



## Press Release

### **RedHill Biopharma and IntelGenx Announce RIZAPORT™ Commercialization Term Sheet with Grupo JUSTE for Spain and Additional Potential Territories**

- **RedHill and its co-development partner, IntelGenx Corp., have entered into a binding term sheet with Grupo JUSTE granting an exclusive license to commercialize their acute migraine drug RIZAPORT™ in Spain, and a right of first refusal for additional territories**
- **Grupo JUSTE is a prominent private Spanish company with over 90 years of experience in the research, development and commercialization of proprietary pharmaceutical products, including migraine and other central nervous system (CNS) drugs in Europe, Latin America and other territories**
- **RIZAPORT™ was recently approved for marketing in Germany under the European Decentralized Procedure (DCP); RedHill and IntelGenx continue to work together to secure additional commercialization partners for RIZAPORT™ in the U.S., Europe and other territories**
- **Re-submission of the RIZAPORT™ U.S. New Drug Application (NDA) to the FDA and receipt of a new PDUFA date are expected in the fourth quarter of 2016**
- **A new U.S. patent covering RIZAPORT™ is valid until 2034**

**TEL-AVIV, Israel, March 29, 2016** RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) (“RedHill” or the “Company”), a 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, together with IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) (“IntelGenx”), a Canadian drug delivery company focused on oral drug delivery, today announced that they have

entered into a binding term sheet with Grupo JUSTE S.A.Q.F (“Grupo JUSTE”) granting Grupo JUSTE the exclusive license to commercialize RIZAPORT™ in Spain and a right of first refusal for additional territories. RIZAPORT™ is a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraines.

Under the term sheet, subject to remaining conditions, a definitive agreement is planned to be entered into within 60 days of the execution of the term sheet.

Pursuant to the signing of a definitive agreement, RedHill will grant Grupo JUSTE the exclusive rights to register and commercialize RIZAPORT™ in Spain and a right of first refusal for the territories of Belize, Caribbean, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Middle East and Morocco. Under the term sheet, RedHill and IntelGenx will 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. Financial terms of the term sheet were not disclosed. The initial term of the definitive agreement is expected to be for ten years from the date of first commercial sale with an automatic renewal for an additional two-year term. Commercial launch in Spain is estimated to take place in the second half of 2017.

RedHill further announced that the previously announced new U.S. formulation patent covering RIZAPORT™ will be issued by the U.S. Patent and Trademark Office (USPTO) on April 5, 2016. The patent is valid until 2034.

**Adi Frish, RedHill’s Senior VP Business Development & Licensing, said:** “We are very pleased to enter into this term sheet with Grupo JUSTE, which sets the ground for the first commercialization agreement for RIZAPORT™ and once again demonstrates RedHill’s ability to carefully and selectively secure high-quality partners for its products. Grupo JUSTE is a prominent and well-established Spanish company with a proven track record in commercializing migraine and other CNS drugs in Spain and additional territories. With a unique dissolvable oral thin film delivery form, RIZAPORT™ is a potentially attractive therapeutic alternative for many migraine patients, including the estimated 80% of the total migraine population suffering from migraine-related nausea. We continue our discussions with potential commercialization partners for RIZAPORT™ in the U.S., Europe, and additional territories and are working diligently with IntelGenx to gain FDA marketing approval for RIZAPORT™ in the U.S.”

**Inés Juste, President of Grupo JUSTE added:** “We are extremely satisfied to announce the planned arrival of this new formulation of a leading treatment for migraine. Our partners, IntelGenx and RedHill possess a deep knowledge in the pharmaceutical industry including strong leadership in innovative formulations that improve the compliance and the administration pattern of gold standard drugs. This term sheet should allow Grupo JUSTE to bring this new comprehensive treatment to Spain and potentially some Latin American and Middle East countries and to reinforce its presence in Neurology.”

The Federal Institute for Drugs and Medical Devices of Germany (BfArM) recently granted marketing authorization of RIZAPORT™ 5 mg and 10 mg 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 of RIZAPORT™.

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. No deficiency was raised relating to the safety or bio-equivalence data of RIZAPORT™. RedHill and IntelGenx expect to re-submit the RIZAPORT™ New Drug Application (NDA) to the FDA in the fourth quarter of 2016 and subsequently receive a new PDUFA (Prescription Drug User Fee Act) and are 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<sub>1</sub> 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. 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<sup>1</sup>. 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<sup>2</sup> 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 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 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 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

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<sup>1</sup> EvaluatePharma WW annual sales report.

<sup>2</sup> Lipton RB, Buse DC, Sainers 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.

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**<sup>®</sup> - 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**<sup>™</sup> (**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. For more information please visit: [www.RedHillBio.com](http://www.RedHillBio.com).

#### **About Grupo JUSTE:**

Grupo JUSTE is a Spanish corporate group with more than 90 years' experience in research, development and distribution of drugs and active pharmaceutical ingredients. Its activity is aimed at improving the quality of life of patients, with the Central Nervous System therapies as one of its main areas of expertise since 1990 and a core strategic focus for the group.

Grupo JUSTE has two areas of activity: the Pharmaceutical Division, with broad experience in Radiology, Gynaecology, Primary Care and the Central Nervous System; and JUSTEsa Imagen, a fine-chemicals company committed to the research, development and production of active pharmaceutical ingredients, with substantial expertise in contrast media. The group has a significant presence in all the major world markets, directly or through partnerships with leading pharmaceutical companies. For more information, please visit: [www.grupoJUSTE.com](http://www.grupoJUSTE.com)

#### **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<sup>™</sup>, VersaTab<sup>™</sup> and AdVersa<sup>™</sup>. IntelGenx has developed a broad and diverse product portfolio addressing unmet market needs and offering lifecycle management opportunities. Forfivo XL<sup>™</sup>, launched in 2012, is the first and only FDA approved once-daily bupropion HCl 450 mg dose in a single tablet for the treatment of major depressive disorder. IntelGenx's highly skilled team provides comprehensive pharmaceutical services to pharmaceutical partners, including R&D, clinical monitoring, IP protection, analytical method development and regulatory services. IntelGenx's state-of-the art manufacturing facility, established for the VersaFilm<sup>™</sup> technology platform, supports lab-scale to pilot and commercial-scale production, offering full service capabilities to our clients. For more information on IntelGenx, visit: [www.intelgenx.com](http://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.*

**Company contact:**

Adi Frish  
Senior VP Business Development &  
Licensing  
RedHill Biopharma  
+972-54-6543-112  
[adi@redhillbio.com](mailto:adi@redhillbio.com)

**IR contact (U.S.):**

Marcy Nanus  
Senior Vice President  
The Trout Group  
+1-646-378-2927  
[Mnanus@troutgroup.com](mailto:Mnanus@troutgroup.com)