Press Release

RedHill Biopharma Announces Allowance of a Patent in Japan Supporting RHB-104 for Multiple Sclerosis

- **RedHill has received from the Japan Patent Office a Notice of Allowance for a new patent covering RHB-104 for multiple sclerosis (MS), expected to be valid until 2032, once granted**

- **RedHill's robust RHB-104 patent portfolio covering its oral antibiotic combination therapy includes more than 26 patents in many countries, including the U.S., Australia, Canada, Japan and multiple European countries, with additional patent claims being pursued**

- **Top-line final results expected in the coming weeks from the Phase IIa proof-of-concept study evaluating RHB-104 in patients treated for relapsing-remitting multiple sclerosis (the CEASE-MS study)**

- **Encouraging interim results from the Phase IIa CEASE-MS study, after completion of the 24-week treatment period with RHB-104 as an add-on therapy to interferon beta-1a, demonstrated positive safety and efficacy signals that support further clinical development**

- **2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively**

- **A first Phase III clinical study with RHB-104 for Crohn's disease is ongoing (the MAP US study), with an independent safety-focused data and safety monitoring board (DSMB) meeting on track for later this quarter and a second meeting expected in the second quarter of 2017, including an interim efficacy analysis and evaluation of an option for an early stop for success for overwhelming efficacy**

TEL-AVIV, Israel, October 18, 2016 RedHill Biopharma Ltd. (NASDAQ: RDHL) (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 gastrointestinal and inflammatory diseases and cancer, today announced that it has received from the Japan Patent Office a Notice of

Allowance for a new patent covering RHB-104 for the treatment of multiple sclerosis (MS), which is expected to be valid until 2032, once granted. This notice follows RedHill's recent announcement that the counterpart European patent application was approved by the European Patent Office.

RHB-104 is a proprietary, orally-administered, potentially groundbreaking antibiotic combination therapy with potent intracellular, anti-mycobacterial and anti-inflammatory properties. A first Phase III study with RHB-104 for the treatment of Crohn's disease is currently ongoing. RHB-104 is also being evaluated as a treatment for relapsing-remitting multiple sclerosis (RRMS), with top-line final results from a Phase IIa proof-of-concept study expected in the coming weeks (the CEASE-MS study).

The Phase IIa CEASE-MS open-label study was initiated following several successful pre-clinical studies conducted by RedHill and was designed to evaluate RHB-104 as an add-on therapy to interferon beta-1a in patients treated for RRMS. Patients enrolled in the study received 24 weeks of treatment with RHB-104 as an add-on therapy to interferon beta-1a and were then evaluated for an additional 24-week follow-up period during which they were treated with interferon beta-1a alone. Top-line interim results announced in March 2016, after completion of the 24-week treatment period, demonstrated positive safety and efficacy signals, including an encouraging relapse-free rate, Expanded Disability Status Scale (EDSS) scores and MRI results, which support further clinical development.

RedHill's robust RHB-104 patent portfolio, covering its oral antibiotic combination therapy, includes more than 26 patents in many countries, including the U.S., Australia, Canada, Japan and multiple European countries with additional patent claims being pursued.

A first Phase III study with RHB-104 for the treatment of Crohn's disease is currently ongoing (the MAP US study). The randomized, double-blind, placebo-controlled MAP US study is planned to enroll a total of 410 subjects in up to 150 clinical sites in the U.S., Canada, Europe, Australia, New Zealand and Israel. A safety-focused independent data and safety monitoring board (DSMB) meeting is on track to take place in the fourth quarter of 2016. A second independent DSMB meeting is expected in the second quarter of 2017, after the first 205 patients complete 26 weeks of study participation. Patient 205 was randomized in August 2016.

The second DSMB meeting in the MAP US study will include safety and interim efficacy analysis and could potentially provide the opportunity to expedite the data locking process for the final analysis, once the study is complete. Importantly, this independent DSMB meeting will evaluate the option of an early stop for success, according to a pre-specified statistical significance threshold for analysis requiring overwhelming efficacy of RHB-104 versus placebo in the primary endpoint.

RedHill recently announced several improvements and enhancements to the Phase III Crohn's disease program to provide a more comprehensive assessment of RHB-104's treatment effect and bolster the likelihood of the study's success even further. No changes are planned to the MAP US Phase III study's primary endpoint or 90% power. Assuming

enrollment of all 410 planned subjects, completion of patient recruitment is expected by the end of 2017.

The MAP US Phase III study and the CEASE-MS Phase IIa study are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

About Multiple Sclerosis:
Multiple sclerosis (MS) is a chronic inflammatory, demyelinating disease of the central nervous system with an unknown etiology, believed to be multifactorial. A dysfunctional immune system in MS patients causes recurrent inflammatory attacks on the central nervous system (CNS), leading to neurological disability. Diffuse inflammatory and demyelinating lesions, also known as plaques, are the main pathological finding in MS neural tissue. The lesions are primarily found in the spinal cord, optic nerves, brainstem and periventricular white matter. The symptoms of MS are dictated by the location of the lesions within the CNS. Geographic variation in MS distribution, which cannot be solely explained by population genetics, supports the notion that environmental factors also hold etiological importance. There is currently no known cure for MS and available treatments are mainly intended to manage or prevent relapses or reduce symptoms. In 2015, there were estimated to be over 900,000 diagnosed patients with MS worldwide. Approximately 85% of MS patients initially exhibit relapse-remitting disease (RRMS). The 2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively[1].

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, orally-administered, potentially groundbreaking antibiotic combination therapy, 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 Pharmacia/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 the CEASE-MS 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 announced and top-line final results expected in the coming weeks.

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 gastrointestinal and inflammatory diseases and cancer. RedHill's current pipeline of

[1] GlobalData PharmaPoint report, August 2015.

proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful 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 for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON -** a Phase II-stage first-in-class, orally-administered uPA inhibitor, 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, orally-administered Hsp27 inhibitor, 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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