Press Release

RedHill Biopharma Announces Last Patient Visit in the Phase I Study with YELIVA™ (ABC294640) for Advanced Solid Tumors

- **The open-label, dose-escalation, pharmacokinetic (PK) and pharmacodynamic (PD) Phase I study with YELIVA™ (ABC294640) in patients with advanced solid tumors was supported by grants from the National Cancer Institute (NCI) and the FDA's Office of Orphan Products Development (OOPD)**

- **Analysis of the study is ongoing, with top-line results expected early in the fourth quarter of 2015, and a full analysis and final Clinical Study Report (CRS) expected by the end of this year or early 2016**

- **Preliminary positive results were reported at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics in November 2013**

- **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) was recently initiated in the U.S. in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) and is supported by a grant from the NCI**

- **A second Phase II study is planned to evaluate YELIVA™ as a radioprotectant in cancer patients undergoing therapeutic radiotherapy; a third Phase II study, to be supported by an NCI grant, is planned for the treatment of multiple myeloma**

TEL-AVIV, Israel, September 1, 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 gastrointestinal cancers, today announced that the last patient has completed the final scheduled follow-up visit in the Phase I study evaluating YELIVA™ (ABC294640), the Company's orally-administered first-in-class sphingosine kinase-2 (SK2) selective inhibitor, for the treatment of advanced solid tumors (the ABC-101 study).

The ABC-101 Phase I study was conducted at the Medical University of South Carolina Hollings Cancer Center and was led by Principal Investigators Melanie Thomas, MD, and Carolyn Britten, MD. The open-label, dose-escalation, pharmacokinetic (PK) and pharmacodynamic (PD) first-in-human Phase I study of YELIVA™ (ABC294640) enrolled 22 patients with advanced solid tumors. The patients were continuously treated with the study drug in the absence of disease progression and evaluated for an additional period of up to one year after discontinuing treatment with YELIVA™ (ABC294640). The primary objectives of the study were to identify the maximum tolerated dose (MTD) and the dose limiting toxicities (DLTs) and to evaluate the safety of YELIVA™ (ABC294640). The secondary objectives of the study were to determine the pharmacokinetic (PK) and pharmacodynamic (PD) properties of YELIVA™ (ABC294640) and to assess its antitumor activity.

The study was supported by grants from the National Cancer Institute (NCI) and the FDA's Office of Orphan Products Development (OOPD). Preliminary positive data from the Phase I study was presented by Apogee Biotechnology Corporation 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.

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.

Reza Fathi, Ph.D., RedHill's Senior VP Research & Development said: "The completion of the final follow-up visit by the last patient in the Phase I study of YELIVA™ (ABC294640) is an important milestone for RedHill, and we look forward to completing the analysis of the study, which includes analysis of plasma S1P levels as a potential new pharmacodynamic biomarker for anti-cancer activity of a sphingolipid targeted drug."

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 patients with HIV-related DLBCL, supported by a grant from the NCI Small

Business Technology Transfer (STTR) program. Additional Phase II clinical studies are planned, including a multiple myeloma study to be conducted at Duke University and supported by the NCI, and a radioprotection study to evaluate potential prevention of mucositis in cancer patients undergoing therapeutic radiotherapy. Numerous successful pre-clinical studies were conducted with YELIVA™ (ABC294640) in GI, inflammation, radioprotection and oncology models.

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 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 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 first Phase I/II 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 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.

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