## Vivjoa™ (oteseconazole) – New drug approval

- On April 28, 2022, Mycovia Pharmaceuticals announced the FDA approval of Vivjoa (oteseconazole) to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

- RVVC is a chronic yeast infection that affects 138 million women worldwide each year. Women with RVVC have three or more symptomatic acute episodes of yeast infection in a year, with primary symptoms including vaginal itching, burning, irritation, and inflammation.

- Vivjoa is an azole antifungal that targets CYP51, which affects fungal cell membrane formation and integrity to ultimately inhibit fungal growth.

- The efficacy of Vivjoa was established in two double-blind, randomized, placebo-controlled studies (Trial 1 and Trial 2) in 656 adults and post-menarchal pediatric females with RVVC (≥ 3 episodes of vulvovaginal candidiasis). Both studies consisted of an open-label induction phase with fluconazole and then an 11-week maintenance phase in which patients were either randomized to Vivjoa or placebo. The primary endpoint was the proportion of patients with ≥ 1 culture-verified acute vulvovaginal candidiasis (VVC) episode during the maintenance phase through week 48.

    - In Trial 1, 6.7% of Vivjoa patients had ≥ 1 culture-verified acute VVC episode vs. 42.8% of those who received placebo (treatment difference p-value < 0.001).
    - In Trial 2, 3.9% of Vivjoa patients had ≥ 1 culture-verified acute VVC episode vs. 39.4% of those who received placebo (treatment difference p-value <0.001).

- Additionally, Vivjoa was also actively compared to fluconazole in another double-blind, randomized study in 219 adults and post-menarchal pediatric females with RVVC (Trial 3). Trial 3 consisted of an induction phase in which patients received either Vivjoa or fluconazole, and then received Vivjoa or placebo for 11 weeks. The primary endpoint was the proportion of patients with ≥ 1 culture-verified acute VVC episode during the maintenance phase through week 50 or who failed clearing their infection during the induction phase.

    - In Trial 3, 10.3% of Vivjoa patients had ≥ 1 culture-verified acute VVC episode or unresolved VVC episode during induction phase vs. 42.9% of patients who received fluconazole/placebo (treatment difference p-value < 0.001).

- Vivjoa is contraindicated in females of reproductive potential, pregnant and lactating women, and patients with known hypersensitivity to oteseconazole.

- A warning and precaution for Vivjoa is embryo-fetal toxicity.

- The most common adverse reactions (> 2%) with Vivjoa use were headache and nausea.

- The recommended Vivjoa dosage regimens include a Vivjoa-only regimen and a fluconazole/Vivjoa regimen. Vivjoa and fluconazole are administered orally.

    - *Vivjoa-only dosage regimen*: Vivjoa 600 mg (single dose) on day 1; Vivjoa 450 mg (single dose) on day 2; then beginning on day 14, Vivjoa 150 mg weekly for 11 weeks (weeks 2 through 12).

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    - — *Fluconazole/Vivjoa dosage regimen*: Fluconazole 150 mg on days 1, 4, 7; then Vivjoa 150 mg once daily for 7 days on days 14 through 20; then beginning on day 28, Vivjoa 150 mg weekly for 11 weeks (weeks 4 through 14).

- Mycovia Pharmaceuticals plans to launch Vivjoa in the second quarter of 2022. Vivjoa will be available as a 150 mg capsule.