



Press Release

RedHill Biopharma Announces National Cancer Institute Grant Awarded to Apogee Biotechnology Corp. for YELIVA™ (ABC294640) Prostate Cancer Research

- **The \$225,000 U.S. National Cancer Institute (“NCI”) grant was awarded to Apogee Biotechnology Corporation, from which RedHill acquired the exclusive worldwide rights to YELIVA™ (ABC294640) in March 2015**
- **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 to Apogee Biotechnology Corporation**
- **A second Phase II study of YELIVA™ (ABC294640) for the treatment of refractory or relapsed multiple myeloma is planned to commence by early 2016 and is supported by a \$2 million NCI grant awarded to Apogee Biotechnology Corporation; 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 Ib study with YELIVA™ (ABC294640) in patients with advanced solid tumors are expected to be announced in the coming weeks**

TEL-AVIV, Israel, October 22, 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 that the U.S. National Cancer Institute (“NCI”) has awarded Apogee Biotechnology Corporation (“Apogee”) a \$225,000 Small Business Innovation Research Program (“SBIR”) grant to support a

pre-clinical study with YELIVA™ (ABC294640) for the treatment of prostate cancer. In March 2015, RedHill acquired from Apogee the exclusive worldwide rights to YELIVA™ (ABC294640), a proprietary, first-in-class, orally-administered sphingosine kinase-2 (“SK2”) selective inhibitor.

Following prior pre-clinical studies in early-stage and advanced prostate cancer models, the NCI grant is intended to support additional studies with YELIVA™ (ABC294640) to determine its therapeutic efficacy in *in vitro* and *in vivo* models of prostate cancer in combination with radiotherapy. These pre-clinical studies could potentially support future clinical studies with YELIVA™ (ABC294640) for this important indication with over 200,000 estimated new cases of prostate cancer in the U.S. in 2015¹.

The previous prostate cancer pre-clinical study, supported by a grant from the Pennsylvania Department of Health, a Prostate Cancer Foundation Young Investigator award, and a Prostate Cancer Foundation Mazzone Challenge award, is described in an article authored by scientists from Apogee and from the Kimmel Cancer Center at Thomas Jefferson University, and was initially published online in *Molecular Cancer Research*. The article, entitled “*Downregulation of Critical Oncogenes by the Selective SK2 Inhibitor ABC294640 Hinders Prostate Cancer Progression*”², describes the findings of the pre-clinical study, suggesting that oral administration of YELIVA™ (ABC294640) disrupts multiple oncogenic signaling pathways that are deregulated in prostate cancer, including significant inhibition of tumor growth, proliferation and cell cycle progression. In particular, the article noted that YELIVA™ (ABC294640) inhibited, *in vitro*, several very resistant types of prostate cancer. The authors of the article conclude that their pre-clinical findings support the hypotheses that SK2 activity is required for prostate cancer growth and that YELIVA™ (ABC294640) could represent a new pharmacological agent for the treatment of aggressive prostate cancer.

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.

A Phase II study of 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 (DUHS IRB). The study is supported by a \$2 million grant awarded to Apogee, in conjunction with Duke University, from the NCI SBIR Program.

¹ National Cancer Institute - Surveillance, Epidemiology and End Results Program: seer.cancer.gov/statfacts/html/prost.html

² Randy S Schreengost, Staci N Keller, Matthew J Schiewer, Karen E Knudsen, and Charles D Smith, “Downregulation of Critical Oncogenes by the Selective SK2 Inhibitor ABC294640 Hinders Prostate Cancer Progression” (August 13, 2015) *Mol Cancer Res*, 10.1158/1541-7786.MCR-14-0626

A third Phase II clinical study is planned to evaluate YELIVA™ (ABC294640) as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy. This study is planned to be funded directly by RedHill, which is also funding the data management and providing the drug for the NCI-supported studies.

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 Ib study in patients with advanced solid tumors, supported by grants awarded to Apogee from the National Cancer Institute (NCI) and the FDA's Office of Orphan Products Development (OOPD).

The Phase I/II clinical study in patients with refractory/relapsed diffuse large B-cell lymphoma and the Phase Ib 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 anti-cancer 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 anti-cancer 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 Ib 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.

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