August 1, 2016

RedHill Biopharma Announces Last Patient Visit in Phase IIa Study with RHB-104 for Multiple Sclerosis

- **The Phase IIa proof-of-concept study evaluates the safety and potential efficacy of fixed oral dose RHB-104 as an add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (RRMS)**
- **Analysis of the study is ongoing, with top-line final results expected in the fourth quarter of 2016**
- **Previously announced interim results after completion of the 24-week RHB-104 treatment period of the study demonstrated positive safety and efficacy signals and support further clinical development**
- **2016 U.S. and worldwide sales of multiple sclerosis therapies are estimated to exceed $12 billion and $18 billion, respectively**
- **RHB-104 is also being evaluated as a treatment for Crohn's disease with an ongoing first Phase III clinical study (the MAP US study) with interim DSMB analysis expected in the fourth quarter of 2016**

TEL-AVIV, Israel, Aug. 01, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases and cancer, today announced that the last patient has completed the final scheduled follow-up visit in the Phase IIa proof-of-concept clinical study evaluating RHB-104 in patients treated for relapsing-remitting multiple sclerosis (RRMS).

The open label Phase IIa study (the CEASE-MS study) enrolled eighteen patients suffering from RRMS and was designed with a series of exploratory endpoints to evaluate the safety and potential efficacy of fixed oral dose RHB-104 as an add-on therapy to interferon beta-1a. Patients received treatment with RHB-104 for 24 weeks and were evaluated for an additional 24-week follow-up period during which they were treated with interferon beta-1a without RHB-104 add-on.

The analysis of the study is currently ongoing and top-line final results are expected to be announced in the fourth quarter of 2016, subject to completion of review requirements and completion of the clinical study report (CSR).

RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy in oral capsule formulation, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. Multiple sclerosis (MS) is a chronic inflammatory, demyelinating disease of the central nervous system (CNS) with an unknown etiology, believed to be multifactorial. Thought to be autoimmune, the MS inflammatory process is also consistent with persistent infection. The 2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively[1].

RedHill announced in March 2016 encouraging top-line interim results from the single-arm, open-label CEASE-MS study. Top-line interim results, after completion of the 24-week treatment period of the study, demonstrated positive safety and efficacy signals and support further clinical development, based on encouraging preliminary data.

As previously announced, the top-line interim results demonstrated an annualized relapse rate (ARR) at 24 weeks of 0.288 in the modified intent-to-treat (mITT) population and 0.0 in the per-protocol (PP) population, comparing favorably with previously reported pivotal studies of interferon beta-1a therapies Avonex® (0.67) [2] and Rebif® (0.87-0.91) [3].

88% of the mITT patient population and 100% of the PP patient population were relapse free at 24 weeks, comparing favorably with previously reported pivotal data on the use of Rebif® (75%) in comparison with Avonex® (63%) as standalone first-line therapies[4]. No patient in the CEASE-MS study relapsed after week 8 of treatment.

Expanded Disability Status Scale (EDSS) scores, a standard measure of MS disability, indicated the disease was stable during the treatment period and there was a signal of improvement; No increase in total EDSS was observed in any of the patients in the study.

With only a single active T1 post gadolinium lesion noted among all patients followed, combined unique active lesions

(CUAs) - the primary outcome measure in the CEASE-MS study - were almost entirely MRI T2 lesions. Although not powered for efficacy, a reduction in total MRI T2 lesion volume was observed at 24 weeks, as compared to baseline, suggesting a decreased burden of disease and comparing favorably with previously reported Avonex®[5] and Rebif ®[6] data. No clinically significant change was observed for total CUA lesions at week 24, which is supportive of a stable disease state.

RHB-104 was found to be safe and well tolerated, with no drug-related serious adverse events or other clinically relevant or unexpected adverse events.

RHB-104 is a multifaceted drug that, in addition to bactericidal properties against intracellular infections, has potentially distinct mechanisms of action that include both anti-inflammation and neuroprotection. The Phase IIa CEASE-MS study was initiated following several successful pre-clinical studies conducted by RedHill with RHB-104.

RHB-104 is also currently undergoing a first Phase III study for Crohn's disease in the U.S., Canada, Israel, Australia and Europe (the MAP US study). Interim data and safety monitoring board (DSMB) analysis of the ongoing randomized, double-blind, placebo-controlled MAP US study is expected in the fourth quarter of 2016.

The MAP US Phase III study and the CEASE-MS Phase IIa study are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

About Multiple Sclerosis:
Multiple sclerosis (MS) is a chronic inflammatory, demyelinating disease of the central nervous system with an unknown etiology, believed to be multifactorial. A dysfunctional immune system in MS patients causes recurrent inflammatory attacks on the central nervous system (CNS), leading to neurological disability. Diffuse inflammatory and demyelinating lesions, also known as plaques, are the main pathological finding in MS neural tissue. The lesions are primarily found in the spinal cord, optic nerves, brainstem and periventricular white matter. The symptoms of MS are dictated by the location of the lesions within the CNS. Geographic variation in MS distribution, which cannot be solely explained by population genetics, supports the notion that environmental factors also hold etiological importance. There is currently no known cure for MS and available treatments are mainly intended to manage or prevent relapses or reduce symptoms. In 2015, there were estimated to be over 900,000 diagnosed patients with MS worldwide. Approximately 85% of MS patients initially exhibit relapse-remitting disease (RRMS). The 2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively[7].

About RHB-104:
Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study), RHB-104 is a proprietary and potentially groundbreaking oral antibiotic combination therapy, 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 *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 the CEASE-MS 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), with top-line interim results announced.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases and cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful 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 and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (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 an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON® -** a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class 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 discussion with the FDA and marketing authorization received in Germany in October 2015; 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 Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) 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 25, 2016. 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] GlobalData PharmaPoint report, August 2015.

[2] Jacobs LD et al.: Ann Neurol 1996;39:285-294.

[3] PRISMS Study Group: Lancet 1998; 352: 1498-504.

[4] EVIDENCE Trial, Panitch H et al.: Neurology 2002;59:1496-1506.

[5] Cohen J A et al.: Oral Fingolimod or Intramuscular Interferon for Relapsing Remitting Multiple Sclerosis. NEJM. 2010, 362: 402-15.

[6] Cohen J A et al.: Alemtuzumab versus Interferon Beta 1a as First-Line Treatment for Patients with Relapsing-Remitting Multiple Sclerosis: a Randomised Controlled Phase 3 Trial. The Lancet. 2012, 380: 1819-28.

[7] GlobalData PharmaPoint report, August 2015.

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

Source: RedHill Biopharma Ltd.

News Provided by Acquire Media