Press Release

RedHill Biopharma Announces Positive European Scientific Advice Meeting Regarding RHB-102 and Plans to Submit a European Marketing Application

- **The Company concluded a positive scientific advice meeting with the UK MHRA regarding RHB-102 and plans to submit, during the second half of the year, a European marketing application for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting in cancer patients**

- **RHB-102 is a proprietary, once-daily, oral pill formulation of the anti-emetic oncology support drug ondansetron**

- **The Company commenced a comparative bioavailability study with RHB-102 to support its planned European marketing application, with study results expected by July 2014**

- **In addition to the currently pursued indications, the MHRA provided guidance regarding a new undisclosed indication which may significantly expand RHB-102's potential market; A Phase III study for this indication is planned in the U.S. for later this year**

TEL-AVIV, Israel, April 7, 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 it had concluded a positive European scientific advice meeting with the UK Medicines and Healthcare

Products Regulatory Agency (MHRA) regarding RHB-102, a proprietary, extended-release (once-daily) oral pill formulation of the anti-emetic oncology support drug ondansetron for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively).

In light of the positive feedback from the UK MHRA, RedHill intends to submit, during the second half of the year, a Marketing Authorization Application (MAA) in Europe with the UK as the reference EU member state for the European Mutual Recognition Procedure (MRP).

To support the planned MAA submission, RedHill has commenced a comparative bioavailability study comparing RHB-102 to the European reference drug. The two-arm crossover comparative bioavailability study includes 20 healthy volunteers and is intended to explore the relative bioavailability between RHB-102 and GlaxoSmithKline's European reference drug. The secondary objective of the study is to further assess the safety and tolerability of RHB-102.

The Company anticipates that the results of the bioavailability study will be available by July 2014. Subject to the results of the study and to the required regulatory process, and in light of the data from prior successful clinical studies conducted with RHB-102, the Company plans to submit a European MAA during the second half of 2014.

RedHill announced on March 7, 2014, that it had held a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) regarding the development of RHB-102 for CINV and RINV prevention. Following the pre-NDA meeting, and in light of FDA's feedback, RedHill provided the FDA with additional information and is currently awaiting the FDA's response.

In parallel to pursuing the current indications, RedHill is also pursuing a new undisclosed indication for RHB-102. The Company has received guidance from the MHRA with regard to this additional indication, and is planning to commence a Phase III clinical study with RHB-102 in the U.S. later this year to support a potential future submission of marketing applications in the U.S. and Europe. RedHill expects that, if the marketing applications are approved, the new indication would significantly expand the potential market for RHB-102.

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 anti-emetic market, estimated to have worldwide sales of approximately $940 million in 2013[1]. RedHill has completed several clinical studies with RHB-102 and is developing the drug for multiple indications. RedHill announced on March 7, 2014, that it had held a pre-NDA meeting with the FDA regarding the development of RHB-102 for CINV and RINV prevention. 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. In parallel to pursuing the CINV and RINV indications, RedHill is also

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

pursuing a new, undisclosed indication for RHB-102 in the U.S. and Europe and is planning a Phase III clinical study in the U.S. for this indication later this year.

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. The Company'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; (v) **RHB-102 -** a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting and, (vi) **RHB-101 -** a once-daily oral 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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