January 12, 2017

RedHill Biopharma Provides 2017 Semi-Annual Business Update

TEL-AVIV, Israel, Jan. 12, 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 provided an update on key programs, potential milestones and estimated timelines.

Micha Ben Chorin, RedHill's CFO, said: "We are heading into 2017 with important potential catalysts in the coming months and with several ongoing Phase III and Phase II programs for gastrointestinal indications. Following the recently announced U.S. co-promotion agreement for Donnatal®[1], RedHill is advancing its strategic transition into a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company with commercial presence in the U.S. This transition is planned to support potential future commercialization of RedHill's Phase III-stage gastrointestinal drugs, if approved by the FDA. We are backed by strong institutional investors and maintain a debt-free balance sheet with approximately $70 million in cash, allowing us to continue to diligently execute our plans."

RHB-105 - *H. pylori* bacterial infection (confirmatory Phase III)

- The confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection, expected to enroll 440 patients in up to 55 U.S. sites, is planned to be initiated by April 2017 following completion of an ongoing supportive pharmacokinetic (PK) program.

RHB-104 - Crohn's disease (Phase III)

- 254 of the planned total of 410 subjects have been enrolled to date in the randomized, double-blind, placebo-controlled first Phase III study in the U.S. and additional countries with RHB-104 for Crohn's disease (the MAP US study).
- A second independent data and safety monitoring board (DSMB) meeting of the MAP US study is expected in the second quarter of 2017, with an interim efficacy analysis and an option for early stop for success for overwhelming efficacy.

BEKINDA® (RHB-102) - acute gastroenteritis (Phase III) and IBS-D (Phase II)

- 291 of the planned total of 320 subjects have been enrolled to date in the randomized, double-blind, placebo-controlled Phase III clinical study with BEKINDA® 24 mg in the U.S. for acute gastroenteritis and gastritis (the GUARD study). Top-line results are expected by mid-2017.
- 83 of the planned total of 120 subjects have been enrolled to date in the randomized, double-blind, placebo-controlled Phase II clinical study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Top-line results are expected in mid-2017.

YELIVA® - Phase I/II studies for multiple oncology and inflammatory indications

- RedHill is currently pursuing several Phase I/II clinical studies with YELIVA® in the U.S., targeting oncology indications, with support from National Cancer Institute (NCI) grants awarded to Apogee Biotechnology and U.S. universities, including ongoing studies for advanced hepatocellular carcinoma (Medical University of South Carolina), refractory or relapsed multiple myeloma (Duke University Medical Center) and refractory/relapsed diffuse large B-cell lymphoma and Kaposi sarcoma (Louisiana State University Health Sciences Center).
- Additional Phase I/II studies with YELIVA® are in various stages of preparation, including a Phase Ib study to evaluate YELIVA® as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy, planned to be initiated in the first half of 2017.

Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)

- As part of RedHill's strategic transition into a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company with a commercial presence in the U.S., the Company entered earlier this month into an exclusive co-promotion agreement with a subsidiary[2] of Concordia International Corp. (NASDAQ:CXRX) (TSX:CXR), granting RedHill certain U.S. promotion rights 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)[3]. RedHill expects to initiate promotion of Donnatal® in the coming months.

RIZAPORT® (RHB-103) - acute migraines (approved for marketing in Germany)

- Re-submission of the RIZAPORT® NDA to the FDA is expected in the first half of 2017. RIZAPORT® was approved for marketing in Germany under the European Decentralized Procedure (DCP) in October 2015 and a first commercialization agreement was signed with Grupo JUSTE S.A.Q.F for Spain and a second commercialization agreement was signed with Pharmatronic Co. for South Korea. RedHill continues discussions with additional potential commercialization partners for RIZAPORT® in the U.S., Europe and other territories.

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 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®**, 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 a QIDP status for NTM; (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.

[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.

[2] Concordia Pharmaceuticals Inc.

[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.

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

IR contact (U.S.):

Marcy Nanus

Senior Vice President

The Trout Group

+1-646-378-2927

Mnanus@troutgroup.com
