

Press Release

RedHill Biopharma Announces Peer-Reviewed Publication Demonstrating Therapeutic Potential of ABC294640 (YELIVA™) in Prostate Cancer

- The publication in the peer-reviewed journal **Molecular Cancer Research** details promising pre-clinical results suggesting ABC294640 significantly inhibits prostate cancer tumor growth
- RedHill filed a trademark application with the U.S. Patent and Trademark Office for the new brand name YELIVA™ for ABC294640
- YELIVA™ (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
- A Phase I/II study of YELIVA™ (ABC294640), supported by a grant from the National Cancer Institute (NCI), was recently initiated in the U.S. in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL), primarily in patients with HIV-related DLBCL
- A second Phase II study is planned to evaluate YELIVA™ (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 NCI grant

TEL-AVIV, Israel, August 24, 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 the publication of an article evaluating the therapeutic potential of ABC294640, the Company’s orally-administered first-in-class Sphingosine kinase 2 (SK2) selective inhibitor, in the treatment of prostate cancer. The article, authored by scientists from Apogee Biotechnology Corporation (“Apogee”) and from the Kimmel Cancer Center at Thomas Jefferson University, will be published in *Molecular Cancer Research* and is available online on the journal’s website. RedHill acquired the rights to YELIVA™ (ABC294640) in March 2015 from U.S.-based Apogee.

RedHill has also filed a trademark application with the U.S. Patent and Trademark Office (USPTO) for the new brand name YELIVA™ for ABC294640. Subject to USPTO and FDA approval, the new brand name for the potential commercial product will be YELIVA™.

The article¹, entitled “*Downregulation of Critical Oncogenes by the Selective SK2 Inhibitor ABC294640 Hinders Prostate Cancer Progression*”, describes a pre-clinical study conducted with YELIVA™ (ABC294640) in early stage and advanced prostate cancer models. The findings from the study suggest that oral administration of ABC294640 (YELIVA™) disrupts multiple oncogenic signaling pathways that are deregulated in prostate cancer, corresponding with significant inhibition of tumor growth, proliferation and cell cycle progression. In particular, the compound inhibited in vitro several very resistant types of prostate cancer. The authors of the article conclude that these pre-clinical findings support the hypotheses that SK2 activity is required for prostate cancer function and that ABC294640 (YELIVA™) could represent a new pharmacological agent for the treatment of early stage and aggressive prostate cancer. The study was 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.

Charles Smith, Ph.D., President and CEO of Apogee Biotechnology Corporation and one of the authors of the article, said: “This paper provides further definition of the mechanism of the anticancer activities of ABC294640, including the first demonstration of inhibition of signaling through the androgen receptor pathway, which is critical for prostate cancer growth. The growing body of mechanistic and clinical data on ABC294640 suggests that this drug may be useful for the treatment of early-stage and castrate-resistant prostate cancer.”

Patricia Bandeira, RedHill’s Product Manager for YELIVA™ (ABC294640), added: “We are pleased to have these important findings, suggesting that ABC294640 could be effective in treating prostate cancer, published in a peer-reviewed journal. ABC294640, under its new brand name YELIVA™, is a novel and promising drug candidate with multiple potential oncology and inflammatory indications. RedHill recently initiated a Phase I/II study of YELIVA™ (ABC294640) in patients with refractory/relapsed diffuse large B-cell lymphoma, and is progressing towards a second Phase II study to evaluate YELIVA™ (ABC294640) as a radioprotectant in cancer patients undergoing therapeutic radiotherapy, and a third Phase II clinical study for the treatment of multiple myeloma.”

¹ The article was authored by Randy S Schrecengost, Staci N Keller, Matthew J Schiewer, Karen E Knudsen, and Charles D Smith.

YELIVA™ (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, YELIVA™ (ABC294640) could potentially be effective in treating multiple inflammatory, gastrointestinal and oncology 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). The Phase I/II study is intended to evaluate the safety and tolerability of YELIVA™ (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 supported by a grant from the National Cancer Institute (NCI) Small Business Technology Transfer (STTR) program.

A second Phase II study is planned to evaluate YELIVA™ (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 a pending grant from the National Cancer Institute.

Numerous successful pre-clinical studies were conducted with YELIVA™ (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.

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 inflammatory, oncology 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 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 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 through 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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