



Press Release

RedHill Biopharma and IntelGenx Submit European Marketing Authorization Application for Migraine Drug RIZAPORT[®] (formerly RHB-103)

TEL-AVIV, Israel, October 1st, 2014 RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (“RedHill”), an Israeli biopharmaceutical company 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 they have submitted a Marketing Authorization Application (“MAA”) to the German Federal Institute for Drugs and Medical Devices (“BfArM”) seeking European marketing approval of RHB-103, an oral thin film formulation of rizatriptan for acute migraines, under the brand name RIZAPORT[®]. The brand name RIZAPORT[®] for RHB-103 was also conditionally approved by the U.S. Food and Drug Administration (“FDA”) as part of the New Drug Application (“NDA”) review process in the U.S., subject to a Complete Response Letter (“CRL”) received from the FDA in February 2014 and currently under discussions with the FDA.

The MAA was submitted under the European Mutual Recognition Procedure (“MRP”) with Germany as the reference member state. The submission is supported by several studies, including a recently completed comparative bioavailability study which successfully established the bioequivalence between RIZAPORT[®] and the European reference drug, Maxalt[®] Lingua, and follows a positive scientific advice meeting with BfArM. 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 population¹.

RedHill and IntelGenx previously conducted a successful bioavailability study which demonstrated the required FDA criteria for therapeutic bioequivalence between the RIZAPORT[®] soluble oral thin film and the U.S. reference drug, Maxalt-MLT[®]. Following the successful bioequivalence study, RedHill and IntelGenx announced in March 2013 the submission to the FDA and acceptance for review of an NDA seeking marketing approval of RHB-103 in the U.S., also under the brand name

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

RIZAPORT[®]. Following a CRL received from the FDA in February 2014, which raised questions primarily related to Chemistry, Manufacturing and Controls (“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.

"We are very pleased with the submission of a European marketing application for RIZAPORT[®], which follows our submission of a U.S. New Drug Application currently under discussions with the FDA" **said Dr. Elkan Gamzu PhD, RedHill's RIZAPORT[®] Product Manager.** "This regulatory submission in Europe brings us closer to offering a new and potentially advantageous therapeutic alternative for patients suffering from migraines, including those who suffer from migraines with nausea and vomiting. We believe that RIZAPORT[®] oral thin film's rapid dissolution, pleasant flavoring and ease of use from the ability to administer without water, potentially improves compliance and adherence, and we look forward to making the product available to patients in Europe."

"From a commercial perspective, obtaining marketing authorization in Europe would expand the commercialization of RIZAPORT[®] into the second largest market of Maxalt[®]" **said Dr. Horst G. Zerbe, President and CEO of IntelGenx.** "Pursuing development activities in Europe demonstrates our commitment to bring RIZAPORT[®] to migraine patients across the world and maximize the value of this asset."

About RIZAPORT[®] (formerly RHB-103):

RIZAPORT[®] is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT₁ 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 2013².

RIZAPORT[®] is based on IntelGenx' proprietary “VersaFilm™” technology. RIZAPORT[®] 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 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 population³.

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,

² EvaluatePharma, 2013 WW annual sales by pharmacological class, 5-HT_{1B} (serotonin) & 5HT_{1D} (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

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 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**[®] (formerly **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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