RedHill Biopharma Increases Patient Access to Talicia® with EnvisionRx Formularies

July 27, 2020

Talicia® is the first and only FDA-approved rifabutin-based therapy for H. pylori infection designed as a first-line option to address the high and growing resistance of H. pylori to clarithromycin-based therapies

Talicia® is targeting an estimated two million U.S. patients treated annually for H. pylori infection

H. pylori bacterial infection is a Group 1 carcinogen and the strongest risk factor for gastric cancer; H. pylori affects approximately 35% of the U.S. population

EnvisionRx is a pharmacy benefit manager (PBM), serving more than 3.5 million members nationally

TEL-AVIV, Israel and RALEIGH, N.C., July 27, 2020 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that EnvisionRx, a Pharmacy Benefit Manager (PBM) and division of EnvisionRxOptions, a wholly owned subsidiary of Rite Aid, added Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[1] to its Formularies, as the unrestricted branded agent for *H. pylori* treatment, effective July 1, 2020.

"The addition of Talicia® to the EnvisionRx national formularies as the unrestricted brand will allow its 3.5 million members nationally to gain access to Talicia®. We continue to work diligently to further expand patient access to Talicia®, the first and only FDA-approved rifabutin-based therapy for the treatment of *H. pylori* infection," **said Rick Scruggs, RedHill's Chief Commercial Office** r. "Despite the ongoing limitations due to the COVID-19 pandemic, our dedicated sales reps are back in the field, continuing their engagements with health care providers. We look forward to working closely with our partners to increase the availability of Talicia® to more patients."

About Talicia®

Talicia® is the only rifabutin-based therapy approved for the treatment of *H. pylori* infection and is designed to address the high resistance of *H. pylori* bacteria to clarithromycin-based standard-of-care therapies. The high rates of *H. pylori* resistance to clarithromycin have led to significant rates of treatment failure with clarithromycin-based standard-of-care therapy and are a strong public health concern, as highlighted by the FDA and the World Health Organization (WHO) in recent years.

Talicia® is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (PPI) (omeprazole). In November 2019, Talicia® was approved by the U.S. FDA for the treatment of *H. pylori* infection in adults. In the pivotal Phase 3 study, Talicia® demonstrated 84% eradication of *H. pylori* infection in the intent-to-treat (ITT) group vs. 58% in the active comparator arm ($p<0.0001$). Minimal to zero resistance to rifabutin, a key component of Talicia®, was detected in RedHill's pivotal Phase 3 study. Further, in an analysis of data from this study, it was observed that subjects who were confirmed adherent[2] to their therapy had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm[3].

Talicia® is eligible for a total of eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation and is also covered by U.S. patents which extend patent protection until 2034 with additional patents and applications pending and granted in various territories worldwide.

About *H. pylori*

H. pylori bacterial infection affects approximately 35%[4] of the U.S. population, with an estimated two million patients treated annually[5]. Worldwide, more than 50% of the population is affected by *H. pylori* infection, which is classified by the WHO as a Group 1 carcinogen, remains the strongest known risk factor for gastric cancer[6] and a major risk factor for peptic ulcer disease[7] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[8]. More than 27,000 Americans are diagnosed with gastric cancer annually[9]. Eradication of *H. pylori* is becoming increasingly difficult, with current standard-of-care therapies failing in approximately 25-40% of patients who remain *H. pylori*-positive due to high resistance of *H. pylori* to antibiotics commonly used in standard combination therapies[10].

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[11], **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults[12] and **Aemcolo®** for the treatment of travelers' diarrhea in adults [13]. 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-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 and is also being evaluated for COVID-19. More information about the Company is available at www.redhillbio.com.

About EnvisonRx
EnvisionRx is a pharmacy benefits and services company and a wholly owned subsidiary of Rite Aid. Nationally accredited, EnvisionRx provides affordable and effective prescription drug coverage for employers, unions and health plans. The first PBM to offer true transparency, EnvisionRx provides flexible services, unique network and formulary design, and specialty pharmacy care. Using its proprietary EnvisionCare model, EnvisionRx optimizes all aspects of the pharmacy care experience to consistently achieve better patient and plan outcomes.

About Talicia® (omeprazole magnesium, amoxicillin and rifabutin)

INDICATION AND USAGE
Talicia® is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of *Helicobacter pylori* infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Talicia® and other antibacterial drugs, Talicia® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION
Talicia® contains omeprazole, a proton pump inhibitor (PPI), amoxicillin, a penicillin-class antibacterial and rifabutin, a rifamycin antibacterial. It is contraindicated in patients with known hypersensitivity to any of these medications, any other components of the formulation, any other beta-lactams or any other rifamycin.

Talicia® is contraindicated in patients receiving rilpivirine-containing products.

Talicia® is contraindicated in patients receiving delavirdine or voriconazole.

Serious and occasionally fatal hypersensitivity reactions have been reported with omeprazole, amoxicillin and rifabutin.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.
Talicia® may cause fetal harm. Talicia® is not recommended for use in pregnancy.

Talicia® may reduce the efficacy of hormonal contraceptives. An additional non-hormonal method of contraception is recommended when taking Talicia®.

Talicia® should not be used in patients with hepatic impairment or severe renal impairment.

Acute Interstitial Nephritis has been observed in patients taking PPIs and penicillins.

Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs. These events have occurred as both new onset and exacerbation of existing autoimmune disease.

The most common adverse reactions (≥1%) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

To report SUSPECTED ADVERSE REACTIONS, contact RedHill Biopharma INC. at
1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Full prescribing information for Talicia® is available at www.Talicia.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, the risk that the Company will be unable to secure additional PBMs formulary coverage for Talicia® as well as other 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 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 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.

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):
Timothy McCarthy, CFA, MBA
Managing Director, Relationship Manager
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

---

[1] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) delayed-release capsules 10 mg/250 mg/12.5 mg is indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. For full prescribing information see: www.Talicia.com.

[2] Defined as the PK population which included those subjects in the ITT population who had demonstrated presence of any component of investigational drug at visit 3 (approx. day 13) or had undetected levels drawn >250 hours after the last dose.

[3] The pivotal Phase 3 study with Talicia® demonstrated 84% eradication of *H. pylori* infection with Talicia® vs. 58% in the active comparator arm (ITT analysis, p<0.0001).

[4] Hooi JKY et al. Global Prevalence of *Helicobacter pylori* Infection: Systematic Review and Meta-Analysis. Gastroenterology 2017; 153:420-429.

[5] IQVIA Custom Study for RedHill Biopharma, 2019

[6] Lamb A et al. Role of the *Helicobacter pylori*-Induced inflammatory response in the development of gastric cancer. J Cell Biochem 2013;114.3:491-497.

[7] NIH – *Helicobacter pylori* and Cancer, September 2013.

[8] Hu Q et al. Gastric mucosa-associated lymphoid tissue lymphoma and *Helicobacter pylori* infection: a review of current diagnosis and management. Biomarker research 2016;4.1:15.

[9] National Cancer Institute, Surveillance, Epidemiology, and End Results Program (SEER).

[10] Malfertheiner P. et al. Management of *Helicobacter pylori* infection - the Maastricht IV/ Florence Consensus Report, Gut 2012;61:646-664; O'Connor A. et al. Treatment of *Helicobacter pylori* Infection 2015, Helicobacter 20 (S1) 54-61; Venerito M. et al. Meta-analysis of bismuth quadruple therapy versus clarithromycin triple therapy for empiric primary treatment of *Helicobacter pylori* infection. Digestion 2013;88(1):33-45.

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

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

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

Source: RedHill Biopharma Ltd.