Osphena® (ospemifene) – New indication

- On January 29, 2019, Duchesnay announced the FDA approval of Osphena (ospemifene), for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy (VVA), due to menopause.
    - Osphena is also approved for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause.
- Vaginal dryness is one of the two most common and most bothersome symptoms (MBS) of VVA due to menopause.
- The new indication for Osphena was based on three studies that evaluated vaginal dryness. Patients were treated with Osphena or placebo for 12 weeks.
    - In study 2, a statistically significant improvement in the moderate to severe MBS of vaginal dryness was not demonstrated.
    - In study 1, the least squares mean change from baseline in the moderate to severe MBS of vaginal dryness was -1.3 for the Osphena group (N = 113) vs. -0.9 for the placebo group (N = 104); p = 0.0136.
    - In study 3, the mean change from baseline in the moderate to severe MBS of vaginal dryness was -1.3 for the Osphena group (N = 269) vs. -0.9 for the placebo group (N = 263); p < 0.0001.
- Osphena carries a boxed warning for endometrial cancer and cardiovascular disorders.
- The recommended dosage of Osphena for either indication is one 60 mg tablet with food once daily.
    - Use of Osphena should be for the shortest duration consistent with treatment goals and risks for the individual woman.
    - Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary.