Mycovia Pharmaceuticals is seeking a Director, Medical Information. This position will report to the Vice President, Medical Affairs and will be responsible for managing of all medical communication responses to unsolicited requests for product information and ensuring compliant and efficient processes to provide appropriate medical and drug information to patients, consumers, and healthcare professionals in a timely manner. Supports executing operational requirements for the provision of Medical Information services including updating and writing new SOPs, case detail review, custom and standard response development, and all call center reporting activities.

## Position Summary: DIRECTOR, MEDICAL INFORMATION

### Essential Duties and Responsibilities of the Position:

- Collaborate with Pharmacovigilance, Medical Director or similar, Quality Assurance and other internal stakeholders in processing adverse events, product complaints, and other triaged requests per policies and procedures
- Provide primary support for escalated questions from contact center staff; writing and editorial services for replies to out-of-scope questions; standard response (reply) document repository maintenance, and replies to internal requests for information
- Act as the principal contact for call center related activities for Mycovia internal stakeholders and collaborate with internal/external stakeholders to ensure the Medical Information call center is functioning optimally
- Write and/or review standard responses and frequently asked questions
- Write and/or review replies to out-of-scope questions escalated from call center staff
- Reply to internal requests for information
- Educate staff to ensure an appropriate level of understanding of Medical Information Request submission processes, and standard response practices providing Medical Information services
- Staff medical information/medical affairs booth in accordance with Mycovia policies
- Review all call center case detail responses to ensure accuracy, compliance, and detection of adverse events or product complaints
- Create and/or update product, disease state, and other necessary training materials for call center training
- Assist in the development/enhancement and implementation of policies, procedures, and processes for call center related activities
- Uphold company values and participate and contribute to the company's culture of compliance
- Understand and abide by policies, procedures, guidelines, and business practices developed and implemented for efficient and compliant operations
- Travel requirements: Approximately 10%

### Qualifications:

- PharmD, MD, PhD, nurse, or pharmacist in health science related field
- 5-10 years of relevant experience in the pharmaceutical industry or a comparable setting
- Experience in clinical therapeutics with understanding of medical information processes and call center function

- Experience in drug development and various R&D disciplines involved in overall drug lifecycle
- Familiarity with medical communication and writing practices
- Familiarity with pharmaceutical industry regulations, including FDA regulations, GCP, and ICH guidelines as they relate to Medical Affairs
- Understanding of industry best practices as well as applicable laws, regulations, and guidelines
- Superior organizational abilities and excellent attention to detail
- Strong literature evaluation skills
- Ability to be flexible and adapt to change in a fast paced, small company environment
- Ability to prioritize and handle multiple tasks and work across functions
- Strong written and verbal communication skills
- Knowledge and experience in medical information in infectious diseases or women's health is desirable

**About Recurrent Vulvovaginal Candidiasis**

RVVC is a debilitating, chronic infectious condition that affects 138 million women worldwide each year. RVVC, also known as chronic yeast infection, is a distinct condition from vulvovaginal candidiasis (VVC) and defined as 3 or more symptomatic acute episodes of yeast infection in 12 months. Primary symptoms include vaginal itching, burning, irritation and inflammation. Some women may experience abnormal vaginal discharge and painful sexual intercourse or urination, causing variable but often severe discomfort and pain.

**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 – 2 global, pivotal VIOLET studies and one US-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.