



RedHill Biopharma Announces Presentation on YELIVA® (opaganib) for Multiple Myeloma at EORTC-NCI-AACR Symposium

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TEL-AVIV, Israel and RALEIGH, N.C., Nov. 14, 2018 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](#) (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal diseases and cancer, today announced a poster presentation on YELIVA® (opaganib, ABC294640)¹ for multiple myeloma at the upcoming EORTC-NCI-AACR Symposium² on Molecular Targets and Cancer Therapeutics, on Friday, November 16th in Dublin.

The abstract³ (poster board number PB-045), which will be presented by Yubin Kang, MD, of Duke Health, is entitled "*Sphingosine kinase 2 (SK2) targeting in the treatment of multiple myeloma: preclinical and phase I studies of opaganib, an SK 2 inhibitor, in multiple myeloma*". The abstract describes data from preclinical studies and a Phase Ib/II study conducted by Dr. Kang with YELIVA® for the treatment of multiple myeloma.

The open-label, dose escalation Phase Ib/II study evaluating YELIVA® in patients with refractory or relapsed multiple myeloma that were previously treated with proteasome inhibitors and immunomodulatory drugs is ongoing at Duke University Medical Center. Enrollment for the Phase Ib portion of the study has been completed with a total of 11 patients enrolled and treated in three dose cohorts. Results from the Phase Ib portion of the study did not show any dose-limiting toxicities. Additionally, while efficacy was not the primary endpoint of the Phase I study, it was observed that out of 10 evaluable subjects, two subjects had stable disease for over four months and one patient achieved a very good partial response (VGPR).

In addition, results from preclinical studies demonstrated that SK2 is overexpressed in multiple myeloma cell lines and in human multiple myeloma specimens and plays a critical role in myeloma cell growth, proliferation and survival. Additional preclinical studies described in the abstract demonstrated that treatment with YELIVA® effectively inhibited myeloma tumor growth *in vitro* and *in vivo* in mouse xenograft models. The authors conclude that YELIVA® as a single agent or in combination with a B-cell lymphoma 2 (Bcl-2) inhibitor has the potential for treatment of relapsed/refractory multiple myeloma patients that were previously treated with proteasome inhibitors and immunomodulatory agents.

The Phase Ib/II study with YELIVA® for multiple myeloma is supported by a \$2 million grant from the National Cancer Institute (NCI) Small Business Innovation Research Program (SBIR) awarded to Apogee Biotechnology Corp., in conjunction with Duke University, with additional support provided by RedHill.

Dr. Yubin Kang, MD, associate professor in the division of hematologic malignancies and cellular therapy in the department of medicine at Duke University School of Medicine, is the lead investigator for the Phase Ib/II study with YELIVA® for multiple myeloma, as well as the head of the laboratory performing the preclinical studies.

YELIVA® is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor being developed by RedHill and targeting multiple oncology, inflammatory and gastrointestinal indications. A single-arm Phase IIa study evaluating the activity of YELIVA® as a single agent in patients suffering from advanced, unresectable intrahepatic, perihilar and extrahepatic cholangiocarcinoma is being conducted at renowned clinical institutions in the U.S.

About YELIVA® (opaganib, ABC294640):

YELIVA® (opaganib, ABC294640), a new chemical entity, 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 SK2, 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 preclinical studies in oncology, inflammation, GI and radioprotection models, as well as a Phase I clinical study in cancer patients with advanced solid tumors. YELIVA® received Orphan Drug designation from the U.S. FDA for the treatment of cholangiocarcinoma. 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 ongoing studies with YELIVA® (opaganib, ABC294640) for cholangiocarcinoma, multiple myeloma and advanced hepatocellular carcinoma (HCC) 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 RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases and cancer. RedHill commercializes and promotes four gastrointestinal products in the U.S.: **Donnatal®**- a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi®**- an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg** - a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions, and **EnteraGam®**- a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i)

TALICIA® (RHB-105) for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104**, with positive top-line results from a first Phase III study for Crohn's disease; (iii) **RHB-204**, with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102)**, with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (v) **YELIVA® (ABC294640)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) **RHB-106**, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107 (formerly MESUPRON)**, a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.

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 successfully promote Donnatal®, Myles® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam®; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) 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; (viii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; and (xiv) competition from other companies and technologies within the Company's industry. 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 22, 2018. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise, unless required by law.

¹ YELIVA® (opaganib, ABC294640) is an investigational new drug, not available for commercial distribution.

² European Organisation for Research and Treatment of Cancer (EORTC), the National Cancer Institute (NCI) and the American Association for Cancer Research (AACR).

³ The abstract was authored by Yubin Kang, Shengjun Fan, Pasupathi Sundaramoorthy, Cristina Gasparetto, Gwynn Long, Emily Sellars, Anderson Garrett, Jackie McIntyre, Lynn Maines, Vered Katz Ben-Yair, Charles Smith and Terry Plasse.

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