Press Release

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Lupin launches Solosec™ (secnidazole) 2g Oral Granules in the US

First and only single-dose oral therapy for bacterial vaginosis – the most common vaginal infection – approved by the U.S. FDA in 2017

Mumbai, Baltimore, May 31, 2018: Pharma major Lupin announced the launch of Solosec™ (secnidazole) 2g oral granules in the US market, having received an approval from the United States Food and Drug Administration (FDA) earlier.

Last year, Lupin announced that its US subsidiary, Lupin, Inc., acquired Symbiomix Therapeutics, LLC., a privately held company focused on bringing innovative therapies to market for gynecologic infections that can have serious health consequences.

Lupin's Solosec™ (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis (BV) in adult women. Solosec™, the first new oral antibiotic to treat BV in more than a decade, is designed to deliver a full course of therapy in a single 2g oral dose and is the first and only single-dose oral therapy for BV, the most common vaginal infection in the U.S. among women of childbearing age.

New, single oral-dose Solosec™ was designed to be a simpler solution for patients with BV. BV affects 21 million women aged 14 to 49 annually. Many women have expressed frustration and dissatisfaction with current treatments, which require that they choose between multiple days of pills or messy creams, abstain from drinking alcohol, and use a backup form of birth control – all of which make completing treatment a challenge. In fact, numerous studies have revealed that the longer and more complex a drug regimen is, the more it may lead to poor adherence and treatment failure. It only takes one packet of Solosec™ to complete treatment and the single dose stays in the body and continues to treat BV for four days without an alcohol restriction: in vitro drug alcohol studies show Solosec™ does not inhibit the enzyme that metabolizes alcohol.

"With more than four million women treated for BV in the U.S. annually, and only 50% completing 5 to 7 day treatments, there is a clear need for an effective, single-dose oral treatment," said **Vinita Gupta, Chief Executive Officer, Lupin Limited.** "We are proud that Lupin has been at the forefront of advancing safe and affordable healthcare for women globally for decades, and we are committed to helping prevent and manage women's health conditions with serious consequences, including BV."

The FDA approval of Solosec™ was supported by a comprehensive set of studies, including two pivotal trials in BV and an open label safety study, which found efficacy for single-dose secnidazole 2g. Across both studies, Solosec™ was generally well tolerated with a low incidence of side effects. The FDA designated Solosec™ as a Qualified Infectious Disease Product (QIDP) for the treatment of BV and granted it Fast Track designation, which made Solosec™ eligible for at least 10 years of U.S. market exclusivity.

About Solosec™

Solosec™ (secnidazole) 2g oral granules is a potent, next-generation, 5-nitroimidazole antibiotic with enhanced pharmacokinetic properties that enable delivery in a single dose for bacterial vaginosis (BV), the most common

gynecologic infection. Solosec™ is the first and only single-dose oral therapy approved by the U.S. Food and Drug Administration (FDA) for BV in adult women. Solosec™ has been shown to be efficacious and well tolerated in clinical trials for the treatment of BV. Additional information on Solosec™ and BV can be found at www.Solosec.com, along with a step-by-step video on how to complete the treatment.

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 12th and 8th largest generics pharmaceutical company by market capitalization (March 31st, 2018, Bloomberg) and revenues (December 30th 2017, Bloomberg LTM) respectively. The Company is the 4th largest pharmaceutical player in the US by prescriptions (IQVIA MAT March 2018); 3rd largest Indian pharmaceutical company by global revenues (December 30th 2017, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT March 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits were at Rs. 155,598 million (USD 2.41 billion) and Rs. 2,513 million (USD 39 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

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