



Mycovia Pharmaceuticals to Host Product Theater for VIVJOA™ (oteseconazole) during 2022 American College of Obstetricians and Gynecologists Annual Meeting

- *VIVJOA™ is the first and only FDA-approved medication for recurrent vulvovaginal candidiasis (chronic yeast infection)*

Durham, N.C. – May 5, 2022 – [Mycovia Pharmaceuticals, Inc.](#) (Mycovia), an emerging biopharmaceutical company, will sponsor a product theater showcase for its recently FDA-approved VIVJOA™ (oteseconazole capsules), during the 2022 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting. VIVJOA™ is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

On Friday, May 6 at 11:45 a.m. PDT, Mycovia will sponsor a product theater titled *“Introducing the first and only medication approved by FDA to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC).”* The session will be hosted by Dr. Jack Sobel, distinguished professor of medicine and the Dean of the Wayne State University School of Medicine. The session will be held at Salon 1 AB and open to all meeting attendees.

RVVC, also known as chronic yeast infection, is defined by the Centers for Disease Control and Prevention as three or more symptomatic acute episodes of yeast infection in 12 months. RVVC is a distinct condition from vulvovaginal candidiasis, and until recently, there have been no FDA-approved medications specifically indicated for it. Nearly 75% of all adult women will have at least one yeast infection in their lifetime, with approximately half experiencing a recurrence. Of those women, up to 9% develop RVVC.

About VIVJOA™

VIVJOA™ (oteseconazole) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. VIVJOA is the first and only FDA-approved medication that provides sustained efficacy demonstrated by significant long-term reduction of RVVC recurrence through 50 weeks versus comparators. Oteseconazole is designed to inhibit fungal CYP51, which is required for fungal cell wall integrity, and this selective interaction is also toxic to fungi, resulting in the inhibition of fungal growth. Due to its chemical structure, oteseconazole has a lower affinity for human CYP enzymes as compared to fungal CYP enzymes. The FDA approved VIVJOA based upon the positive results from three Phase 3 clinical trials of oteseconazole – two global, pivotal VIOLET studies and one U.S.-focused ultraVIOLET study, including 875 patients at 232 sites across 11 countries.

Please click [here](#) for full Prescribing Information.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VIVJOA is contraindicated in females of reproductive potential. Females who are NOT of reproductive potential are defined as: persons who are biological females who are postmenopausal or have another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy).

VIVJOA is contraindicated in pregnant and lactating women.

VIVJOA is contraindicated in patients with known hypersensitivity to oteseconazole.

WARNINGS AND PRECAUTIONS

Based on animal studies, VIVJOA may cause fetal harm. The drug exposure window of approximately 690 days (based on 5 times the half-life of oteseconazole) precludes adequate mitigation of the embryo-fetal toxicity risks. Advise patients that VIVJOA is contraindicated in females of reproductive potential, and in pregnant and lactating women because of potential risks to a fetus or breastfed infant.

ADVERSE REACTIONS

The most frequently reported adverse reactions among VIVJOA-treated patients in clinical studies included headache (7.4%) and nausea (3.6%).

DRUG INTERACTIONS

VIVJOA is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VIVJOA with BCRP substrates (e.g., rosuvastatin) may increase the exposure of BCRP substrates, which may increase the risk of adverse reactions associated with these drugs.

Please see full [Prescribing Information](#) and [Patient Information](#).

To report SUSPECTED ADVERSE REACTIONS, contact Mycovia Pharmaceuticals, Inc. at 1-855-299-0637 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Mycovia Pharmaceuticals

Mycovia Pharmaceuticals is an emerging biopharmaceutical company dedicated to recognizing and empowering those living with unmet medical needs by developing novel therapies. VIVJOA™ (oteseconazole), the first FDA-approved product for Mycovia, is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. Oteseconazole received FDA Qualified Infectious Disease Product and Fast-Track designations to become the first FDA-approved therapy for RVVC. In 2019, Mycovia licensed oteseconazole to Jiangsu Hengrui Pharmaceuticals Co., Ltd., to develop and commercialize oteseconazole in China, including mainland China, Hong Kong, Macau and Taiwan, and Gedeon Richter Plc., a Hungary-based pharmaceutical company, to commercialize and manufacture oteseconazole in Europe, Russia, the Commonwealth of Independent States, Latin America and Australia. Mycovia also recognizes a tremendous potential for its oral fungal inhibitors and a growing need to treat a range of multi-drug resistant fungal pathogens. For more information, please visit www.mycovia.com.

About NovaQuest Capital Management

NovaQuest Capital Management, located in North Carolina's Research Triangle, is a life science investment firm with a specialization in biopharmaceuticals. Founded in 2010, and with more than \$2.5 billion raised across four funds, NovaQuest provides tailored capital solutions that fund innovation in biopharmaceutical development and invests in compelling healthcare companies with products and technologies aimed at helping humans and animals live healthier, longer, more productive lives. Learn more at www.novaquest.com.

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