Press Release

RedHill Biopharma Announces Positive Scientific Advice Meeting and European Marketing Application Strategy for RHB-103 (Migraine)

- **The Company and its co-development partner, IntelGenx Corp., held a Scientific Advice meeting with the German pharmaceuticals regulation authority (BfArM) and plan to submit a Marketing Authorization Application (MAA) to market RHB-103 in Europe during the first half of 2014**

- **RHB-103 is a proprietary oral thin film formulation of rizatriptan, the active drug in Merck & Co.'s Maxalt MLT®**

- **A U.S. New Drug Application (NDA) for RHB-103 is currently being reviewed by the FDA with a PDUFA goal date of February 3, 2014**

TEL-AVIV, Israel, November 18, 2013 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 formulations and combinations of existing drugs, today reported that the Company and its co-development partner, IntelGenx Corp. ("IntelGenx"), have recently concluded a positive European Scientific Advice meeting with the German Federal Institute for Drugs and Medical Devices (BfArM) regarding RHB-103, a proprietary, oral thin film formulation of rizatriptan for the treatment of acute migraine.

The Scientific Advice meeting with the BfArM provided sufficient clarity with regard to the regulatory path. Consequently, RedHill plans to conduct a small bioavailability study comparing RHB-103 to the European reference product.

RedHill previously conducted a successful bioequivalence trial which demonstrated the required U.S. Food and Drug Administration (FDA) criteria for therapeutic bioequivalence between the soluble oral thin film of RHB-103 and Merck & Co.'s Maxalt MLT®, the reference drug available in the U.S. In March 2013, following the successful bioequivalence study, RedHill submitted to the FDA a New Drug Application (NDA) seeking marketing approval of RHB-103. The FDA is currently conducting a substantive review of the NDA and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of February 3, 2014.

Following the positive meeting with the BfArM, RedHill plans to complete the bioavailability study and submit a Marketing Authorization Application (MAA) for marketing approval of RHB-103 in Europe, with Germany as the reference member state under the European Mutual Recognition Procedure (MRP), during the first half of 2014.

"We are encouraged by the positive feedback we received from the German BfArM", **said Dr. Reza Fathi, RedHill's Senior VP R&D**. "We now plan to conduct a relatively short bioavailability study and we expect to file a European Marketing Authorization Application for RHB-103 during the first half of 2014." **Dr. Fathi added;** "If approved, RHB-103 will be an attractive new treatment option for migraine sufferers and physicians, with significant potential advantages. We are very excited by the upcoming FDA PDUFA date of February 3, 2014 for the U.S. New Drug Application and by the prospect of bringing RHB-103 to the European market."

RHB-103 is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT_1 receptor agonist and the active drug in Merck & Co.'s Maxalt®. Rizatriptan is considered one of the most effective oral triptans, a class of molecules that constrict blood vessels in the brain to relieve swelling and other migraine symptoms. The worldwide annual sales of triptans were estimated to have exceeded $1.6 billion in 2012[1], and the worldwide direct sales of Merck & Co.'s rizatriptan-based drugs exceeded $600 million in 2012[2].

RHB-103 is based on IntelGenx's proprietary "*VersaFilm*™" technology. The RHB-103 thin film strip dissolves rapidly in the mouth, leading to the absorption of the drug through the gastro intestinal track and into the bloodstream. The unique administration method of the RHB-103 thin film does not require the patient to swallow a pill or consume water, and presents a potentially attractive therapeutic alternative for many migraine patients, including those who suffer from migraine-related nausea - approximately 80% of the total migraine patient population[3].

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. The Company's current product pipeline includes: (i) **RHB-103** - an oral thin film formulation of a leading drug for the treatment of acute migraines,

[1] EvaluatePharma, 2013, WW annual sales by pharmacological class, 5-HT1B (serotonin) & 5HT1D (serotonin) agonist
[2] 2012 annual report of Merck & Co., Inc.
[3] Lipton RB, Buse DC, Saiers J, Fanning KM, Serrano D, Reed ML. (2013) Frequency and burden of headache-related nausea: results from the American Migraine Prevalence and Prevention (AMPP) study, Headache. 2013 Jan;53(1):93-103. doi: 10.1111/j.1526-4610.2012.02292.x. Epub 2012 Nov 13

with a U.S. NDA accepted for review by the FDA in June 2013 and a PDUFA date of February 3, 2014, (ii) **RHB-102** - a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, planned for U.S. NDA submission in the first quarter of 2014, (iii) **RHB-104** - a combination antibiotic therapy for the treatment of (a) Crohn's disease, with a first Phase III trial currently underway, (b) Multiple sclerosis (MS), with a Phase IIa proof of concept trial currently underway, (c) rheumatoid arthritis (RA), with plans for a Phase IIa proof of concept trial, and (d) systemic lupus erythematosus, (iv) **RHB-105** - a combination therapy for *Helicobacter pylori* infection, with a Phase III trial currently underway, (v) **RHB-101** - a once-daily formulation of a leading congestive heart failure and high blood pressure drug, and (vi) **RHB-106** - an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy and other GI procedures. 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 not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status 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 under their respective licensing agreements; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xi) competitive companies, technologies and the Company's industry; and (xii) the impact of the political and security situation in Israel on the Company's business. 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 From 20-F filed with the SEC on February 19, 2013, and its Reports on Form 6-K. Investors and security holders are urged to read these documents free of charge on the SEC's web

site at http://www.sec.gov. 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 made by us or on our behalf as a result of new information, future events or other factors.

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