Press Release

RedHill Biopharma Announces Completion of Patient Enrollment in the Phase IIa Study of RHB-104 for Multiple Sclerosis

- **The last patient has been enrolled in the Phase IIa, proof-of-concept clinical study evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (the CEASE-MS study)**

- **Interim results from the Phase IIa CEASE-MS study are expected in Q4/2015 - Q1/16**

- **RHB-104 is also being evaluated as a treatment for Crohn's disease with an ongoing Phase III clinical study (the MAP US study) and a second Phase III study being planned (the MAP EU study)**

TEL-AVIV, Israel, June 9, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that the last patient has been enrolled in the Phase IIa, proof-of-concept clinical study evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing remitting multiple sclerosis (RRMS). RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties.

Seventeen patients were enrolled in the open label Phase IIa study (the CEASE-MS study), which is designed to assess the efficacy and safety of RHB-104 as an add-on therapy to interferon beta-1a in patients suffering from RRMS following 24 weeks of treatment. Patients are evaluated for an additional term of 24 weeks after completing treatment with RHB-104. The primary endpoint of the study is the number of combined unique active lesions after 24 weeks of treatment, as compared to baseline, and secondary endpoints include changes in cytokine levels, *Mycobacterium avium subsp. paratuberculosis* (MAP) status, relapse rate, Expanded Disability Status Scale (EDSS) and safety

and tolerability of RHB-104. The CEASE-MS study is being conducted at two medical centers in Israel and interim results are expected either in the fourth quarter of 2015 or the first quarter of 2016.

Clara Fehrmann, RedHill's Director of Clinical Operations, said: "We are very pleased to have completed patient enrollment in the Phase IIa CEASE-MS study with RHB-104. The CEASE-MS study was initiated following four successful pre-clinical studies and is based on the hypothesis that a bacterially induced dysregulated immune system plays a role in the pathogenesis of multiple sclerosis. We are hopeful that the interim results from the CEASE-MS study, expected in late 2015 or early 2016, will contribute to the understanding of the development of multiple sclerosis and will provide new treatment alternatives for patients suffering from this disease."

RHB-104 is also being evaluated as a treatment for Crohn's disease and is currently undergoing a first Phase III clinical study in the U.S. and other countries (the MAP US study). Interim analysis of the MAP US study is expected in the second half of 2016. The primary endpoint is remission at week 26 of treatment. A second Phase III study with RHB-104 for Crohn's disease is planned in Europe (the MAP EU study) and clinical trial applications have been submitted.

About RHB-104:
Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study), RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by the *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. Clinical trials conducted with earlier formulations of RHB-104, include an Australian Phase III study conducted by Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a long-term population pharmacokinetic (Pop-PK) study is ongoing as part of the Phase III MAP US study. RHB-104 is covered by several issued and pending patents. RedHill is also conducting a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing remitting multiple sclerosis (RRMS).

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development 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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