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RedHill Biopharma Provides Update on Development Progress and Planned NDA Submission for RHB-102 (Oncology Support Anti-Emetic)

- **Following a successful comparative bioavailability trial, the Company met with the FDA to discuss its planned New Drug Application (NDA) filing for RHB-102**
- **Company plans to file the RHB-102 NDA in Q4/2013**
- **RHB-102 is a proprietary, extended release, once-daily oral formulation of ondansetron, a leading drug for the prevention of nausea and vomiting in cancer patients**

TEL-AVIV, Israel, Feb. 25, 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 Type B meeting and has held additional communications with the U.S. Food and Drug Administration ("FDA") regarding RedHill's RHB-102, a patent protected, oral, extended-release (24 hours) formulation of ondansetron. Ondansetron is the active ingredient in GlaxoSmithKline's Zofran® immediate release tablets for the prevention of radiotherapy induced nausea and vomiting (RINV) and chemotherapy induced nausea and vomiting (CINV).

The purpose of these communications with the FDA was to discuss the filing of a U.S. new drug application ("NDA") for RHB-102, following the Company's 2012 comparative bioavailability study. Based on these communications and subject to additional regulatory and other activities, RedHill currently estimates that an NDA for RHB-102 will be filed during the fourth quarter of 2013. In the meantime, RedHill is focused on completing additional studies and product information required for the NDA data package and plans to seek additional regulatory guidance from the FDA ahead of the planned NDA submission.

With potentially significant advantages to cancer patients over the immediate release oral ondansetron tablets, RHB-102 is targeting a significant segment of the 5-HT3 anti-emetic oncology support drug products' market, which was estimated to be approximately $1 billion in 2010 by BCC Research, a leading market intelligence and information resource.

Gilead Raday, RedHill Biopharma's Senior VP Corporate and Product Development, commented; "We are very pleased with the progress that has been made with RHB-102 through the completion of the comparative bioavailability study and the positive communications we have had with the FDA. We are another step closer to an NDA filing, which is planned for later this year, advancing RHB-102 toward the market for the benefit of cancer patients who suffer from nausea and vomiting."

About RedHill Biopharma Ltd.:

RedHill Biopharma 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 ahead of certain gastro procedures. 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 Registration Statement on From 20-F filed with the SEC on December 26, 2012, 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.

CONTACT: PR contact (US):

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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