# Press Release

## RedHill Biopharma to Host Conference Call Today to Review Positive Phase III Top-Line Results with RHB-105 for *H. pylori* Infection

**TEL-AVIV, Israel, June 15, 2015** RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced positive top-line results from its Phase III study with RHB-105 for the treatment of *Helicobacter pylori* (*H. pylori*) bacterial infection. Top-line results from the study demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105.

The ERADICATE Hp first Phase III study successfully met its primary endpoint of superiority over historical standard of care efficacy levels of 70%, with high statistical significance ($p < 0.001$). No serious adverse events, new or unexpected safety issues were identified in the study.

**RedHill will host two conference calls, in English and in Hebrew, to review the top-line results from the RHB-105 ERADICATE Hp Phase III study.**

**Today's English Conference Call and Webcast Information:**

The Company will host a conference call and an audio webcast today, **Monday, June 15, 2015, at 8:30 a.m. ET (15:30 Israel time)**.

To participate in the conference call, please dial the following numbers five to ten minutes prior to the start of the call: **United States: +1-877-280-2296; International: +1-212-444-0896; and Israel: +972-3-721-9510. The access code for the call is 5779339**.

**The conference call will be broadcasted simultaneously and available for replay on the Company's website, http://ir.redhillbio.com/events.cfm**, for 30 days. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

**Tomorrow's Conference Call in Hebrew:**

**A second conference call will be held, Tuesday, June 16, 2015, at 10:00 am Israel time.** The call will be conducted in Hebrew.

To participate in the conference call, **please dial 03-9180609** five to ten minutes prior to the start of the call.

**The conference call will be broadcasted simultaneously and available for replay on the Company's website, http://ir.redhillbio.com/events.cfm**, for 30 days. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

The top-line results from the RHB-105 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, and completion of the clinical study report (CSR), expected in the third 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, 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 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 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, it 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.

The top-line results from the Company's ERADICATE Hp study are preliminary in nature, as they are based solely on top-line information provided to the Company by an independent third-party contractor. The Company intends to examine the data from this study in greater detail, along with all of the information gathered during this study, including all safety, secondary and outcome measures. Such analysis may result in findings inconsistent with the top-line data disclosed in this release. As such, investors should not rely on the top-line results reported in this release as the final definitive results of the ERADICATE Hp study. Once the Company has fully analyzed the results from the ERADICATE Hp study, including the clinical study report, it will issue a release with the definitive findings.

*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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