



March 7, 2017

## **RedHill Biopharma's Co-Promotion Partner Concordia Announces U.S. District Court Grants Treble Damages Relating to Donnatal®**

- ▮ **RedHill and Concordia recently entered into an exclusive co-promotion agreement, granting RedHill certain promotion rights in the U.S. for Donnatal®**
- ▮ **RedHill expects to initiate promotion of Donnatal® in the second quarter of 2017**

TEL-AVIV, Israel, March 07, 2017 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (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 updated that Concordia International Corp. (NASDAQ:CXR) (TSX:CXR) ("Concordia"), RedHill's co-promotion partner for the gastrointestinal drug Donnatal®, announced that a U.S. district court granted a Concordia subsidiary treble damages related to false claims made by Method Pharmaceuticals, LLC ("Method") and its principal owner.

According to Concordia's announcement, the court awarded Concordia treble damages of \$2.2 million, an increase from the original damages award of \$733,000, concluding that Method willfully engaged in false advertising under the Lanham Act by falsely listing the product on pharmaceutical databases, and asserting that its medication was a legal generic alternative to Concordia's Donnatal® drug.

In January 2017, RedHill announced an exclusive co-promotion agreement with a subsidiary<sup>1</sup> of Concordia, granting RedHill certain promotional rights in the U.S. for Donnatal®. RedHill expects to initiate promotion of Donnatal® in the second quarter of 2017.

Concordia stated that it believes that the treble damages awarded by the U.S. court further vindicates their marketing rights of the Donnatal® brand and should serve as notice to any other company marketing an illegal copy of Donnatal® that the judicial system in the U.S. will hold them financially accountable for such actions.

Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription oral drug used with other drugs in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis (inflammation of the small bowel)<sup>2</sup>.

### **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](http://www.donnatal.com).

Please see the following website for important safety information about Donnatal<sup>®</sup>: <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. The company has an international footprint with sales in more than 90 countries, and has a diversified portfolio of more than 200 established, off-patent products. Concordia also markets orphan drugs through its Orphan Drugs Division, consisting of Photofrin<sup>®</sup> 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.

#### **About RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ:RDHL) (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<sup>®</sup>**, 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, a completed proof-of-concept Phase IIa study for multiple sclerosis and QIDP status for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA<sup>®</sup> (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<sup>®</sup> (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<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. More information about the Company is available at: [www.redhillbio.com](http://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 successfully market Donnatal<sup>®</sup>, (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.*

<sup>1</sup> Concordia Pharmaceuticals Inc.

<sup>2</sup> Donnatal<sup>®</sup> (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon,

spastic colon, mucous colitis) and acute enterocolitis. 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>.

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)

 Primary Logo

Source: RedHill Biopharma Ltd.

News Provided by Acquire Media