Press Release

RedHill Biopharma Announces FDA Clearance for Phase III Study with RHB-102 Planned to Commence in Q3/2014

- **FDA's clearance of RedHill's Investigational New Drug ("IND") amendment allows the initiation of a Phase III clinical study for a new undisclosed indication with RHB-102[1], a proprietary, once-daily, extended release oral pill formulation of the antiemetic drug ondansetron**

- **In parallel to pursuing the new undisclosed indication, RedHill is pursuing marketing approval of RHB-102 for the indications of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively) in Europe and the U.S.**

TEL-AVIV, Israel, May 22, 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, today announced that the U.S. Food and Drug Administration ("FDA") has allowed the initiation of the Company's planned Phase III clinical study for the treatment of a new, undisclosed indication with RHB-102, an extended release oral pill formulation of the antiemetic drug ondansetron. RedHill plans to begin enrolling patients for the Phase III study during the third quarter of 2014.

The double-blind placebo-controlled Phase III study is planned to be conducted in eight clinical sites in the U.S. and will include 320 subjects. Based on prior discussions with the FDA and the UK Medicines and Healthcare Products Regulatory Agency ("MHRA"), the study is intended to support potential future submissions of marketing applications for a new undisclosed indication in both the

[1] FDA clearance to initiate the study was granted by virtue of the lapse of 30 days with no comments received from the FDA to the IND amendment submitted by RedHill.

U.S. and Europe. RedHill estimates that, if the Phase III clinical study is successful and the marketing applications are filed and approved by the FDA and the MHRA, the new indication would significantly expand the potential market for RHB-102.

In parallel to pursuing the new undisclosed indication, RedHill is pursuing marketing approval of RHB-102 for the indications of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively) in Europe and the U.S.

Following a European scientific advice meeting with the UK's MHRA, RedHill recently reported positive results from a comparative bioavailability study comparing RHB-102 and a European reference drug. In light of the positive results from the bioavailability study and data from prior successful clinical studies, and subject to various regulatory requirements, RedHill plans to submit a European Marketing Authorization Application ("MAA") for RHB-102 during the third quarter of 2014 for the indications of CINV and RINV prevention.

Additionally, RedHill announced in March 2014 that it had held a pre-New Drug Application ("pre-NDA") meeting with the FDA regarding the development of RHB-102 for CINV and RINV prevention in the U.S. Following the pre-NDA meeting, and in light of the FDA's feedback, RedHill provided the FDA with additional information and is currently awaiting the FDA's response.

About RHB-102:
RHB-102 is a patent-protected, extended-release (24 hours) oral pill formulation of ondansetron, the active ingredient in GlaxoSmithKline's Zofran® for the prevention of radiotherapy-induced nausea and vomiting ("RINV") and chemotherapy-induced nausea and vomiting ("CINV"). With clear potential advantages to cancer patients over the immediate release oral ondansetron tablets currently on the market, including enhanced patient compliance and adherence due to increased convenience of use, RHB-102 is targeting a considerable segment of the 5-HT3 antiemetic market, estimated to have worldwide sales of approximately $940 million in 2013[2]. RedHill has completed several clinical studies with RHB-102 and is developing the drug for multiple indications.

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 and, (vi) **RHB-101 -** a once-

[2] EvaluatePharma 2013, 5-HT3 (serotonin) antagonist, worldwide sales by pharmacological class.

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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