

## **PRESS RELEASE**

### **RedHill Biopharma is Preparing for an Advanced Clinical Trial with RHB-102, a Drug for the Prevention of Nausea and Vomiting in Cancer Patients Undergoing Chemotherapy and Radiotherapy**

#### **The Company Reported an Engagement with a Canadian CRO, Algorithm Pharma, for the Execution of the RHB-102 Clinical Trial**

#### **The Drug Market for Serotonin Receptor Inhibitors is estimated at \$700 million in the US alone**

Tel Aviv, November 3<sup>rd</sup>, 2011 - 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, reported an engagement with Algorithm Pharma, Inc. a Canadian CRO (Clinical Research Organization), for the execution of an advanced clinical trial with RHB-102, a drug designated to prevent chemotherapy and radiotherapy induced nausea and vomiting.

RedHill Biopharma estimates that the RHB-102 clinical trial is expected to be conducted during the first half of 2012, subject to obtaining the relevant approvals.

Algorithm Pharma, which specializes in executing clinical trials for the global pharmaceutical industry will conduct the planned clinical trial in accordance with the regulatory requirements of the FDA and Canada Health.

Based on prior correspondence and discussions with FDA, it is estimated that should the trial accommodate FDA requirements, it is possible that FDA will consider the trial as a pivotal one (Phase III equivalent), such that it will be used by the Company for US marketing approval submission purposes.

The planned RHB-102 clinical trial is a bioequivalence study, which aims to test the pharmacological similarity between RedHill's once-daily controlled release tablet formulation which is administered once a day prior to chemotherapy treatment, and Zofran®, GlaxoSmithKline's well known, leading, approved anti-emetic drug which is administered several times per day (prior to and following chemotherapy treatment). The clinical trial is planned to be performed in a small number of volunteers, in line with a special FDA regulatory development path named 505(b)(2). This regulatory path generally enables, subject to adherence to certain conditions, to minimize development costs and expenses, decrease development risks and shorten its duration.

RHB-102 encompasses patent protected technology for a once-daily controlled release tablet formulation of the active ingredient Ondansetron, a serotonin 5-HT 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 \$700 million in the US alone.

"The agreement with Algorithm Pharma serves as an important step towards bringing RHB-102 to the market", said **Mr. Gilead Raday, VP Corporate & Product Development and Project Manager of the RHB-102 drug development program at RedHill Biopharma**, and added: "We expect that patients receiving chemotherapy would prefer to consume RHB-102, a once-daily drug, prior to chemotherapy, rather than consuming several drug doses throughout the day, including post chemotherapy administration. As such, we hope that RHB-102 will provide enhanced relief to cancer patients who suffer from nausea and vomiting".

#### **About RedHill Biopharma Ltd.:**

RedHill Biopharma is an emerging Israeli biopharmaceutical company focused primarily on development and acquisition of late clinical-stage 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 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 and two additional gastrointestinal drugs. The Company's team includes prominent pharmaceutical experts. For more information please visit: [www.redhillbio.com](http://www.redhillbio.com).

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**PR contact:**

Hagai Schwartz

Gelbert-Kahana

+972 (0)54-4569120

[hagais@gk-biz.com](mailto:hagais@gk-biz.com)

**Company contact:**

Adi Frish

VP Business Development & Licensing

RedHill Biopharma

+972 (0)54-6543112

[adi@redhillbio.com](mailto:adi@redhillbio.com)