PRESS RELEASE 27 November 2019

Recipharm announces commercial manufacturing to support Talicia® Q1/2020 Launch following U.S. FDA approval

Recipharm, the contract development and manufacturing organisation (CDMO), announced today ongoing large-scale commercial manufacturing of RedHill Biopharma's (Nasdaq: RDHL) drug, Talicia® (omeprazole magnesium, amoxicillin and rifabutin) delayed-release capsules 10 mg[1]/250 mg/12.5 mg, for its planned launch in the first quarter 2020.

RedHill and Recipharm have been working in partnership since 2015 to develop and manufacture the product, which is the first rifabutin-based therapy approved treatment for the treatment of *Helicobacter pylori* infection.

Throughout the development process Recipharm has been responsible for establishing manufacturing methods, scaling up from small scale concept to technology batch and clinical trial material, and establishing a compliant commercial manufacturing process.

Erik Haeffler, VP of Manufacturing Services said: "Recipharm's end-to-end development and manufacturing capabilities mean we have been able to support RedHill throughout the entire journey to market.

"We've been working closely with RedHill over the past few years to develop and manufacture Talicia®, so gaining FDA approval marks an important milestone in the journey and is testament to the hard work of both teams."

H. pylori infection, which is caused by a type of bacteria that grows in the digestive tract, affects over 50% of the population worldwide and approximately 35%, or over 100 million people, in the US.

Reza Fathi, Senior Vice President R&D at RedHill said: "This is a significant moment in our shared collaboration with Recipharm. We have been working diligently to develop and receive FDA approval for Talicia®. This would not have been possible without the mutual activities and work by all of the teams at RedHill and Recipharm, at three different sites."

Talicia® is designed to address the challenge of high and growing bacterial resistance and diminished efficacy of existing treatments. It is eligible for eight years of US market exclusivity under QIDP designation and its patent protection extends until 2034.

[1] Each delayed-release capsule contains omeprazole 10 mg (equivalent to 10.3 mg omeprazole magnesium), amoxicillin 250 mg, and rifabutin 12.5 mg.

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About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) in the pharmaceutical industry employing almost 7,000 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material and APIs, and pharmaceutical product development. Recipharm manufactures several hundred different products to customers ranging from big pharma to smaller research and development companies. Recipharm's turnover is approximately SEK 7.2 billion. The company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and is headquartered in Stockholm, Sweden. The Recipharm B-share (RECI B) is listed on Nasdaq Stockholm.

For more information on Recipharm and our services, please visit www.recipharm.com

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S., **Donnatal®**, **EnteraGam®** and **Mytesi®**, and is planning to launch **Aemcolo®** and **Talicia®** in the U.S.[2] 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) **ABC294640 (Yeliva®),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (v) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. 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

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.

[2] For full prescribing information see: Aemcolo®: www.Aemcolo.com; Mytesi®: www.Mytesi.com; EnteraGam® https://bit.ly/2N3q7DW; Talicia®: www.accessdata.fda.gov

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

- Known hypersensitivity to omeprazole, amoxicillin or any other beta-lactam antibacterial drugs, rifabutin or any other rifamycin, or any component of TALICIA.
- Rilpivirine-containing products.
- Delavirdine.
- Voriconazole.

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions: Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of TALICIA. If hypersensitivity reactions occur, discontinue TALICIA and institute immediate therapy (e.g., anaphylaxis management).
- ***Clostridioides difficile***-Associated Diarrhea (CDAD): Evaluate if diarrhea occurs.
- Reduction in the Efficacy of Hormonal Contraceptives: Additional non-hormonal highly effective methods of contraception should be used while taking TALICIA.
- Acute Interstitial Nephritis (AIN): Observed in patients taking Proton Pump Inhibitors (PPIs) and penicillins. Discontinue TALICIA if AIN develops.
- Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue TALICIA and evaluate.

ADVERSE REACTIONS

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

DRUG INTERACTIONS

Components of TALICIA have the potential for clinically important drug interactions. See full prescribing information for important drug interactions with TALICIA.

USE IN SPECIFIC POPULATIONS

- TALICIA may cause fetal harm.
- Renal Impairment: Avoid use in severe renal impairment.
- Hepatic Impairment: Avoid use.

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.

Please also see full Prescribing Information.