April 18, 2016

RedHill Biopharma Announces Positive FDA Meeting on RHB-105 Path to Approval and Planned Confirmatory Phase III Study for H. pylori Infection

- **The FDA has confirmed, subject to final minutes of the meeting, the planned two-arm, randomized, double-blind, active comparator design of the confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection, expected to be initiated in the second half of 2016**

- **Based on FDA feedback, and subject to successful completion, the planned confirmatory Phase III study, along with the successfully completed first Phase III study and data from a supportive PK program, are expected to support a U.S. New Drug Application (NDA) for RHB-105**

- **The first Phase III study with RHB-105 successfully demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105 ($p < 0.001$), supporting the potential superior efficacy of RHB-105 over current standard-of-care (SoC) therapies**

- **RHB-105 has received FDA QIDP designation under the GAIN Act, including Fast-Track development, Priority Review and extended market exclusivity for a total of eight years**

- **With *H. pylori* infection estimated to affect over half of the adult population worldwide and increasing failure rates of SoC therapies due to antibiotic resistance, the 2015 global and U.S. market potential for *H. pylori* eradication therapies are estimated at approximately $4.83 billion and $1.45 billion, respectively**

- **RHB-105 is one of RedHill's three ongoing Phase III GI programs in the U.S., along with RHB-104 for Crohn's disease, with Phase III interim DSMB analysis expected in the second half of 2016, and BEKINDA(TM) for gastroenteritis, with Phase III top-line results also expected in the second half of 2016**

TEL-AVIV, Israel, April 18, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced that it has concluded a positive Type B Meeting with the U.S. Food and Drug Administration (FDA) regarding the path to marketing approval of RHB-105 and the planned confirmatory Phase III study. RHB-105 is a proprietary, fixed-dose, oral combination therapy for the eradication of *H. pylori* infection.

"We are very pleased with the outcome of the FDA meeting and would like to thank the Agency for its constructive feedback," **said Gilead Raday, Chief Operating Officer**. "The FDA meeting provided a pathway for potential marketing approval of RHB-105 in the U.S. We plan to initiate the RHB-105 confirmatory Phase III study discussed with the FDA during the second half of 2016 and hope to bring this new potential blockbuster drug to the market as soon as possible as a best-in-class, first-line therapy for eradication of *H. pylori*."

RedHill met with the FDA to discuss the successful results of the recently completed first Phase III study with RHB-105 (the ERADICATE Hp study) and the proposed design of the confirmatory Phase III study for the treatment of *H. pylori* infection. As a result of the productive and supportive feedback received from the FDA, RedHill intends, subject to finalization of the FDA meeting minutes, to complete the design of the planned confirmatory Phase III randomized, double-blind, active comparator, two-arm clinical study, comparing RHB-105 against a high dose amoxicillin and omeprazole regimen.

As per FDA recommendation, RedHill will complete a supportive pharmacokinetic (PK) program prior to initiating the confirmatory Phase III study in the second half of 2016. Subject to a successful outcome, the confirmatory Phase III study and supportive PK program are expected to complete the clinical package required for a U.S. New Drug Application (NDA) for RHB-105.

H. pylori bacterial infection is a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa-associated lymphoid tissue (MALT) lymphoma. *H. pylori* infection is estimated to affect over half of the adult population worldwide. The growing resistance of the *H. pylori* bacteria to metronidazole and clarithromycin has resulted in increasing failure rates of current standard-of-care therapies (SoC) for *H. pylori* eradication, reaching an estimated 30%1. Despite the strong unmet medical need, no new drug has been approved by the FDA for this indication in over a decade. The 2015 U.S. and global market potential for *H. pylori* eradication therapies, at current branded prices, were estimated at approximately $1.45 billion and $4.83 billion, respectively, and could potentially grow with increasing awareness of the health risks associated with *H. pylori* infection and the benefits of its eradication2.

The ERADICATE Hp first Phase III study with RHB-105 successfully met its protocol-defined primary endpoint of superiority over historical SoC eradication rate levels of 70%, with high statistical significance ($p < 0.001$). The final results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105. Subsequent open-label treatment of patients in the placebo arm with SoC therapy for persistent *H. pylori* infection demonstrated a 63% eradication rate with SoC, further supporting the potential superior efficacy of RHB-105 over SoC. RHB-105 was also shown to be safe and well-tolerated.

RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as Priority Review status, potentially leading to a shorter review time by the FDA of an NDA, if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity, in addition to the standard exclusivity period, for a total of 8 years of market exclusivity.

With RHB-105, RedHill is pursuing an indication of first-line treatment of *H. pylori* infection, regardless of ulcer status, a significantly broader indication than current standard treatments for *H. pylori*, which are typically indicated only for patients with active or recent history of duodenal ulcer disease. If approved, RHB-105 may be the first *H. pylori* eradication therapy to target this broader indication, which would significantly expand the potential patient population for this drug candidate.

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 the 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. A first Phase III study with RHB-105 was completed in the U.S. with positive results (the ERADICATE Hp study). The study demonstrated an overall success rate of 89.4% in eradicating *H. pylori*, and met its protocol-defined primary endpoint of superiority in eradication of *H. pylori* infection over historical standard of care efficacy levels of 70%, with high statistical significance ($p < 0.001$). A confirmatory Phase III study is planned to be initiated in the U.S. in the second half of 2016. Additional studies may be required, subject to FDA feedback. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as Priority Review status, potentially leading to a shorter review time by the FDA of an NDA, if filed. If approved, RHB-105 will also receive an additional five years of exclusivity, in addition to the standard exclusivity period, for a total of 8 years of U.S. market exclusivity.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) is a 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 inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products 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 an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA(TM) (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA(TM) (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON® -** a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT(TM) (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; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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.

1 Malfertheiner P. *et al.* Management of *Helicobacter pylori* infection - the Maastricht IV/ Florence Consensus Report, Gut 2012;61:646-664.

2 Jerry Rosenblatt, Ph.D., a member of RedHill's Advisory Board and Partner at Foster Rosenblatt, RedHill Biopharma press release: *RedHill Biopharma's Investor Webcast Forum Provides Update on the RHB-105 Phase III Program and Potential H. Pylori Eradication Market*, May 18, 2015.

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