September 12, 2016

RedHill Biopharma Announces Research Collaboration with Stanford University for YELIVA™

TEL-AVIV, Israel, Sept. 12, 2016 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (TASE:RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today announced a research collaboration with Stanford University School of Medicine ("Stanford") for the evaluation of RedHill's proprietary Phase II-stage drug, YELIVA™ (ABC294640).

The research collaboration is intended to complement RedHill's planned Phase Ib clinical study to evaluate YELIVA™ as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy.

As part of the collaboration, Stanford will evaluate the effect of YELIVA™ on mucositis reduction and tumor control in a murine model of head and neck cancer. YELIVA™ will be administered in combination with a chemotherapy agent and radiotherapy, similar to the design of RedHill's planned radioprotectant Phase Ib clinical study with YELIVA™, expected to run in parallel with the Stanford research collaboration. Results from the research collaboration are expected in mid-2017.

The Stanford research collaboration is led by Dr. Quynh-Thu Le, MD, a radiation oncologist, Chair of the Stanford Radiation Oncology Department, Co-Director of the Radiation Biology Program of the Stanford Cancer Institute and the Chair of the Head and Neck Cancer Committee of the NRG Oncology Group, part of the National Cancer Institute (NCI) supported National Clinical Trial Network (NCTN).

YELIVA™ is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anti-cancer and anti-inflammatory activities. By inhibiting the SK2 enzyme, YELIVA™ blocks the synthesis of sphingosine 1-phosphate (S1P), a lipid signaling molecule that promotes cancer growth and pathological inflammation.

RedHill is pursuing with YELIVA™ multiple clinical programs in oncology, inflammatory and gastrointestinal indications. RedHill is evaluating potential clinical studies for additional oncology and inflammatory indications, as well as potential collaboration opportunities to evaluate YELIVA™ as an add-on therapy.

Results from the Phase I study with YELIVA™ in patients with advanced solid tumors confirmed that the study, conducted at the Medical University of South Carolina (MUSC), 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.

Among the 16 subjects that were assessable for response by RECIST 1.1 criteria (Response Evaluation Criteria in Solid Tumors), one subject had a partial response with a progression-free survival of 16.9 months, and six subjects had stable disease with a progression-free survival of between 3.5 and 17.6 months. Of the three patients with cholangiocarcinoma, one had a partial response and the other two had stable disease, one for over a year. YELIVA™ was well-tolerated over a prolonged period at doses inducing the expected pharmacodynamic effects.

A Phase Ib/II study with YELIVA™ for the treatment of refractory or relapsed multiple myeloma has recently been initiated at Duke University Medical Center. The study is supported by a $2 million grant from the National Cancer Institute (NCI) Small Business Innovation Research Program (SBIR) awarded to Apogee Biotechnology Corp. (Apogee), in conjunction with Duke University, with additional support from RedHill.

A Phase II study with YELIVA™ for the treatment of advanced hepatocellular carcinoma is planned to be initiated in the coming weeks. The study will be conducted at MUSC Hollings Cancer Center and additional clinical centers in the U.S. It is supported by a $1.8 million grant from the NCI awarded to MUSC, intended to fund a broad range of studies on the feasibility of targeting sphingolipid metabolism for the treatment of a variety of solid tumor cancers, including the Phase II

study with YELIVA™ and will be further supported by additional funding from RedHill.

A Phase I/II clinical study evaluating YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) was initiated at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans in June 2015 and is expected to resume later this year following administrative hold and pending a protocol amendment aimed at improving overall recruitment. The study is supported by a grant awarded to Apogee from the NCI as well as additional support from RedHill.

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 Phase II-stage, proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anti-cancer and anti-inflammatory activities. RedHill is pursuing with YELIVA™ multiple clinical programs in oncology, inflammatory and gastrointestinal indications. By inhibiting the SK2 enzyme, YELIVA™ 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™ 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. The development of YELIVA™ was funded to date primarily by grants and contracts from U.S. federal and state government agencies awarded 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:RDHL) (TASE:RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and 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 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 and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON -** a Phase II-stage first-in-class, orally-administered uPA inhibitor, 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, orally-administered Hsp27 inhibitor, 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 marketing authorization received in Germany in October 2015; 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 Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) 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 25, 2016. 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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Source: RedHill Biopharma Ltd.

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