Press Release

RedHill Biopharma Announces First Patients Enrolled in the Phase III Study of RHB-102 (BEKINDA™) for Gastroenteritis and Gastritis

- **The randomized, double-blind, placebo-controlled Phase III study with RHB-102 for acute gastroenteritis and gastritis (the GUARD study) is underway in the U.S., with a planned enrollment of 320 patients**

- **Top-line results from the Phase III GUARD study are expected during H2/2015**

- **RedHill recently submitted a European Marketing Authorization Application (MAA) seeking approval of RHB-102, newly branded as BEKINDA™, for cancer patients suffering from chemotherapy and radiotherapy-induced nausea and vomiting**

TEL-AVIV, Israel, December 17, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that the first patients have been enrolled in the Phase III clinical study of RHB-102 (BEKINDA™) for acute gastroenteritis and gastritis (the GUARD study), inflammations of the gastrointestinal tract which cause, among other symptoms, nausea and vomiting. RHB-102 is a proprietary, extended-release, once-daily oral pill formulation of the antiemetic drug ondansetron.

Top-line results from the Phase III GUARD study are expected during the second half of 2015 and are intended to support potential future submissions of marketing applications in both the U.S. and Europe for this indication. If approved for marketing by the FDA, RHB-102 could become the

first 5-HT3 antiemetic drug indicated for the treatment of acute gastroenteritis and gastritis, targeting a potential worldwide market estimated to exceed $650 million annually[1].

Dr. Reza Fathi, PhD, RedHill's Senior VP R&D noted: "We are very pleased with the enrollment of the first patients in the Phase III GUARD study of RHB-102 for this important new indication. Gastroenteritis and gastritis are very common conditions, with over 179 million cases annually in the U.S. alone, and there is a significant need to provide patients with new treatment options. RHB-102 is intended to provide patients with relief from nausea and vomiting symptoms for a full 24 hour period with a single oral tablet and could also reduce the burden on health systems by reducing hospital readmissions."

In parallel to the Phase III GUARD study in acute gastroenteritis and gastritis, RedHill is pursuing marketing approval for RHB-102 for the indications of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively) in Europe and the U.S. RedHill submitted a European Marketing Authorization Application (MAA) for RHB-102 for these indications, under the brand name BEKINDA™, in December 2014. Following a pre-New Drug Application (pre-NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding the development of RHB-102 for CINV prevention, and in light of FDA's feedback, RedHill provided the FDA with supplementary information and is currently awaiting the FDA's response. Along with the data generated from prior studies, RedHill plans on using post-marketing data from Europe to further support a potential submission of a U.S. NDA for RHB-102 for CINV.

About the Phase III GUARD study:
The randomized, double-blind, placebo-controlled, parallel group Phase III GUARD study for RHB-102 (BEKINDA™) is being conducted in the U.S. with a planned enrollment of 320 adults and children over the age of 12 who suffer from acute gastroenteritis or gastritis. The primary endpoint for the study is the absence of vomiting commencing 30 minutes after administration of the first dose through emergency room discharge. Secondary endpoints include frequency of vomiting, severity and time to resolution of nausea, and time to resumption of normal activities. Top-line results from the study are expected during the second half of 2015.

The GUARD Phase III 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.

About RHB-102 (BEKINDA™):
RHB-102 (BEKINDA™) is a patent-protected, extended-release (24 hours) oral pill formulation of ondansetron, the active ingredient in GlaxoSmithKline's Zofran™. RedHill is developing RHB-102 for the treatment of acute gastroenteritis and gastritis as well as for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting (CINV and RINV, respectively). A Phase III clinical study of RHB-102 for acute gastroenteritis and gastritis is ongoing in the U.S., with top-line results expected during the second half of 2015. RedHill submitted in December 2014 a Marketing Authorization Application (MAA) seeking marketing approval of RHB-102 (under the brand name BEKINDA™) in Europe for the oncology support indications of CINV and RINV prevention and

[1] Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727–741 and Company analysis.

has also held a pre-NDA meeting with the FDA regarding the potential submission of a New Drug Application (NDA) in the U.S. for CINV.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing 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; (iii) **RHB-102 (BEKINDA™) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application submitted in December 2014 for chemotherapy and radiotherapy-induced nausea and vomiting (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON®** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT® (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **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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