

## PRESS RELEASE

### **RedHill Biopharma is Advancing Towards a Clinical Trial with RHB-102 for Prevention of Nausea and Vomiting in Cancer Patients**

### **RedHill Reported Obtaining a Clinical Trial Application (CTA) Approval from Health Canada to Commence an Advanced Clinical Trial**

**RHB-102 is a once-daily controlled release drug compared with GSK's Zofran® - a leading and approved drug administered several times per day**

Tel Aviv, February 5, 2012 - RedHill Biopharma Ltd. (TASE: RDHL), an emerging Israeli biopharmaceutical company focusing primarily on development and acquisition of late clinical-stage new formulations and combinations of existing drugs, announced obtaining a CTA (Clinical Trial Application) from Health Canada (similar to FDA's IND (Investigational New Drug Application) status) for the commencement of an advanced clinical trial in Canada with RHB-102 for the prevention of nausea and vomiting in cancer patients.

RedHill Biopharma estimates, based on its regulatory advisors and preliminary discussions held with FDA regarding the requisite regulatory route, that if positive results are obtained, 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).

RedHill Biopharma recently reported an engagement with the Canadian based CRO (Clinical Research Organization), Algorithm Pharma, Inc., for the execution of the advanced clinical trial with RHB-102.

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 anti-emetic drug administered several times per day.

RHB-102 encompasses a patent protected technology for a 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.

RedHill Biopharma estimates that 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. In addition, RedHill Biopharma estimates that the development costs of RHB-102, until NDA submission, will total up to approximately \$2-3 million.

**Mr. Gilead Raday, VP Corporate & Product Development and Project Manager of the RHB-102 program at RedHill Biopharma** stated today: "The CTA is a significant step towards execution of the planned RHB-102 clinical trial, in anticipation of a US marketing approval application. Once daily RHB-102 will be compared with GSK's Zofran® which is administered several times per day and which together with its generic versions currently sells several hundreds of millions of dollars per year. 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 and acquisition 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 treatment of 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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