Press Release

RedHill Biopharma Initiates Phase I/II Study of ABC294640 for Refractory Lymphoma

- **The Phase I/II study, led by Dr. Chris Parsons, MD, associate professor at Louisiana State University Health Sciences Center, is intended to evaluate the safety and tolerability of ABC294640 in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL), primarily patients with HIV-related DLBCL**

- **ABC294640 is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, gastrointestinal and oncology indications**

- **To date, the development of ABC294640 has been funded primarily through grants and contracts in excess of $14 million from U.S. federal and state government agencies, such as the FDA, Department of Defense (DoD) and the National Institutes of Health (NIH), including the National Cancer Institute and BARDA**

- **A second Phase II study is planned to evaluate ABC294640 as a radioprotectant in cancer patients undergoing therapeutic radiotherapy; A third Phase II study is planned for the treatment of multiple myeloma and is subject to a pending National Cancer Institute/STTR grant**

TEL-AVIV, Israel, June 29, 2015 RedHill Biopharma Ltd. (NASDAQ/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 initiated a Phase I/II clinical study in the U.S. evaluating ABC294640 in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL).

ABC294640 is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, gastrointestinal (GI) and oncology indications. SK2 is an innovative molecular target for anti-cancer therapy because of its critical role in catalyzing the formation of the lipid-signaling molecule sphingosine 1-phosphate (S1P), which is known to regulate cell proliferation and activation of inflammatory pathways. By inhibiting SK2, ABC294640 could potentially be effective in treating multiple inflammatory, oncologic and gastrointestinal diseases.

The Phase I/II study is intended to evaluate the safety and tolerability of ABC294640, as well as provide a preliminary evaluation of efficacy of the drug in patients with refractory/relapsed DLBCL, primarily patients with HIV-related DLBCL. Up to 33 patients are expected to be enrolled in the study, which will be conducted at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans. The study is funded primarily by a grant awarded by the National Cancer Institute (NCI) Small Business Technology Transfer (STTR) program. Dr. Chris Parsons, MD, an associate professor in the Departments of Medicine and Microbiology, Immunology & Parasitology at LSUHSC, is the lead investigator for the study.

Dr. Terry Plasse, MD, RedHill's Medical Director, said: "We are excited to initiate this translational study with ABC294640, carrying Dr. Parson's laboratory evaluations into an important clinical population of patients with refractory/relapsed diffuse large B-cell lymphoma, primarily patients with HIV-related DLBCL, a group of patients with substantial unmet medical needs. RedHill continues to advance towards additional Phase II clinical studies with ABC294640 as a radioprotectant in cancer patients undergoing therapeutic radiotherapy and, subject to a pending NCI/SBIR grant, multiple myeloma."

DLBCL is the most common subtype of non-Hodgkin's lymphoma, accounting for an estimated 30% of the 70,000 projected non-Hodgkin's lymphoma cases diagnosed in the U.S. in 2015[1]. Many DLBCLs are etiologically linked to the human viruses which encode unique oncogenes contributing to tumor onset and progression. Standard treatments for DLBCL exhibit limited efficacy and incur significant toxicities.

The Phase I/II study was initiated following positive pre-clinical studies, led by Dr. Parsons, indicating the therapeutic activity of ABC294640 for virus-associated DLBCL, in an established xenograft model for Kaposi's sarcoma-associated herpesvirus-associated DLBCL, including reversal of disease progression for established tumors. The pre-clinical studies were performed in parallel with a successful Phase I study that demonstrated the drug's safety and assessed its pharmacokinetics and pharmacodynamics in cancer patients with advanced solid tumors.

[1] American Cancer Society, Cancer Facts and Figures 2015.

RedHill acquired the rights to ABC294640 in March 2015 from U.S.-based Apogee Biotechnology Corporation ("Apogee"). Prior to the acquisition, Apogee completed numerous successful pre-clinical studies with ABC294640 in GI, inflammation, radioprotection and oncology models, as well as a successful Phase I clinical study in cancer patients with advanced solid tumors. The open-label, dose-escalation, Phase I clinical study demonstrated the drug's safety and assessed its pharmacokinetics and pharmacodynamics in cancer patients with advanced solid tumors. The development of ABC294640 was funded to date primarily through grants and contracts in excess of $14 million from U.S. federal and state government agencies, such as the FDA, Department of Defense (DoD) and the National Institutes of Health (NIH), including the National Cancer Institute and BARDA.

A second Phase II study of ABC294640 is planned to evaluate ABC294640 as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy. RedHill also plans a third Phase II clinical study for the treatment of multiple myeloma, subject to funding by a pending grant from the National Cancer Institute.

The Phase I/II study with ABC294640 for refractory/relapsed diffuse large B-cell lymphoma 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/NCT02229981?term=abc294640&rank=2.

About ABC294640:
ABC294640 is a first-in-class, proprietary sphingosine kinase-2 (SK2) selective inhibitor, administered orally, with anti-cancer and anti-inflammatory activities, targeting multiple potential inflammatory, oncology and gastrointestinal indications. By inhibiting the SK2 enzyme, ABC294640 blocks the synthesis of sphingosine 1-phosphate (S1P), a lipid that promotes cancer growth and pathological inflammation. ABC294640 was originally developed by U.S.-based Apogee Biotechnology Corp. and completed multiple successful pre-clinical studies in inflammatory, GI, radioprotection and oncology models, as well as a Phase I clinical study in cancer patients with advanced solid tumors. A Phase I/II clinical study evaluating ABC294640 in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) has been initiated in the U.S. The development of ABC294640 was funded to date primarily through grants and contracts in excess of $14 million from U.S. federal and state government agencies.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/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 undergoing 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 solid tumor 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.

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