



## Press Release

### **RedHill Biopharma Provides Update on RHB-102 Development and Intellectual Property**

- **RHB-102 is a proprietary once-daily oral antiemetic**
- **RedHill has secured from Temple University direct rights to the original RHB-102 patents and has terminated its agreement with SCOLR Pharma Inc.**
- **Following a pre-NDA meeting on RHB 102's development for oncology support, RedHill has provided the FDA with additional information and is awaiting the FDA's response**
- **In addition to the currently pursued indications, the Company is pursuing a new indication for RHB-102, with a Phase III study planned later this year, significantly expanding RHB-102's potential market**
- **In parallel to the U.S. regulatory pathway, RedHill plans to seek marketing approval of RHB-102 in Europe for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting**

**TEL-AVIV, Israel, March 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 reported that it has secured direct rights from Temple University to the original RHB-102 patents, a once-daily oral formulation of the anti-emetic drug ondansetron.

As previously reported by the Company, SCOLR Pharma Inc. ("SCOLR"), which originally licensed certain patents to RedHill for RHB-102, announced that it had ceased business operations. Since SCOLR had itself licensed those patents from Temple University, the original owner of the patents, RedHill has now licensed those same patents directly from Temple University. The new licensing agreement with Temple University is under similar financial terms as the previous agreement with SCOLR, which has been terminated by RedHill.

The Company also reports that, following the completion of several previously-announced clinical studies, a pre-New Drug Application ("NDA") meeting was held with the U.S. Food and Drug Administration ("FDA") regarding RHB-102's development for chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively). 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. Given the ongoing discussions with the FDA, the Company believes that the NDA for RHB-102 will not be submitted in the first quarter of 2014 as planned. RedHill will provide an update on the expected timeline for NDA submission of RHB-102 as soon as sufficient regulatory clarity is obtained, based on the outcome of the discussions with the FDA.

In parallel to pursuing the CINV and RINV indications, RedHill is also pursuing a new indication for RHB-102. The Company expects that, if approved by the FDA, the new indication would significantly expand the potential market for RHB-102. To support the submission of an NDA targeting this additional new indication, RedHill is planning a Phase III clinical study later this year.

In parallel to advancing the regulatory pathways in the U.S. for multiple indications, RedHill also plans to submit, later this year, a Marketing Authorization Application ("MAA") for RHB-102 in Europe for CINV and RINV. RedHill plans to conduct a comparative bioavailability study comparing RHB-102 to a European reference product ahead of the MAA submission.

#### **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® immediate release tablets 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 the potential to enhance patient compliance and adherence thanks to increased convenience of use, RHB-102 is targeting a considerable segment of the 5-HT<sub>3</sub> antiemetic market, estimated to have worldwide sales of approximately \$940 million in 2013<sup>1</sup>. 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. 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

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<sup>1</sup> EvaluatePharma 2013, 5-HT<sub>3</sub> (serotonin) antagonist, worldwide sales by pharmacological class

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 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 carvedilol. For more information please visit: [www.redhillbio.com](http://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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