Press Release

RedHill Biopharma Announces Exclusive U.S. License from Entera Health for Commercial GI Product EnteraGam®

- **RedHill expects to initiate U.S. promotion of its two commercially-available gastrointestinal specialty products, Donnatal®[1] and EnteraGam®[2], in mid-2017**

- **Under the terms of the agreement, RedHill will pay Entera Health royalties on net sales generated from the sale of EnteraGam® by RedHill**

TEL-AVIV, Israel, April 5, 2017 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 (GI) and inflammatory diseases and cancer, today announced the signing of an exclusive license agreement with Entera Health Inc. ("Entera Health"), a privately held U.S. company focused on the research, manufacturing, and commercialization of value-added proteins and protein co-products, granting RedHill the exclusive U.S. rights to EnteraGam®[2].

EnteraGam® is a commercially-available medical food intended for the dietary management of chronic diarrhea and loose stools which must be administered under medical supervision. 2016 net sales of EnteraGam® in the U.S. were over $5 million. EnteraGam® is a serum-derived bovine immunoglobulin/protein isolate (SBI) with a unique mechanism of action intended to restore gut balance. EnteraGam® has been studied for various uses, such as diarrhea-predominant irritable bowel

[1] Donnatal® (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.

[2] EnteraGam® (a serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

syndrome (IBS-D), inflammatory bowel disease (IBD) and human immunodeficiency virus (HIV)-associated enteropathy[3].

Guy Goldberg, RedHill's Chief Business Officer, said: "We look forward to initiating the promotion of Donnatal®[4] and EnteraGam® in mid-2017. We are currently in advanced stages of building RedHill's commercial operations in the U.S. and are excited to complement our product portfolio with a second commercial product geared towards gastroenterologists. We would like to thank our new partners at Entera Health and look forward to a successful long-term partnership."

Adi Frish, RedHill's Senior VP, Business Development and Licensing, said: "This is another important step in implementing our strategic plan of becoming a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company in the U.S. We continue to pursue additional commercial product opportunities in the specialty GI area to further expand our commercial operations. In parallel, we continue to advance the development of our three Phase III GI products, which, if approved by the FDA, we intend to commercialize in the U.S."

Aage Lauridsen, Entera Health's CEO, said: "We are very pleased to partner with RedHill to secure the continued marketing of EnteraGam® in the U.S. and are confident that RedHill's sales team will continue to grow the value of this unique product."

Under the terms of the agreement, RedHill licensed the exclusive U.S. rights to EnteraGam® for all indications for human use. RedHill will pay Entera Health tiered royalties on net sales generated from the sale of EnteraGam® by RedHill, and is not required to make any upfront or milestone payments. Under the terms of the agreement, Entera Health will also grant RedHill certain U.S. rights to its FDA-approved dicyclomine hydrochloride[5] oral solution USP (10 mg/5 ml), an antispasmodic and anticholinergic (antimuscarinic) agent indicated for the treatment of functional bowel/irritable bowel syndrome.

Numerous publications of clinical studies and retrospective chart reviews support the use of SBI in the dietary management of chronic diarrhea and loose stools[4]. The combined effect of SBI is intended to fulfill a distinctive nutritional requirement associated with various gastrointestinal conditions, where chronic diarrhea or loose stools are present and normal dietary proteins alone are insufficient. SBI has been shown in clinical studies to reduce loose stools and improve stool consistency as well as other symptoms, such as abdominal pain, bloating and urgency, in patients with chronic diarrhea and loose stools[4]. Several studies in patients suffering from inflammatory bowel diseases, such as ulcerative colitis and Crohn's disease, suggest that SBI improves clinical symptomatic management of patients who are not fully managed on traditional therapies[4]. SBI has also been studied in patients

[3] See full list of publications at: http://enteragam.com/assets/lib/EnteraGam_Product_Information.pdf.

[4] Donnatal® (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.

[5] For more information, please see the prescribing information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/007409s041lbl.pdf.

with fecal incontinence with chronic diarrhea, in patients with celiac and non-celiac gluten sensitivity with chronic diarrhea and in additional gastrointestinal indications[4].

No significant interactions of EnteraGam® with commonly prescribed medications or therapies have been reported. According to Entera Health, it is estimated that since EnteraGam® was introduced in 2013, nearly 3 million doses of EnteraGam® have been administered to patients in the U.S., with an overall adverse events rate of less than 0.2%, with no serious adverse events attributed to EnteraGam® during post-marketing surveillance.

In January 2017, RedHill announced an exclusive co-promotion agreement with a subsidiary[6] of Concordia International Corp., granting RedHill certain promotional rights in the U.S. for Donnatal®, 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).

About EnteraGam®:
EnteraGam® (a serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam® must be administered under medical supervision. EnteraGam® binds microbial components[7], such as toxic substances released by bacteria, that upset the intestinal environment. This helps prevent them from penetrating the lining of the intestine, which may contribute to chronic diarrhea and loose stools in people who have specific intestinal disorders[8][9].

Safety Information:
EnteraGam® contains beef protein; therefore, patients who have an allergy to beef or any other component of EnteraGam® should not take this product. EnteraGam® has not been studied in pregnant women, in women during labor and delivery, or in nursing mothers. The choice to administer EnteraGam® during pregnancy, labor and delivery, or to nursing mothers is at the clinical discretion of the prescribing physician.

EnteraGam® does not contain any milk-derived ingredients such as lactose, casein, or whey. EnteraGam® is gluten-free, dye-free and soy-free.

Please see full Product Information.

To report suspected adverse reactions, contact Entera Health, Inc. at 1-855-4ENTERA (1-855-436-8372), or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

[6] Concordia Pharmaceuticals Inc.
[7] Horgan A, Maas K, Henderson A, Detzel C, Weaver E. Serum-derived bovine immunoglobulin/protein isolate binds to pathogen-associated molecular patterns. Poster presented at: Federation of American Societies for Experimental Biology; April 26-30, 2014; San Diego, CA.
[8] Petschow BW, Burnett B, Shaw AL, Weaver EM, Klein GL. Serum-derived bovine immunoglobulin/protein isolate: postulated mechanism of action for management of enteropathy. Clin Exp Gastroenterol. 2014;7:181-190.
[9] Gasbarrini A, Lauritano EC, Garcovich M, Sparano L, Gasbarrini G. New insights into the pathophysiology of IBS: intestinal microflora, gas production and gut motility. Eur Rev Med Pharmacol Sci. 2008;12 Suppl 1:111-117.

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.

Important Safety Information:
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 complete important safety information about Donnatal®:
http://www.donnatal.com/professionals/important-safety-information/

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.

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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