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RedHill Biopharma Announces Positive Preliminary Pre-Clinical Data With RHB-104 for the Treatment of Type 1 Diabetes

- **The Company, primarily focused on gastrointestinal and inflammatory-related diseases and conditions, including cancer, is currently assessing the possibility of a Phase II proof of concept study for type 1 diabetes, subject to final results and an independent report expected in the coming weeks**
- **A Phase III study with RHB-104 for Crohn's disease is in progress in the U.S., Canada and Israel, and a second Phase III study is planned to commence during the second half of 2014 in Europe**
- **A Phase II proof of concept clinical study with RHB-104 for the treatment of multiple sclerosis (MS) is in progress, following several positive pre-clinical studies in MS and other autoimmune disease models, including rheumatoid arthritis (RA) and Lupus**
- **RHB-104 is a proprietary and potentially groundbreaking therapy administered by oral capsule, with potent intracellular, anti-mycobacterial and anti-inflammatory properties**

TEL-AVIV, Israel, June 26, 2014 (GLOBE NEWSWIRE) -- 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 drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer, today announced preliminary positive data from a pre-clinical study with RHB-104 for the treatment of type 1 diabetes, a chronic autoimmune disease with an unknown cause. In light of the preliminary positive data, and subject to the final results and an independent report expected in the coming weeks, the Company is currently assessing the next steps in the development program, including a possible Phase II proof of concept clinical study for type 1 diabetes.

The pre-clinical study was designed to evaluate the potential therapeutic effects of RHB-104 using a pre-clinical diabetes model when administered orally. The preliminary data from the pre-clinical study suggests that RHB-104 is effective in treating type 1 diabetes in the study, as measured by blood glucose levels and body weight. Final results and an independent report are expected in the coming weeks.

Type 1 diabetes, previously known as juvenile diabetes, is a chronic autoimmune disease in which the pancreas produces little or no insulin, a hormone required to allow glucose to enter cells to produce energy. The disease surfaces when the body's immune system mistakenly attacks and destroys the insulin-producing cells in the pancreas, called beta cells. Type 1 diabetes is typically diagnosed at a young age but can also develop in adults. There is currently no cure for type 1 diabetes and the cause of the disease is uncertain, but it is believed that both genetic factors and environmental triggers are involved. Managing the disease is a lifelong challenge for patients, who are dependent on insulin injections or an insulin pump to control blood glucose levels. Long-term complications of type 1 diabetes develop gradually and can affect major organs including the heart, blood vessels, nerves, eyes and kidneys. In the U.S. alone, more than 18,000 young people are diagnosed each year with type 1 diabetes¹, and the worldwide sales of type 1 diabetes therapies are estimated to have exceeded \$12 billion in 2013².

About RHB-104:

Currently in a Phase III study for the treatment of Crohn's disease, RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy administered by oral capsule, with potent intracellular, antimycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by the *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. The RHB-104 formulation was originally developed by Professor Thomas Borody, a leading innovator of therapeutic approaches to treating gastrointestinal tract diseases, who also developed the original triple therapy for peptic ulcer disease associated with *H. pylori*. Several clinical trials were conducted with earlier formulations of the drug, including an Australian Phase III study published by Pfizer and other studies, both with earlier formulations and the current formulation of the drug. RHB-104 is covered by several issued and pending patents.

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 drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105** - an oral combination therapy for *Helicobacter pylori* infection, with an ongoing Phase III study; (iii) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals Ltd.; (iv) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting, in advanced development stages for multiple indications, including a European marketing application for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting planned for the third quarter of 2014 and a Phase III study for an undisclosed indication planned to commence in 2014, (v) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned for the third quarter of 2014, and (vi) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit: 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 based on certain assumptions 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, including any independent reports relating thereto; (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; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; and (xi) competitive companies, technologies and the Company's industry. 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 25, 2014. 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 unless required by law.

¹ National Diabetes Statistics Report, 2014, National Center for Chronic Disease Prevention and Health Promotion

² GlobalData Pharma eTrack Type 1 Diabetes Sales Analytics

CONTACT: Company contact:

Adi Frish

Senior VP Business Development & Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

PR contact (U.S.):

Lauren Glaser

Vice President

The Trout Group

+1-646-378-2972

lglaser@troutgroup.com

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