February 17, 2022

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

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

Dear Sir/Madam,

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

Enclosed is a Press Release as regards the U.S. FDA approval for the Company's supplemental New Drug Application to expand the use of SOLOSEC® (secnidazole) in the treatment of bacterial vaginosis for female patients 12 years of age and older and in the treatment of trichomoniasis for all patients 12 years of age and older.

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

Thanking you,

Yours faithfully,
For LUPIN LIMITED

LUPIN LIMITED INDIA MUMBAI

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) in Adolescents for both the Treatment of Bacterial Vaginosis in Females and Trichomoniasis

Mumbai, Baltimore, February 17, 2022: Lupin Pharmaceuticals Inc., (Lupin) today announced that the U.S. Food and Drug Administration has approved the company's supplemental New Drug Application (sNDA) to expand the use of SOLOSEC® (secnidazole) in the treatment of bacterial vaginosis (BV) for female patients 12 years of age and older and in the treatment of trichomoniasis for all patients 12 years of age and older. Bacterial vaginosis is a common vaginal infection and trichomoniasis is the most common non-viral, curable sexually transmitted infection in the U.S.[1-4] The supplemental adolescent approval enhances SOLOSEC's® strong position as the first and only single-dose oral prescription antimicrobial agent approved for the treatment of both trichomoniasis and BV.

"The FDA's approval expands the indication for SOLOSEC® to treat adolescents and builds upon our commitment to support women's health. This expansion brings to health care professionals a treatment option for both BV and Trichomoniasis in Adolescents which provides a complete course of therapy in a single dose, one which helps to address gaps in care related to adherence[5], and may reduce risk factors associated with BV and trichomoniasis[6-7], such as other sexually transmitted diseases (STIs)[8-9]," said **Tom Merriam, Executive Director - Specialty, Lupin.** "We are optimistic about this new treatment option for both healthcare practitioners and their adolescent patients."

About SOLOSEC®

SOLOSEC® (secnidazole) 2 g oral granules is the first and only single-dose oral prescription approved to treat both bacterial vaginosis (BV), a common vaginal infection, in female patients 12 years of age and older and trichomoniasis, a sexually transmitted infection, in patients 12 years of age and older.[1-4] SOLOSEC® is designed to be easy to take and one oral dose contains a complete course of treatment.[1]
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 bacterial vaginosis in female patients 12 years of age and older and trichomoniasis in patients 12 years of age and older. 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 and in patients with Cockayne syndrome
- 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, diarrhoea, abdominal pain, and vulvovaginal pruritus.
- In patients with Cockayne syndrome, after initiation of systemic use of metronidazole, another nitroimidazole agent, cases of severe irreversible hepatotoxicity/acute liver failure (including cases of fatal outcomes) have been reported.

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.
Manufactured for and Distributed by: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202
Marketed by: Exeltis USA, Inc., Florham Park, NJ 07932

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.

PP-SOL-0231, February 2022

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 –

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References:

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