Press Release

RedHill Biopharma Business Outlook and Anticipated Key Milestones for 2015

Upcoming milestones include:

- **Top-line data from ongoing first Phase III study with RHB-105 for *H. pylori* infection expected Q2/2015**
- **Top-line data from ongoing Phase III study with BEKINDA™ (RHB-102) for gastroenteritis and gastritis expected Q3-Q4/2015**

TEL-AVIV, Israel, January 5, 2015 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced selected key milestones and events anticipated in 2015.

Dror Ben-Asher, RedHill's CEO, noted: "Heading into 2015, our pipeline is well balanced, with three ongoing Phase III programs and two products for which three marketing applications have been filed, as well as a number of new earlier-stage development programs reflecting our continued commitment to addressing unmet medical needs. We are looking forward to important development and regulatory milestones throughout the year."

Gastrointestinal-Inflammatory Diseases and Oncology

RHB-105 for *H. pylori* bacterial infection

- **Q2/2015** - Top-line data expected from the first Phase III study with RHB-105, currently ongoing in the U.S. (the ERADICATE Hp study).

The Phase III ERADICATE Hp study follows a successful Phase II study which demonstrated eradication rates exceeding 90% in 130 subjects who had previously failed at least one course of standard of care therapy for *H. pylori* infection.

In November 2014, the U.S Food and Drug Administration (FDA) designated RHB-105 as a Qualified Infectious Disease Product (QIDP) under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, intended to encourage new antibiotic drugs for the treatment of serious or life-threatening infections. This designation allows for an additional five years of market exclusivity, Fast-Track status (an expedited development pathway) and Priority Review status (shortened review time for marketing applications).

In addition, RedHill is pursuing a significantly broader indication with RHB-105 than existing treatments by targeting *H. pylori* infection as a first line treatment regardless of ulcer status, and estimates the potential target U.S. market at approximately $1-1.5 billion annually[1]. Approximately two-thirds of the world's population is infected with *H. pylori*, a major cause of chronic gastritis, peptic ulcer disease and gastric cancer[2].

BEKINDA™ (RHB-102) - for gastroenteritis and gastritis, and for chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV respectively)

- **Q3-Q4/2015** - Top-line data expected from the Phase III study for acute gastroenteritis and gastritis (the GUARD study), currently ongoing in the U.S. The results are intended to support potential future submissions of marketing applications in both the U.S. and Europe, targeting an estimated potential worldwide market exceeding $650 million annually[3].

- **H2/2015** - Expected regulatory feedback regarding the European Marketing Authorization Application (MAA) submitted by RedHill in December 2014 for the oncology support indications of CINV and RINV. If approved in Europe, RedHill intends to use post-marketing data, along with data generated from prior studies, to further support a potential New Drug Application (NDA) in the U.S. for CINV.

- **Q2-Q3/2015** - Planned commencement of a Phase IIa proof of concept study for a new undisclosed indication.

RHB-104 - for Crohn's disease and other inflammatory diseases

- **Q2/2015** - Expected announcement of planned timelines for the interim analysis by the independent DSMB (Data Safety and Monitoring Board) and for the completion of the ongoing first Phase III study with RHB-104 for the treatment of Crohn's disease (the MAP US study).

- **H1/2015** - Expected announcement of regulatory and development plan for the *Mycobacterium avium subspecies paratuberculosis* (MAP) diagnostic test following FDA meeting scheduled for January 2015.

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[1] Approximately three million *H. pylori* infected patients are treated per annum in the U.S. (Colin W. Howden, MD, et. al (2007), The American Journal of Managed Care). Market size is estimated by the Company based on the above number and the price of current treatments.

[2] Centers of Disease Control and Prevention (CDC) - http://www.cdc.gov/ulcer/keytocure.htm.

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

- **Q2-Q3/2015** - Potential European regulatory clearance of the Clinical Trial Authorization (CTA) application for the second Phase III study with RHB-104 for the treatment of Crohn's disease (the MAP Europe study).

