July 1, 2015

RedHill Biopharma Receives Notice of Allowance for Two Additional U.S. Patents Covering RHB-104 Ongoing Phase III Crohn's Disease Program

- **Once granted, the two new U.S. patents covering RHB-104 are expected to be valid through 2029**
- **RHB-104 is undergoing a first Phase III study for the treatment of Crohn's disease in the U.S. and additional countries**
- **A second Phase III study with RHB-104 for Crohn's disease is planned in Europe, following Clinical Trial Application approval by the UK MHRA**
- **A Phase IIa proof-of-concept study evaluating RHB-104 in patients treated for relapsing-remitting multiple sclerosis is currently ongoing, with interim results expected in Q4/2015-Q1/2016**

TEL-AVIV, Israel, July 1, 2015 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today announced that it has received two notices of allowance from the United States Patent and Trademark Office (USPTO) regarding its patent application numbers 13/722,395 and 14/271,758 covering RHB-104.

RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties, currently undergoing a first Phase III study for Crohn's disease and a Phase IIa study for multiple sclerosis.

Patent application number 13/722,395, entitled "*Methods and Compositions for Treating Inflammatory Bowel Disease*", once granted, is expected to be valid until October 2029.

Patent application number 14/271,758 entitled "*Methods and Compositions Comprising Rifabutin, Clarithromycin, and Clofazamine*", once granted, is expected to be valid until at least February 2029.

Danielle Abramson, Ph.D., RedHill's Director of Intellectual Property & Research said: "Once issued, these two new U.S. patents, carrying a patent term through at least 2029, will further enhance RedHill's global patent portfolio covering RHB-104, a potential groundbreaking treatment for Crohn's disease."

RHB-104 is currently undergoing a first Phase III study for the treatment of Crohn's disease in the U.S. and additional countries (the MAP US study). The ongoing randomized, double-blind, placebo-controlled MAP US Phase III study is expected to enroll 270 patients with moderately to severely active Crohn's disease. Patients are randomized 1:1 to receive either RHB-104 or a placebo for 52 weeks and evaluated for the primary endpoint of remission at week 26 of treatment. Interim analysis of the MAP US study is expected in the second half of 2016, after half of the patients expected to be enrolled in the study will have completed 26 weeks of treatment.

The MAP US Phase III study is registered on www.ClinicalTrials.gov, a web-based service by the U.S. National Institute of Health which provides public access to information on publicly and privately supported clinical studies: https://www.clinicaltrials.gov/ct2/show/NCT01951326.

RedHill also plans to initiate a second Phase III study with RHB-104 for Crohn's disease (the MAP EU study) following the recent acceptance in the UK of its Clinical Trial Application (CTA). The MAP EU study is planned to commence in a select number of European counties, and, once initiated, will run in parallel with the currently ongoing MAP US first Phase III study. The randomized, double-blind, placebo-controlled MAP EU Phase III study is expected to enroll 360 patients with moderately active Crohn's disease. Patients will be randomized 2:1 to receive either RHB-104 or a placebo for 52 weeks and then evaluated for remission at week 26 as the primary endpoint.

RHB-104 is also being evaluated as a treatment for relapsing-remitting multiple sclerosis (RRMS). The last patient has been enrolled in an open label Phase IIa, proof-of-concept clinical study evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for RRMS (the CEASE-MS study). Interim results are expected either in the fourth quarter of 2015 or the first quarter of 2016.

About RHB-104:

Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study) and a second Phase III study being prepared (the MAP EU study), RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial 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. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104, and a long-term population pharmacokinetic (Pop-PK) study is ongoing as part of the Phase III MAP US study. RHB-104 is covered by several issued and pending patents. RedHill is also conducting a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (RRMS).

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) is an emerging Israeli biopharmaceutical company focused on the development of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection, with successful top-line results from a first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease, with an ongoing first Phase III study; (iii) **BEKINDA™ (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis and a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106 -** an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **ABC294640 -** an orally-administered SK2 selective inhibitor targeting multiple inflammatory-GI diseases and related oncology indications with a first Phase I/II initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON® -** a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 research, manufacturing, 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, approvals and feedback; (iv) the manufacturing, 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 research, 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 (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 26, 2015. 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.

CONTACT: Company contact:

Adi Frish

Senior VP Business Development &

Licensing

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

IR contact (U.S.):

Marcy Nanus

Senior Vice President

The Trout Group

+1-646-378-2927

Mnanus@troutgroup.com

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