FDA approves first nonhormonal drug to ease menopause hot flashes

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The U.S. Food and Drug Administration on Friday approved the first

nonhormonal medication aimed at easing menopause hot flashes.

The new pill, called Veozah (fezolinetant), is a neurokinin 3 (NK3) receptor antagonist. "It works by binding to and blocking the activities of the NK3 receptor, which plays a role in the brain's regulation of body temperature," the FDA explained in a news release issued Friday.

According to the FDA, more than 80 percent of menopausal women experience sudden, often debilitating hot flashes lasting several minutes that can be accompanied by sweating, flushing, and chills. While estrogen-based hormone replacement therapy has long been used to help ease these symptoms, long-term use has been linked to a heightened risk for breast cancer and stroke. Furthermore, hormone therapies are contraindicated in women with a history of vaginal bleeding, stroke, heart attack, blood clots, or liver disease.

The agency based its approval on the results of two phase 3 clinical trials involving women who averaged 54 years of age. Women first took either Veozah or placebo for 12 weeks in a blinded trial. Then all women were given Veozah for an additional 40 weeks to assess safety.

"The most common side effects of Veozah include abdominal pain, diarrhea, insomnia, back pain, [and] hot flush," the agency said. There was also a risk for elevated hepatic transaminase, or liver injury, so "before using Veozah, patients should have blood work done to test for liver damage or infection," the FDA said. "While on Veozah, routine blood work should be performed every three months for the first nine months of using the medication."

Approval of Veozah was granted to Astellas.

More information: More Information