NEWS RELEASE

RedHill Biopharma's Movantik® Added as Preferred and Unrestricted Brand To Major National Medicare Formulary Serving Millions of Americans

12/1/2021

Movantik® approved for inclusion as preferred and unrestricted brand on a major National Medicare Part D formulary serving more than 10 million Americans as of January 1, 2022

Movantik's total commercial coverage extends to 152 million American patients' lives and will grow to 46 million Medicare lives and will increase to over 94% coverage of Medicare Part D lives

Movantik is the U.S. market-leading oral peripherally acting mu-opioid receptor antagonist (PAMORA), approved to treat opioid-induced constipation in adults with chronic non-cancer pain

TEL AVIV, Israel and RALEIGH, N.C., Dec. 1, 2021 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that one of America's largest payors, serving more than 10 million Americans through multiple Medicare plans, has approved the inclusion of Movantik® (naloxegol), a peripherally acting mu-opioid receptor antagonist (PAMORA) for opioid-induced constipation, as a preferred and unrestricted brand on its National Medicare Part D formulary starting January 1, 2022.

"It is important for optimal chronic pain treatment that patients are able to manage the debilitating constipation that often accompanies opioid therapy and have access to treatments such as Movantik," **said Rick Scruggs, RedHill's Chief Commercial Officer.** "This important new listing for Movantik, the market-leading PAMORA for opioid-induced constipation, as a preferred and unrestricted brand on a major National Medicare Part D formulary provides that access to more than 10 million more Americans covered by this formulary. Movantik now has

coverage of 90% of U.S. commercial lives and will increase to over 94% coverage of Medicare Part D lives, as we continue our efforts to increase patient access to Movantik."

About Movantik® (naloxegol)

Movantik® is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Important Safety Information About Movantik

Movantik® (naloxegol) is contraindicated in:

- Patients with known or suspected gastrointestinal (GI) obstruction and patients at risk of recurrent obstruction, due to the potential for GI perforation.
- Patients receiving strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole) because these medications can significantly increase exposure to naloxegol which may precipitate opioid withdrawal symptoms.
- Patients with a known serious or severe hypersensitivity reaction to Movantik or any of its excipients.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, irritability, and yawning, occurred in patients treated with Movantik. Patients receiving methadone as therapy for their pain condition were observed in the clinical trials to have a higher frequency of GI adverse reactions that may have been related to opioid withdrawal than patients receiving other opioids. Patients with disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal or reduced analgesia. These patients (e.g., multiple sclerosis, recent brain injury, Alzheimer's disease, and uncontrolled epilepsy) were not enrolled in the clinical studies. Take into account the overall risk-benefit profile when using Movantik in such patients. Monitor for symptoms of opioid withdrawal when using Movantik in such patients.

Severe abdominal pain and/or diarrhea have been reported, generally within a few days of initiation of Movantik. Monitor and discontinue if severe symptoms occur. Consider restarting Movantik at 12.5 mg once daily.

Cases of GI perforation have been reported with the use of peripherally acting opioid antagonists, including Movantik. Postmarketing cases of GI perforation, including fatal cases, were reported when Movantik was used in patients at risk of GI perforation (e.g., infiltrative gastrointestinal tract malignancy, recent gastrointestinal tract surgery, diverticular disease including diverticulitis, ischemic colitis, or concomitantly treated with bevacizumab). Monitor for severe, persistent, or worsening abdominal pain; discontinue if this symptom develops.

The most common adverse reactions with Movantik as compared to placebo in clinical trials were: Abdominal pain

(21% vs 7%), diarrhea (9% vs 5%), nausea (8% vs 5%), flatulence (6% vs 3%), vomiting (5% vs 4%), headache (4% vs 3%), and hyperhidrosis (3% vs <1%).

Movantik (naloxegol) is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Click here for the **Medication Guide** and full **Prescribing Information** for Movantik.

You are encouraged to report Adverse Reactions to RedHill Biopharma Inc. at 1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

MOVANTIK is a registered trademark of the AstraZeneca group of companies.

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[1], **Talicia®** for the treatment of Helicobacter pylori (H. pylori) infection in adults[2], and **Aemcolo®** for the treatment of travelers' diarrhea in adults[3]. 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** / **https://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. 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 Company will be unable to secure additional PBMs formulary coverage for Movantik, ; 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 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.

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[1] Full prescribing information for Movantik® (naloxegol) is available at: **www.Movantik.com**.
[2] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: **www.Talicia.com**.
[3] Full prescribing information for Aemcolo® (rifamycin) is available at: **www.Aemcolo.com**.

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