Press Release

RedHill Biopharma and IntelGenx Announce RIZAPORT™ (RHB-103) Marketing Authorization Application is Approvable Under the European Decentralized Procedure

- **The German Federal Institute for Drugs and Medical Devices (BfArM) has confirmed the positive outcome of the European Decentralized Procedure and informed RedHill and IntelGenx that the European Marketing Authorization Application (MAA) for RIZAPORT™ (RHB-103) is approvable**

- **RedHill and IntelGenx plan to submit the final required documentation to the BfArM and to the Luxembourg regulatory authority next week, which is expected to lead to marketing approval of RIZAPORT™ in both countries, and will continue their close cooperation in order to obtain national phase approvals in other Decentralized Procedure (DCP) European territories**

- **RIZAPORT™, an oral thin film formulation of rizatriptan for acute migraines, offers an innovative and potentially advantageous therapeutic alternative for many migraine patients, primarily patients who suffer from dysphagia or migraine-related nausea, due to its convenient dosing, facile intake due to the lack of need for water and pleasant flavor**

- **RedHill and IntelGenx continue to work with the FDA to advance potential approval of the U.S. New Drug Application (NDA) submitted by the companies**

TEL-AVIV, Israel, September 10, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, the positive outcome of the European Decentralized

Procedure (DCP) for the approval of RIZAPORT™ (formerly RHB-103) oral thin film formulation of rizatriptan for the treatment of acute migraines.

Following the issuance of the Final Assessment Report, the Federal Institute for Drugs and Medical Devices of Germany (BfArM), the Reference Member State, has informed RedHill and IntelGenx that the RIZAPORT™ Marketing Authorization Application (MAA) is approvable.

Dror Ben-Asher, RedHill's CEO, said: "We are very pleased that RIZAPORT™ has received a positive recommendation from the German BfArM, supporting its approval in many European markets. This is a significant milestone for RedHill which reflects our team's strong capabilities, dedication and commitment, as well as the joint effort of RedHill and IntelGenx to bring RIZAPORT™ to market for the benefit of migraine patients."

The regulatory process will now enter the national licensing phase of the DCP in which Germany, the Reference Member State, and Luxemburg, the Concerned Member State, are expected to grant national licenses that will allow RIZAPORT™ to be marketed in each country. RedHill and IntelGenx plan to submit the final required documentation next week, which should lead to marketing approval of RIZAPORT™ in Germany and Luxembourg. RedHill and IntelGenx will continue to work together to obtain national phase approvals in other DCP territories.

Dr. Reza Fathi, Ph.D., RedHill's Senior VP R&D added: "RIZAPORT™ is an innovative and differentiated new oral thin film formulation of rizatriptan and we are excited about the prospect of this product, which we believe can benefit migraine patients. We look forward to completing in the near future the national phase of approval in Germany, one of the largest European markets. RedHill continues to advance its activities to secure commercialization partners in the U.S., Europe and additional territories, in order to introduce this promising new product to these markets."

RIZAPORT™, an oral thin film formulation of rizatriptan for the treatment of acute migraines, offers a potentially attractive therapeutic alternative for many migraine patients. The RIZAPORT™ oral thin film has a pleasant taste and dissolves rapidly in the mouth without the need for water. It is a potentially advantageous therapeutic alternative for patients suffering from dysphagia, and patients who suffer from migraine-related nausea, estimated to be approximately 80% of the total migraine patient population[1]. 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.

RedHill and IntelGenx submitted a New Drug Application (NDA) to the FDA in March 2013 seeking marketing approval of RIZAPORT™ in the U.S. In February 2014, the companies received a complete response letter (CRL) from the FDA which raised questions primarily

[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.

related to CMC. It is noted that no deficiency was raised relating to the safety and bio-equivalence data of RIZAPORT™. 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.

After receipt of the CRL, additional issues were raised by the FDA directly with Apotex Pharmachem India Pvt. Ltd. ("Apotex"), the manufacturer of the active pharmaceutical ingredient (API) in RIZAPORT™, none of which were related directly to RIZAPORT™. In April 2015, an inspection held by the European Directorate for the Quality of Medicines and HealthCare (EDQM) at the Apotex, manufacturing site came out positive, which led to the issuance of a Certificate of Suitability (CEP) in June 2015. Other reputable international agencies, Australia's Therapeutic Goods Administration and Health Canada, also inspected the Apotex site in 2015 and did not object to having products manufactured by the site imported into their territories.

RedHill and IntelGenx continue their cooperative effort 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 $870 million in 2014[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 flavor, 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.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful top-line results from a 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) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a European

[2] EvaluatePharma 2013 WW annual sales report

marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple inflammatory, gastrointestinal and oncology indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussion with the FDA and a European marketing application submitted in October 2014; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 research, manufacturing, 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, approvals and feedback; (iv) the manufacturing, 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 research, 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 (xi) competitive companies and technologies within 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 26, 2015. 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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