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RedHill Biopharma and IntelGenx Announce Marketing Approval of RIZAPORT® for Migraines in Luxembourg

- **The national marketing approval in Luxembourg completes the current approval process of RIZAPORT® under the European Decentralized Procedure (DCP); RIZAPORT® is also approved for marketing in Germany and a national Marketing Authorization Application (MAA) has been submitted in Spain**
- **RIZAPORT® is a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraines**
- **Commercialization agreements for RIZAPORT® were signed with Grupo JUSTE S.A.Q.F (now Exeltis Healthcare, S.L.) for Spain and Pharmatronic Co. for South Korea**
- **RedHill and IntelGenx currently expect to re-submit the RIZAPORT® 505(b)(2) U.S. New Drug Application (NDA) to the FDA in the third quarter of 2017**

TEL-AVIV, Israel, April 13, 2017 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, together with IntelGenx Corp. (TSX-V: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 the Ministry of Health of Luxembourg has granted national marketing authorization for RIZAPORT® (5 mg and 10 mg), a proprietary oral thin film formulation of rizatriptan benzoate for the treatment of acute migraines.

The national marketing authorization was granted in Luxembourg on the basis of the European Decentralized Procedure (DCP), in which Luxembourg served as the Concerned Member State. The approval in Luxembourg marks the completion of the current marketing approval process for RIZAPORT® under the European DCP. This process requires marketing approval in at least two European states, a Reference Member State and a Concerned Member State[1]. RIZAPORT® (5 mg and 10 mg) was previously approved for marketing in Germany, which served as the Reference Member State. 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.

RIZAPORT® 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.

A first commercialization agreement for RIZAPORT® was signed with Grupo JUSTE S.A.Q.F (now Exeltis Healthcare, S.L.) for Spain and, subsequently, a national Marketing Authorization Application (MAA) for RIZAPORT® was submitted by Grupo JUSTE.

A second commercialization agreement for RIZAPORT® was recently signed with Pharmatronic Co. for South Korea.

RedHill and IntelGenx expect to re-submit the RIZAPORT® 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the third quarter of 2017. The companies are continuing discussions with additional potential commercialization partners for RIZAPORT® in the United States., Europe and other territories.

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 also filed with the U.S. FDA in 2013 and a Complete Response Letter 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. 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: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 has a U.S. co-promotion agreement with Concordia for **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, as well as an exclusive license agreement with Entera Health for **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) **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, a completed proof-of-concept Phase IIa study for multiple sclerosis and QIDP status for nontuberculous mycobacteria (NTM) infections; (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 protease inhibitor, targeting pancreatic cancer 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. More information about the Company is available at: www.redhillbio.com.

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's common shares are listed on the TSX-V and OTCQX.

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 is available about the company at: www.intelgenx.com.

[1] European Commission Health and Food Safety Directorate-General, Volume 2A, Procedures for marketing authorization, Chapter 2.

[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.

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) 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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