Press Release

RedHill Biopharma Announces Completion of Dosing in Phase IIa Study of RHB-104 for Multiple Sclerosis

- **Top-line interim results from the Phase IIa proof-of-concept clinical study of RHB-104 in patients treated for relapsing-remitting multiple sclerosis (the CEASE-MS study) are expected by early Q1/2016**

- **The Phase IIa study is intended to evaluate the safety and efficacy of RHB-104 as an add-on therapy to interferon beta-1a following 24 weeks of treatment**

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

TEL-AVIV, Israel, November 30, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli 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 completion of the last dosing and scheduled follow-up patient visit ahead of top-line interim analysis in the Phase IIa proof-of-concept clinical study evaluating RHB-104 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.

The open label Phase IIa study (the CEASE-MS study) is being conducted in two medical centers in Israel. Eighteen patients suffering from RRMS were enrolled in the study, which was designed to assess the efficacy and safety of RHB-104 as an add-on therapy to interferon beta-1a. Patients received 24 weeks of treatment with RHB-104 and are being evaluated for an additional period of 24 weeks after completing treatment. The primary endpoint of the Phase IIa CEASE-MS study is the number of combined unique active lesions after 24 weeks of treatment with RHB-104, as compared to baseline. Additional endpoints include changes

in cytokines, relapse rate, Expanded Disability Status Scale (EDSS) and the safety and tolerability of RHB-104.

Top-line interim results are expected to be announced early in the first quarter of 2016. A full analysis and the final Clinical Study Report (CSR) are expected during the second quarter of 2016.

Clara Fehrmann, RedHill's Director of Clinical Operations, **said:** "The completion of the final dosing in the active treatment phase of the Phase IIa CEASE-MS study is an important milestone in RedHill's RHB-104 development program. Top-line interim results will become available in the coming months and we are hopeful that they will support the hypothesis that RHB-104 may counterbalance a dysregulated immune system which plays a critical role in the pathogenesis of multiple sclerosis."

Multiple sclerosis is an inflammatory, demyelinating and neurodegenerative disease of the central nervous system of uncertain etiology. It exhibits characteristics of both infectious and autoimmune pathology. It is estimated that the worldwide market for multiple sclerosis therapies will exceed $17 billion in 2015[1].

RHB-104 is a multifaceted drug that, in addition to bactericidal properties against intracellular infections, has potentially distinct mechanisms of action that include both anti-inflammation and neuroprotection. The Phase IIa CEASE-MS study was initiated following several successful pre-clinical studies conducted by RedHill with RHB-104. The pre-clinical studies demonstrated that RHB-104 inhibited production of pro-inflammatory cytokines IL-6 and TNF, indicating that RHB-104 could be a potential therapy for inflammatory diseases where these cytokines have been shown to play a critical pathological role.

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 being planned in Europe (the MAP EU study), with Clinical Trial Applications (CTA) already accepted by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and additional European agencies.

About RHB-104:
Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study) and a second Phase III study which is being prepared (the MAP EU 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 *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)

[1] GlobalData Pharma eTrack Multiple Sclerosis Estimated Market Size, November 2015.

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), with top-line interim results expected early in the first quarter of 2016.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company 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; (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; (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 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.

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):
Marcy Nanus
Senior Vice President
The Trout Group
+1-646-378-2927
Mnanus@troutgroup.com