Press Release

RedHill Biopharma and IntelGenx Receive Complete Response Letter from FDA for RHB-103 Oral Film for Acute Migraines

- **FDA's letter accepted the bioequivalence study and safety information submitted and requires no additional clinical studies; RedHill and IntelGenx plan to address remaining issues, primarily related to third party manufacturing, packaging and labeling, within weeks, based on available data**

- **In light of the increased regulatory clarity, RedHill and IntelGenx plan to rapidly advance ongoing discussions with potential partners for the commercialization of RHB-103**

- **In addition to pursuing marketing approval in the U.S., RedHill and IntelGenx plan to complete the development program for the European market and submit a Marketing Authorization Application later this year**

TEL-AVIV, Israel, February 4, 2014, RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage drugs, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) ("IntelGenx"), a Canadian drug delivery company focusing on oral drug delivery, today announced that they received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding the New Drug Application ("NDA") for RHB-103 for the treatment of acute migraines. 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®.

A CRL is issued by the FDA's Center for Drug Evaluation and Research to inform companies that certain questions and deficiencies remain that preclude the approval of the application in its present form. The questions raised by the FDA in the CRL regarding the NDA for RHB-103 primarily relate to third party Chemistry, Manufacturing and Controls ("CMC") and to the packaging and

labeling of the product. No questions or deficiencies were raised relating to the product's safety and the FDA's CRL does not require additional clinical studies.

While continuing to review the FDA's CRL, RedHill and IntelGenx believe that they can supply the requested information based on available data. IntelGenx and RedHill further believe that the majority of issues raised by the FDA were recently addressed in an amendment submitted by the companies to the FDA that has yet to be reviewed. The companies will work with the FDA to address the remaining questions in the CRL and plan to submit the requested information within a few weeks.

RedHill and IntelGenx have been in active discussions with potential partners for the commercialization of RHB-103 and expect to advance these discussions rapidly following FDA's CRL which provides increased regulatory clarity, indicates that no further clinical trials are required, and raises no issues regarding RHB-103's safety.

"We appreciate the thorough review of the RHB-103 NDA by the FDA. We remain committed to bringing RHB-103 to market as quickly as possible and will work closely with the FDA to advance the application and address all questions raised by the FDA." **said Rajiv Khosla, IntelGenx' President and CEO and Dror Ben-Asher, RedHill's CEO in a joint statement.** "We believe that the questions raised by the FDA can be addressed based on available data, and we plan to work vigorously to submit our response within a few weeks in order to bring this product to market as a new therapeutic option for the benefit of patients suffering from migraines."

In addition to pursuing marketing approval in the U.S., and following a positive meeting with the German pharmaceuticals regulation authority "BfArM" in October 2013, RedHill and IntelGenx plan to complete the development program for the European market and submit a Marketing Authorization Application for marketing approval of RHB-103 in Europe later this year, with Germany as the reference member state under the European Mutual Recognition Procedure.

About RHB-103

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' proprietary "*VersaFilm*™" technology. It dissolves rapidly in the mouth, leading to the absorption of the drug through the gastro intestinal track and into the bloodstream. The administration method of the RHB-103 oral thin film does not require the patient to swallow a pill or consume water, and presents a potentially attractive therapeutic alternative for

[1] EvaluatePharma, 2013, WW annual sales by pharmacological class, 5-HT1B (serotonin) & 5HT1D (serotonin) agonist

[2] 2012 annual report of Merck & Co., Inc.

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 pipeline of proprietary products includes: (i) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines; (ii) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of chemotherapy and radiotherapy induced nausea and vomiting (iii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study, (iv) **RHB-105** – an oral combination therapy for *Helicobacter pylori* infection, with an ongoing phase III study; (v) **RHB-106** - an encapsulated formulation for bowel preparation and (vi) **RHB-101** - a once-daily formulation of carvedilol. For more information please visit: www.redhillbio.com

About IntelGenx:
IntelGenx is a drug delivery company focused on the development of oral controlled-release products as well as novel rapidly disintegrating delivery systems. IntelGenx uses its unique multiple layer delivery system to provide zero-order release of active drugs in the gastrointestinal tract. IntelGenx has also developed novel delivery technologies for the rapid delivery of pharmaceutically active substances in the oral cavity based on its experience with rapidly disintegrating films. IntelGenx' development pipeline includes products for the treatment of indications such as severe depression, hypertension, erectile dysfunction, migraine, insomnia, CNS indications, idiopathic pulmonary fibrosis, oncology and pain, as well as animal health products. More information is available about the company at www.intelgenx.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

[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

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 Form 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.

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

PR contact (U.S.):
Lauren Glaser
Vice President
The Trout Group
+1-646-378-2972
lglaser@troutgroup.com