



Press Release

RedHill Biopharma and IntelGenx Submit Response to FDA CRL for RHB-103 Migraine Oral-Film

TEL-AVIV, Israel, March 3, 2014, RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (“RedHill”), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage drugs, today announced, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) (“IntelGenx”), a Canadian drug delivery company focusing on oral drug delivery, that they submitted a response to the Complete Response Letter (“CRL”) of the U.S. Food and Drug Administration (“FDA”) for the New Drug Application (“NDA”) for RHB-103, an oral thin-film rizatriptan for the treatment of acute migraines.

The companies previously reported on February 4, 2014 that they received the FDA's CRL which raised questions primarily related to third party Chemistry, Manufacturing and Controls (CMC) and to the packaging and labeling of the product. The FDA's CRL did not raise any questions or deficiencies relating to RHB-103's safety and did not require additional clinical studies. RedHill and IntelGenx believe that their response to the FDA addresses all the issues raised in the CRL.

RedHill and IntelGenx will continue working with the FDA on the continuing review of the RHB-103 NDA, and will provide additional updates as and when applicable.

About RHB-103

RHB-103 is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT₁ 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 billion in 2013¹.

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 many migraine patients, including those who suffer from migraine-related nausea - approximately 80% of the total migraine patient population².

¹ EvaluatePharma, 2013, WW annual sales by pharmacological class, 5-HT_{1B} (serotonin) & 5HT_{1D} (serotonin) agonist

² 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

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 for the treatment of inflammatory and gastrointestinal diseases, including cancer and related conditions. The Company'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 *Helicobacter pylori* infection, with an ongoing phase III study; (iii) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals Ltd.; (iv) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with U.S. NDA under FDA review; (v) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of chemotherapy and radiotherapy induced nausea and vomiting and, (vi) **RHB-101** - a once-daily oral 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 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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