FDA approves pill for hot flashes in menopausal women

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TherapeuticsMD announced Monday that its single-pill hormone therapy for menopausal hot flashes has been approved for marketing by the U.S. Food and Drug Administration.

The new drug, which combines estradiol (estrogen) and progesterone in an oral softgel capsule, has been named Bijuva, and is expected to be available in the United States by April or May, the Boca Raton, Fla., company said.

For menopausal women, the approval means a new option for hormone therapy. Currently, women who want bio-identical hormone therapy—molecularly identical to the hormones produced by a woman's body—have to take two pills.

For the company, it means further entrance into a multibillion-dollar market of menopausal health care for women.

Dr. James Liu, president of the North American Menopause Society and chairman of Obstetrics and Gynecology at University Hospitals Cleveland Medical Center, said this is the first FDA approval of a combination hormone therapy "evaluated in a large, well-controlled, randomized clinical trial that has demonstrated both safety and efficacy for the treatment of moderate to severe hot flashes due to menopause.

"The approval of Bijuva represents an important, novel and effective treatment option for women," Liu said.

The FDA approved Bijuva's higher dosage of 1 milligram of estradiol and 100 milligrams of progesterone. TherapeuticsMD had also proposed a capsule with a lower dose of estradiol. The FDA "thought there was no reason for a lower dose," the company said.

In August, TherapeuticsMD began distributing Imvexxy, its new treatment for menopausal women who experience painful sex due to vaginal atrophy. Imvexxy was approved for marketing by the FDA in May.