

## PRESS RELEASE

**RedHill Biopharma Commences Advanced Clinical Trial with RHB-102 (Prevention of Nausea and Vomiting in Cancer Patients); Subjects Recruitment Completed; First Dosing Took Place; Results Expected Within Months**

**RedHill Has Obtained FDA IND Approval As Well As CTA Approval from Health Canada. Subject to Certain Conditions, the Study May be Considered a Pivotal Trial (Phase III-equivalent).**

**RHB-102 is a once-daily controlled release Ondansetron formulation referencing GSK's Zofran® - a leading and approved drug administered several times per day, with annual sales of hundreds of millions of Dollars (including generic versions)**

Tel Aviv, February 14, 2012 - RedHill Biopharma Ltd. (TASE: RDHL), an emerging Israeli biopharmaceutical company focusing primarily on development of late clinical-stage new formulations and combinations of existing drugs, has announced today the commencement of an advanced clinical trial with RHB-102 for the prevention of nausea and vomiting in cancer patients. RedHill completed screening and recruitment of all subjects for this clinical trial and announced subjects' first dosing on February 13<sup>th</sup>, 2012.

Earlier this week RedHill Biopharma announced IND (Investigational New Drug Application) approval from FDA. RedHill previously obtained CTA (Clinical Trial Application) approval from Health Canada.

The RHB-102 clinical trial is a bioequivalence study which aims to test the pharmacokinetic similarity between RedHill's once-daily controlled release tablet formulation and Zofran®, GlaxoSmithKline's well known, leading, approved antiemetic drug administered several times per day, with annual sales of hundreds of millions of Dollars (including generic versions).

The RHB-102 clinical trial is expected to last several months up to final analysis of its results.

Based on advice from the Company's regulatory advisors and preliminary discussions held with FDA regarding the requisite regulatory route, if positive results are obtained and certain FDA requirements are met, the clinical trial may be considered a pivotal one (Phase III-equivalent), to be used by the Company for submitting a US marketing approval application (NDA - New Drug Application).

RHB-102 is a patent protected once-daily controlled release tablet formulation of the active ingredient Ondansetron, a serotonin 5-HT<sub>3</sub> receptor antagonist used mainly as an antiemetic (i.e. for prevention of nausea and vomiting). The drug market for serotonin receptor inhibitors (the drug family of RHB-102) is estimated at approximately \$1 billion.

**Mr. Gilead Raday, VP Corporate & Product Development at RedHill Biopharma** stated today: "We are excited about the commencement of the RHB-102 advanced clinical trial which we hope will lead to a US marketing application filing. RHB-102 is designed to prevent nausea and vomiting during a time window of up to 24 hours post administration, and is therefore expected to provide enhanced relief to cancer patients undergoing radiotherapy, relieving such patients from the requirement to take additional doses post radiotherapy treatment".

**About RedHill Biopharma Ltd.:**

RedHill Biopharma is an emerging Israeli biopharmaceutical company focused primarily on development of late clinical-stage new formulations 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 radiotherapy induced nausea and vomiting prevention drug, an oral thin film formulation of a leading triptan for the treatment of acute migraine, a combination therapy for the treatment of MAP infection in Crohn's as well as a companion diagnostic test for detection of the MAP bacteria, a combination therapy against resistant H. pylori bacteria causing ulcers, and a patent protected encapsulated formulation for bowel preparation ahead of certain gastro procedures. The Company's team includes prominent pharmaceutical experts. For more information please visit: [www.redhillbio.com](http://www.redhillbio.com).

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