



Press Release

RedHill Biopharma Announces Exclusive U.S. Co-Promotion Agreement with Concordia for GI Drug Donnatal[®]

- **RedHill and Concordia entered into an exclusive co-promotion agreement, granting RedHill certain U.S. promotion rights for Donnatal[®]**
- **Donnatal^{®1}, Tablets and Elixir (syrup), is a prescription oral drug used with other drugs for the treatment of irritable bowel syndrome (IBS) and acute enterocolitis (inflammation of the small bowel)**
- **Under the terms of the agreement, RedHill and Concordia will share the revenues generated from the promotion of Donnatal[®] by RedHill, based on an agreed upon split between them**
- **RedHill's U.S. commercial operations team expects to commence gradual promotion of Donnatal[®] in the coming months**

TEL-AVIV, Israel, January 3, 2017 RedHill Biopharma Ltd. (NASDAQ/TASE: 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, today announced the signing of an exclusive co-promotion agreement with a subsidiary² of Concordia International Corp. (NASDAQ: CXRX) (TSX: CXR) (“Concordia”), an international specialty pharmaceutical company focused on generic and legacy pharmaceutical products and orphan drugs, granting RedHill certain U.S. promotion rights for Donnatal[®], a prescription oral drug used with other drugs

¹ Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide.

² Concordia Pharmaceuticals Inc.

in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis (inflammation of the small bowel)³.

Under the terms of the agreement, RedHill will be responsible for certain promotional activities related to Donnatal®. Concordia will continue to be responsible for the manufacturing and supply of Donnatal® in all territories. Donnatal® accounted for 7.7% of Concordia's consolidated revenues in the first half of 2016⁴. RedHill and Concordia will share the revenues generated from the promotion of Donnatal® by RedHill based on an agreed upon split between them. The initial term of the co-promotion agreement with Concordia is for three years. RedHill expects to initiate gradual promotion of Donnatal® in the coming months.

Dror Ben-Asher, Chief Executive Officer of RedHill, said: “We are pleased to partner with Concordia for the U.S. promotion of Donnatal®, a trusted brand among physicians for symptoms of IBS and acute enterocolitis⁵. With a core U.S. commercial team in place, we plan to initiate promotional activities in the U.S. in the coming months with a specialty gastrointestinal sales force. RedHill's strategic transition into a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company with commercial presence in the U.S., is planned to support potential future commercialization of our Phase III-stage potential blockbusters BEKINDA® for gastroenteritis and other GI indications, RHB-105 for *H. pylori* infection and RHB-104 for Crohn's disease, if approved by FDA.”

“This agreement is a cost-effective approach to promoting Donnatal® in a manner consistent with our long-term strategic focus on operational excellence,” **said Allan Oberman, Chief Executive Officer of Concordia.** “RedHill's commercial team is highly motivated and has previous experience in gastroenterology sales. We look forward to partnering with them to market Donnatal® to more key prescribers who we believe can help raise the product's profile and potentially allow us to reach more patients in the U.S.”

About IBS:

Irritable bowel syndrome (IBS) is a chronic multifactorial disorder characterized by recurrent abdominal pain or discomfort associated with altered bowel function. Certain factors that may alter gastrointestinal function can contribute to IBS symptoms, including stress, prior gastroenteritis and changes in the gut microbiome. However, the etiology of IBS is not understood and the underlying cause of IBS remains unknown. IBS negatively impacts patients' quality of life and can affect patients physically, emotionally, socially and economically. IBS is one of the most common

³ This drug has been evaluated as possibly effective for these indications. For more information, please see the prescribing information: <http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-information-DTC-REV.-SE.pdf>.

⁴ Concordia International Investor Presentation October 2016.

⁵ An inflammation of the small bowel.

gastrointestinal disorders. It is estimated that at least 30 million Americans suffer from IBS⁶. The U.S. potential market for IBS treatments is estimated to exceed \$2.3 billion by 2020⁷. Studies estimate that IBS affects 10 to 15 percent of U.S. adults, with about twice as many women as men and most often occurs in people younger than age 45⁸.

About Donnatal[®]:

Donnatal[®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide), a prescription drug, is classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. Donnatal[®] slows the natural movements of the gut by relaxing the muscles in the stomach and intestines and acts on the brain to produce a calming effect. Donnatal[®] comes in two formulations: immediate release Donnatal[®] Tablets, and immediate release Donnatal[®] Elixir, a fast acting liquid.

Donnatal[®] is contraindicated in patients who have glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, paralytic ileus, unstable cardiovascular status, severe ulcerative colitis, myasthenia gravis, hiatal hernia with reflux esophagitis, or known hypersensitivity to any of the ingredients. Patients who are pregnant or breast-feeding or who have autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia or hypertension should notify their doctor before taking Donnatal[®]. Side effects may include: dryness of the mouth, urinary retention, blurred vision, dilation of pupils, rapid heartbeat, loss of sense of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, and allergic reactions which may be severe.

Further information, including prescribing information, can be found on www.donnatal.com.

Please see the following website for important safety information about Donnatal[®]: <http://www.donnatal.com/professionals/important-safety-information/>

About Concordia:

Concordia is a diverse, international specialty pharmaceutical company focused on generic and legacy pharmaceutical products and orphan drugs. The Company has an international footprint with sales in more than 100 countries, and has a diversified portfolio of more than 200 established, off-patent molecules that make up more than 1,300 SKUs. Concordia also markets orphan drugs through its Orphan Drugs Division, consisting of Photofrin[®] for the treatment of certain rare forms of cancer. Concordia operates out of facilities in Oakville, Ontario and, through its subsidiaries, operates out of facilities in Bridgetown, Barbados; London, England and Mumbai, India.

⁶ Lovell RM, Ford AC, Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis, *Clin Gastroenterol Hepatol* (2012), 10(7)712-721; Saito YA et al, The epidemiology of irritable bowel syndrome in North America: a systemic review, *Am J Gastroenterol* (2002), 97(8): 1910-5.

⁷ EvaluatePharma - Irritable bowel syndrome Indication Profile.

⁸ Grundmann O, Yoon SL. Irritable bowel syndrome: epidemiology, diagnosis, and treatment: an update for health-care practitioners. *Journal of Gastroenterology and Hepatology*. 2010;25:691–699.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: 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. 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 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. More information about the Company is available at: www.redhillbio.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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