Press Release

RedHill Biopharma Announces New RHB-104 Patent in Japan and Provides Update on Phase III Crohn's Program

- **The Japan Patent Office (JPO) has issued a Decision to Grant a Patent covering RHB-104 with a 2029 expiry date**
- **RedHill has initiated a long-term population pharmacokinetic study with RHB-104 for Crohn's disease, designed to satisfy regulatory requirements for future potential marketing applications**
- **The planned number of clinical sites in the ongoing Phase III RHB-104 MAP US study has been increased to up to 90 sites in the U.S., Canada and Israel, with 44 sites already enrolling patients following regulatory approvals in all three countries**
- **RedHill is preparing a second Phase III study with RHB-104 for Crohn's disease in Europe (the MAP Europe study), planned to commence during the second half of the year**
- **RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties**

TEL-AVIV, Israel, June 5, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage proprietary drugs for the treatment of inflammatory and gastrointestinal diseases and related conditions, including cancer, today reported that the Japan Patent Office (JPO) has issued a Decision to Grant a Patent for a new patent covering RHB-104 in Japan. The patent is expected to be issued during 2014 and will have a 2029 expiry date. RHB-104 is a proprietary antibiotic combination oral capsule formulation for the treatment of

Crohn's disease, currently undergoing a Phase III study in the U.S., Canada and Israel (the MAP US study).

RedHill further noted that it has initiated a long-term population pharmacokinetic (Pop PK) study as part of the ongoing RHB-104 Phase III MAP US study. The Pop PK study, together with other supportive studies, including a recently completed food effect study, a drug-drug interaction (DDI) study currently being reviewed and additional clinical and other studies, are designed to satisfy various regulatory requirements for future potential marketing applications of RHB-104.

In January 2014, the Company reported that it had received preliminary results from a Phase I study with RHB-104 that was designed to evaluate the effect of co-administration of food on the pharmacokinetics of the constituent components of RHB-104 and two metabolites, and the safety and tolerability of RHB-104 under fed and fasting conditions. RedHill has since received the final Clinical Study Report (CSR) which confirms the previously announced preliminary results.

In addition to existing FDA clearance in the U.S., RedHill has received regulatory clearance to commence the Phase III MAP US study in Canadian and Israeli sites, and the first clinical sites in both countries have already initiated patient enrollment. As a result, there are currently 44 clinical sites in the U.S., Canada and Israel actively enrolling patients for the RHB-104 Phase III MAP US study. RedHill has increased the total number of planned clinical sites to up to approximately 90 sites in the U.S., Canada and Israel, and is planning additional clinical sites in other countries.

RedHill has also become an official sponsor of the Crohn's and Colitis Foundation of America ("CCFA") and is working together with the CCFA to create awareness and advance recruitment in the U.S. among the U.S. Crohn’s patient population. As more clinical sites are activated in the coming months, and sufficient clarity is obtained, RedHill aims to provide an update regarding its estimated timeline for completion of recruitment in the Phase III MAP US study.

The Phase III MAP US study is registered on www.ClinicalTrials.gov, a web-based service by the U.S. National Institute of Health which provides public access to information on publicly and privately supported clinical studies.

RedHill is planning to commence a second Phase III study with RHB-104 for Crohn's disease in Europe (the MAP Europe study) following successful Scientific Advice Meetings with the UK and Swedish pharmaceutical regulatory agencies and discussions with key opinion leaders in Europe. The Company is currently in the process of selecting a contract research organization (CRO) for the MAP Europe study. Subject to receiving all the required regulatory approvals and other preparations, the MAP Europe study is planned to commence during the second half of this year.

About RHB-104:
Currently in a Phase III study for the treatment of Crohn’s disease, RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, antimycobacterial 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. The RHB-104 formulation was originally developed by Professor Thomas Borody, a leading innovator of therapeutic

approaches to treating gastrointestinal tract diseases, who also developed the original triple therapy for peptic ulcer disease associated with *H. pylori*. Several clinical trials were conducted with earlier formulations of the drug, including an Australian Phase III study published by Pfizer, as well as other studies, both with earlier formulations and the current formulation of the drug. The formulation of RHB-104 is covered by several issued and pending patents.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, proprietary formulations and combinations of existing drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer and related conditions. RedHill's current pipeline of proprietary products includes: (i) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105 -** an oral combination therapy for *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals Ltd.; (iv) **RHB-103 -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned for the third quarter of 2014; (v) **RHB-102 -** a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting, in advanced development stages for multiple indications, including a Phase III study for an undisclosed indication planned to commence in 2014, and (vi) **RHB-101 -** a 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 and approvals; (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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