



Press Release

RedHill Biopharma to Host Investor Webcast Forum Following Completion of RHB-105 Dosing in Phase III Study

- **RedHill will host an interactive investor forum on *H. pylori* bacterial infection and RHB-105, on Thursday, May 14, 2015, at 8:00-9:30 am Eastern Time. Participants are invited to join the forum through the Company's website or by telephone**
- **RHB-105 dosing has been completed in the blinded stage of the ERADICATE Hp study - a randomized, placebo-controlled, first Phase III study evaluating RHB-105 as a first-line therapy for *H. pylori* bacterial infection - a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and MALT lymphoma**
- **Top-line results from the ERADICATE Hp Phase III study with RHB-105 are expected in mid-end June 2015. The primary endpoint of the study is superiority over historical standard of care efficacy levels of 70% effectiveness**
- **RHB-105 has been granted QIDP designation by the FDA under the GAIN Act, allowing RedHill to benefit from fast-track development status, priority review, and extended market exclusivity for a total of 8 years**
- **RHB-105 targets a significantly broader indication than existing *H. pylori* therapies, as a first line treatment of *H. pylori* bacterial 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, May 7, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, announced today that it will host an interactive Investor Webcast Forum and conference call on *Helicobacter pylori* (*H. pylori*) bacterial infection and RHB-105, a proprietary fixed-dose oral combination therapy for treatment of *H. pylori* bacterial infection, on **Thursday, May 14, 2015, at 8:00-9:30 a.m. Eastern Time. RedHill invites all interested parties to participate in the live webcast through the Company's website or by telephone, as instructed below.**

RedHill also announced today that dosing has been completed in the blinded stage of the ERADICATE Hp Phase III clinical study with RHB-105. Top-line results from the study are expected in mid-end June 2015. The primary endpoint of the study is to show superiority in eradication of *H. pylori* bacterial infection over historical standard of care efficacy levels of 70% effectiveness. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA under the GAIN Act, allowing RedHill to benefit from fast-track development status for RHB-105, priority review, and extended market exclusivity for a total of 8 years. RHB-105 targets a significantly broader indication than existing *H. pylori* therapies, as a first line treatment of *H. pylori* bacterial infection regardless of ulcer status, with the U.S. market for *H. pylori* eradication therapies estimated at approximately \$1-1.5 billion annually¹.

The Investor Webcast Forum and conference call will be held on Thursday, May 14, 2015, at 8:00-9:30 a.m. Eastern Time. **Participants who wish to ask questions during the event can do so through the interactive webcast or by telephone.**

The live interactive webcast of the event, including the slide presentations, followed by a question-and-answer session, will be available through the Company's website at: <http://ir.redhillbio.com/events.cfm>. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

Audio-only access to the webcast will also be available by telephone, using the following dial-in information: **United States: +1-877-280-1254; Israel: +972-3-763-0145; International: +1-646-254-3365. The access code for the call is: 9862753.** The webcast and accompanying presentation materials will be archived and available for replay on the Company's website for 30 days.

The objective of the webcast is to provide an overview of *H. pylori* bacterial infection, the resulting unmet medical need and potential market opportunity for RHB-105, and to provide an update on the design and objectives of the ongoing ERADICATE Hp Phase III clinical study with RHB-105. The live webcast will be hosted by Mr. Gilead Raday, RedHill's Senior VP Product and Corporate Development. Presenters include:

¹ Approximately three million *H. pylori* infected patients are treated per annum in the U.S. (Colin W. Howden, MD, et al (2007), The American Journal of Managed Care). Market size is estimated by the Company based on the above number and the price of current treatments.

- **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* bacterial infection and Principal Investigator of the ongoing Phase III study of RHB-105. Prof. Graham will provide an overview of *H. pylori* bacterial infection and will discuss the relationship between *H. pylori* and gastric cancer, the challenges to and benefits of eradication therapy and the significant unmet medical needs associated with *H. pylori*.
- **Jerry Rosenblatt, Ph.D.**, a member of RedHill's Advisory Board and partner at Foster Rosenblatt, an international market research and advisory firm, exclusively focused on life sciences. Dr. Rosenblatt will provide an overview of the market potential for *H. pylori* eradication therapies.
- **Ira Kalfus, M.D.**, Medical Director at RedHill, will provide an overview of the clinical development of RHB-105 including prior studies, the design of the ongoing ERADICATE Hp Phase III clinical study with RHB-105 and its planned indication.

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. Additional studies may be required subject to FDA feedback. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing for a fast track development pathway as well as priority review status, potentially leading to a shorter review time by the FDA of a New Drug Application (NDA), if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period, for a total of 8 years of market exclusivity.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered 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 an ongoing 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 a 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 formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **ABC294640** - a Phase II-stage orally-administered SK2 inhibitor targeting multiple inflammatory-GI diseases and related oncology indications; (vi) **MESUPRON®** - a Phase II-stage 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 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

discussions 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.

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