Press Release

RedHill Biopharma Provides Update on Development Pipeline and Expected Timing for RHB-105 Phase III Top-Line Results

Key highlights and upcoming anticipated milestones include:

- **Phase III top-line results with RHB-105 for the treatment of *H. pylori* bacterial infection are expected during the third week of June 2015, subject to completion of review requirements**
- **Phase III top-line results with BEKINDA™ for gastroenteritis and gastritis are expected in Q4/15 - Q1/16**
- **Phase III interim analysis of MAP US Crohn's study with RHB-104 expected in H2/16; European applications submitted for a second Phase III Crohn's study with RHB-104**
- **Notice of Allowance received from the USPTO for two new U.S. patents covering RHB-104, expected to be valid until at least 2029**
- **Last patient screened in the Phase IIa Proof of Concept study with RHB-104 for multiple sclerosis, with interim results expected in Q4/15 - Q1/16**
- **Phase Ib/II study of ABC294640 for refractory/relapsed diffuse large B cell lymphoma, supported by the National Cancer Institute, expected to commence in Q2 - Q3/2015**

TEL-AVIV, Israel, June 3, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL), an Israeli biopharmaceutical company focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today provided an update on its development pipeline and anticipated key milestones.

RHB-105 - for *H. pylori* bacterial infection

- Top-line results from the first Phase III clinical study with RHB-105 are expected in the third week of June 2015. The Phase III study (the ERADICATE Hp study) is currently ongoing in the U.S. for the treatment of *H. pylori* bacterial infection, a major cause of chronic gastritis, peptic ulcer disease, gastric cancer, and mucosa associated lymphoid tissue (MALT) lymphoma
- RHB-105 was designated by the FDA as a Qualified Infectious Disease Product (QIDP) under the Generating Antibiotic Incentives Now (GAIN) Act, allowing RedHill to benefit from fast-track development status for RHB-105, priority review, and, if ultimately approved by the FDA, an additional five years of marketing exclusivity, for a total of 8 years
- The 2015 global and U.S. market potential for *H. pylori* eradication therapies, at current branded prices, were recently estimated at approximately $4.83 billion and $1.45 billion, respectively, and could potentially grow with increasing awareness of the health risks associated with *H. pylori* infection and the benefits of its eradication[1]

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

- Top-line results from the Phase III study with BEKINDA™ for acute gastroenteritis and gastritis (the GUARD study), currently ongoing in the U.S., are expected either in the fourth quarter of 2015 or the first quarter of 2016. 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[2]
- A meeting with the FDA is planned during the third quarter of 2015 to discuss the regulatory path of BEKINDA™ for the indications of acute gastroenteritis and gastritis, as well as a potential filing of a New Drug Application (NDA) for CINV
- RedHill recently received feedback from European regulatory agencies regarding the European Marketing Authorization Application (MAA) submitted by RedHill in December 2014 for the oncology support indications of CINV and RINV. Clinical and manufacturing-related comments have been discussed with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and a six-month extension was agreed to, in principle, with the MHRA
- A Phase IIa Proof of Concept study for a new undisclosed indication is planned to commence in the second half of 2015

[1] 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.

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

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

- Interim analysis of the Phase III study with RHB-104 for Crohn's disease (the MAP US study) is expected in the second half of 2016, after half of the 270 patients expected to be enrolled in the study have completed 26 weeks of treatment. The primary endpoint is remission at week 26 of treatment
- The Phase III MAP US study is currently enrolling patients in approximately 80 sites in the U.S., Canada, Israel and New Zealand, with new sites in Australia, New Zealand and Europe currently being added, for a total of up to 120 clinical sites
- Clinical trial applications have been submitted in Europe, and initial comments received and responded to, for RHB-104's second Phase III Crohn's disease study (the MAP EU study) with potential European regulatory clearance expected in the third quarter of 2015
- RedHill recently received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for two new patents covering RHB-104. Once granted, the patents are expected to be valid until at least 2029
- The last patient has been screened in the ongoing Phase IIa Proof of Concept study with RHB-104 for the treatment of multiple sclerosis (MS) (the CEASE-MS study), with interim results expected either in the fourth quarter of 2015 or the first quarter of 2016

ABC294640 - for multiple inflammatory-GI diseases and related oncology indications

ABC294640 is a proprietary, first-in-class, orally administered, new chemical entity (NCE) sphingosine kinase-2 (SK2) inhibitor, which has successfully completed numerous pre-clinical studies and a Phase I study in cancer patients with advanced solid tumors.

ABC294640 targets multiple inflammatory, gastrointestinal and oncology indications within RedHill's therapeutic focus.

- A Phase Ib/II study of ABC294640 for refractory/relapsed diffuse large B cell lymphoma, primarily funded by the National Cancer Institute/STTR, is planned to commence either in the second or third quarter of 2015
- A Phase II study in multiple myeloma is planned, subject to a pending National Cancer Institute/SBIR grant
- A Phase II study to assess ABC294640 as a radio-protectant and radiation enhancer in cancer patients receiving radiotherapy is being planned by RedHill

RHB-106 - bowel cleanser pill

- In February 2014, RedHill and Salix Pharmaceuticals, Inc. ("Salix") entered into a license agreement under which Salix acquired worldwide exclusive rights to RHB-106 and other purgative developments. In April 2015, Valeant Pharmaceuticals International, Inc.

("Valeant") announced the completion of its acquisition of Salix. The RHB-106 program is under review by Valeant following its acquisition of Salix

MESUPRON® - for pancreatic cancer and other solid tumors

- RedHill is preparing nonclinical studies to further evaluate the mechanism of action and define the patient population for MESUPRON®, a Phase II orally-administered small molecule drug targeting pancreatic cancer and other solid tumors. MESUPRON® is a first-in-class urokinase-type plasminogen activator (uPA) inhibitor

RP101 - for pancreatic cancer and other solid tumors

- RedHill is preparing nonclinical studies to further evaluate the mechanism of action and define the patient population for RP101, a Phase II orally-administered small molecule drug targeting pancreatic cancer and other solid tumors. RP101 is a first-in-class heat shock protein 27 (Hsp27) inhibitor

Ebola virus disease - early stage development program

- As part of a previously disclosed nonclinical research collaboration with a U.S. government agency, initial nonclinical studies have been completed, and RedHill is currently planning the next stage of development

RIZAPORT™ (RHB-103) - for acute migraines

- Regulatory feedback regarding the MAA submitted in October 2014 is expected either in the fourth quarter of 2015 or the first quarter of 2016
- RedHill and its Canadian co-development partner IntelGenx Corp. continue to work with the FDA to address the remaining Chemistry, Manufacturing and Controls (CMC) matters, and to secure a compliant source of raw material. The existing source of raw material for RIZAPORT™ has been successfully audited in recent months by non-U.S. regulatory agencies, as well as an independent auditor on behalf of RedHill, and is currently awaiting another FDA inspection, after which, and subject to a successful audit, a new FDA PDUFA date is expected

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered small molecule 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 an ongoing 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) **ABC294640** – a Phase II-stage orally-administered SK2 inhibitor targeting multiple inflammatory-GI diseases and related oncology indications; (vi) **MESUPRON®** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vii) **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; (viii) **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 (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 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; (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 (xi) competitive companies and technologies within the Company's industry; and (xii) 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 26, 2015. 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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