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RedHill Biopharma Receives Positive Feedback From a Scientific Advice Meeting in Europe Regarding RHB-101 (Hypertension) Marketing Application Plan

- **The Company held a Scientific Advice meeting regarding RHB-101 with the Danish Health and Medicines Authority (DKMA)**
- **Following the positive results of the meeting, the Company intends to submit a Marketing Authorization Application (MAA) to market RHB-101 in Europe, with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP)**
- **The Company is also continuing to explore the parallel regulatory path for marketing approval of RHB-101 in the U.S.**
- **RHB-101 is a proprietary, controlled release, once-daily formulation of carvedilol, for the treatment of hypertension**

TEL-AVIV, Israel, March 19, 2013 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) (the "Company" or "RedHill"), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, patent-protected, new formulations and combinations of existing drugs, reported that it recently concluded a positive European Scientific Advice meeting with the Danish Health and Medicines Authority (DKMA) regarding its cardio drug RHB-101, a controlled release, proprietary, once-daily formulation of carvedilol, for the treatment of hypertension.

RedHill intends to submit a Marketing Authorization Application (MAA) in Europe with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP). Based on the positive response in the official minutes of the meeting with the DKMA, RedHill believes that no further clinical studies will be required prior to submission of the MAA. The Company plans to focus on certain chemistry, manufacturing and control modules, the completion of which is expected to allow the submission of an MAA.

The Scientific Advice Meeting and the intended MAA submission follow the prior successful completion of four pharmacokinetic (PK) clinical trials comparing RHB-101 to Eucardic®, the branded immediate release carvedilol marketed by Roche in Europe (the equivalent U.S. market brand name is Coreg®, marketed by GSK).

In parallel, RedHill is continuing to explore the regulatory path for marketing approval of RHB-101 in the U.S.

"We are very encouraged by the positive feedback received from the Danish Health and Medicines Authority (DKMA), and appreciate the informative interactions and clarity provided by the DKMA," **said Dr. Reza Fathi, RedHill's Senior VP R&D.** "We intend to advance the preparations for a planned MAA submission with RHB-101, which, if approved, may be the first once-daily controlled release formulation of carvedilol in the European market."

RHB-101 is a once-daily controlled release formulation of carvedilol, a non-selective β-adrenergic blocking agent with α1-blocking activity. RHB-101 is based on a patented technology for the controlled release of drugs administered orally.

With clear potential advantages over the generic immediate release carvedilol available in the European market today, RHB-101 is targeting the European carvedilol market of approximately $220 million (2011)[1], as well as the $240 million U.S. Coreg CR® market (2011) and the $273 million U.S. generic immediate release carvedilol market (2010)[2].

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, patent protected, new formulations and combinations of existing drugs. The Company's current product pipeline includes a once-daily formulation of a leading congestive heart failure and high blood pressure drug, a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, an oral thin film formulation drug for the treatment of acute migraine, a combination therapy for the treatment of Crohn's disease as well as Multiple Sclerosis (MS), a combination therapy for the treatment of *Helicobacter pylori* bacteria causing ulcers, and an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy. 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 not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status 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) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (x) competitive companies, technologies and the Company's industry; and (xi) statements as to 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 From 20-F filed with the SEC on February 19, 2013, and its Reports on Form 6-K. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. 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 made by us or on our behalf as a result of new information, future events or other factors.

[1] IMS Health

[2] IMS Health

CONTACT: PR contact (U.S.):

Lauren Glaser

Vice President

The Trout Group

+1-646-378-2972

lglaser@troutgroup.com

Company contact:

Adi Frish

Senior VP Business Development & Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

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