# Press Release

## RedHill Biopharma and IntelGenx Announce Definitive Agreement for Commercialization of RIZAPORT® for Migraines with Pharmatronic Co. in South Korea

- **RedHill and its co-development partner, IntelGenx Corp. (IntelGenx), have signed a definitive agreement with Pharmatronic Co., granting an exclusive license to commercialize the acute migraine drug RIZAPORT® in South Korea**

- **This agreement follows the previously announced commercialization agreement with Grupo JUSTE S.A.Q.F for Spain, and the subsequent submission of a national marketing authorization application for RIZAPORT® in Spain**

- **RedHill and IntelGenx expect to re-submit the RIZAPORT® U.S. New Drug Application (NDA) to the FDA in the first half of 2017 and subsequently receive a new PDUFA date**

**TEL-AVIV, Israel, December 14, 2016** RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) ("IntelGenx"), a Canadian drug delivery company focused on oral drug delivery, today announced the signing of an exclusive license agreement with Pharmatronic Co. ("Pharmatronic Co.") for the commercialization of RIZAPORT® in the Republic of Korea (South Korea). RIZAPORT® is a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraines.

Under the terms of the agreement, RedHill granted Pharmatronic Co. the exclusive rights to register and commercialize RIZAPORT® in South Korea. RedHill and IntelGenx are entitled to receive an upfront payment and will be eligible to receive additional milestone payments upon achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. The initial term of the definitive agreement with Pharmatronic Co. is for ten years from the date of first commercial sale and shall automatically renew for an additional two-

year term. Commercial launch in South Korea is estimated to take place in the first quarter of 2019.

**Mr. Adi Frish, RedHill's Senior VP Business Development & Licensing, said**: "We are pleased to enter into our second commercialization agreement for RIZAPORT® and look forward to building a long-term relationship with Pharmatronic Co. This agreement for South Korea follows our recent commercialization agreement with Grupo JUSTE S.A.Q.F for Spain. We continue working diligently together with our partner IntelGenx to bring this unique migraine drug to additional markets and expect to re-submit the RIZAPORT® NDA to the FDA in the first half of 2017."

"We are most pleased to enter the Asian market for the first time with Pharmatronic, a Korean organization committed to customer service excellence," **said Dr. Horst G. Zerbe, President and CEO of IntelGenx.** "We will be working hard with our partners RedHill and Pharmatronic to bring our innovative product to market for patients in South Korea suffering from migraines. The execution of two commercialization agreements for RIZAPORT® in less than six months demonstrates our relentless execution of strategy to bring our innovative products to the global market."

RIZAPORT® (5 mg and 10 mg) was granted marketing authorization by the Federal Institute for Drugs and Medical Devices of Germany (BfArM) under the European Decentralized Procedure (DCP), in which Germany served as the Reference Member State for other European Union (EU) countries. This authorization was the first national marketing approval for RIZAPORT®. A first commercialization agreement was signed with Grupo JUSTE S.A.Q.F (Grupo JUSTE) for Spain and additional potential territories and, subsequently, a national Marketing Authorization Application (MAA) for RIZAPORT® was submitted by Grupo JUSTE in Spain under the European DCP.

RedHill and IntelGenx expect to re-submit the RIZAPORT® New Drug Application (NDA) to the FDA in the first half of 2017 and subsequently receive a new PDUFA (Prescription Drug User Fee Act) date and are currently in discussions with potential commercialization partners for the U.S. market.

**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®. RIZAPORT® 5 mg and 10 mg were 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. RedHill has entered into licensing agreements to commercialize RIZAPORT® in Spain (with Grupo JUSTE S.A.Q.F) and in South Korea (with Pharmatronic Co.). Rizatriptan is considered to be 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 $690 million in 2015[1]. 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 migraine patients, specifically for patients who suffer from migraine-related nausea, estimated to be approximately 80% of the total migraine patient population[2] and patients suffering from dysphagia (difficulty swallowing).

**About RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill's pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful 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 and a completed proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA® (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON -** a Phase II-stage first-in-class, orally-administered uPA inhibitor, targeting gastrointestinal and other solid tumors and (vii) **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.

**About Pharmatronic. Co:**

Pharmatronic Co. is a privately held pharmaceutical company headquartered in Seoul, South Korea which distributes exclusively licensed pharmaceutical products with innovative sales and marketing know-how. Since its establishment in 2005, Pharmatronic Co. has focused R&D and marketing resources on the specialized target field of neurology, ENT and urology, building a strong image as a leading provider in the pharmaceutical and healthcare industry.

[1] EvaluatePharma WW annual sales report.

[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.

**About IntelGenx:**

IntelGenx is a leading oral drug delivery company primarily focused on the development and manufacturing of innovative pharmaceutical oral films based on its proprietary VersaFilm™ technology platform. Established in 2003, the Montreal-based company is listed on the TSX-V and OTC-QX.

IntelGenx highly skilled team provides comprehensive pharmaceuticals services to pharmaceutical partners, including R&D, analytical method development, clinical monitoring, IP 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 Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) 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 25, 2016. 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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