



August 14, 2020

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 results from pivotal Phase 3 clinical trial to assess efficacy and safety of single-dose Solosec[®] (secnidazole) 2g oral granules in female patients with trichomoniasis, the most common non-viral, curable sexually transmitted infection in the U.S.

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

Yours faithfully,
For **LUPIN LIMITED**

R. V. SATAM
COMPANY SECRETARY
(ACS -1 1973)

Lupin Presents Phase 3 Data for Solosec[®] (secnidazole) Demonstrating Significant Response Rate in Female Patients with Trichomoniasis

- Results presented at the 2020 Infectious Diseases Society for Obstetrics & Gynecology (IDSOG) Virtual Annual Meeting
- Single-dose treatment with Solosec[®] resulted in a highly statistically significant response rate, or microbiological cure, in 92-95% of patients versus 1.5-1.7% in placebo
- Lupin plans to submit a supplemental New Drug Application for Solosec[®] to the FDA for the treatment of trichomoniasis later this year

Mumbai, Baltimore, August 14, 2020: Lupin Pharmaceuticals Inc. (Lupin) the U.S. based wholly owned subsidiary of Lupin Limited, today announced results from its pivotal Phase 3 clinical trial to assess efficacy and safety of single-dose Solosec[®] (secnidazole) 2g oral granules in female patients with trichomoniasis, the most common non-viral, curable sexually transmitted infection (STI) in the U.S. The trial results showed a clinically and statistically significant response rate, or microbiological cure, in patients treated with Solosec[®] as compared to placebo ($p < 0.001$). The data were presented at the 2020 Infectious Diseases Society for Obstetrics & Gynecology (IDSOG) Virtual Annual Meeting.

“The efficacy results of the Phase 3 study are quite encouraging and could support the utility of Solosec[®] in clinical practice as a treatment option for trichomoniasis once the new indication is approved,” said **Christina Muzny, M.D., MSPH, University of Alabama at Birmingham**, who presented the abstract at IDSOG. “Trichomoniasis increases risk of HIV infection, disproportionately affects African American women and can lead to adverse health outcomes. It is critical to screen women at high risk and treat with therapy that is convenient to use, to help improve patient compliance.”

Based on the data, Lupin will submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for Solosec[®] for the treatment of trichomoniasis later this year. Solosec[®] is only currently approved by the FDA to treat bacterial vaginosis (BV) in adult women.

The trial titled “A Phase 3, multi-center, prospective, randomized, placebo-controlled, delayed treatment, double-blind study to evaluate the effectiveness and safety of a single oral dose of 2 grams of secnidazole for the treatment of trichomoniasis in women,” met its primary endpoint of microbiological cure at the test-of-cure (TOC) visit on study Day 6-12. Microbiological cure was defined as a negative trichomonas vaginalis culture (i.e., InPouch[™] TV test negative for *T. vaginalis*) in the modified Intent-To-Treat (mITT) population (all randomized subjects who were culture positive for *T. vaginalis* and negative for gonorrhea and chlamydia at baseline). In the trial, 92.2% of patients in the Solosec[®] group (59/64) achieved the primary endpoint versus 1.5% (1/67) in the placebo group ($p < 0.001$). In the Per-Protocol population, the cure rate was 94.9% (56/59) for Solosec[®] versus 1.7%

(1/60) for placebo ($p < 0.001$). Solosec[®] was generally well-tolerated. The most commonly reported adverse events were vulvovaginal candidiasis (2.7%) and nausea (2.7%). No serious adverse events were observed in the trial.

“Trichomoniasis is the most common non-viral, STI that impacts an estimated 3-5 million people in the U.S.,” **Gregory Kaufman, M.D., Senior Vice President, Global Clinical and Medical Affairs, Specialty at Lupin said.** “We look forward to working with the FDA as we file for this new indication.”

About the Phase 3 Study

The Phase 3 multicenter, randomized, delayed treatment, placebo-controlled, double-blind study enrolled 147 adult female patients to evaluate the effectiveness and safety of a single oral dose of Solosec[®] (secnidazole) granules for the treatment of trichomoniasis. Subjects were diagnosed with trichomoniasis at the screening visit (Visit 1, baseline) that was confirmed by a positive culture for *T. vaginalis*. At Visit 1, subjects were randomly assigned in a 1:1 ratio to either Solosec or matching placebo. Subjects were evaluated for TOC at the second visit (Visit 2, Day 6 -12), at which (following sampling for the TOC culture), subjects also received active treatment if they had received placebo at baseline, and subjects received placebo if they had received active treatment at baseline. Subjects were then followed at subsequent visits for resolution of trichomoniasis as well as any need for additional therapy.

