Press Release

RedHill Biopharma Provides 2016 R&D Update

RedHill's advanced pipeline includes three Phase III programs, several Phase II programs and additional early-stage programs.

RedHill maintains a strong and debt-free balance sheet, allowing the Company to continue to execute its development plans.

Key potential highlights for 2016 include:

- **RedHill has completed enrollment of over half of the patients in the RHB-104 Phase III study for Crohn's disease and expects interim analysis of the Phase III study in H2/2016**
- **Top-line results from the Phase III study with BEKINDA™ for gastroenteritis are expected in H2/2016**
- **Initiation of a confirmatory Phase III study with RHB-105 for *H. pylori* infection is expected in Q3/16**
- **Initiation of a Phase II study with BEKINDA™ for IBS-D and interim top-line results from the Phase IIa proof-of-concept study with RHB-104 for multiple sclerosis are expected in the coming weeks**
- **Following initial non-clinical studies, RedHill continues to advance its collaboration with a U.S. government agency to test its proprietary experimental combination therapy for treatment of Ebola virus disease**

TEL-AVIV, Israel, March 1, 2016 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced select key research and development milestones and events anticipated in 2016.

RedHill's pipeline includes several Phase III and Phase II-stage programs, as well as earlier–stage development programs. Select potential highlights for 2016 include:

RHB-104 - Crohn's disease (Phase III) and multiple sclerosis (Phase IIa)

- RedHill has completed enrollment of over half of the planned 270 patients in the Phase III MAP US study for Crohn's disease in the U.S. and additional countries. Interim analysis of the MAP US study is expected in the second half of 2016, after half of the patients enrolled in the study complete 26 weeks of treatment. If approved for marketing, RHB-104 is expected to become a potential paradigm changer in the treatment of Crohn's disease, targeting a worldwide market estimated to exceed $6 billion in 2017[1].

- Interim top-line results from the CEASE-MS study, an open label Phase IIa, proof-of-concept clinical study exploring RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (RRMS), are expected in the coming weeks.

- RedHill and Quest Diagnostics (Q Squared Solutions LLC) continue to make progress with the development of the *Mycobacterium avium subspecies paratuberculosis* (MAP) companion diagnostic test following a pre-submission meeting held with the U.S. Food and Drug Administration (FDA) in 2015.

RHB-105 - *H. pylori* bacterial infection (Phase III)

- A meeting with the FDA is scheduled for April 2016 to discuss the planned confirmatory Phase III study with RHB-105 in the U.S. for the treatment of *H. pylori* infection.

- The FDA meeting follows positive top-line results from the ERADICATE Hp first Phase III study with RHB-105, conducted in the U.S., which successfully met its primary endpoint, demonstrating 89.4% efficacy in eradicating *H. pylori* with high statistical significance ($p<0.001$). The Complete Study Report (CSR) is expected in the coming weeks.

- The FDA has granted RHB-105 Qualified Infectious Disease Product (QIDP) designation under the GAIN Act, allowing for a total of eight years of market exclusivity, Fast-Track development and Priority Review status which shortens review time for future marketing applications. RHB-105 is targeting a potential worldwide market estimated at approximately $4.83 billion in 2015[2].

[1] EvaluatePharma, Crohn's disease indication report.

[2] Jerry Rosenblatt, Ph.D., a member of RedHill's Advisory Board and Partner at Foster Rosenblatt, RedHill Biopharma press release: RedHill Biopharma's Investor Webcast Forum Provides Update on the RHB-105 Phase III Program and Potential *H. pylori* Eradication Market, May 18, 2015.

BEKINDA™ (RHB-102) - acute gastroenteritis (Phase III) and IBS-D (Phase II)

- Top-line results from the GUARD Phase III study with BEKINDA™ 24 mg in the U.S. for acute gastroenteritis and gastritis are expected in the second half of 2016. If approved for marketing by the FDA, BEKINDA™ is expected to be the first-ever 5-HT3 antagonist drug indicated for acute gastroenteritis, targeting a potential worldwide market estimated to exceed $650 million annually[3].

- A Phase II study with BEKINDA™ 12 mg for diarrhea-predominant irritable bowel syndrome (IBS-D) is planned to be initiated in the U.S. in the coming weeks, subject to regulatory clearance. The U.S. potential market for IBS-D treatments is estimated to exceed $1.3 billion by 2020[4].

- RedHill is also pursuing potential marketing approval of BEKINDA™ in Europe for the oncology support indications of chemotherapy and radiotherapy-induced nausea and vomiting, pending additional discussions and feedback from European Member States as to whether additional clinical and CMC work is required.

YELIVA™ (ABC294640) - diffuse large B-cell lymphoma (Phase I/II), refractory or relapsed multiple myeloma (Phase I/II) and radioprotection (Phase II)

- A Phase I/II clinical study was initiated to evaluate YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL). The study is being conducted at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans and is supported by a grant awarded to Apogee Biotechnology Corp. ("Apogee"), from which RedHill acquired the rights to YELIVA™, from the NCI Small Business Technology Transfer (STTR) program, as well as additional support from RedHill.

- A Phase I/II study with YELIVA™ for the treatment of refractory or relapsed multiple myeloma is planned to be initiated during the second quarter of 2016. The study will be conducted at Duke University Medical Center and is supported by a $2 million grant from the NCI Small Business Innovation Research Program (SBIR) awarded to Apogee in conjunction with Duke University, with additional support from RedHill.

- A Phase II clinical study to evaluate YELIVA™ as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy is planned to be initiated in the U.S. during the second half of 2016, subject to regulatory and other conditions.

[3] Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727–741 and Company analysis.
[4] GlobalData, EvaluatePharma.

- RedHill is pursuing additional oncology and gastrointestinal indications with YELIVA™ and plans to initiate additional clinical programs, subject to regulatory and other conditions.

MESUPRON® and RP101 - orally-administered oncology drug candidates (Phase II-stage)

- **RP101** - Results from the ongoing pre-clinical studies conducted in collaboration with the Fraunhofer Institute for Cell Therapy and Immunology (IZI), are expected during the first half of 2016. The research collaboration tests RP101 in pre-clinical oncology models, including pancreatic cancer, in combination with standard-of-care chemotherapies, and is intended to support the existing Phase I and Phase II clinical data with RP101 and to assess the drug's clinical development path.

- **MESUPRON®** - Nonclinical studies are currently ongoing and are intended to support the clinical data from previous Phase I and Phase II studies with MESUPRON®.

RIZAPORT™ (RHB-103) - acute migraines

- In 2015, the Federal Institute for Drugs and Medical Devices of Germany (BfArM) granted marketing authorization of RIZAPORT™ 5 mg and 10 mg under the European Decentralized Procedure (DCP), in which Germany served as the Reference Member State. RedHill and IntelGenx Corp. ("IntelGenx") continue to work together to obtain national-phase approvals of RIZAPORT™ in additional European DCP territories.

- RedHill and IntelGenx also continue to work together to bring RIZAPORT™ to the U.S. market. The companies expect to re-submit the RIZAPORT™ New Drug Application (NDA) to the FDA and receive a new PDUFA (Prescription Drug User Fee) date in the fourth quarter of 2016.

Ebola virus disease – early stage, non-clinical development program

- Following positive initial non-clinical studies, RedHill continues to advance its collaboration with a U.S. government agency to test the antiviral activity of its proprietary experimental combination therapy of orally-administered actives for the treatment of Ebola virus disease**.**

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of

proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful top-line results from a first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a planned Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 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; (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 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 establish and maintain corporate collaborations; (vi) 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; (vii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company;

(xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. 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 25, 2016. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

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