Solosec® (secnidazole) – Expanded indication

- On January 26, 2022, the FDA approved Lupin Pharmaceuticals' Solosec (secnidazole), for the treatment of:

    — Bacterial vaginosis in female patients 12 years of age and older
    — Trichomoniasis caused by *Trichomonas vaginalis* in patients 12 years of age and older. Because trichomoniasis is a sexually transmitted disease with potentially serious sequelae, partners of infected patients should be treated simultaneously in order to prevent reinfection.

- Solosec was previously approved for these indications in adult patients only.

- The approval of Solosec for the expanded indication for bacterial vaginosis was supported by evidence from an open-label safety study in 40 pediatric female patients with bacterial vaginosis and evidence from adequate and well-controlled studies in adult women.

- The approval of Solosec for the expanded indication for trichomoniasis was based on the extrapolation of clinical trial data from adult women with trichomoniasis, four open-label studies in males with trichomoniasis, and an open-label safety study in pediatric female patients with bacterial vaginosis.

- The recommended dosage of Solosec for the treatment of bacterial vaginosis in female patients 12 years of age and older is a single 2-gram packet of granules taken once orally, without regard to the timing of meals.

- The recommended dosage of Solosec for the treatment of trichomoniasis in patients 12 years of age and older is a single 2-gram packet of granules taken once orally, without regard to the timing of meals. Since trichomoniasis is a sexually transmitted disease, sexual partners should be treated with the same dose and at the same time.