Press Release

RedHill Biopharma and IntelGenx Announce Acceptance for Review of European Marketing Application for RIZAPORT™ for Migraines

- **The German Federal Institute for Drugs and Medical Devices (BfArM) has validated the European Marketing Authorization Application submitted for RIZAPORT™ (RHB-103) and initiated its formal review of the application on November 25, 2014**
- **RedHill and IntelGenx continue to work with the FDA to resolve the remaining Chemistry, Manufacturing and Controls (CMC) issues and secure a compliant source of the raw material, in order to advance potential FDA approval of the U.S. New Drug Application submitted by the companies**
- **RIZAPORT™ oral thin film formulation of rizatriptan for acute migraines presents a potentially attractive therapeutic alternative for many migraine patients, including those suffering from migraine-related nausea, due to its convenient dosing, lack of need for water intake and pleasant flavoring**

TEL-AVIV, Israel, December 1, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) ("RedHill"), an Israeli biopharmaceutical company primarily focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, that the German Federal Institute for Drugs and Medical Devices (BfArM) validated the Marketing Authorization Application (MAA) for RIZAPORT™, an oral thin film formulation of rizatriptan for acute migraines, and has initiated the formal review process of the application on November 25, 2014. BfArM's potential feedback regarding the MAA is expected during the second half of 2015.

RIZAPORT™ oral 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, estimated to be approximately 80% of the total migraine patient population[1].

The MAA was submitted under the European Mutual Recognition Procedure (MRP) with Germany as the reference member state and Luxemburg as the Concerned Member State. The submission is supported by several studies and follows a positive scientific advice meeting with the BfArM.

RedHill and IntelGenx submitted a New Drug Application (NDA) to the FDA in March 2013 seeking marketing approval of RIZAPORT™ in the U.S. Following a complete response letter (CRL) received from the FDA in February 2014, which raised questions primarily related to CMC, RedHill and IntelGenx reported that they believe that FDA approval of the RIZAPORT™ NDA is subject to the satisfactory resolution of the remaining CMC questions, as well as securing a compliant source of the raw material. Accordingly, the companies continue to work with the FDA in order to address and resolve all remaining CMC questions and to secure a compliant source of the raw material.

About RIZAPORT™ (RHB-103):

RIZAPORT™ 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®. Marketing applications for RIZAPORT™ have been filed both in the U.S. (NDA filed in March 2013) and in Europe (MAA filed in October 2014). 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 billion in 2013[2].

RIZAPORT™ is based on IntelGenx' proprietary "*VersaFilm*™" technology. It dissolves rapidly and releases its active ingredient in the mouth, leading to an efficient absorption of the drug through the gastro intestinal tract. The administration method of the RIZAPORT™ oral thin film which does not require the patient to swallow a pill or consume water, along with its pleasant flavoring, presents a potentially attractive therapeutic alternative for many migraine patients, including those who suffer from migraine-related nausea, estimated to be 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 on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including

[1] 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

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

[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

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 -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a planned European marketing application 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

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 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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