- **H2/2015** - Top-line interim results expected from the ongoing Phase IIa proof of concept study with RHB-104 for the treatment of multiple sclerosis (MS) (the CEASE-MS study).

- **H2/2015** - Planned commencement of a proof-of-concept study to further assess the efficacy and safety of RHB-104 for the treatment of rheumatoid arthritis (RA).

RHB-106 - encapsulated bowel cleanser

- **Q2-Q3/2015** - Planned initiation of a clinical study by Salix Pharmaceuticals, Inc. ("Salix").

In February 2014, RedHill and Salix entered into an exclusive worldwide license agreement for RHB-106 and other purgative developments.

RedHill received an upfront payment of $7 million and Salix agreed to pay an additional $5 million in subsequent potential milestone payments to RedHill, as well as tiered royalties on net sales ranging from low single digits up to low double digits.

Salix publicly estimated its encapsulated bowel prep prescription share outlook at 20% of the market and annual revenues of $280 million (peak year).

MESUPRON® and RP101 - for GI-oncology indications

- **H2/2015** - Initial data from nonclinical studies which RedHill plans to conduct to further evaluate the mechanisms of action and define the patient populations for its newly acquired Phase II orally-administered oncology drugs targeting GI (pancreatic cancer in particular) and other solid tumors; MESUPRON®, a first-in-class urokinase-type plasminogen activator (uPA) inhibitor, and RP101, a first-in-class heat shock protein 27 (Hsp27) inhibitor.

Other Programs

RIZAPORT™ (RHB-103) - for acute migraines

- **H2/2015** - Expected regulatory feedback regarding the European Marketing Authorization Application (MAA) submitted in October 2014 by RedHill and its Canadian co-development partner IntelGenx Corp. ("IntelGenx").

- **H2/2015** - Expected FDA announcement of a new PDUFA date. RedHill and IntelGenx continue to work with the FDA to address the remaining Chemistry, Manufacturing and Controls (CMC) matters and secure a compliant source of raw material.

- **H1/2015** - RedHill and IntelGenx continue negotiations with potential commercialization partners and, to the extent feasible, plan to conclude discussions with a U.S. commercialization partner.

RHB-101 for heart failure, left ventricular dysfunction and hypertension

- **H1/2015** - A non-binding letter of intent (LoI) for the out-licensing of RHB-101 has been executed between RedHill and a potential European partner for the manufacturing and commercialization of RHB-101 in a specified EU territory, as well as the supply of finished product to RedHill or its sublicensees for the rest of the EU. RedHill plans, to the extent feasible, to complete the above-mentioned transaction during the first half of 2015.

Following a Scientific Advice meeting with the Danish Health and Medicines Authority (DKMA) and a Type B meeting with the FDA, RedHill believes that no further clinical studies will be required prior to submission of the MAA in Europe, and that a comparative bioavailability study and a dose linearity study will be required prior to submission of an NDA to the FDA.

Ebola virus disease - early stage, nonclinical, development program

- **H1/2015** - As part of its commitment to address unmet medical needs, RedHill is planning to commence in the coming weeks a first nonclinical research collaboration with a U.S. government agency to test the antiviral activity of a proprietary experimental combination therapy of orally-administered actives**.**

The Ebola virus is highly prioritized by the U.S. government (as a "Category A" agent) and other governments. RedHill is currently focused on establishing additional early-stage research collaborations with other governments and public health authorities for the development of a treatment for the Ebola virus infection and secondary bacterial infections. The Ebola virus can cause severe hemorrhagic fever in humans and has a mortality rate ranging from 25% to 90%[4].

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing 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; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON®** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101 -** a

[4] WHO – World Health Organization.

once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit 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 and uncertainties associated with (i) the initiation, timing, progress and results of the Company's 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 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 interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi) competitive companies, technologies and 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 February 25, 2014. 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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