for use in the treatment of nausea and vomiting associated with acute gastroenteritis and gastritis and for the treatment of IBS-D, RedHill has recently concluded a positive FDA meeting with regard to the pediatric study plans required to potentially obtain pediatric labeling for Bekinda. RedHill is advancing preparations toward a confirmatory Phase 3 study to support a potential NDA filing for Bekinda for the treatment of nausea and vomiting associated with acute gastroenteritis and gastritis.

Yeliva® (opaganib, ABC294640)[1] - Cholangiocarcinoma and Additional Indications

Yeliva is being investigated in an ongoing Phase 2a study in advanced cholangiocarcinoma (bile duct cancer). The study has achieved its pre-specified efficacy goal for the first stage of the two-stage study design and is expected to complete enrollment of the full cohort by the end of the year. In addition, the National Cancer Institute (NCI) grant that was previously awarded to the Medical University of South Carolina (MUSC) to support a study with Yeliva in hepatocellular carcinoma (HCC) has been diverted to support a Phase 2 study with Yeliva in prostate cancer. The investigator-sponsored study is expected to be initiated by early 2020 at MUSC Hollings Cancer Center and will be led by Dr. Michael B. Lilly. The study is supported by several pre-clinical studies in early and advanced prostate cancer models, suggesting that the administration of Yeliva disrupts multiple oncogenic-signaling pathways that are deregulated in prostate cancer.

The clinical studies with RHB-105 (Talicia), RHB-104 , RHB-102 (Bekinda) and Yeliva are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institute of Health, which provides access to information on publicly and privately-supported clinical studies. (ClinicalTrials.gov Identifiers: NCT03009396, NCT02757105 and NCT03377179, NCT03198507 respectively).

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.: **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 top-line 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.

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 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.

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