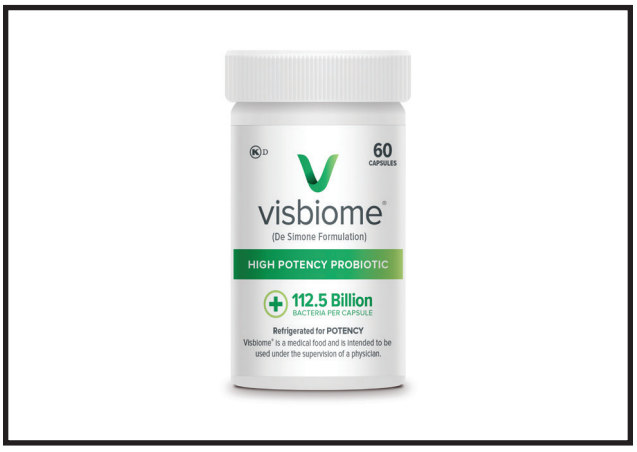

VISBIOME® - HIGH POTENCY PROBIOTIC

Visbiome is intended for the dietary management of dysbiosis associated with irritable bowel syndrome (IBS), ulcerative colitis (UC), antibiotic-associated diarrhea (AAD), pouchitis and hepatic encephalopathy (HE).

Visbiome is a medical food, non-drug therapy, that addresses distinct nutritional requirements which promote microbial balance that cannot be addressed by modifying the diet alone. Visbiome is a unique blend of 8 strains of bacteria, a formulation with more than 75 clinical trials, and more than 20 years of research, making it the most studied multi-strain probiotic formulation on the market. The product is made in the USA, available in capsule or powder format, and shipped cold with temperature monitoring sensors.

Q: Is Visbiome® the most studied multi-strain probiotic?

A: Yes, Visbiome, a probiotic medical food, has been the subject of over 75 peer reviewed clinical studies, the most of any multi-strain probiotic. There have been 10 studies in the dietary management of irritable bowel syndrome (IBS) and eight studies in the dietary management of ulcerative colitis (UC). The studies included both adults and children and consisted of more than 500 subjects for each condition.

Q: Is Visbiome® effective in the management of IBS?

A: Yes, in studies for the dietary management of IBS, Visbiome showed significant relief of symptoms associated with IBS, such as abdominal bloating, pain/discomfort and flatulence, and it was well tolerated.[1,2,3] In one study of children with IBS (4 to 18 years of age), Visbiome was superior to placebo in the primary endpoint of subjective assessment of relief of symptoms.[3]

Visbiome has also been studied in patients utilizing the low-FODMAP diet for management of IBS symptoms. In this placebo-controlled study, patients on the low-FODMAP diet exhibited a reduced level of Bifidobacterium species suggesting a level of dysbiosis caused by the diet itself. Patients who were co-administered Visbiome with the low-FODMAP diet maintained levels of Bifidobacterium consistent with controls.[4]

Bifidobacterium species are part of the normal inhabitants of a healthy gut and have certain immunomodulatory effects; alterations of Bifidobacterium species have been linked to IBS and other gastrointestinal diseases.[4,5]

Q: How does Visbiome® help in the management of UC?

A: In the dietary management of UC, Visbiome taken in conjunction with conventional therapies has been shown to be beneficial in patients with mild-to-moderate UC.[6,7] Visbiome also has been associated with a decrease in rectal bleeding, and demonstrated a reduction of up to 50% in UC disease activity index (UCDAI) scores, when used as a medical food.[8]

Q: What factors should be considered when recommending a Probiotic for IBS and UC patients?

