Milprosa™ (progesterone) – New drug approval

- On April 29, 2020, the FDA approved Ferring Pharmaceuticals' Milprosa (progesterone), to support embryo implantation and early pregnancy (up to 10 weeks post-embryo transfer) by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women up to and including 34 years of age.

    - Efficacy in women 35 years of age and older has not been established.

- The efficacy of Milprosa was established in a randomized, assessor-blind, active concurrently-controlled study in 1,297 infertile women. Patients in the treatment arm received 10 weeks of Milprosa for support of implantation and early pregnancy in an ART treatment program. Efficacy was assessed by the co-primary endpoints of clinically recognized pregnancy rate, defined as the presence of at least one fetal heartbeat seen on ultrasound at 6 weeks and at 10 weeks post-embryo transfer.

    - The pregnancy rates at week 6 and week 10 post-embryo transfer for women treated with Milprosa were non-inferior to those for women treated with the active comparator.
    - The clinical pregnancy rate was 48.0% with Milprosa at 6 weeks post-embryo transfer (percentage difference vs. active comparator: 0.8; 95% CI: -4.6, 6.3).
    - The clinical pregnancy rate was 46.4% with Milprosa at 10 weeks post-embryo transfer (percentage difference vs. active comparator: 1.3; 95% CI: -4.1, 6.7).

- Milprosa is contraindicated in patients with:

    - Known sensitivity to progesterone or any of the ingredients of Milprosa
    - Undiagnosed vaginal bleeding
    - Severe hepatic impairment or disease
    - Known or suspected malignancy of the breast
    - Active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these events

- Warnings and precautions for Milprosa include cardiovascular or cerebrovascular disorders, depression, toxic shock syndrome, and use of other vaginal products.

- The most common adverse reactions (≥ 2%) with Milprosa use were headache, vaginal discharge, nausea, breast tenderness, post procedural discomfort, abdominal distension, abdominal pain, pelvic pain, and constipation.

- The recommended dosage and administration for Milprosa is insertion of one vaginal system starting on the day after oocyte retrieval. The system should be left in place continuously (for a minimum of 23 hours per day) for 7 days, and then removed and a new Milprosa system should be inserted. Milprosa should be replaced weekly for up to 10 weeks

    - Milprosa is not recommended for use with other vaginal products (such as antifungal products, vaginal lubricants, diaphragms, and condoms) because this concomitant use has not been studied and may alter the progesterone release and absorption from the vaginal system.

Continued . . .

- Ferring Pharmaceuticals' launch plans for Milprosa are pending. Milprosa will be available as a 1.78 grams non-biodegradable silicone ring (toroidal-shape).