September 8, 2015

RedHill Biopharma Announces Standard-of-Care Eradication Data From the RHB-105 Phase III Study Further Supporting the Study's Positive Results

- **Patients enrolled in the placebo arm of the ERADICATE Hp Phase III study received open-label standard-of-care (SoC) therapy for persistent *Helicobacter pylori* (*H. pylori*) infection; results from this group demonstrated a 63% *H. pylori* eradication rate, compared to the previously announced 89.4% eradication rate demonstrated in the RHB-105 arm of the study**
- **These results further support the potential superior efficacy of RHB-105 over SoC, and validate the use of the historical SoC eradication threshold of 70% implemented as the control for the Phase III study's primary endpoint**
- **RedHill entered into an agreement with Recipharm AB, a leading Swedish manufacturer, for the planned second Phase III study and potential future commercial supply of RHB-105; Recipharm will invest approximately $1.55 million in RHB-105 manufacturing capabilities**
- **The 2015 global and U.S. market potential for *H. pylori* eradication therapies, at current branded prices, were recently estimated at approximately $4.83 billion and $1.45 billion, respectively**
- **RedHill reported in June 2015 that the RHB-105 ERADICATE Hp Phase III study successfully met its primary endpoint with high statistical significance ($p < 0.001$); no serious adverse events related to the drug product or unexpected safety issues were identified; the clinical study report (CSR) for the study is expected in the fourth quarter of 2015**
- **A meeting with the FDA is planned for Q4/2015 or Q1/2016, to discuss the path for approval of RHB-105 as a potential best-in-class, first-line therapy for *H. pylori* infection, a major cause of gastric diseases, gastric cancer and MALT lymphoma; RHB-105 received FDA QIDP designation under the GAIN Act, including Fast-Track development, Priority Review and extended market exclusivity for a total of eight years**

TEL-AVIV, Israel, Sept. 8, 2015 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL), ("RedHill" or the "Company"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today announced additional supportive data from the first Phase III study with RHB-105 for eradication of *H. pylori* (the ERADICATE Hp Study). Results from the subsequent open-label treatment of patients in the placebo arm with standard-of-care (SoC) therapy for persistent *H. pylori* infection demonstrated a 63% eradication rate with SoC, compared to the previously reported 89.4% eradication rate demonstrated in the RHB-105 arm of the controlled study.

These results further support the potential superior efficacy of RHB-105 over SoC and validate the use of the historical SoC efficacy threshold of 70% implemented in the ERADICATE Hp study as the control for the study's primary endpoint. RedHill announced in June 2015 positive top-line results from the ERADICATE Hp Phase III study for the treatment of *H. pylori* bacterial infection. The top-line results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105. The study successfully met its primary endpoint of superiority over historical SoC eradication rate levels of 70%, with high statistical significance ($p < 0.001$). No serious adverse events related to the drug product, new or unexpected safety issues were identified in the study.

Prof. David Graham, M.D., M.A.C.G., of the Baylor College of Medicine, a key opinion leader in the field of gastric cancer and *H. pylori* infection and Principal Investigator of the ERADICATE Hp Study, said: "The study's results of 63% eradication rate of *H. pylori* infection with standard-of-care (SoC) are in-line with recent literature and clinical experience and are indicative of the increasing and alarming rates of resistance of *H. pylori* bacteria to SoC treatment. Furthermore, it strengthens the RHB-105 Phase III study's primary endpoint results, and supports the potential superior efficacy of RHB-105 over SoC, with an 89.4% eradication rate. *H. pylori* is a leading cause of gastric cancer, peptic ulcer disease and MALT lymphoma, and the falling cure rates of SoC therapies represent a significant concern for healthcare authorities worldwide. Despite existing therapies becoming increasingly ineffective in eradicating *H. pylori*, no new therapies have been approved for this indication in the last decade."

Gilead Raday, RedHill's Senior VP Corporate and Product Development, added: "The positive top-line results from the first Phase III study with RHB-105 and the new SoC data lead us to believe that RHB-105 can potentially be positioned as a best-in-class, first-line therapy for eradication of *H. pylori*. We plan to meet with the FDA during the fourth quarter of 2015 or the first quarter of 2016 to discuss the future development plan of RHB-105 and the path to marketing approval of this important drug candidate in the U.S."

The randomized, placebo-controlled, ERADICATE Hp Phase III study was intended to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* bacterial infection. A total of 118 non-investigated dyspepsia patients with confirmed *H. pylori* infection were enrolled and treated in the study, which was conducted in the U.S. Subjects were randomized in a 2:1 ratio to receive either RHB-105 or a placebo for a period of 14 days and assessed for the eradication of *H. pylori* infection. Subsequent to completion of the treatment period and the un-blinding of the study, subjects enrolled in the placebo arm were entitled to receive SoC therapy as prescribed by the treating physician in an open-label setting, and were assessed for the eradication of *H. pylori* infection 28-35 days after completion of treatment.

RedHill recently entered into an agreement with Recipham AB, a leading CMO (Contract Manufacturing Organization) for the manufacture of RHB-105. Under the terms of the agreement, Recipharm will be responsible for manufacturing RHB-105 for the planned second Phase III study and for future potential commercial supply of RHB-105. In order to support the manufacturing of RHB-105, Recipharm will invest approximately 13 million SEK (approximately $1.55 million) in manufacturing capabilities. Recipharm operates development and manufacturing facilities with approximately 2,200 employees in Sweden, France, the UK, Germany, Spain, Italy and Portugal and is headquartered in Jordbro, Sweden.

The 2015 global and U.S. market potential for *H. pylori* eradication therapies, at current branded prices, were recently estimated at approximately $4.83 billion and $1.45 billion, respectively, and could potentially grow with increasing awareness of the health risks associated with *H. pylori* infection and the benefits of its eradication[1].

Top-line and other results from the ERADICATE Hp Phase III study, demonstrating achievement of primary endpoint, were provided to RedHill by an independent third party following an independent analysis and remain subject to completion of the independent review and analysis of the underlying data, including all safety, secondary and other outcome measures. Completion of the clinical study report (CSR) is expected in the fourth quarter of 2015.

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 is ongoing in the U.S. with positive top-line 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 ($p < 0.001$). RedHill plans to conduct a second Phase III study. 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 U.S. market exclusivity, in addition to the standard exclusivity period, for a total of 8 years of market exclusivity.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful top-line 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; (iii) **BEKINDA™ (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 European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple inflammatory, gastrointestinal and oncology 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 tumor cancers; (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™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussion with the FDA and a European marketing application submitted in October 2014; 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 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; (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 (xi) competitive companies and technologies within the Company's industry; and (xii) 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 26, 2015. 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] 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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