Slynd® (drospirenone) – New drug approval

- On May 23, 2019, the FDA approved Exeltis' Slynd (drospirenone), for use by females of reproductive potential to prevent pregnancy.
- Slynd is a progestin-only oral contraceptive which lowers the risk of becoming pregnant primarily by suppressing ovulation.
- The efficacy of Slynd was evaluated in a single arm study in an efficacy population consisting of 953 females ≤ 35 years of age with 5,547 evaluable cycles.
    - During these cycles, a total of 17 (1.8%) females reported pregnancy, leading to a Pearl Index of 4.0 (95% CI: 2.3, 6.4).
- Slynd is contraindicated in females with the following conditions: renal impairment; adrenal insufficiency; presence or history of cervical cancer or progestin sensitive cancers; liver tumors, benign or malignant, or hepatic impairment; and undiagnosed abnormal uterine bleeding.
- Warnings and precautions for Slynd use include hyperkalemia, thromboembolic disorders, bone loss, cervical cancer, liver disease, ectopic pregnancy, risk of hyperglycemia in patients with diabetes, bleeding irregularities and amenorrhea, and depression.
- The most common adverse reactions (> 1%) with Slynd use were acne, metrorrhagia, headache, breast pain, weight increased, dysmenorrhea, nausea, vaginal hemorrhage libido decreased, breast tenderness, menstruation irregular.
- The recommended dose of Slynd is one tablet taken daily for 28 days; one white active tablet daily during the first 24 days and one green inactive tablet daily during the 4 following days.
    - Refer to the Slynd drug label for additional dosing recommendations.
- Exeltis' launch plans for Slynd are pending. Slynd will be available in blister cards with 24 white tablets each containing 4 mg of drospirenone and 4 green inert tablets.