Press Release

RedHill Biopharma and IntelGenx Submit New Drug Application to FDA for RIZAPORT® for Migraines

- **RIZAPORT® is a proprietary oral thin-film formulation of rizatriptan for the treatment of acute migraines**
- **A Prescription Drug User Fee Act (PDUFA) date is expected to be set by the FDA for the first half of 2018, if the submission is deemed complete and permits a full review**
- **RIZAPORT® (5mg and 10mg) was granted marketing authorization in Germany and Luxembourg under the European Decentralized Procedure (DCP) and a national Marketing Authorization Application (MAA) has been submitted in Spain**
- **Commercialization agreements for RIZAPORT® were signed with Grupo JUSTE S.A.Q.F. for Spain and with Pharmatronic Co. for South Korea**
- **RedHill and IntelGenx continue discussions with additional potential commercialization partners for RIZAPORT® in the U.S., Europe and other territories**

TEL-AVIV, Israel / RALEIGH, NC, November 1, 2017 RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) ("IntelGenx"), 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, today announced that they have resubmitted the 505(b)(2) New Drug Application (NDA) for RIZAPORT® 10mg to the U.S. Food and Drug Administration (FDA).

RIZAPORT® is a proprietary oral thin-film formulation of rizatriptan for the treatment of acute migraines. RIZAPORT® offers an innovative 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 neutral flavor.

Following a first NDA submission to the FDA in March 2013, RedHill and IntelGenx received a Complete Response Letter (CRL) from the FDA. The questions raised by the FDA, which triggered the current resubmission, primarily related to third party chemistry, manufacturing and controls (CMC) and to the packaging and labeling of the product. The FDA letter raised no questions or deficiencies relating to RIZAPORT®'s safety and bio-equivalence data and did not require additional clinical trials.

If the RIZAPORT® NDA resubmission is deemed complete and permits a full review by the FDA, a Prescription Drug User Fee Act (PDUFA) date is expected to be set by the FDA for the first half of 2018.

Reza Fathi, PhD, RedHill's Senior VP Research & Development, said: "We are very pleased with the resubmission of the U.S. NDA for RIZAPORT®, which follows the marketing authorization received for RIZAPORT® in Germany and Luxembourg under the European Decentralized Procedure. Our efforts are focused on commercializing RIZAPORT® through partners in the U.S., Europe and other territories in the near future, and we are continuing the dialogue with potential partners."

"This resubmission of the RIZAPORT® 505(b)(2) NDA is an important milestone for IntelGenx," **commented Dr. Horst G. Zerbe, President and CEO of IntelGenx**. "We look forward to continuing to work with the FDA as we seek to bring this product to market as a new therapeutic option for the benefit of patients suffering from migraines."

RIZAPORT® was granted marketing authorization in Germany and in Luxembourg on the basis of the European Decentralized Procedure (DCP). A national Marketing Authorization Application (MAA) has been submitted for RIZAPORT® in Spain. Under the European DCP, marketing authorization approval of RIZAPORT® in additional European countries is subject to a separate procedure to obtain additional national marketing authorizations in each country. A first commercialization agreement for RIZAPORT® was signed with Grupo JUSTE S.A.Q.F. (now Exeltis Healthcare, S.L.) for Spain, and a second commercialization agreement for RIZAPORT® was signed with Pharmatronic Co. for South Korea.

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 and in Luxembourg in April 2017 under the European Decentralized Procedure. A New Drug Application for RIZAPORT® was resubmitted to the U.S. FDA in October 2017. RedHill entered into licensing agreements to commercialize RIZAPORT® in Spain (with 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. 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 soluble 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[1] and patients suffering from dysphagia (difficulty swallowing)[1].

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill promotes three gastrointestinal products in the U.S.: **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg,** a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions, and **EnteraGam®**, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's clinical-stage pipeline includes: (i) **TALICIA™ (RHB-105) -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study and an ongoing confirmatory Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study, a completed proof-of-concept Phase IIa study for multiple sclerosis, and a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with successful top-line results from a Phase III study in acute gastroenteritis and gastritis and successful top-line results from a Phase II study in 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 protease inhibitor, targeting pancreatic cancer and inflammatory gastrointestinal diseases and (vii) **RIZAPORT® (RHB-103) -** an oral thin-film formulation of rizatriptan for acute migraines, with a U.S. NDA resubmitted to the FDA and marketing authorization received in two EU member states under the European Decentralized Procedure (DCP). More information about the Company is available at: www.redhillbio.com.

[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.

About IntelGenx:

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

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 its clients. More information about the company can be found 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 successfully market Donnatal® and EnteraGam®, (vi) the Company's ability to establish and maintain corporate collaborations; (vii) 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; (viii) 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; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; and (xii) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xiii) the Company's Expanded Access Program, which allows patients with life-threatening diseases potential access, subject to regulatory and other approvals, to RedHill's investigational new drugs that have not yet received regulatory marketing approval, if a patient suffers an adverse experience using such investigative drug, potentially

adversely affecting the clinical development program of that investigational product or the Company generally; (xiv) competitive companies and technologies within 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 23, 2017. 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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