FUJIFILM EARNS FDA "BREAKTHROUGH DEVICE" DESIGNATION FOR ENDOSURGICAL IMAGE ENHANCEMENT TECHNOLOGY

Company announces development of new image processing technologies designed to enhance visualization during therapeutic procedures

Lexington, MA – FUJIFILM Medical Systems U.S.A., Inc., a leading provider of endoscopic imaging solutions, announced that the U.S. Food and Drug Administration (FDA) granted its Breakthrough Device Designation – reserved for medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions – for Fujifilm's new, in-development, endoscopic light and image processing technology. Although not yet 510(k) cleared, the goal of Fujifilm's in-development image processing technology is to arm surgeons with the resources needed to care for patients at risk for ischemic states of the gastrointestinal tract.

"Leveraging our 80+ year imaging legacy, we develop technologies designed to enhance visualization and guide healthcare providers as they make critical clinical decisions caring for their patients," says Taisuke Fujita, General Manager-Endoscopy, FUJIFILM Medical Systems U.S.A., Inc. "We're proud to receive this designation through the FDA's Breakthrough Devices Program on the heels of several advancements in 2019, and we look forward to bringing more innovations to the endoscopic and endosurgical markets in the years to come."

Fujifilm's new image processing technology is being developed to enhance endosurgical visualization and will be an upgrade to the ELUXEO Surgical System-the company's in-market video imaging system which leverages 4-LED multi-light technology to enable advanced visualization modes including White Light Endoscopy, Linked Color Imaging (LCI), and Blue Light Imaging (BLI). These imaging modes are designed to improve visualization, detection, and characterization during procedures.

In gastrointestinal procedures such as colorectal surgeries, anastomosis is performed following resections, sometimes resulting in a serious complication – anastomotic leaks. One of the major causes of anastomotic leaks is necrosis of ischemic tissue where the anastomosis is performed, and Fujifilm's new technology is designed to assist physicians in identifying ischemic areas of tissue.

Anastomotic leaks can result in septic complications, and are shown to have a 10% higher mortality rate as compared to patients who did not develop anastomotic leaks (14% vs. 4%). In a Medicare data analysis of more than 200,000 patients who underwent colorectal surgery between January 1, 2013 and August 31, 2015, care admission costs for patients with anastomotic leaks were reported more than $30,500 greater and the length of stay was 12 days longer as compared to those without. The commercial analysis of both the bariatric and colorectal populations trended similarly to the Medicare population in regards to all outcomes measured. These staggering statistics have led industry to research and develop technologies to prevent and/or reduce anastomotic leaks.

"For decades Fujifilm has invested in the research and development of technologies to improve patient outcomes and reduce healthcare costs, and in recent years, we've elevated our focus in endosurgery," says Stephen Mariano, Vice President of Global Endosurgical R&D, FUJIFILM Medical Systems U.S.A., Inc. "We look forward to working with the FDA as we prioritize the development and access of some of our exciting endosurgical innovations."

About Fujifilm

FUJIFILM Medical Systems U.S.A., Inc. is a leading provider of innovative diagnostic imaging products and medical informatics solutions that meet and exceed the evolving needs of healthcare facilities today and into the future. It's ever expanding medical imaging solutions span digital radiography (DR), detectors, portables and suites, mammography systems with digital breast tomosynthesis, computed tomography solutions for oncology and radiology applications, technologically advanced flexible and surgical endoscopy and fluoroscopy solutions. Fujifilm enables interoperability through its Systems Integration offering as well as its comprehensive, AI-supported Synapse® Enterprise Imaging portfolio, which includes the TeraMedica Division of Fujifilm. Fujifilm's in vitro diagnostics (IVD)

portfolio includes clinical lab reagents, and biomarkers to assess the risk for the development of hepatocellular carcinoma in patients with chronic liver disease. FUJIFILM Medical Systems U.S.A., Inc. is headquartered in Lexington, Massachusetts.

For more information, please visit:
fujifilmhealthcare.com

FUJIFILM Holdings Corporation, Tokyo, Japan, brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, graphic systems, highly functional materials, optical devices, digital imaging and document products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2020, the company had global revenues of $22.1 billion, at an exchange rate of 109 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship.

