Intrarosa™ (prasterone) – New Drug Approval

- On November 17, 2016, the FDA announced the approval of Endoceutics' Intrarosa (prasterone), for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA), due to menopause.

- Approximately 50% of postmenopausal women suffer from VVA. The symptoms of VVA are vaginal dryness, pain during sexual activity (dyspareunia) and irritation and itching.

- Intrarosa contains the active ingredient, prasterone that is also known as dehydroepiandrosterone (DHEA). Prasterone is an inactive endogenous steroid and is converted into active androgens and/or estrogens.

    - Although DHEA is included in some dietary supplements, the efficacy and safety of those products have not been established for diagnosing, curing, mitigating, treating or preventing any disease.

- The efficacy of Intrarosa was evaluated in two 12-week placebo-controlled trials enrolling 813 postmenopausal women with moderate to severe dyspareunia. The four co-primary efficacy endpoints were severity of dyspareunia, the % of vaginal superficial cells, the % of parabasal cells, and vaginal pH.

    - The mean change in severity of dyspareunia was -0.87 vs. -1.27 ($p = 0.0132$) in trial 1 and -1.06 vs. -1.42 ($p = 0.0002$) in trial 2 for placebo vs. Intrarosa, respectively.
    - The mean change in % superficial cells was 0.91% vs. 5.62% ($p < 0.0001$) in trial 1 and 1.75% vs. 10.2% ($p < 0.0001$) in trial 2 for placebo vs. Intrarosa, respectively.
    - The mean change in % parabasal cells was -1.62% vs. -47.4% ($p < 0.0001$) in trial 1 and -11.98% and -41.51% ($p < 0.0001$) in trial 2 for placebo vs. Intrarosa, respectively.
    - The mean change in vaginal pH was -0.21 vs. -1.04 ($p < 0.0001$) in trial 1 and -0.27 vs. -0.94 ($p < 0.0001$) in trial 2 for placebo vs. Intrarosa, respectively.

- Intrarosa is contraindicated in patients with undiagnosed abnormal genital bleeding.

- Other warnings and precautions of Intrarosa include current or past history of breast cancer.

- The most common adverse events (≥ 2%) with Intrarosa use were vaginal discharge and abnormal Pap smear.

- The recommended dose of Intrarosa is one vaginal insert once daily at bedtime.

- Endoceutics' launch plans for Intrarosa are pending. Intrarosa will be available as 6.5 mg vaginal inserts.