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Lupin gets US FDA nod for SOLOSEC to treat trichomoniasis

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SOLOSEC is the first and only single-dose oral prescription antimicrobial agent

Lupin Pharmaceuticals, the US-based wholly-owned subsidiary of global pharma major Lupin, announced that the US 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 US, affecting an estimated three to five million people every year. SOLOSEC was approved in the US 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 per cent of women with trichomoniasis are PCR positive for BV," said Jon Stelzmiller, President – Specialty, Lupin Pharmaceuticals.

SOLOSEC is now available for both treatments of patients and their partners. 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 per cent (165/180) to 100 per cent (30/30) at time points ranging from two to 20 days (n=437, 211 males and 226 females).