November 10, 2014

FDA Grants QIDP Fast-Track Designation to RedHill Biopharma's Phase III H. pylori Drug RHB-105

- **Under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, the Qualified Infectious Disease Product (QIDP) designation allows for additional five years of market exclusivity in addition to existing exclusivity, Fast-Track status (an expedited development pathway) and Priority Review status (shortened review time for marketing applications)**
- **With half of the targeted 120 patients already recruited, top-line data from the ongoing RHB-105 first Phase III study in the U.S. is expected in the second quarter of 2015**
- **RHB-105 is targeting a significantly broader indication than that of existing *H. pylori* therapies, as a first line treatment of *H. pylori* infection regardless of ulcer status, with the U.S. market for *H. pylori* eradication therapies estimated at approximately $1-1.5 billion annually**

TEL-AVIV, Israel, Nov. 10, 2014 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) (the "Company" or "RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that its Phase III *Helicobacter pylori (H. pylori)* eradication therapy, RHB-105, has been granted Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA. The QIDP designation has been granted under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, which is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections. *H. pylori,* a major cause of chronic gastritis, peptic ulcer disease and gastric cancer, has recently been added by the FDA to the list of qualifying pathogens that have the potential to pose a serious threat to public health.

The granted QIDP designation allows RedHill to benefit from Fast-Track development status with an expedited development pathway for RHB-105 and Priority Review status which provides for a shorter review time by the FDA of a future potential marketing application. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period.

Gilead Raday, RedHill's Senior VP Corporate and Product Development, said: "We are very pleased to have received the QIDP designation for RHB-105 by the FDA. The growing resistance rates of *H. pylori* to existing antibiotic therapies pose significant challenges to health organizations worldwide and the recent addition of *H. pylori* to the list of qualifying pathogens under the FDA's GAIN Act highlights the need for new therapeutic alternatives to treat *H. pylori* infected patients. RHB-105 is a new and proprietary all-in-one triple combination oral therapy which has demonstrated promising results in a Phase II study, and we hope to repeat these results in the ongoing Phase III study. The QIDP designation granted by the FDA provides important recognition of the potential of RHB-105 to address unmet needs in the treatment of *H. pylori* infection and we believe it will help accelerate the development process, potentially allowing patients faster access to the drug. We are pleased with the progress in the ongoing RHB-105 first Phase III study and expect top-line data in the second quarter of 2015."

RHB-105 is a proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI) in an all-in-one oral capsule, specifically selected due to their potential for improved efficacy and superior resistance profile in eradicating *H. pylori* infection. RHB-105 is currently undergoing a Phase III clinical study in the U.S. for the treatment of *H. pylori* infection (the ERADICATE Hp study) following a successful Phase II study in Australia which demonstrated eradication rates exceeding 90% in 130 subjects.

RedHill is pursuing a significantly broader indication with RHB-105 targeting *H. pylori* infection as a first line treatment regardless of ulcer status, while current standard treatments for *H. pylori* are typically indicated to treat patients with active or recent history of ulcers. If approved, RHB-105 may be the first *H. pylori* eradication therapy to pursue this broader indication, which would significantly expand the potential patient population for the drug.

It is estimated that approximately two-thirds of the world's population is infected with *H. pylori*, a bacterial infection which is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. Over three million patients are treated annually in the U.S. to eradicate *H. pylori* infection[1]. The potential market of *H. pylori* eradication therapies in the U.S. is estimated at approximately $1-1.5 billion annually[2].

About RHB-105:

RHB-105 is a new and proprietary fixed-dose oral combination therapy of two antibiotics and a proton pump inhibitor (PPI) in an all-in-one oral capsule with a planned indication for treatment of *H. pylori* infection. *H. pylori* bacterial infection is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. RHB-105 is currently undergoing a first Phase III clinical study in the U.S. (named ERADICATE Hp) planned to be followed, if successful, by a second Phase III study. The RHB-105 combination was originally developed as a next-generation therapy by Professor Thomas Borody, a leading innovator of therapeutic approaches to gastrointestinal tract diseases, who developed the first approved triple therapy treatment for *H. pylori* associated with peptic ulcer disease. RHB-105 has been granted Qualifying Infectious Disease Product designation by the U.S. FDA, which allows for Fast-Track development, Priority Review by the FDA of a potential future New Drug Application (NDA) and additional five years of exclusivity for the product.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing first Phase III study; (ii) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing first Phase III study; (iii) **RHB-102 -** a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a planned European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON® -** a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT® (formerly RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit 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 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 and approvals; (iv) the 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 interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi) competitive companies, technologies and 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 25, 2014. 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.

[1] Javier P. Gisbert MD, PhD, et. al (2013), Helicobacter Pylori "Test-and-Treat" Strategy for Management of Dyspepsia: A Comprehensive Review, *Clinical and Translational Gastroenterology* (2013) 4(3): e32.

[2] Approximately three million *H. pylori* infected patients are treated per annum in the U.S. (Javier P. Gisbert, MD, et. al (2013) Clinical and Translational Gastroenterology). Potential market size is estimated by the Company based on the above number and the estimated prices of current treatments of *H. pylori* infection in the U.S.

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Source: RedHill Biopharma Ltd.

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