

PRESS RELEASE

RedHill Biopharma Announces IND Approval from FDA to Conduct an Advanced Clinical Trial with RHB-102 (Prevention of Nausea and Vomiting in Cancer Patients)

The IND Approval Follows the Recent CTA Approval from Health Canada. Subject to Certain Conditions, the Study May be Considered a Pivotal Trial (Phase III-equivalent). Results Expected within a Few Months

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 12, 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 Investigational New Drug Application (IND) approval from the FDA, for an advanced clinical trial with RHB-102 for the prevention of nausea and vomiting in cancer patients. The IND approval follows the recent Clinical Trial Application (CTA) approval from Health Canada.

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).

The IND means that the FDA has no objection to the commencement of the clinical trial on the basis of the submitted trial protocol.

The planned 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.

The RHB-102 clinical trial is expected to commence in Canada during the first quarter of 2012 and is expected to last several months up to final analysis of its results.

RHB-102 is a patent protected once-daily controlled release tablet formulation of the active ingredient Ondansetron, a serotonin 5-HT₃ 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: "The IND from the FDA is an important step in the regulatory development of RHB-102. The clinical results previously demonstrated by RHB-102 were encouraging. Should RHB-102 be approved for marketing in the future, it may become an important therapy in support of cancer patients suffering from nausea and vomiting".

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.

This Press Release does not constitute an offer or solicitation to acquire and/or sell the Company's securities or to participate in any investment in the Company. Statements in this Press Release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. All of these forward-looking statements are subject to risks and uncertainties that may change at any time, and, therefore, actual results may differ materially from those expected. 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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