Press Release

RedHill Biopharma Announces $2 Million National Cancer Institute Grant for YELIVA™ (ABC294640) Phase II Study for Multiple Myeloma

- **The National Cancer Institute (NCI) $2 million grant is intended to support the Phase II study with YELIVA™ (ABC294640) for refractory or relapsed multiple myeloma, planned to be initiated by RedHill at Duke University Medical Center by the end of 2015**
- **YELIVA™ (ABC294640) is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications**
- **A Phase I/II study with YELIVA™ (ABC294640), also supported by a grant from the NCI, was recently initiated in the U.S. in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL)**
- **A third Phase II study is planned to evaluate YELIVA™ (ABC294640) as a radioprotectant in cancer patients undergoing therapeutic radiotherapy**
- **Top-line results from the Phase I study with YELIVA™ (ABC294640) for the treatment of advanced solid tumors are expected early in the fourth quarter of 2015, and a full analysis and final Clinical Study Report (CSR) are expected by the end of this year or early 2016**

TEL-AVIV, Israel, September 9, 2015 RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) ("RedHill" or the "Company"), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal (GI) diseases, including cancer, today announced that the National Cancer Institute (NCI) has awarded a $2 million Small Business Innovation Research

Program (SBIR) grant to support the planned Phase II study with YELIVA™ (ABC294640) for the treatment of refractory or relapsed multiple myeloma.

The grant covers a three year period and was awarded to Apogee Biotechnology Corporation ("Apogee") in conjunction with Duke University. RedHill acquired the rights to YELIVA™ (ABC294640), a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, from Apogee in March 2015.

RedHill plans to initiate the Phase II study of YELIVA™ (ABC294640) for the treatment of refractory or relapsed multiple myeloma by the end of 2015. The open-label, dose escalation Phase II study will be conducted at Duke University Medical Center and is planned to enroll up to 77 patients with refractory or relapsed multiple myeloma who have previously been treated with proteasome inhibitors and immunomodulatory drugs. Dr. Yubin Kang, MD, Associate Professor in the Division of Hematologic Malignancies and Cellular Therapy in the Department of Medicine at Duke University Medical Center, will be the lead investigator for the study, which received Institutional Review Board (IRB) approval from Duke University (DUHS IRB).

The primary objectives of the first portion of the study (Phase Ib) are to assess safety and determine the maximum tolerated dose (MTD) in this group of patients. Secondary objectives include assessment of antitumor activity and determination of the pharmacokinetic (PK) and pharmacodynamic (PD) properties of YELIVA™ (ABC294640) in refractory or relapsed multiple myeloma patients.

The primary objectives of the second portion of the study (Phase II) are to assess the overall treatment response rate and overall survival. Secondary objectives include evaluating the treatment response of YELIVA™ (ABC294640) in patients with refractory or relapsed multiple myeloma after three cycles of treatment and evaluation of pharmacodynamic markers.

YELIVA™ (ABC294640) is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, with anti-cancer and anti-inflammatory activities, targeting multiple oncology, inflammatory and GI 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, YELIVA™ (ABC294640) could potentially be effective in treating multiple oncology, inflammatory, and gastrointestinal indications.

RedHill recently initiated a Phase I/II clinical study in the U.S. evaluating YELIVA™ (ABC294640) in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL), primarily in patients with HIV-related DLBCL, also supported by a grant from the NCI Small Business Technology Transfer (STTR) program. A third Phase II clinical study is planned to evaluate YELIVA™ (ABC294640) as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy.

The ongoing and planned Phase II studies follow numerous successful pre-clinical studies conducted with YELIVA™ (ABC294640) in GI, inflammation, radioprotection and oncology models, as well as a Phase I study in patients with advanced solid tumors, supported by grants from the National Cancer Institute (NCI) and the FDA's Office of Orphan Products Development (OOPD). RedHill recently announced that the last patient has completed the final scheduled follow-up visit in the Phase I study with YELIVA™ (ABC294640). Preliminary positive data from the Phase I study was presented by Apogee at the November 2013 Molecular Targets and Cancer Therapeutics meeting. The analysis of the study is currently ongoing and top-line results are expected to be announced early in the fourth quarter of 2015. A full analysis and the final Clinical Study Report (CSR) are expected by the end of the year or early 2016.

The studies with YELIVA™ (ABC294640) are 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.

About YELIVA™ (ABC294640):
YELIVA™ (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 oncology, inflammatory and gastrointestinal indications. By inhibiting the SK2 enzyme, YELIVA™ (ABC294640) blocks the synthesis of sphingosine 1-phosphate (S1P), a lipid that promotes cancer growth and pathological inflammation. YELIVA™ (ABC294640) was originally developed by U.S.-based Apogee Biotechnology Corp. and completed multiple successful pre-clinical studies in oncology, inflammation, GI, and radioprotection models, as well as the ABC-101 Phase I clinical study in cancer patients with advanced solid tumors. A Phase I/II clinical study evaluating YELIVA™ (ABC294640) in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) has been initiated in the U.S. The development of YELIVA™ (ABC294640) was funded to date primarily by grants and contracts from U.S. federal and state government agencies.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including 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 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 bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple inflammatory, gastrointestinal and oncology indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell

lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class 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 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 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.

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