July 1, 2021

BSE Limited
Department of Corporate Services,
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

✔ **National Stock Exchange of India Limited**
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Sub: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Dear Sir/Madam,

Enclosed is a Press Release as regards receipt of U.S. FDA approval for the Company's supplemental New Drug Application to expand the use of SOLOSEC® (secnidazole) to include the treatment of trichomoniasis in adults.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Thanking you,

FOR LUPIN LIMITED

Rajvardhan Vishnu Satam

Digitally signed by Rajvardhan Vishnu Satam
DN: c=IN, o=Personal, 2.5.4.20=e8a002ede68da3b7e41e01d21c2b9062761a29a5f00491762a5ac549cb034cae, postalCode=400104, st=Maharashtra, serialNumber=df8ebe60a88c796663c738ea25bfa0b475d195f726cdb67a2ff09c4242771b2a, cn=Rajvardhan Vishnu Satam
Date: 2021.07.01 17:13:09 +05'30'

R. V. SATAM
COMPANY SECRETARY
(ACS-11973)

Encl- : a/a.

Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPCIN

Lupin Announces FDA Approval of Supplemental New Drug Application for SOLOSEC® (secnidazole) for the Treatment of Trichomoniasis

- SOLOSEC® demonstrated a 92.2% clinically and statistically significant cure rate for patients with trichomoniasis based on a landmark Phase 3 clinical trial
- SOLOSEC® is the first and only single-dose oral prescription antimicrobial agent for the treatment of both trichomoniasis and bacterial vaginosis approved by the FDA in the U.S.

MUMBAI, BALTIMORE, July 01, 2021 Lupin Pharmaceuticals, Inc., the U.S. based wholly-owned subsidiary of global pharma major Lupin Limited (Lupin), announced today that the U.S. Food and Drug Administration (FDA) has approved the company's supplemental New Drug Application (sNDA) to expand the use of SOLOSEC® (secnidazole) to include the treatment of trichomoniasis in adults. Trichomoniasis *vaginalis* is the most common non-viral, curable sexually transmitted infection (STI) in the U.S., affecting an estimated three to five million people every year.[1] SOLOSEC® was approved in the U.S. in 2017 for the treatment of bacterial vaginosis (BV) in adult women. The supplemental approval makes SOLOSEC® the first and only single-dose oral prescription antimicrobial agent approved for the treatment of both trichomoniasis and BV.

"The FDA's approval for the additional indication for SOLOSEC® to treat trichomoniasis builds upon our commitment to support women's health and provides health care professionals with an option to treat patients with trichomoniasis and bacterial vaginosis (BV). Research demonstrates that approximately 70% of women with trichomoniasis are PCR positive for BV,[2]" said **Jon Stelzmiller, President – Specialty, Lupin Pharmaceuticals, Inc**. He also stated, "Additionally, having a treatment option for both trichomoniasis and BV that provides a complete course of therapy in a single dose will help address gaps in care related to adherence,[3] and therefore, may reduce risk factors associated with trichomoniasis or BV,[4,5] such as pelvic inflammatory disease (PID)[6,7,8] and other STIs.[9,10]"

The approval is based, in part, on trial results that demonstrated a clinically and statistically significant cure rate of 92.2% for patients with trichomoniasis treated with SOLOSEC® (n=64) as compared to placebo ($p<0.001$) (n=67) in the modified intent-to-treat population, patients who had trichomoniasis and no other STIs (94.9% in the Per-Protocol population) in the landmark Phase 3 clinical trial. SOLOSEC® was generally well-tolerated. No serious adverse events were observed in the trial, and the most commonly reported adverse events were vulvovaginal candidiasis (2.7%) and nausea (2.7%). The data were recently published in *Clinical Infectious Diseases* in March 2021 and presented at the 2020 Infectious Diseases Society for Obstetrics & Gynecology (IDSOG) Virtual Annual Meeting.

SOLOSEC® is now available for both treatment of patients and their partners.[11] The FDA approval of SOLOSEC® for the treatment of trichomoniasis in men was granted based on four open-label trials in males; one comparative study with metronidazole and ornidazole in males only and three single-arm studies in males and females.[11] Parasitological evaluation was performed both pre- and post-treatment and reported cure rates ranging from 91.7% (165/180) to 100% (30/30) at time points ranging from two to 20 days (n=437, 211 males and 226 females).[11]

"Trichomoniasis is a highly prevalent STI that can increase an individual's risk for contracting or spreading other STIs, including human immunodeficiency virus (HIV). For approximately 70% of patients, trichomoniasis infection is asymptomatic.[12,13,14] If left untreated, trichomoniasis can persist for months or years[14] and result in adverse reproductive health outcomes, including infertility and preterm birth,[3]" said **Steven Chavoustie, M.D., FACOG, CCRP, Obstetrician and Gynecologist, Segal Institute for Clinical Research**. He also stated, "For these reasons, screening and treatment for trichomoniasis is crucial and I am pleased that there is a new treatment option available to help meet the needs of this patient population."

Since trichomoniasis is a sexually transmitted disease, sexual partners should be treated with the same dose and at the same time, to prevent reinfection. Prescribers may consider presumptively treating partners by expedited partner therapy (EPT) where allowed by law.