For more information, please visit:
fujifilmholdings.com

REDHILL BIOPHARMA EXTENDS TALICIA® UNRESTRICTED NATIONAL AND REGIONAL COMMERCIAL COVERAGE TO OVER 40 MILLION ADDITIONAL AMERICANS

Talicia® unrestricted access in the U.S. now extends to over 70% of commercial lives covered

Approximately 35% of Americans are affected by H. pylori infection, a Group 1 carcinogen and the strongest risk factor for gastric cancer; eradication of H. pylori has been shown to reduce the risk of gastric cancer by up to 75%

Talicia addresses the high and growing resistance of H. pylori bacteria to commonly used antibiotics

TEL AVIV, Israel and RALEIGH, N.C., RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that it has increased unrestricted national and regional commercial coverage for Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[i] to more than 40 million additional Americans.

"With this addition of unrestricted coverage for over 40 million more lives, Talicia is now available to over 70% of commercial lives. The unrestricted commercial coverage achieved for Talicia to date far exceeds our expectations at such an early stage following the product's launch. We continue to work diligently to increase unrestricted coverage of Talicia, in an effort to make a significant difference in ending sub-optimal treatment of H. pylori," said Rick Scruggs, RedHill's Chief Commercial Officer. "Antibiotic resistance is a major issue in the treatment of H. pylori infections and yet, despite current guideline recommendations from the American College of Gastroenterology calling for use of the most effective first-line treatment, physicians are still prescribing treatment regimens containing antibiotics such as clarithromycin that face high levels of bacterial resistance. This growth in unrestricted commercial access helps change that dynamic by increasing access to Talicia to more than 167 million Americans."

RedHill has previously announced listings of Talicia as a preferred brand on the national formularies of Prime Therapeutics, EnvisionRx, and Express Scripts.

About Talicia
(omeprazole magnesium, amoxicillin and rifabutin)

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 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[ii] to their therapy had response rates of 90.3% in the Talicia arm vs. 64.7% in the active comparator arm[iii].

Talicia is eligible for a total of eight years of post-approval U.S. market exclusivity under both its Qualified Infectious Disease Product (QIDP) designation and New Clinical Investigation exclusivities. In addition, Talicia is protected by a robust U.S. patent portfolio which provides patent protection until at least 2034, with additional patents and applications pending and granted in various territories worldwide.

About H. pylori

H. pylori bacterial infection affects approximately 35%[iv] of the U.S. population, with an estimated two million patients treated annually[v]. 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[vi] and a major risk factor for peptic ulcer disease[vii] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[viii]. More than 27,000 Americans are diagnosed with gastric cancer annually[ix], while eradication of H. pylori has been shown to reduce the risk of gastric cancer by up to 75%[x]. 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[xi].

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[xii], Talicia® for the treatment of Helicobacter pylori (H. pylori) infection in adults[xiii], and Aemcolo® for the treatment of travelers' diarrhea in adults[xiv]. 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 (Yeliva®), a first-in-class 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-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 (upamostat), a Phase 2-stage serine protease inhibitor with a planned Phase 2/3 study in symptomatic COVID-19 and targeting multiple other cancer and inflammatory gastrointestinal diseases; and (vi) RHB-106, an encapsulated bowel preparation.

More information about the company is available at:

redhillbio.com

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 rifamycins.

Talicia is contraindicated in patients receiving delavirdine, voriconazole or rilpivirine-containing products.

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

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

Clostridioides difficile-associated diarrhea has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.

Talicia may cause fetal harm and is not recommended for use in pregnancy. It may also 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.

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lupus erythematosus 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 **fda.gov/medwatch**.

Full prescribing information for Talicia is available at:
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 including, without limitation, the risk that the Company will be unable to secure additional pharmacy benefit management's 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 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, including the development of a commercial companion diagnostic for the detection of MAP; (iii) the lack of sufficient financial resources which may result in material adverse impact on the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development activities including delay or termination of preclinical or clinical activities or of any other such activities (iv) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials (v) 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; (vi) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and commercial products; (vi) the Company's ability to successfully commercialize and promote Talicia®, and Aemcolo® and Movantik®; (vii) the Company's ability to establish and maintain corporate collaborations; (viii) 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; (ix) 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; (x) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (xi) 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; (xii) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xiii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiv) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xv) competition from other companies and technologies within the Company's industry; and (xvi) 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.