Brexafemme® (ibrexafungerp) – New indication

- On December 1, 2022, Scynexis announced the FDA approval of Brexafemme (ibrexafungerp), in adult and post-menarchal pediatric females, for reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC).

- Brexafemme is also approved in adult and post-menarchal pediatric females for treatment of vulvovaginal candidiasis (VVC).

- The approval of Brexafemme for the new indication was based on a randomized placebo-controlled study in 260 females presenting with a symptomatic VVC episode and a history of recurrent VVC. The symptomatic episode at screening was treated with 3 doses of fluconazole 150 mg 3 days apart. Patients were then randomized to receive Brexafemme or placebo administered as a single-day treatment repeated every 4 weeks for a total of 6 single-day treatments. Efficacy was assessed as the percentage of patients with clinical success, defined as patients with no culture proven, presumed or suspected recurrence of VVC requiring antifungal therapy up to test of cure at week 24.

    - Clinical success at test of cure at week 24 was 65.4% with Brexafemme and 53.1% with placebo (treatment difference 12.7, 95% CI: 2.2, 23.1; p = 0.020).
    - The clinical success rate was lower for patients in the U.S. when compared to patients outside the U.S. for both Brexafemme and placebo groups.

- Brexafemme carries a boxed warning for risk of embryo-fetal toxicity.

- The most common adverse reactions (≥ 2%) with Brexafemme use for reduction in the incidence of RVVC were headache, abdominal pain, diarrhea, nausea, urinary tract infection and fatigue.

- The recommended dosage of Brexafemme to prevent recurrences of VVC is 300 mg (two 150 mg tablets) administered approximately 12 hours apart (eg, in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets) monthly for six months.

    - Refer to the Brexafemme drug label for dosing for treatment of VVC.