

Press Release

RedHill Biopharma Announces Positive Top-line Results from YELIVA™ (ABC294640) Phase I Study in Advanced Solid Tumors

- **The Phase I study with YELIVA™ (ABC294640) successfully met its primary and secondary endpoints, demonstrating that the drug is well tolerated and can be safely administered to cancer patients at doses that provide circulating drug levels that are predicted to have therapeutic activity**
- **Twenty-one patients with advanced solid tumors were treated with YELIVA™ in the study, the majority of which were gastrointestinal cancer patients, including pancreatic, colorectal and cholangiocarcinoma cancers**
- **Administration of YELIVA™ resulted in a rapid and pronounced decrease in levels of sphingosine 1-phosphate (S1P) with several patients having prolonged stabilization of disease**
- **The U.S. Phase I study was conducted at the Medical University of South Carolina (MUSC) and supported by a grant from the National Cancer Institute (NCI) awarded to MUSC, and a grant from the FDA's Office of Orphan Products Development (OOPD) awarded to Apogee Biotechnology Corp.**
- **YELIVA™ is a proprietary, novel, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications, for which several Phase II studies are ongoing and planned, supported by NCI grants awarded to Apogee Biotechnology Corp., as well as directly supported by RedHill**
- **RedHill maintains a strong and debt-free balance sheet with approximately \$66 million in cash as of the end of July, supporting the ongoing and planned Phase II clinical studies with YELIVA™**

TEL-AVIV, Israel, October 26, 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 diseases, including cancer, today announced positive top-line results from the Phase I study with YELIVA™ (ABC294640) in patients with advanced solid cancers. The study successfully met its primary and secondary endpoints, providing key information about the drug’s safety, toxicities, pharmacokinetics (PK) and pharmacodynamics (PD), supporting the ongoing and planned Phase II studies with YELIVA™ (ABC294640).

The top-line results from the Phase I study with YELIVA™ (ABC294640), demonstrating achievement of primary and secondary endpoints, were provided to RedHill by Apogee Biotechnology Corporation (“Apogee”) and remain subject to the completion of an independent review and analysis of the underlying data, including all safety, secondary and other outcome measures, and completion of the clinical study report (CSR), expected by the end of the year or early 2016. Final results of the study will be presented in the appropriate scientific and medical forums following completion of the CSR.

Charles D. Smith, Ph.D., Apogee’s President and CEO, said: “Sphingosine kinase-2 (SK2) is a new potential target for anticancer therapy because it produces sphingosine 1-phosphate (S1P) which regulates cancer cell proliferation and inflammatory pathways. YELIVA™ (ABC294640), a first-in-class, orally-available inhibitor of SK2, is the only agent in its category in clinical trials. The drug has demonstrated anticancer activity in many preclinical models, and the results from this Phase I study in patients with advanced solid tumors indicate that it can be safely administered to cancer patients at doses that provide circulating drug levels that are predicted to have therapeutic activity.”

Terry F. Plasse, MD, RedHill’s Medical Director, said: “We are very pleased with the results from this first-in-man study with YELIVA™ in advanced solid tumors, which successfully met its primary and secondary objectives. The results demonstrated the safety and tolerability of this novel drug candidate at a pharmacologically active dose, supporting the ongoing and planned Phase II clinical studies with YELIVA™. We continue to aggressively pursue development with this promising drug candidate across multiple cancer and inflammatory indications.”

The Phase I study, supported by grants from the U.S. National Cancer Institute (“NCI”) awarded to the Medical University of South Carolina (“MUSC”) and from the U.S. FDA’s Office of Orphan Products Development (OOPD) awarded to Apogee, was conducted at the MUSC Hollings Cancer Center and 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 with YELIVA™ (ABC294640) treated 21 patients with advanced solid tumors, the majority of which were gastrointestinal cancer patients, including pancreatic, colorectal and cholangiocarcinoma cancers. The patients were continuously treated in cycles of 28 days with the study drug, in the absence of disease progression, and tumors were reimaged every two cycles. Patients were evaluated for an

additional period of up to one year after discontinuing treatment with YELIVA™ (ABC294640). The last patient completed the final scheduled follow-up visit in July 2015.

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 primary objectives were all met and the drug was found to be safe and well tolerated, with grade 1-2 fatigue and nausea being the most common side effects.

The secondary objectives of the study, to determine the pharmacokinetic (PK) and pharmacodynamic (PD) properties of YELIVA™ (ABC294640) and to assess its antitumor activity, were also met.

The results demonstrated that YELIVA™ (ABC294640) can be safely administered to cancer patients at doses that provide circulating drug levels that are predicted to have therapeutic activity, based on levels required in preclinical models. The study included the first-ever longitudinal analyses of plasma S1P levels as a potential pharmacodynamic (PD) biomarker for activity of a sphingolipid-targeted drug. The administration of YELIVA™ (ABC294640) resulted in a rapid and pronounced decrease in S1P levels over the first 12 hours, with return to baseline at 24 hours, which is consistent with clearance of the drug, with several patients having prolonged stabilization of disease.

Multiple preclinical studies previously conducted with YELIVA™ (ABC294640) in oncology and inflammation models demonstrated the drug's therapeutic effect, as well as good pharmacokinetics (PK), oral bioavailability and biodistribution (including to the brain), and no hematologic toxicity.

Preliminary positive data from the Phase I study was presented by Apogee at the November 2013 Molecular Targets and Cancer Therapeutics meeting.

A Phase I/II clinical study was recently initiated 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. The study is being conducted at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans and is supported by a grant awarded to Apogee from the NCI Small Business Technology Transfer (STTR) program, as well as additional support from RedHill.

A Phase I/II study with YELIVA™ (ABC294640) for the treatment of refractory or relapsed multiple myeloma is planned to be initiated by early 2016. The study will be conducted at Duke University Medical Center and has received Institutional Review Board (IRB) approval from Duke University Health Sciences (DUHS IRB). The study is supported by a \$2 million grant from the NCI Small Business Innovation Research Program (SBIR) awarded to Apogee in conjunction with Duke University, with additional support from RedHill.

RedHill maintains a strong and debt-free balance sheet with approximately \$66 million in cash as of the end of July, supporting the ongoing and planned Phase II clinical studies with

YELIVA™, including a planned Phase II study to evaluate YELIVA™ as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy.

The Phase I/II clinical study in patients with refractory/relapsed diffuse large B-cell lymphoma and the Phase I clinical study in cancer patients with advanced solid tumors 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 proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anticancer and anti-inflammatory activities, targeting multiple oncology, inflammatory and gastrointestinal indications. By inhibiting the SK2 enzyme, YELIVA™ (ABC294640) blocks the synthesis of sphingosine 1-phosphate (S1P), a lipid signaling molecule that promotes cancer growth and pathological inflammation. SK2 is an innovative molecular target for anticancer therapy because of its critical role in catalyzing the formation of S1P, which is known to regulate cell proliferation and activation of inflammatory pathways. 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 to Apogee Biotechnology Corp., including the U.S. National Cancer Institute, the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA), the U.S. Department of Defense and the FDA Office of Orphan Products Development.

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 oncology, inflammatory and gastrointestinal 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 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 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