Annovera™ (segesterone acetate/ethinyl estradiol) – New drug approval

- On August 10, 2018, the FDA announced the approval of TherapeuticsMD's Annovera (segesterone acetate/ethinyl estradiol) for use by females of reproductive potential to prevent pregnancy.
    - Annovera has not been adequately studied in females with a BMI > 29 kg/m^2.
- Annovera is combination product containing a progestin (segesterone acetate) and an estrogen (ethinyl estradiol).
    - Annovera is a reusable donut-shaped (ring), non-biodegradable, flexible vaginal system that is placed in the vagina for 3 weeks followed by 1 week out of the vagina, at which time women may experience a period (a withdrawal bleed).
    - Annovera is the first vaginal ring contraceptive that can be used for an entire year.
- The efficacy of Annovera was based on two 1-year clinical trials of 2,111 adult, sexually-active females with regular menstrual cycles.
    - Based on pooled data from 17,427 evaluable 28-day cycles (with no back-up contraception), the pregnancy rate was 2.98 per 100 woman-years of Annovera use (95% CI: 2.13, 4.06).
- Annovera contains a boxed warning regarding cigarette smoking and serious cardiovascular events.
- Annovera is contraindicated in females who are known to have the following conditions: high risk of arterial or venous thrombotic diseases; current or history of breast cancer or other estrogen- or progestin-sensitive cancer; liver tumors, acute hepatitis, or severe (decompensated) cirrhosis; undiagnosed abnormal uterine bleeding; use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for alanine transaminase elevations; and hypersensitivity to any of the components of Annovera.
- Warnings and precautions of Annovera include thromboembolic disorders and other vascular conditions; liver disease; risk of liver enzyme elevations with concomitant hepatitis C treatment; hypertension; age-related considerations; gallbladder disease; adverse carbohydrate and lipid metabolic effects; headache; bleeding irregularities and amenorrhea; depression; cervical cancer; effect on binding globulins; hereditary angioedema; chloasma; toxic shock syndrome; and vaginal use.
- The common adverse reactions (> 5%) with Annovera use were headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, abdominal pain lower/upper, dysmenorrhea, vaginal discharge, urinary tract infection, breast tenderness/pain/discomfort, bleeding irregularities including metrorrhagia, diarrhea, and genital pruritus.
- The recommended dosage is one Annovera placed in the vagina. Annovera is to remain in the vagina continuously for 21 days and is removed for a 1-week (7-days) dose-free interval. This pattern of Annovera use represents 1 cycle.
    - One Annovera vaginal system will provide contraception for thirteen 28-day cycles.
    - Consider the possibility of ovulation and conception prior to the first use of Annovera.

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    - Refer to the Annovera drug label for additional dosage and administration information.

- TherapeuticsMD estimates that Annovera may be commercially available as early as the 3rd quarter of 2019.