



NEWS RELEASE

RedHill and Kukbo Enter Oral Opaganib License for COVID-19 in South Korea

3/15/2022

RedHill to receive \$1.5 million upfront and is eligible for up to \$5.6 million in milestone payments in addition to royalties on net sales from Kukbo

Opaganib's Phase 2/3 clinical data shows improved viral RNA clearance, reduced mortality on top of remdesivir & corticosteroids and faster time to recovery for moderate to severe hospitalized COVID-19 patients treated with opaganib; potent in vitro inhibition of multiple variants also demonstrated

TEL-AVIV, Israel, and RALEIGH, N.C., March 15, 2022 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, announced that it has entered into an exclusive license agreement with Kukbo Co. Ltd. (Kospi: 001140) ("Kukbo"), a South Korean corporation, for oral opaganib^[1] for the treatment of COVID-19, in South Korea.

Under the terms of the license agreement, which follows the **previously announced strategic investment** by Kukbo, RedHill will receive an upfront payment of \$1.5 million and is eligible for up to \$5.6 million in milestone payments as well as low double-digit royalties on net sales of oral opaganib in South Korea. Kukbo will receive the exclusive rights to commercialize opaganib in South Korea for COVID-19.

Dror Ben-Asher, RedHill's CEO, said: "South Korea is currently experiencing a spike in COVID-19 cases with the **Korea Disease Control & Prevention Agency** reporting almost 4 million new cases already registered in the first half of March alone. Together with our partner, Kukbo, we are working hard to bring opaganib to Korean patients in need of new COVID-19 therapeutic options."

"Every day this month we are seeing an average of almost 2000 people hospitalized due to COVID-19 in South Korea and we desperately need medications that can effectively treat these patients," **said Hyun Ha, Kukbo's CEO.** "With the data supporting opaganib for COVID-19, and the expanded partnership with RedHill, Kukbo is determined to work with local regulators with the aim of bringing opaganib to South Korean patients, as soon as possible."

The partnership with Kukbo also includes a right of first offer for RedHill's late-stage clinical assets, opaganib, RHB-107 (upamostat)^[2] and Talicia®, for one or more of the territories of South Korea, Japan, Indonesia, Vietnam, Thailand and/or Malaysia. The right of first offer has been extended as part of the new license agreement until the end of October 2022.

About Opaganib (ABC294640)

Opaganib, a new chemical entity, is a proprietary, first-in-class, orally-administered, sphingosine kinase-2 (SK2) selective inhibitor, with proposed dual anti-inflammatory and antiviral activity. Opaganib is host-targeted and is expected to be effective against emerging viral variants, having already demonstrated inhibition against variants of concern, including Delta. Opaganib has also shown anticancer activity and positive preclinical results in renal fibrosis, and has the potential to target multiple oncology, viral, inflammatory, and gastrointestinal indications.

In prespecified analyses of Phase 2/3 clinical data, oral opaganib has demonstrated improved viral RNA clearance, significant mortality reduction on top of remdesivir and corticosteroids and faster time to recovery. Opaganib previously delivered promising U.S. Phase 2 data in patients with moderate to severe COVID-19, submitted for peer review and recently published in medRxiv.

Opaganib has also received Orphan Drug designation from the U.S. FDA for the treatment of cholangiocarcinoma and is being evaluated in a Phase 2a study in advanced cholangiocarcinoma and in a Phase 2 study in prostate cancer. Patient accrual, treatment and analysis in this study are ongoing.

Opaganib demonstrated potent antiviral activity against SARS-CoV-2, the virus that causes COVID-19, inhibiting viral replication of the original SARS-CoV-2 and variants tested to date in an in vitro model of human lung bronchial tissue. Additionally, preclinical in vivo studies have demonstrated opaganib's potential to decrease renal fibrosis, have shown decreased fatality rates from influenza virus infection, and amelioration of bacteria-induced pneumonia lung injury with reduced levels of IL-6 and TNF-alpha in bronchoalveolar lavage fluids^[3].

The ongoing clinical studies with opaganib 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

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious 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-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (ABC294640)**, a first-in-class oral SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and Phase 2 studies for prostate cancer and cholangiocarcinoma ongoing; (iii) **RHB-107 (upamostat)**, an oral serine protease inhibitor in a U.S. Phase 2/3 study as treatment for symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (v) **RHB-102**, with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com/ twitter.com/RedHillBio.

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 and include the plan for potential emergency and marketing authorization applications in certain ex-U.S. countries in the first half of 2022. 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 the Phase 2/3 COVID-19 study for opaganib and its results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional COVID-19 studies for opaganib are likely to be required by regulatory authorities to support such potential applications and the use or marketing of opaganib for COVID-19 patients, that emergency and marketing authorization applications in certain ex-U.S. countries will be delayed, that opaganib will not be effective against emerging viral variants, 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 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 preclinical studies or clinical trials (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 Movantik®, Talicia® and Aemcolo®; (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 and sustain 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 commercial products 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 events 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 March 18, 2021. 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.

Company contact:

Adi Frish
Chief Corporate & Business Development Officer
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

Media contacts:

U.S. / UK: Amber Fennell, Consilium
+44 (0) 7739 658 783
fennell@consilium-comms.com

Category: Corporate

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

^[2] RHB-107 (upamostat) is an investigational new drug, not available for commercial distribution.

^[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.

[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**.

View original content: **<https://www.prnewswire.com/news-releases/redhill-and-kukbo-enter-oral-opaganib-license-for-covid-19-in-south-korea-301502839.html>**

SOURCE RedHill Biopharma Ltd.