Nextstellis® (drospirenone/estetrol) – New drug approval

- On April 16, 2021, Mayne Pharma and Mithra Pharmaceuticals announced the FDA approval of Nextstellis (drospirenone/estetrol), for use by females of reproductive potential to prevent pregnancy.
    - Nextstellis may be less effective in females with a body mass index (BMI) ≥ 30 kg/m^2. In females with BMI ≥ 30 kg/m^2, decreasing effectiveness may be associated with increasing BMI.
- Nextstellis is the first oral contraceptive containing estetrol. Estetrol is a naturally produced estrogen during pregnancy, which can now be made from a plant source.
- The efficacy of Nextstellis was established in an open-label, single-arm study of one-year duration that enrolled 1,674 females 16 to 35 years of age.
    - A total of 26 on-treatment pregnancies occurred in 1,524 females contributing 12,763 at-risk cycles. The overall Pearl Index was 2.65 (95% CI: 1.73, 3.88) per 100 woman-years of use.
    - A trend of decreasing effectiveness with increasing BMI was observed in the study.
- Nextstellis carries a boxed warning for cigarette smoking and serious cardiovascular events.
- Nextstellis is contraindicated in females who develop or are known to have the following conditions:
    - A history of, increased risk for, or current arterial or venous thrombotic/thromboembolic diseases
    - Current or history of a hormonally-sensitive malignancy (eg, breast cancer)
    - Hepatic adenoma, hepatocellular carcinoma, acute hepatitis, or severe (decompensated) cirrhosis
    - Use of hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir
    - Abnormal uterine bleeding that has an undiagnosed etiology
    - Renal impairment
    - Adrenal insufficiency
- Additional warnings and precautions for Nextstellis include hyperkalemia; hypertension; migraine; hormonally-sensitive malignancies; liver disease; risk of liver enzyme elevations with concomitant hepatitis C treatment; glucose tolerance and hypertriglyceridemia; gallbladder disease and cholestasis; effect on binding globulins; bleeding irregularities and amenorrhea; depression; cervical cancer; hereditary angioedema; and chloasma.
- The most common adverse reactions (≥ 2%) with Nextstellis use were bleeding irregularities, mood disturbance, headache, breast symptoms, dysmenorrhea, acne, increased weight, and decreased libido.
- The recommended dosage of Nextstellis is one tablet orally daily for 28 consecutive days. Refer to the Nextstellis drug label for complete dosing and administration recommendations.

Continued . . .

- Mayne Pharma plans to launch Nextstellis by the end of June 2021. Nextstellis will be available as a blister card with 24 active tablets (each tablet containing 3 mg drospirenone and 14.2 mg of estetrol) and 4 inert tablets.