Press Release

RedHill Biopharma Provides Initial Update from its Opaganib COVID-19 Compassionate Use Program in Israel

Objective improvement in first two patients treated with opaganib in Israel who have demonstrated measurable clinical improvement within days of treatment initiation, including decreased supplemental oxygen requirements, decreased C-reactive protein (CRP) levels and increased lymphocyte levels

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One patient was treated in the ICU, was considered for intubation, and was released within days of treatment-initiation

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Opaganib was administered in addition to standard-of-care, including hydroxychloroquine background therapy, and was well tolerated

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Opaganib's unique mechanism of action has both anti-viral and anti-inflammatory activities, targeting a critical host factor, minimizing potential development of resistance due to viral mutations

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Compassionate use program approved in Italy with 160 patients planned to be treated; Discussions ongoing in the U.S. and other countries to increase the accessibility of opaganib under similar programs, as well as potential emergency clinical development programs

TEL-AVIV, Israel and RALEIGH, N.C., April 13, 2020, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, provided an initial update on the compassionate use program with its investigational drug, opaganib (Yeliva®, ABC294640)[1], in patients with confirmed SARS-CoV-2 infection (COVID-19) in Israel.

[1] Opaganib is an investigational new drug, not available for commercial distribution.

The first two patients have been treated with opaganib at a leading hospital in Israel. At the time of treatment initiation, both patients suffered from moderate to severe acute respiratory symptoms related to SARS-CoV-2 infection, required supplemental oxygenation and were hypoxic despite being treated with maximum flow of oxygen with cannulas.

Preliminary findings from both patients demonstrated clinical improvement within days post treatment-initiation with opaganib. To date, both patients have shown decreased supplemental oxygen requirements and decreased C-reactive protein (CRP) levels, an important inflammatory biomarker correlated with lung lesions which could reflect disease severity[2]. Both patients have also shown an increase in lymphocyte levels, a sign of improvement from virus-induced lymphopenia. One of the patients was being treated in the intensive care unit (ICU), was considered for intubation, and was released from the ICU within days of treatment initiation with opaganib.

Opaganib was administered to the hospitalized patients in addition to standard-of-care, which included hydroxychloroquine (HCQ) as background therapy. Opaganib was well tolerated at the doses administered and no opaganib-related treatment emergent adverse events have been reported to date.

"We are very encouraged by the preliminary findings showing clinical improvement in the first COVID-19 patients treated with opaganib, which further supports its safety and potential benefit to patients. Our hope is that the unique mechanism of action of opaganib, with both anti-viral and anti-inflammatory activity, will help COVID-19 patients by reducing lung inflammation, and thus preventing the disease from progressing to a stage which requires mechanical ventilation. Importantly, opaganib is targeting a critical host factor that the coronavirus is unlikely to evade via mutation in possible future outbreaks of the pandemic," **said Mark L. Levitt, MD, Ph.D., Medical Director at RedHill. "**We are committed to expanding the availability of opaganib under compassionate use to additional hospitals and countries and are hopeful that this treatment could potentially benefit COVID-19 patients with life-threatening manifestations."

In addition, approximately 160 patients are planned to be treated in three major hospitals in northern Italy under an expanded access program approved by the Italian National Institute for Infectious Diseases, allowing compassionate use of opaganib, for patients with confirmed SARS-CoV-2 infection with life-threatening manifestations.

To find out more about RedHill Biopharma's Expanded Access policy, please look here for additional information: www.redhillbio.com/expandedaccess.

[2] Ling W. C-reactive protein levels in the early stage of COVID-19. Med Mal Infect. 2020 Mar 31. pii: S0399-077X(20)30086-X.

Discussions are ongoing in the U.S. and other countries to increase the accessibility of opaganib under compassionate use program authorizations, as well as potential emergency clinical development programs.

A total of 131 subjects have been dosed with opaganib to date in ongoing and completed Phase 1 and Phase 2 clinical studies in oncology indications in the U.S., in pharmacokinetic studies in healthy volunteers in the U.S., and under the existing FDA-approved expanded access requests from physicians for individual oncology patients, establishing safety and tolerability in humans both in the U.S. and ex-U.S.

