Press Release

RedHill Biopharma Provides Update on Opaganib (Yeliva®)

Phase 2 study evaluating RedHill's proprietary NCE[1] opaganib (Yeliva®, ABC294640) in prostate cancer initiated at Medical University of South Carolina, supported by an NCI grant

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Recruitment initiated in second arm of Phase 1/2a study evaluating opaganib in combination with hydroxychloroquine in advanced cholangiocarcinoma; third arm in planning to evaluate combination of opaganib with RHB-107 (upamostat), a second proprietary NCE

RedHill is pursuing an exploratory program of opaganib and RHB-107 individually and in combination with hydroxychloroquine and other compounds for the treatment of COVID-19 (novel coronavirus), based on pre-clinical data and literature indicating potential anti-viral activity

TEL-AVIV, Israel and RALEIGH, N.C., March 11, 2020 -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company focused on gastrointestinal diseases, today provided an update on its clinical development programs for opaganib (Yeliva®, ABC294640)[2].

An investigator-sponsored Phase 2 study evaluating opaganib in prostate cancer has been initiated at the Medical University of South Carolina (MUSC) Hollings Cancer Center. The study is intended to evaluate the safety and efficacy of opaganib in patients with metastatic castration-resistant prostate cancer (mCRPC) that is progressing during treatment with androgen-signaling blockers abiraterone or enzalutamide. The study is planned to enroll up to 60 patients and is supported by a National Cancer Institute (NCI) grant awarded to MUSC. Professor Michael Lilly, MD, is the Principal Investigator of the study.

[1] New chemical entity

[2] Opaganib (Yeliva®) (formerly designated as ABC294640) is a drug candidate under development and not approved by the FDA.

RedHill has completed the enrollment of the full cohort of 39 patients evaluable for efficacy in the Phase 1/2a study evaluating the activity of orally-administered opaganib in patients suffering from advanced, unresectable intrahepatic, perihilar and extrahepatic cholangiocarcinoma.

Preliminary data from the open-label Phase 1/2a study conducted at renowned clinical institutions in the U.S., has indicated a signal of activity in a number of subjects with advanced cholangiocarcinoma. RedHill plans to submit these data for presentation at an upcoming scientific meeting. In light of this, and in light of positive data from a pre-clinical program evaluating opaganib in combination with additional compounds and input from several key opinion leaders, RedHill has added a second arm to the study, evaluating opaganib in combination with hydroxychloroquine, an anti-autophagy agent. Recruitment for the second arm of the Phase 1/2a study has been initiated. RedHill also plans to add a third arm to the study, evaluating opaganib in combination with RHB-107 (upamostat), a second proprietary new chemical entity (NCE), subject to discussions with the U.S. Food and Drug Administration (FDA).

Based on pre-clinical data and literature indicating potential anti-viral activity, RedHill is actively pursuing an exploratory program intended to evaluate the activity of opaganib and RHB-107, individually and in combination with hydroxychloroquine and other compounds in the treatment of COVID-19 (novel coronavirus).

About Opaganib (ABC294640, Yeliva®)

Opaganib, a new chemical entity, 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. By inhibiting SK2, opaganib blocks the synthesis of sphingosine 1-phosphate (S1P), a lipid-signaling molecule that promotes cancer growth and pathological inflammation. Opaganib 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 1 clinical study in cancer patients with advanced solid tumors. Opaganib received Orphan Drug designation from the U.S. FDA for the treatment of cholangiocarcinoma. The initial development of opaganib 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. NCI.

About RHB-107

RHB-107 (INN: upamostat) is a first-in-class, orally-administered inhibitor of S1 family of trypsin-like serine proteases with potential for use in multiple oncology, gastrointestinal and inflammatory indications. RHB-107 clinical safety profile has been demonstrated in over 300 patients, including in Phase 2 studies in locally advanced pancreatic cancer and metastatic breast cancer. RedHill licensed the worldwide rights to RHB-107 from Heidelberg Pharma AG (formerly Wilex AG), excluding China, Taiwan, Macao, and Hong Kong.

The studies with opaganib for cholangiocarcinoma and prostate cancer are registered on www.clinicaltrials.gov (ClinicalTrials.gov Identifiers NCT03377179 and NCT04207255, respectively), 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

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on the commercialization and development of proprietary drugs for the treatment of gastrointestinal diseases. RedHill promotes the gastrointestinal drugs **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[3] and **Aemcolo®** for the treatment of travelers' diarrhea[4]. RedHill acquired rights to **Movantik®** for opioid-induced constipation[5]. The acquisition remains subject to certain customary closing conditions and regulatory clearances. RedHill's key clinical late-stage development programs include: (i) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (ii) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iii) **RHB-102** (**Bekinda®**), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (iv) **opaganib (Yeliva®)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 1/2a study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation, and (vi) **RHB-107**, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at www.redhillbio.com.

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 related to the timing of hiring sales representatives as well as 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, and the timing of the commercial launch of its therapeutic candidates and its FDA-approved products; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (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,

[3] For full prescribing information see Talicia® (omeprazole magnesium, amoxicillin, and rifabutin): www.Talicia.com

[4] For full prescribing information see Aemcolo® (rifamycin): www.Aemcolo.com.

[5] For full prescribing information see Movantik® (naloxegol): www.Movantik.com.

approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia®; (v) the Company's ability to successfully commercialize and promote Talicia® and Aemcolo® and following closing of the acquisition, Movantik®; (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; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. 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 March 4, 2020. 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.

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