Press Release

RedHill Biopharma Initiates Phase III Study of RHB-102 for Gastroenteritis

- **The randomized, double-blind, placebo-controlled, parallel group Phase III study with RHB-102 (the GUARD study) will enroll 320 acute gastroenteritis patients in the U.S.**

- **Acute gastroenteritis is an inflammation of the gastrointestinal tract causing nausea and vomiting, with a potential worldwide market estimated to exceed $650 million**

- **If approved for marketing by the FDA, RHB-102 is expected to be the first-ever 5-HT3 antagonist drug indicated for acute gastroenteritis**

- **Dr. Robert A. Silverman, MD, MS, Emergency Medicine specialist at the Hofstra North Shore-Long Island Jewish ("LIJ") Medical Center and Associate Professor at the Hofstra North Shore-LIJ School of Medicine will act as the lead investigator for the GUARD study**

- **RedHill is focused on inflammatory and gastrointestinal ("GI") diseases, including GI cancers, and is currently conducting three Phase III GI studies in the U.S., including the RHB-102 GUARD study for gastroenteritis, the RHB-104 MAP US study for Crohn's disease and the RHB-105 ERADICATE Hp study for *H. pylori* infection**

TEL-AVIV, Israel, September 3, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that it is initiating a Phase III clinical study designed to evaluate the safety and efficacy of RHB-102 in patients suffering from acute gastroenteritis, an inflammation of the gastrointestinal tract which causes, among other symptoms, nausea and vomiting. RHB-102 is a proprietary, oral, extended-release, once-daily formulation of the antiemetic drug ondansetron.

Acute gastroenteritis is an inflammation of the mucus membranes of the gastrointestinal tract, most commonly caused by a viral infection. Symptoms of gastroenteritis include nausea, vomiting, diarrhea and abdominal pain. With over 179 million cases annually in the U.S. alone[1], the worldwide potential market could exceed $650 million annually[2].

The randomized, double-blind, placebo-controlled, parallel group Phase III study will be conducted in up to 10 clinical sites in the U.S. and is expected to enroll 320 adults and children over the age of 12 who suffer from acute gastroenteritis. Patients will be randomized to receive either RHB-102 or a placebo. The primary endpoint for the study is the absence of vomiting from 30 minutes after the first dose through the discharge from the emergency department. 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 RHB-102 Phase III GUARD study are expected during the second half of 2015.

Following prior discussions with the U.S. Food and Drug Administration ("FDA") and the UK Medicines and Healthcare Products Regulatory Agency ("MHRA"), the GUARD study is 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-ever 5-HT3 antiemetic drug indicated for the treatment of acute gastroenteritis.

Dr. Robert A. Silverman, MD, MS, RHB-102 GUARD Phase III study lead investigator, said: "I am very pleased to take part in this important study in which we will assess the efficacy of RHB-102 in patients presenting to the hospital emergency room with acute gastroenteritis. If approved, RHB-102 could potentially decrease the number of emergency room visits of patients suffering from acute gastroenteritis by offering them a long-lasting oral treatment which can be taken in the comfort of their home."

Dr. Reza Fathi, RedHill's Senior VP Research and Development, added: "The GUARD study with RHB-102 for acute gastroenteritis further establishes RedHill's focus on gastrointestinal and inflammatory diseases and expands the Company's reach into this high unmet-need therapeutic space. It is the third GI-focused Phase III study that RedHill is currently conducting in the U.S., along with the RHB-104 MAP US study for Crohn's disease and the RHB-105 ERADICATE Hp study for *H. pylori* infection."

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[1] Hall, J.A. (2013) Acute Gastroenteritis surveillance through the National Outbreak Reporting System, United States. *Emerg Infect Dis*. 19(8): 1305-9.

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

Ondansetron, a 5-HT3 antagonist and the active pharmaceutical ingredient in RHB-102, has been approved in the U.S. and Europe, in oral immediate release and non-oral forms, for the prevention and treatment of chemotherapy and radiotherapy-induced nausea and vomiting. No formulation of ondansetron or any other 5-HT3 antagonist has been approved by the FDA for the treatment of gastroenteritis. RHB-102 is a proprietary, extended-release (24 hours), oral pill formulation of ondansetron.

In parallel to the Phase III study for gastroenteritis, RedHill is pursuing marketing approval of RHB-102 for the indications of chemotherapy-induced and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively) in the U.S. and Europe. Following a positive European scientific advice meeting with the UK's MHRA, and a successful comparative bioavailability study comparing RHB-102 to a European reference drug, RedHill plans to submit a European Marketing Authorization Application for RHB-102 by October 2014 for the indications of CINV and RINV prevention. RedHill has also 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). RedHill is developing RHB-102 for the treatment of gastroenteritis as well as for the prevention of CINV and RINV. A Phase III clinical study of RHB-102 for acute gastroenteritis is currently being initiated in the U.S., with top-line data expected by the second half of 2015. Gastroenteritis is an inflammation of the gastrointestinal tract causing symptoms which include nausea, vomiting, diarrhea and abdominal pain. There are over 179 million cases of acute gastroenteritis in the U.S. annually[3] resulting in estimated related costs to the U.S. healthcare system of 3.88 billion annually[4]. The worldwide potential market for RHB-102 for acute gastroenteritis could exceed $650 million annually[5]. If approved for marketing by the FDA, RHB-102 is expected to be the first-ever 5-HT3 antiemetic indicated for acute gastroenteritis. In addition to gastroenteritis, RHB-102 is being developed for oncology support indications as it holds 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. A pre-NDA meeting with the FDA was held in the first quarter of 2014 and an MAA submission in Europe for prevention of chemotherapy and radiotherapy-induced nausea and vomiting is planned by October of 2014. RHB-102 is targeting a considerable segment of the existing 5-HT3 antiemetic market which is estimated to have worldwide sales of approximately $940 million in 2013[6].

[3] Hall, J.A. (2013) Acute Gastroenteritis surveillance through the National Outbreak Reporting System, United States. *Emerg Infect Dis*. 19(8): 1305-9

[4] Karve S. (2014) Burden of acute gastroenteritis, norovirus and rotavirus in a managed care population. *Hum Vaccin Immunother* 10(6)

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

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

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-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 the treatment of *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-102 -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting planned by October 2014; (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) **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; 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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