Opaganib, a new chemical entity, is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anticancer, anti-viral and anti-inflammatory activities, targeting multiple oncology, inflammatory and gastrointestinal indications. Pre-clinical data have demonstrated both anti-viral and anti-inflammatory activities of opaganib, with the potential to reduce lung inflammatory disorders, such as pneumonia, and mitigate pulmonary fibrotic damage. Several prior pre-clinical studies support the potential role of SK2 in the replication-transcription complex of positive-strand single-stranded RNA viruses, similar to coronavirus, and its inhibition may potentially inhibit viral replication. Pre-clinical *in vivo* studies[3] have demonstrated that opaganib decreased fatality rates from influenza-virus infection and ameliorated *Pseudomonas aeruginosa*-induced lung injury.

Opaganib has undergone a Phase 1 clinical study in patients with advanced solid tumors and is currently being investigated, individually and in combination with hydroxychloroquine, in a Phase 1/2a study in advanced cholangiocarcinoma (bile duct cancer), and in a Phase 2 study in prostate cancer.

The development of opaganib has been supported by grants and contracts from U.S. federal and state government agencies awarded to U.S.-based Apogee Biotechnology Corp., including the U.S. National Cancer Institute (NCI), 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 Opaganib (ABC294640, Yeliva®)

Opaganib, a new chemical entity, is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor with anticancer, anti-viral 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

[3] Xia C. et al. Transient inhibition of sphingosine kinases confers protection to influenza A virus infected mice. Antiviral Res. 2018 Oct; 158:171-177. Ebenezer DL et al. Pseudomonas aeruginosa stimulates nuclear sphingosine-1-phosphate generation and epigenetic regulation of lung inflammatory injury. Thorax. 2019 Jun;74(6):579-591.

promotes cancer growth and pathological inflammation. By inhibiting SK2, opaganib potentially blocks viral replication complex and pathological inflammation. Opaganib 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 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. Opaganib is also being evaluated for the treatment of coronavirus (COVID-19) in confirmed COVID-19 patients in Israel and is also planned to be evaluated in Italy. The development of opaganib has been supported by grants and contracts from U.S. federal and state government agencies awarded to Apogee Biotechnology Corp., including from the NCI, BARDA, the U.S. Department of Defense and the FDA Office of Orphan Products Development.

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal diseases. RedHill promotes the gastrointestinal drugs **Movantik®** for opioid-induced constipation in adults[4], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[5] and **Aemcolo®** for the treatment of travelers' diarrhea in adults[6]. 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, including forward-looking statements regarding the preliminary findings from the treatment of COVID-19 patients with opaganib, the Company's discussions to increase the accessibility of opaganib under compassionate use program authorizations, as well as potential emergency clinical development programs. The treatment with opaganib in Israel is administered under a compassionate use program in accordance with the Israeli Ministry of Health guidelines, with additional patients expected to be treated in the coming days. The findings to date are only preliminary, are based on clinical results of a very limited number of patients and are not part of a clinical study. There is no guarantee that these patients will continue to show

[4] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.

[5] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin, and rifabutin) is available at: www.Talicia.com.

[6] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.

clinical improvement or that other patients will show similar clinical improvement. 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, the risk that the clinical condition of the two patients will not continue to improve and may worsen, the risk that other COVID-19 patients treated with opaganib will not show any clinical improvement, the risk that clinical trials of opaganib for the treatment of COV-19, if conducted, will not show any improvement in patients, the development risks of early-stage discovery efforts for a disease that is still little understood, including difficulty in assessing the efficacy of opaganib for the treatment of COVID-19, if at all; intense competition from other companies developing potential treatments and vaccines for COVID-19; the effect of a potential occurrence of patients suffering serious adverse events using COVID-19 under the compassionate use programs as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number and type 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 and Talicia®; (v) the Company's ability to successfully commercialize and promote Talicia®, and Aemcolo® and 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, pre-clinical 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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