About Trichomoniasis

Trichomoniasis is the most common non-viral, curable sexually transmitted infection (STI) in the U.S., and is caused by a protozoan parasite called Trichomonas Vaginalis (*T. vaginalis*).[12] An estimated three to five million people have the infection every year.[1]

Trichomoniasis is four-to-five times more prevalent in women compared to men.[15] However, 72% of male partners of women with trichomoniasis were also infected and 77% of those males were asymptomatic.[16] Therefore, it is important for partners to be treated at the same time so that the infection is not passed back and forth. Signs and symptoms in women can include itching, burning, redness or soreness of the genitals, discomfort with urination and vaginal discharge.[12]

According to the CDC, diagnostic testing for trichomoniasis should be performed in women seeking care for vaginal discharge.[14] Patients receiving care in high-prevalence settings (e.g., sexually transmitted disease clinics) and asymptomatic patients at high risk for infection (e.g., persons with multiple sex partners, history of sexually transmitted diseases/infections) may also be considered for screening.[14] At-risk women with trichomoniasis have an increased risk for PID and a 2.6 times increased risk for persistent endometritis.[8] Women who are pregnant with inadequately treated trichomoniasis are at an increased risk for pregnancy complications such as pre-term birth, premature rupture of membranes, or chorioamnionitis.[17,18,19]

Up to 53% of women with HIV infection also have *T. vaginalis*, which is associated with an increased risk of contracting PID.[14] Routine screening of asymptomatic women with HIV infection for *T. vaginalis* is recommended because of the adverse events associated with asymptomatic trichomoniasis and HIV infection.[14]

About Bacterial Vaginosis

Bacterial Vaginosis (BV) is an infection caused by an imbalance of bacteria naturally found in the vagina.[20] Symptoms of BV include an unpleasant or fishy odor, discharge (thin, milky grayish-white), or excessive discharge, and sometimes itching, burning sensation or irritation.[20,21] However, some women may have no symptoms.[21] BV is the most common vaginal infection for women, affecting more than 21 million women in the U.S. each year.[22]

BV provides a high pH, contributing to a favorable environment allowing *T. vaginalis*, the protozoan parasite that causes trichomoniasis, to grow.[12,23] In a longitudinal study of vaginal flora, women who presented for routine health visits and were diagnosed with BV were 1.5 to two times more likely to develop trichomonal, gonococcal and/or chlamydial infections.[23] Trichomoniasis and BV can increase risks for PID,[6,7,8] acquisition of STIs (gonorrhea, chlamydia, human papillomavirus (HPV) and herpes simplex virus (HSV)),[9,10] and acquisition or transmission of human immunodeficiency virus (HIV).[10]

SOLOSEC® is recommended by the American College of Obstetricians and Gynecologists (ACOG) and the CDC for the treatment of BV.[1,24]

About SOLOSEC®

SOLOSEC® (secnidazole) 2 g oral granules is the first and only single-dose oral prescription approved to treat both BV in adult women and trichomoniasis in adults.[11] SOLOSEC® is designed to be easy to take and one oral dose contains a complete course of treatment.[11,25] Additional information about SOLOSEC® can be found at www.SOLOSEC.com.

INDICATION

SOLOSEC® (secnidazole) 2 g oral granules is an antimicrobial agent indicated for the treatment of BV in adult women and trichomoniasis in adults. Since trichomoniasis is a sexually transmitted disease, treat sexual partners of infected patients with the same dose and at the same time to prevent reinfection.

DOSAGE AND ADMINISTRATION

SOLOSEC® is a single-dose therapy for oral use. The entire contents of SOLOSEC® packet should be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules. SOLOSEC® is not intended to be dissolved in any liquid. Avoid consumption of alcoholic beverages and preparations containing ethanol or propylene glycol during treatment with SOLOSEC® and for at least 2 days after completing therapy.

IMPORTANT SAFETY INFORMATION

- SOLOSEC® is contraindicated in patients with a history of hypersensitivity to secnidazole or other nitroimidazole derivatives.

- Vulvovaginal candidiasis may develop with SOLOSEC® and require treatment with an antifungal agent.

- Potential risk of carcinogenicity is unknown and has not been studied in patients. Carcinogenicity has been seen in rodents chronically treated with nitroimidazole derivatives, which are structurally related to secnidazole. Chronic use should be avoided.

- Breastfeeding is not recommended. Patients should discontinue breastfeeding for 96 hours after administration of SOLOSEC®.

- Most common adverse reactions observed in clinical trials (incidence ≥2%) were vulvovaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Lupin Pharmaceuticals, Inc. at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information.
Or
Please click here for full Prescribing Information.

SOLOSEC® is a registered trademark owned by Lupin Inc.

Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements that involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Many of these risks, uncertainties and other factors include failure of clinical trials, delays in development, registration and product approvals, changes in the competitive environment, increased government control over pricing, fluctuations in the capital and foreign exchange markets and the ability to maintain patent and other intellectual property protection. The information presented in this release represents management's expectations and intentions as of this date. Lupin expressly disavows any obligation to update the information presented in this release.

About Lupin

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women's health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions. The company invested 9.6% of its revenue on research and development in FY21.

Lupin has 15 manufacturing sites, 7 research centres, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

Please visit www.lupin.com for more information.
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Facebook: http://www.facebook.com/LupinWorld/

For further information or queries please contact –

Shweta Munjal
Head – Corporate Communications
Email: shwetamunjal@lupin.com

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