



Press Release

RedHill Biopharma and IntelGenx Announce First European Marketing Approval of RIZAPORT™ (RHB-103) for Migraines

- **The German Federal Institute for Drugs and Medical Devices (BfArM) has granted national marketing approval for RIZAPORT™ (RHB-103) for the treatment of acute migraines under the European Decentralized Procedure (DCP)**
- **RedHill and IntelGenx continue their close cooperation in order to obtain approvals in additional European countries and in the U.S., where a New Drug Application (NDA) was submitted and a Complete Response Letter was received**
- **RedHill and IntelGenx continue to advance their activities to secure commercialization partners in Europe, the U.S. and additional territories**
- **RIZAPORT™, an oral thin film formulation of rizatriptan for acute migraines, offers an innovative therapeutic alternative for many migraine patients, primarily patients who suffer from dysphagia or migraine-related nausea**

TEL-AVIV, Israel, November 9, 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, that the Federal Institute for Drugs and Medical Devices of Germany (BfArM) has granted marketing authorization of RIZAPORT™ (RHB-103) 5mg and 10mg, an oral thin film formulation of rizatriptan benzoate for the treatment of acute migraines.

Over 50 million people in Europe are estimated to be affected by migraines. Approximately 2 million Europeans are prone to migraine attacks every day¹. The worldwide migraine market is expected to exceed \$2 billion in sales in 2016.

The national approval of RIZAPORT™ in Germany was granted under the European Decentralized Procedure (DCP), in which Germany served as the Reference Member State. This authorization is the first national marketing approval of RIZAPORT™. Marketing authorization in Luxemburg, the Concerned Member State, is expected to follow. RedHill and IntelGenx intend to continue to work together to obtain national phase approvals in other European DCP territories.

Dr. Reza Fathi, Ph.D., RedHill's Senior VP R&D, said: “We are very pleased to receive German marketing authorization for RIZAPORT™. This is the first drug in RedHill's advanced pipeline to gain marketing approval, a significant milestone for the Company that reflects our team's commitment and execution capabilities, as well as the successful cooperation with IntelGenx.”

Dr. Elkan Gamzu, Ph.D., RedHill's RIZAPORT™ Product Manager added: “RIZAPORT™ is an innovative new oral thin film formulation of rizatriptan, potentially benefiting many migraine patients who suffer from migraine related nausea, due to its rapid dissolution, pleasant flavor and ease of use. RedHill continues to advance its activities to secure commercialization partners in Europe, the U.S. and additional territories to bring this new therapeutic alternative to market.”

“The European approval of RIZAPORT™ is an important milestone achieved by IntelGenx and RedHill which reflects our team's strong capabilities as partners,” **said Dr. Horst G. Zerbe, President and CEO of IntelGenx.** “We are committed to bringing RIZAPORT™ to market as soon as possible, as we believe it will be a potentially beneficial treatment for patients suffering from migraines. This approval will make RIZAPORT™ the first oral thin film bioequivalent to Maxalt® Lingua.”

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 therapeutic alternative for patients suffering from dysphagia (difficulty swallowing), and patients who suffer from migraine-related nausea, estimated to be approximately 80% of the total migraine patient population². Rizatriptan is considered one of the most effective oral triptans, a class of molecules that constricts blood vessels in the brain to relieve swelling and other migraine symptoms.

¹ World Headache Alliance.

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.

RedHill and IntelGenx submitted a New Drug Application (NDA) to the FDA in 2013 seeking marketing approval of RIZAPORT™ in the U.S. In 2014, the companies received a complete response letter (CRL) from the FDA which raised questions primarily related to CMC. It is noted that no deficiency was raised relating to the safety or 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. 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-HT₁ receptor agonist and the active drug in Merck & Co.'s Maxalt®. RIZAPORT™ 5mg and 10mg was approved for marketing in Germany in October 2015, under the European Decentralized Procedure. A New Drug Application for RIZAPORT™ was also filed with the U.S. FDA in 2013 and a CRL was received in 2014. Rizatriptan is considered one of the most effective oral triptans, a class of molecules that constricts 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 2014³. RIZAPORT™ is based on IntelGenx's proprietary "VersaFilm™" technology. It dissolves rapidly and releases its active ingredient in the mouth, leading to efficient absorption of the drug through the gastrointestinal 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 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 oncology, inflammatory and gastrointestinal 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 tumors; (vii) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class

³ EvaluatePharma 2013 WW annual sales report

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 marketing authorization received in Germany in October 2015; and (ix) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol.

About IntelGenx:

IntelGenx is a leading drug delivery company focused on the development of innovative products based on its proprietary oral drug delivery technologies. Established in 2003, the Montreal-based company, listed on the TSX-V and OTC-QX, develops innovative oral drug delivery solutions based on its proprietary platform technologies, VersaFilm™, VersaTab™ and AdVersa™. IntelGenx has developed a broad and diverse product portfolio addressing unmet market needs and offering lifecycle management opportunities. FORFIVO XL™, launched in 2012, is the first and only FDA approved once-daily bupropion HCI 450mg dose in a single tablet for the treatment of major depressive disorder. IntelGenx highly skilled team provides comprehensive pharmaceuticals services to pharmaceutical partners, including R&D, clinical monitoring, IP protection, analytical method development and regulatory services. IntelGenx state-of-the art manufacturing facility, established for the VersaFilm™ technology platform, supports lab-scale to pilot- and commercial-scale production, offering full service capabilities to our clients. 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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