FDA Approves Low-Dose Hormone Combo for Menopause Symptoms

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March 2, 2012 — The US Food and Drug Administration (FDA) has approved 0.25 mg drospirenone/0.5 mg estradiol (*Angeliq*, Bayer HealthCare) for the treatment of moderate to severe hot flashes and night sweats (ie, vasomotor symptoms) and moderate to severe symptoms of vulvar and vaginal atrophy due to menopause in women who have a uterus.

The previously approved pill contains a higher dose of both drugs, 0.5 mg drospirenone/1 mg estradiol.

"We are pleased by the approval of this important new lower dose option for menopausal women," noted Pamela A. Cyrus, MD, vice president and head of US Medical Affairs, Bayer HealthCare Pharmaceuticals, in a written release. The availability of the new pill "supports current guidelines which recommend that treatment with hormone therapy should aim to use the lowest effective dose."

The approval was based on findings from a randomized trial including 735 postmenopausal women at least 40 years of age who experienced at least 7 to 8 moderate to severe hot flashes daily or 50 to 60 moderate to severe hot flashes weekly.

Compared with those receiving placebo, patients receiving 0.25 mg drospirenone/0.5 mg estradiol achieved a statistically significant reduction in the frequency and severity of moderate to severe vasomotor symptoms at week 4 (a reduction of about 2 episodes per day) and week 12 (a reduction of about 3 episodes per day).

The most common side effects with the pill were gastrointestinal and abdominal pain, female genital tract bleeding, breast pain/discomfort, and headache.