Brexafemme® (ibrexafungerp) – New drug approval

- On June 2, 2021, SCYNEXIS announced the FDA approval of Brexafemme (ibrexafungerp), for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

- VVC, commonly known as a vaginal yeast infection due to *Candida*, is the second most common cause of vaginitis. An estimated 70 to 75% of women worldwide will have at least one episode of VVC in their lifetime, and 40 to 50% of them will experience multiple episodes.

- Brexafemme is a novel triterpenoid antifungal drug.

- The efficacy of Brexafemme was established in two randomized, placebo-controlled studies with a similar design in non-pregnant post-menarchal females with VVC. Study 1 included 290 patients and study 2 included 278 patients. Efficacy was assessed by clinical outcome at the test of cure (TOC) visit. A complete clinical response was defined as the complete resolution of signs and symptoms.

    - In study 1, complete clinical response at TOC was achieved in 50.0% of patients treated with Brexafemme vs. 28.0% of patients treated with placebo (difference of 22.0, 95% CI: 10.2, 32.8; p = 0.001).
    - In study 2, complete clinical response at TOC was achieved in 63.5% of patients treated with Brexafemme and 44.9% of patients treated with placebo (difference of 18.6, 95% CI: 6.0, 30.6; p = 0.009).

- Brexafemme is contraindicated in pregnancy and in patients with hypersensitivity to ibrexafungerp.

- A warnings and precaution for Brexafemme is risk of fetal toxicity.

- The most common adverse reactions (≥ 2%) with Brexafemme use were diarrhea, nausea, abdominal pain, dizziness, and vomiting.

- The recommended dose of Brexafemme 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).

- SCYNEXIS plans to launch Brexafemme in the second half of 2021. Brexafemme will be available as a 150 mg tablet.