



## Press Release

Date: July 30, 2013

### **RedHill Biopharma Announces Positive Pre-Clinical Rheumatoid Arthritis Results with RHB-104 and Plans for a Phase IIa Study**

- The planned phase IIa, proof of concept, clinical study will assess the efficacy and safety of RHB-104 in patients suffering from rheumatoid arthritis (RA)
- RA is one of the most common inflammatory diseases, with 2012 worldwide sales of therapies exceeding \$20 billion
- A Phase III clinical study with RHB-104 for Crohn's disease is in final preparations
- A Phase IIa, proof of concept, clinical study with RHB-104 for multiple sclerosis (MS) is ongoing

**RedHill Biopharma Ltd.** (NASDAQ: RDHL; TASE: RDHL) (the “Company” or “RedHill”), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, proprietary formulations and combinations of existing drugs, today announced positive results from a pre-clinical study with RHB-104 for the treatment of rheumatoid arthritis (RA), one of the most common chronic inflammatory diseases. In light of these positive results, the Company plans to conduct a phase IIa, proof of concept, clinical study to assess the efficacy and safety of RHB-104 in patients suffering from RA.

The pre-clinical study was designed to evaluate the potential therapeutic effects of RHB-104 using the Collagen-Induced Arthritis (CIA) pre-clinical model, the most commonly studied autoimmune model of RA.

The results from the pre-clinical study demonstrated that disease severity was significantly reduced in the RHB-104 arm, indicating that RHB-104 was effective in treating CIA in the study.

RA is a systemic chronic inflammatory disease considered to be one of the most prevalent immune-mediated inflammatory diseases, with worldwide sales of RA therapies estimated to have exceeded \$20 billion in 2012<sup>1</sup>. It is estimated that the prevalence of RA ranges from 0.5% to 1% of the general population<sup>2</sup> with an estimated 1.5 million people affected by the disease in the U.S. alone<sup>3</sup>. The prevalence of RA increases with age and is more common among women<sup>4</sup>. RA is nearly always polyarticular and causes joint destruction, deformity, and loss of function. Extra-articular manifestations include cardiopulmonary diseases, eye diseases, Sjogren's syndrome, rheumatoid vasculitis and neurological diseases. There is no known cure for RA. Common therapies treat the symptoms of the disease and are considered of limited efficacy in the long term.

RHB-104 is a patent protected combination therapy of three antibiotics in a single oral capsule. It is a multifaceted drug with potentially distinct anti-inflammatory and neuroprotective properties, in addition to its bactericidal activity against intracellular infections. RHB-104 is also being evaluated for the treatment of Crohn's disease, with a phase III clinical study planned to commence in the third quarter of 2013 in the U.S., Canada and Israel, and for the treatment of multiple sclerosis, with an ongoing phase IIa proof of concept study.

**Dr. Reza Fathi, RedHill's Senior VP R&D, commented:** "We are delighted with the outcome of the pre-clinical study conducted with RHB-104 for rheumatoid arthritis. We plan to advance our clinical development program towards a phase IIa, proof of concept, clinical study to assess the efficacy and safety of RHB-104 in patients suffering from rheumatoid arthritis. The planned Phase III clinical study with RHB-104 for Crohn's disease, the ongoing Phase IIa study in multiple sclerosis and the planned Phase IIa study in rheumatoid arthritis, are designed to test a new and innovative hypothesis, that a bacterial induced dysregulated immune system plays a critical role in the pathogenesis of these diseases, all of which exhibit characteristics of both infectious and autoimmune pathology."

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

RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, proprietary formulations and combinations of existing drugs. The Company's current product pipeline includes: (i) **RHB-101** - a once-daily formulation of a leading congestive heart failure and high blood pressure drug, with a planned NDA submission in the U.S. subject to further CMC and PK work, and a planned Marketing Authorization Application (MAA) in Europe subject to further

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<sup>1</sup> EvaluatePharma - 2013 worldwide sales by indication

<sup>2</sup> Rheumatoid arthritis, *The Lancet*, Volume 376, Issue 9746, Pages 1094-1108, Scott, Wolfe, Huizinga

<sup>3</sup> Centers for Disease Control and Prevention (CDC)

<sup>4</sup> Centers for Disease Control and Prevention (CDC)

CMC work; (ii) **RHB-102** - a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, planned for U.S. NDA submission in the first quarter of 2014; (iii) **RHB-103** - an oral thin film formulation of a leading drug for the treatment of acute migraine, with a U.S. NDA accepted for review by the FDA in June 2013 and a PDUFA date of February 3, 2014; (iv) **RHB-104** - a combination therapy for the treatment of Crohn's disease, planned to commence a first Phase III trial in the third quarter of 2013, multiple sclerosis (MS), with a Phase IIa proof of concept trial currently underway, and plans for a Phase IIa proof of concept trial in rheumatoid arthritis (RA); (v) **RHB-105** - a combination therapy for *Helicobacter pylori* infection, planned to commence a phase II/III trial in the third quarter of 2013, and (vi) **RHB-106** - an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy and other GI procedures. For more information please visit: [www.redhillbio.com](http://www.redhillbio.com)

*This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (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) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company under their respective licensing agreements; (x) estimates of the Company's expenses, future revenues, capital requirements and the Company's needs for additional financing; (xi) competitive companies and technologies within the Company's industry; and (xii) 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 Annual Report on Form 20-F filed with the SEC on February 19, 2013, 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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