About Trichomoniasis

Trichomoniasis is the most common non-viral STI in the U.S., and is caused by a protozoan parasite called *Trichomonas Vaginalis*.¹ An estimated 3 to 5 million people have the infection,² with African American women having a nearly ten times higher risk of being affected compared with non-Hispanic white women.³ Trichomoniasis is four-to-five times more prevalent in women compared to men.³ Signs and symptoms in women can include itching, burning, redness or soreness of the genitals, discomfort with urination and vaginal discharge.¹ However, most infected persons (70%-85%) have minimal or no symptoms, and untreated infections might last for months to year.^{1,4,8} Trichomoniasis is associated with a two- to three-fold increased risk of HIV infection,^{5,6} as well as adverse reproductive health outcomes, including infertility and preterm birth.⁷ Up to 53% of women with HIV infection also have *T. vaginalis*, which is associated with a significantly increased risk of contracting pelvic inflammatory disease (PID).⁸ 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.⁸ Patients receiving care in high-prevalence settings (e.g. STD clinics) and asymptomatic patients at high risk for infection (e.g., persons with multiple sex partners, history of STDs) may also be considered for screening.⁸

About Solosec[®]

Solosec[®] (secnidazole) 2g oral granules is the first and only single-dose oral prescription treatment option to treat bacterial vaginosis (BV), a common vaginal infection, in adult women.⁹ Solosec[®] is easy to take and one oral dose

contains a full course of treatment.^{9,10} Women who are prescribed Solosec[®] sprinkle the entire packet of granules onto applesauce, yogurt, or pudding and eat the entire mixture without chewing the granules within 30 minutes. One dose delivers a complete treatment and Solosec[®] can be taken at any time of the day, without regard to the timing of meals.⁹ There is no need to avoid any foods or drinks, including alcohol, with Solosec[®]. Laboratory studies show Solosec[®] does not inhibit the enzyme that processes alcohol in the body.⁹ Because Solosec[®] is taken in one oral dose, it may be preferred by women who wish to avoid a multi-day treatment regimen.¹¹

INDICATION

Solosec[®] (secnidazole) 2 g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of BV in adult women.

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.

IMPORTANT SAFETY INFORMATION

- Solosec[®] is contraindicated in patients with a history of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives.
- Vulvo-vaginal candidiasis may develop with Solosec[®] and require treatment with an antifungal agent.
- Potential risk of carcinogenicity is unknown and has not been studied. 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 \geq 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.](#)



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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 and in India by global revenues. The Company invests 9.6 % of its revenues on research and development.

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

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¹ Centers for Disease Control and Prevention. Trichomoniasis - CDC Fact Sheet. Available at: <https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm>. Accessed July 16, 2020.

² American College of Obstetricians and Gynecologists. Vaginitis in Nonpregnant Patients. ACOG Practice Bulletin No. 215. *Obstet Gynecol* 2020;135(1):e1-17.

³ Flagg EW, Meites E, Phillips C, Papp J, Torrone EA. Prevalence of *Trichomonas vaginalis* Among Civilian, Noninstitutionalized Male and Female Population Aged 14 to 59 Years: United States, 2013 to 2016. *Sex Transm Dis*. 2019;46(10):e93–e96. doi:10.1097/OLQ.0000000000001013.

⁴ Daugherty M. Prevalence of *Trichomonas vaginalis* Infection Among US Males, 2013-2016. *Clinical Infectious Diseases*. 2019 Feb.; 68(3): 460–46.

⁵ McClelland, RS. Infection with *Trichomonas vaginalis* increases the risk of HIV-1 acquisition. *Journal of Infectious Diseases*. 2007 Mar 1;195(5):698-702.

⁶ Van Der Pol, B. *Trichomonas vaginalis* infection and human immunodeficiency virus acquisition in African women. *Journal of Infectious Diseases*. 2008 Feb;197(4):548-54.

⁷ Sobel JD, Mitchell C. Trichomoniasis. UpToDate. Available at: <https://www.uptodate.com/contents/trichomoniasis>. Accessed July 14, 2020.

⁸ Centers for Disease Control and Infection. 2015 Sexually Transmitted Diseases Treatment Guidelines. Trichomoniasis. Available at: <https://www.cdc.gov/std/tg2015/trichomoniasis.htm>. Accessed July 14, 2020.

⁹ SOLOSEC [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; 2017.

¹⁰ Data on File, Physician Research. Advantage Healthcare, Inc. Prepared December 23, 2014

¹¹ Broumas AG, Basara LA. Potential patient preference for 3-day treatment of bacterial vaginosis: responses to new suppository form of clindamycin. *Adv Ther*. 2000;17(3):159-166.