FDA Approves Symbiomix Therapeutics' Solosec™ (secnidazole) Oral Granules for the Treatment of Bacterial Vaginosis in Adult Women

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First and Only Single Dose Oral Therapy Approved for Most Common U.S. Gynecologic Infection That Can Have Serious Health Risks if Inadequately Treated

Newark, NJ, September 18, 2017 – Symbiomix Therapeutics today announced the U.S. Food and Drug Administration (FDA) has approved Solosec™ (secnidazole) 2g oral granules for the treatment of bacterial vaginosis (BV) in adult women. Solosec™ is a potent, next-generation, 5-nitroimidazole antibiotic with enhanced pharmacokinetic properties that enable delivery in a single dose that's been shown to be efficacious and well tolerated. Solosec™ is the first and only single-dose oral therapy for BV, the most common gynecologic infection in the U.S. [1,2]

"The FDA's approval of this first-of-its-kind treatment is an important milestone for Symbiomix and most importantly, millions of women suffering from BV," said David L. Stern, CEO of Symbiomix. "The approval of Solosec™ represents a critical moment in our efforts to bring innovative medicines to the women's health market. Solosec™ is the first new oral antibiotic to treat BV in more than a decade and will provide women with a new treatment option. We look forward to making this treatment available to patients in the first quarter of 2018."

BV is the most prevalent gynecologic infection in the U.S., affecting 21 million women ages 14 to 49 annually. [2] The most commonly prescribed oral BV treatment regimen requires

twice-a-day dosing for seven days. Adherence with the current leading therapy for the treatment of BV has been shown to be only approximately 50 percent. [3] If left untreated, BV can increase the risk of contracting sexually transmitted diseases, including chlamydia, gonorrhea, herpes, trichomaniasis and HIV, and can also increase the risk of pre-term birth and low birth weight. [4]

“The approval of Solosec™ finally gives women the option of a single, well-tolerated, oral dose treatment for BV, a common infection which can have many health consequences,” said Paul Nyirjesy, MD, Professor of Obstetrics & Gynecology at Drexel University College of Medicine in Philadelphia, PA and an investigator in the Solosec™ clinical trials. “A single dose regimen may improve adherence and the likelihood of a successful cure.”

More than 50 percent of women treated for BV have a recurrence within 12 months, significantly impacting work productivity and quality of life. [3] In recent studies, 60 percent of recurrent sufferers reported a negative impact on work attendance, job performance and productivity, and 95 percent reported a severe restriction in intimate partner relations. [5]

“One in three women have been affected by BV, impacting their quality of life and potential for serious health risks,” said Beth Battaglino, RN, President & CEO of HealthyWomen, the leading independent, nonprofit health information source for women. “We are excited that for the first time ever, both frequent and infrequent BV adult women sufferers will now have a single-dose treatment option.”

The FDA approval 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. All treatment-emergent adverse events were mild or moderate in intensity; no serious adverse events were reported, and no patients discontinued treatment due to adverse events. [6,7]

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 priority review and at least 10 years of U.S. market exclusivity.

Indication
SOLOSECTM (secnidazole) 2g oral granules is a 5-nitroimidazole antimicrobial agent indicated for the treatment of bacterial vaginosis in adult women.

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 in patients taking single-dose of SOLOSEC to treat bacterial vaginosis is unclear. Chronic use should be avoided.

• SOLOSEC may pass into breast milk. Patients should discontinue breastfeeding for 96 hours after administration of SOLOSEC.

• 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.

• In clinical studies, the most common adverse events occurring in (≥2%) of patients receiving SOLOSEC 2g oral granules were vulvovaginal candidiasis (9.6%), headache (3.6%), nausea (3.6%), dysgeusia (3.4%), vomiting (2.5%), diarrhea (2.5%), abdominal pain (2.0%), and vulvovaginal pruritus (2.0%).

To report SUSPECTED ADVERSE REACTIONS, contact Symbiomix Therapeutics at 1-844-SOLOSEC (1-844-765-6732) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please click **here** for full Prescribing Information.

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. [1,2]

About Symbiomix Therapeutics, LLC
Symbiomix (sim-bye-OH-mix) Therapeutics is a biopharmaceutical company focused exclusively on bringing innovative therapies to market for prevalent gynecologic infections that can have serious health consequences. The Company received FDA approval for Solosec™ (secnidazole) 2g oral granules, the first and only single-dose therapy for the treatment of bacterial vaginosis (BV) in adult women.

Symbiomix was founded in 2012 by a team of experienced industry professionals and entrepreneurs and is backed by three of the world's leading healthcare venture capital firms: OrbiMed, F-Prime Capital Partners, and HBM Partners. Symbiomix is based in New Jersey, with additional offices in Maryland and Connecticut. Please visit https://symbiomix.com/ and follow the Company on LinkedIn and Twitter for more information.

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News & Events

FDA Approves Symbiomix Therapeutics’ Solosec™ (secnidazole) Oral Granules for the Treatment of Bacterial Vaginosis in Adult Women

Symbiomix Therapeutics Announces Publication of Pivotal Phase 3 Data for Investigational Solosec™ for the Treatment of Bacterial Vaginosis

Symbiomix Therapeutics Presents New Data on Solosec™

Symbiomix Therapeutics Announces Publication of Pivotal Data for Investigational Solosec™ for the Treatment of Bacterial Vaginosis

Symbiomix Therapeutics Announces FDA’s Acceptance of New Drug Application for Solosec™ with Priority Review Status

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