RedHill Biopharma Adds Israel Rights to Movantik® From AstraZeneca

October 8, 2020

RedHill obtains Israel rights to Movantik® from AstraZeneca, giving RedHill global rights, excluding Europe and Canada

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Movantik approved for opioid-induced constipation in Israel under the brand name Moventig®

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RedHill to evaluate partnering opportunities for commercialization of Movantik in Israel

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RedHill maintains sole and exclusive U.S. commercialization responsibility for Movantik, which generated approximately $20 million in net revenue in Q2/2020, the first quarter of sales as a RedHill product

TEL AVIV, Israel and RALEIGH, N.C., Oct. 08, 2020 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that it has gained the rights to Movantik (naloxegol)[1] in Israel from AstraZeneca (LSE/STO /Nasdaq: AZN). RedHill now holds the worldwide rights to Movantik, excluding Europe and Canada.

Movantik is approved in Israel, under the brand name Moventig, for the treatment of opioid-induced constipation (OIC) but is not yet commercialized. RedHill is evaluating the potential for a local commercialization partnership for Movantik in order to bring this valuable OIC treatment to patients in Israel.

"Our commercial focus for Movantik remains firmly fixed on the U.S., where we have sole and exclusive commercialization rights. We have built a strong and expanding commercial team to support Movantik, which despite the challenging COVID-19 pandemic environment generated approximately $20 million in net revenue in the second quarter of 2020 - its first quarter as a RedHill product." **said Adi Frish, Senior Vice President Business Development and Licensing at RedHill**. "We would like to thank AstraZeneca for expanding our Movantik partnership and Knight Therapeutics, which previously held the rights for Moventig in Israel, for enabling the smooth transfer of this asset."

In August this year, the Company also announced an amendment to the agreement with Daiichi Sankyo which enabled RedHill to exercise full control over brand strategy and commercialization activities for Movantik in the U.S., while also increasing margins.

About Movantik®

Movantik is a proprietary once-daily oral PAMORA approved by the U.S. Food and Drug Administration 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. Movantik is the first oral PAMORA approved in the U.S. for the treatment of OIC and is recommended by the American Gastroenterological Association (AGA) guidelines[2] and the National Comprehensive Cancer Network (NCCN) guidelines. Movantik is part of the exclusive worldwide license agreement announced in 2009 between AstraZeneca and Nektar Therapeutics. It was developed using Nektar's oral small-molecule polymer conjugate technology. Movantik ® was first approved in 2014 and launched in the U.S. by AstraZeneca and Daiichi Sankyo in 2015. Further information about Movantik is available at: www.Movantik.com.

About Opioid-Induced Constipation (OIC)

OIC is a condition caused by prescription opioid pain medicines. Opioids play an important role in chronic pain relief and work by binding to mu-receptors in the central nervous system, but they can also bind to mu-receptors in the bowel, which can result in patients suffering from OIC. OIC is the most prevalent and disabling adverse effect associated with opioid therapy, estimated to affect between 40-80% of the millions of patients taking chronic opioid therapy each year[4].

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[3], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[4] and **Aemcolo®** for the treatment of travelers' diarrhea in adults [5]. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (ii) **opaganib (Yeliva®)**, a first-in-class SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and ongoing Phase 2 studies for prostate cancer and cholangiocarcinoma; (iii) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (iv) **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; (v) **RHB-107**, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases and is also being evaluated for COVID-19 and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com.

IMPORTANT SAFETY INFORMATION ABOUT MOVANTIK

MOVANTIK may cause serious side effects, including:

- **Opioid withdrawal.** You may have symptoms of opioid withdrawal during treatment with MOVANTIK, including sweating, chills, diarrhea, stomach pain, anxiety, irritability, and yawning. Patients taking methadone to treat their pain may be more likely to experience stomach pain and diarrhea. Tell your doctor if you have any of these symptoms

- **Severe Stomach Pain and/or Diarrhea.** This can happen within a few days of starting MOVANTIK and can lead to hospitalization. If either of these side effects occurs, stop taking MOVANTIK and call your doctor immediately
- **Tear in your stomach or intestinal wall (perforation).** Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that gets worse or does not go away, stop taking MOVANTIK and get emergency medical help right away

Do not take MOVANTIK if you:

- Have a bowel blockage (intestinal obstruction) or have a history of bowel blockage
- Are allergic to MOVANTIK or any of the ingredients in MOVANTIK

MOVANTIK can interact with other medicines and cause side effects, including opioid withdrawal symptoms (see symptoms above). Tell your doctor or pharmacist before you start or stop any medicines during treatment with MOVANTIK

Before you take MOVANTIK, tell your doctor about all of your medical conditions, including if you:

- Have any stomach, bowel (intestines) problems, including inflammation in parts of the large intestine (diverticulitis), or inflammation and injury of the intestines caused by reduced blood flow (ischemic colitis)
- Have had recent surgery on the stomach or intestines
- Have any kidney, or liver problems
- Are pregnant or plan to become pregnant. Taking MOVANTIK during pregnancy may cause opioid withdrawal symptoms in you or your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with MOVANTIK
- Are breastfeeding or plan to breastfeed. It is not known if MOVANTIK passes into your breast milk. Taking MOVANTIK while you are breastfeeding may cause opioid withdrawal in your baby. You and your healthcare provider should decide if you will take MOVANTIK or breastfeed. You should not breastfeed if you take MOVANTIK

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect the way MOVANTIK works

If you stop taking your opioid pain medicine, stop taking MOVANTIK and tell your doctor

Avoid eating grapefruit or drinking grapefruit juice during treatment with MOVANTIK

The most common side effects of MOVANTIK include: Stomach (abdomen) pain, diarrhea, nausea, gas, vomiting, headache, and excessive sweating

APPROVED USE FOR MOVANTIK

MOVANTIK is a prescription medicine used to treat constipation that is caused by prescription pain medicines called opioids, in adults with long-lasting (chronic) pain that is not caused by active cancer.

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.

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 the risk that the Company will be unable to enter into a local commercialization partnership for Movantik® in Israel and 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 commercial products; (v) the Company's ability to successfully commercialize and promote Talicia®, and Aemcolo® and Movantik®*; (vi) the Company's ability to est ablish 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 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 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 maintaining*

employment 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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[i] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com; Approved in Israel under brand name Moventig®.

[ii] Crockett, Seth D., et al. American Gastroenterological Association Institute guideline on the medical management of opioid-induced constipation, *Gastroenterology* 156.1 (2019): 218-226.

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

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

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

Source: RedHill Biopharma Ltd.