Ibrance approval expanded to include men with breast cancer

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(HealthDay)—U.S. Food and Drug Administration approval of Ibrance

(palbociclib) capsules has been widened to include men with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer, the agency said Thursday in a news release.

"Today we are expanding the indication for Ibrance to include male patients based upon data from postmarketing reports and electronic health records showing that the safety profile for men treated with Ibrance is consistent with the safety profile in women treated with Ibrance," Richard Pazdur, M.D., director of the FDA Oncology Center of Excellence, said in a statement.

Ibrance, a kinase inhibitor, was first approved in 2015 in combination with an aromatase inhibitor as the first hormonal-based therapy in women who have gone through menopause. The drug's manufacturer provided results of an analysis of real-world data from electronic health records as further supportive evidence to characterize the use of Ibrance in combination with endocrine therapy in male patients with breast cancer. The data were based on observed tumor responses in this rare subset of patients with breast cancer.

Ibrance's most common side effects are infections, leukopenia, fatigue, nausea, stomatitis, anemia, hair loss, diarrhea, and thrombocytopenia. Doctors should tell male patients with female partners of childbearing age to use contraception during treatment with Ibrance and for three months after the last dose, the agency advised.

Ibrance is produced by Pfizer, based in New York City.

More information: More Information