MedicalXpress

First non-hormonal remedy approved for menopausal hot flashes

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(HealthDay)—Brisdelle (paroxetine) has been approved by the U.S. Food and Drug Administration as the first non-hormonal treatment to treat hot flashes associated with menopause.

All prior FDA-approved drugs for hot flashes contain either the hormone estrogen alone or the hormonal combination of estrogen and progestin, the agency said in a news release.

Brisdelle's active ingredient is paroxetine, in a smaller amount than the same active ingredient in the antidepressant Paxil. It's not understood how paroxetine treats hot flashes, the FDA said.

Hot flashes affect up to 75 percent of all women, and can linger for as long as five years. Brisdelle's safety and effectiveness in treating the condition were evaluated in clinical studies involving 1,175 post-menopausal women with moderate-to-severe hot flashes. The most common side effects of the once-daily drug were headache, fatigue and nausea/vomiting.

Paroxetine, a selective serotonin reuptake inhibitor (SSRI), has the same boxed label warning as other antidepressant drugs in its class. The label warns of possible increased risk of suicide among children and young adults.

Brisdelle's label also warns of a possible reduction in the effectiveness of tamoxifen—a drug prescribed to treat breast cancer—if both

medications are taken together. Other potential serious side effects include increased risk of bleeding and developing a condition called serotonin syndrome, the FDA said.

Brisdelle is marketed by Noven Therapeutics, based in Miami, Fla.

More information: To learn more about this approval, visit the FDA.