A: There are certain factors a clinician should consider when recommending a probiotic to a patient:

- Recommend probiotics that contain the exact strain and species that have proven patient benefits in peer reviewed clinical studies, and do not extrapolate the success of one probiotic species to another. Some companies cite clinical data on other probiotic products and imply that parallel results can be expected simply because similar species are present, but they have not performed research on their specific formulation.
- Consider probiotics that contain a large enough number of viable microorganisms for the conditions.
- Consider probiotics from companies that implement procedures in the supply chain to protect the bacteria strains from harmful factors like heat and humidity, so the bacteria remain viable when they arrive to the patient.[9]

References

1. Kim et al. Neurogastro Motil 2005;17:1-10.
2. Kim et al. Aliment Pharmacol Ther 2003;17:895-904.
3. Guandalini et al. JPGN. 2010;51:24-30.
4. Staudacher H, et al. Gastroenterology 2017; 153:936-947.
5. Tojo R, et al. World J Gastroenterol 2014;20(41).
6. Sood A, et al. Clin Gastroenterol Hepatol 2009;11:1202-1209.
7. Miele E, et al. Am J Gastroenterol 2009;104:437-443.
8. Tursi A, et al. Med Sci Monit (2004); 10(11): PI126-131.
9. Cong D, et al. World J Gastroenterol 2013;19(36):5973-5980.

ExeGi Pharma,LLC, Makers of Visbiome®
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(844) 348-4887

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REDHILL BIOPHARMA'S TALICIA® ADDED TO MEDI-CAL CONTRACT DRUG LIST WITH NO PRIOR AUTHORIZATION REQUIREMENTS

Addition of Talicia® by Medi-Cal Fee-For-Service (FFS) Contract Drug List (CDL) with no prior authorization is an important expansion of coverage for California patients and continues to increase Talicia's overall unrestricted coverage

Coverage commenced for two million patients in Medi-Cal's FFS plan on October 1st, 2021

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 resistance of H. pylori bacteria to standard-of-care therapies

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

TEL-AVIV, Israel and RALEIGH, N.C., October 6, 2021, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that Medi-Cal - California's Medicaid Health Care program covering two million patients - has added Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[1] to its Contract Drug List (CDL) for H. pylori treatment, with no prior authorization required, effective October 1, 2021.

Coverage for Talicia commenced for two million patients in Medi-Cal's California FFS plan on October 1, 2021.

"Medi-Cal's addition of Talicia with no prior authorization required is an important step in Talicia's continuing growth and we are pleased that it will be made available to Medi-Cal's 2 million FFS lives," said Rick Scruggs, RedHill's Chief Commercial Officer. "There is growing recognition of the need to employ effective, first-line therapy against H. pylori infections that does not rely on clarithromycin and that patients can tolerate well and adhere to over 14 days of therapy. Talicia meets those criteria."

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 therapies. The high rates of H. pylori resistance to clarithromycin have led to significant rates of treatment failure with clarithromycin-based therapies 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[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 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 is a bacterial infection that 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 has H. pylori infection, which is classified by the WHO as a Group 1 carcinogen. It 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]. Eradication of H. pylori is becoming increasingly difficult, with current 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[x].

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[xi], Talicia® for the treatment of Helicobacter pylori (H. pylori) infection in adults[xii], and Aemcolo® for the treatment of travelers' diarrhea in adults[xiii]. 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

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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:
redhillbio.com
twitter.com/RedHillBio

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:
Talicia.com

[i] 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.
[ii] 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.
[iii] 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).
[iv] Hooi JKY et al. Global Prevalence of Helicobacter pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology 2017; 153:420-429.
[v] IQVIA Custom Study for RedHill Biopharma, 2019
[vi] 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.
[vii] NIH – Helicobacter pylori and Cancer, September 2013.
[viii] 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.
[ix] National Cancer Institute, Surveillance, Epidemiology, and End Results Program (SEER).
[x] 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.
[xi] Full prescribing information for Movantik® (naloxegol) is available at: www.Movantik.com.
[xii] Full prescribing information for Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.
[xiii] Full prescribing information for Aemcolo® (rifamycin) is available at: www.Aemcolo.com.