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RedHill Biopharma Announces Issuance of New U.S. Patent and Provides Update on RHB-104 for Treatment of Crohn's Disease

Patient Recruitment in an Initial Phase III Study is Planned to Commence Q2/2013; Multi-Site Initiation Process is Underway; Newly Issued Patent Expires no Earlier Than 2029

Additional Planned and Required Studies, Which Include a Second Phase III Crohn's Disease Trial in Europe and Other Supplementary Studies, Are Under Preparation as Part of RHB-104's Development and Regulatory Strategy

TEL-AVIV, Israel, Jan. 7, 2013 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq:RDHL) (TASE:RDHL) (the "Company" or "RedHill Biopharma"), an emerging Israeli biopharmaceutical company focusing primarily on the development and acquisition of late clinical-stage, patent-protected, new formulations and combinations of existing drugs, reported today the issuance of a new U.S. patent and that a multi-site initiation process is underway in the U.S., Canada and Israel for a first multi-center, randomized, double-blind, placebo-controlled, parallel group initial Phase III study (the "MAP US Study") to assess the efficacy and safety of fixed-dose combination RHB-104 in subjects with moderately to severely active Crohn's disease. The MAP US Study will be conducted under an Investigational New Drug (IND) application amended in August 2012 and recruitment is planned to commence in the second quarter of 2013.

240 subjects will be randomized into the MAP US Study across up to 50 sites in the U.S., Canada and Israel. The primary endpoint for this study is the state of remission at week 26 in subjects randomized to receive RHB-104, as compared to subjects randomized to receive placebo. Secondary and exploratory endpoints will include, among others, state of response at 26 weeks, maintenance of remission through week 52 and efficacy outcome measures in relation to presence of MAP (*Mycobacterium avium paratuberculosis*) bacterial infection. The study is exploratory with respect to the clinical validation of the Company's proprietary Polymerase Chain Reaction (PCR) assay used to detect MAP, the initial development of which was recently completed by Quest Diagnostics. An appropriate regulatory path for the validation and approval of the assay is currently being explored by the Company.

The lead investigator for the MAP US study will be Professor David Y. Graham, MD from Baylor College of Medicine, Houston, Texas. Professor Graham is a prominent gastroenterologist and internationally recognized researcher.

In addition to the MAP US Study which is designed to provide insights into safety and efficacy of RHB-104 and initial assessment of the role of MAP in Crohn's disease, the Company is planning and preparing for a Phase III clinical trial in Europe with RHB-104 for the treatment of Crohn's disease (the "MAP Europe Study") as well as supplementary studies required as part of RHB-104's global development program and regulatory strategy.

On January 1, 2013, the United States Patent and Trademark Office issued a new patent covering RHB-104 (No.: 8,343,511) entitled "*Methods and Compositions for Treating Inflammatory Bowel Disease*", which expires no earlier than 2029.

Patrick Mclean, RHB-104 Product Manager at RedHill Biopharma said: "We are extremely pleased that the RHB-104 MAP US Study is about to commence and look forward to further advancing the development plan for this important therapeutic treatment for Crohn's disease. Based on the relevant results of a Phase III study with an earlier formulation of the drug conducted in 2007 by Pfizer/Pharmacia in Australia, and the strong interest we are receiving from Crohn's disease patients and the medical community, we are eager to enroll the first patients into our study."

About RHB-104 and Crohn's disease:

RHB-104 is designed for the treatment of Crohn's disease which is an inflammatory disease of the gastrointestinal system. It is a patent protected combination therapy of three antibiotics in a single capsule. Several clinical trials were conducted with formulations of the combination therapy, including, among others, two Phase II studies and a Phase III study conducted in Australia. RHB-104 builds on the success of Professor Thomas Borody, a leading innovator of therapeutic approaches to gastrointestinal tract diseases and infections, who formulated the original triple therapy for peptic ulcer disease associated with *Helicobacter pylori*. Current therapies target symptomatic relief of Crohn's disease and are widely considered of limited efficacy in the long term and associated with numerous adverse events. The RHB-104 combination therapy is based on increasing evidence supporting the hypothesis that Crohn's disease, rather than being an autoimmune disease, is caused by the dysregulation of immune responses secondary to infection in susceptible patients. According to EvaluatePharma, a source for commercial analysis of the pharmaceutical and biotech sector, the estimated worldwide market in 2011 for diagnosis and drug

treatment of Crohn's disease is $3 billion. In addition to Crohn's disease, RHB-104 is currently being developed for the treatment of Multiple Sclerosis (MS), and the Company is in advanced preparations for a Phase IIa study in Israel.

About RedHill Biopharma Ltd.:

RedHill Biopharma is an emerging Israeli biopharmaceutical company focused primarily on the development 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) disease, 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.

Statements in this Press Release that are not historical facts, including the regulatory status of the programs and the expected timing and description of the clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the Company's current understanding of the regulatory status and expectations of future events and are subject to significant regulatory and development risks and uncertainties that could cause actual results and development and regulatory progress to differ materially from those expressed or implied by such statements, including (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.

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