May 4, 2016

RedHill Biopharma Announces National Cancer Institute Grant Supporting YELIVA™ Phase II Hepatocellular Carcinoma Study

- **The $1.8 million U.S. National Cancer Institute (NCI) grant, awarded to the Medical University of South Carolina (MUSC), is intended to support a research program covering a variety of solid tumor cancers, including a Phase II study with YELIVA™ (ABC294640) for the treatment of advanced hepatocellular carcinoma, planned to be initiated in Q3/2016 at MUSC and collaborating institutions**

- **RedHill previously announced positive top-line results from a Phase I study with YELIVA™ in patients with advanced solid tumors; A Phase I/II study with YELIVA™ was initiated in the U.S. in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL)**

- **A Phase I/II study with YELIVA™ for refractory or relapsed multiple myeloma is planned to be initiated in Q2/2016 and is supported by a $2 million NCI grant awarded to Apogee Biotechnology Corp. (Apogee); A Phase II study to evaluate YELIVA™ as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy is planned to be initiated in H2/2016**

- **YELIVA™ 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**

- **The development of YELIVA™ was funded to date primarily by grants and contracts from U.S. federal and state government agencies awarded to Apogee, including from the NCI, the Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA), the Department of Defense and the FDA Office of Orphan Products Development**

TEL-AVIV, Israel, May 04, 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 inflammatory and gastrointestinal diseases and cancer, today announced that the U.S. National Cancer Institute ("NCI") has awarded the Medical University of South Carolina ("MUSC") a $1.8 million grant to support a broad range of studies on the feasibility of targeting sphingolipid metabolism for the treatment of a variety of solid tumor cancers. One component of the studies includes a planned Phase II study with YELIVA™ (ABC294640) for the treatment of advanced hepatocellular carcinoma ("HCC"), the most common primary malignant cancer of the liver[1]. YELIVA™ is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor.

The Phase II study, planned to be initiated in the third quarter of 2016, will be conducted at MUSC and additional clinical sites and is intended to evaluate the efficacy and safety of YELIVA™ as a second-line monotherapy in patients with advanced HCC. The study is planned to enroll up to 39 patients who have experienced tumor progression following treatment with first-line single-agent sorafenib (Nexavar®). Carolyn D. Britten, MD, Director of Hematology/Oncology Division in the Department of Medicine at MUSC and Associate Director for Clinical Investigations at the MUSC Hollings Cancer Center, will act as Principal Investigator for the study.

Prof. Ran Oren, MD, Head of the Institute of Gastroenterology and Liver Diseases at Hadassah University Hospital, Ein Kerem, and a Member of RedHill's Advisory Board, Said: "Hepatocellular carcinoma (HCC) is one of the most common malignancies worldwide, with one of the highest mortality rates among cancers. It arises most frequently in patients suffering from chronic liver disease and poses an increasing problem in the Western world due to hepatitis B and hepatitis C virus infections, alcoholic cirrhosis and non-alcoholic steatohepatitis resulting from high obesity rates. Curative treatments, such as hepatic resection and liver transplant, are available only to patients diagnosed with early HCC. While these treatments offer good prognosis, they are extremely limited in their application. Over two-thirds of HCC patients in the developed world are diagnosed at advance stages of the disease, emphasizing the strong need for novel therapeutic treatments for both early and late stage HCC."

The NCI grant covers a five-year period. The Phase II HCC study will be further supported by additional funding from RedHill, which acquired the exclusive worldwide rights to YELIVA™ from Apogee Biotechnology Corp. ("Apogee").

HCC is the most common primary malignant cancer of the liver. It is the sixth most prevalent cancer and the third most frequent cause of cancer-related death worldwide[2]. Annual worldwide incidence of liver cancer was estimated to have reached 782,000 cases in 2012, with mortality of 746,000; the corresponding U.S. numbers are 30,000 and 24,000, respectively[3]. Most patients with HCC suffer from liver cirrhosis, which develops following long periods of chronic liver disease. The majority of HCC cases are associated with hepatitis B and hepatitis C virus infections. Additional causes for HCC include heavy alcohol consumption, obesity, diabetes, tobacco smoking, metabolic syndrome leading to fatty liver and hemachromatosis. The prognosis of patients with HCC is affected by the disease stage at diagnosis and by the underlying liver function. Few treatment options exist for patients diagnosed at an advanced stage, representing the majority of HCC patients. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery and do not have severe cirrhosis. The worldwide and U.S. markets for the treatment of HCC are estimated to reach approximately $895 million and $471 million in 2017, respectively[4].

RedHill previously announced positive top-line results from a Phase I study with YELIVA™ in patients with advanced solid tumors, the majority of which were gastrointestinal cancer patients, including pancreatic, colorectal and cholangiocarcinoma cancers. Top-line results demonstrated that YELIVA™ 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. Final results are expected in the coming weeks. The Phase I study included the first-ever longitudinal analysis of plasma sphingosine-1-phosphate (S1P) levels as a potential pharmacodynamic biomarker for activity of a sphingolipid-targeted drug. The administration of YELIVA™ resulted in a rapid and pronounced decrease in S1P levels over the first 12 hours, with return to baseline at 24 hours, consistent with clearance of the drug, with several patients having prolonged stabilization of disease.

A Phase I/II clinical study was initiated in June 2015 in the U.S. evaluating YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL), including 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™ for the treatment of refractory or relapsed multiple myeloma is planned to be initiated in the second quarter of 2016. The study will be conducted at Duke University Medical Center. 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.

A Phase II clinical study to evaluate YELIVA™ as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy is planned to be initiated in the U.S. during the second half of 2016, subject to regulatory and other conditions.

The Phase I/II clinical studies in patients with DLBCL and multiple myeloma, as well as 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 Phase II-stage, 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™ 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. A Phase I/II clinical study evaluating YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) has been initiated in the U.S. 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 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 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 in the U.S. for acute gastroenteritis and gastritis and a 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 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 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.

[1] Gomma AI et al., *Hepatocellular carcinoma: epidemiology, risk factors and pathogenesis,* World J Gastroenterol, 2008 Jul 21; 14(27): 4300-8.

[2] Forner A et al., '*Hepatocellular Carcinoma'*, Lancet, 2012 Mar 31; 379(9822): 1245-55.

[3] World Health Organization International Agency for Research on Cancer, GLOBOCAN 2012: Estimated Cancer Incidence , Mortality and Prevalence Worldwide in 2012.

[4] Datamonitor

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

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