



Press Release

RedHill Biopharma Announces Notice of Allowance for U.S. Patent Covering RIZAPORT™ for Migraines

- **The new U.S. patent is expected to be valid until 2034, once granted**
- **RedHill and its co-development partner, IntelGenx Corp., recently announced the national approval of RIZAPORT™ in Germany under the European Decentralized Procedure (DCP)**
- **RedHill and IntelGenx continue to work together to secure commercialization partners for RIZAPORT™ and to obtain national phase approvals in other European DCP territories, as well as FDA marketing approval in the U.S.**

TEL-AVIV, Israel, February 18, 2016 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) (“RedHill” or the “Company”), an Israeli biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for a new patent covering RIZAPORT™ (RHB-103) for acute migraines.

The patent application, entitled “*Instantly Wettable Oral Film Dosage Form Without Surfactant or Polyalcohol*” covers rapidly disintegrating oral film dosage forms and is expected to be valid until 2034, once granted.

Guy Goldberg, RedHill’s Chief Business Officer, said: “The grant of this new U.S. patent will provide an important intellectual property protection for RIZAPORT™. RIZAPORT™ is the first rizatriptan oral disintegrating film for the treatment of acute migraines and is designed to be a more convenient delivery mechanism for migraine patients such as those who suffer from difficulty swallowing.”

RedHill and its co-development partner, IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) (“IntelGenx”), recently announced the national approval of RIZAPORT™ in Germany under the European Decentralized Procedure (DCP), in which Germany served as the Reference Member State. This authorization was the first national marketing approval of RIZAPORT™.

RedHill and IntelGenx continue to work together to secure commercialization partners for RIZAPORT™ to obtain national phase approvals in other European DCP territories as well as FDA marketing approval in the U.S.

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 is designed to have a pleasant taste and to dissolve in the mouth without the need for water. It is a potential 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 population¹. 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.

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 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. 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 \$690 million in 2015². 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.

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.

² EvaluatePharma WW annual sales report.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development and commercialization 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 with an ongoing first Phase III study for Crohn's disease and an ongoing 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 in the U.S. for acute gastroenteritis and gastritis and a planned Phase II study for IBS-D; (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 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.

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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