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FDA Approves Palbociclib for Advanced Breast Cancer

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The FDA has approved the CDK4/6 inhibitor palbociclib (Ibrance) for the treatment of postmenopausal women with metastatic breast cancer.
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Palbociclib doubled progression-free survival in metastatic breast can...

The US Food and Drug Administration (FDA) earlier today approved the cyclin-dependent kinase (CDK) 4/6 inhibitor palbociclib (Ibrance) for the treatment of postmenopausal women with metastatic breast cancer.

The new drug is to be used in combination with letrozole for the treatment of estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer patients with metastatic disease who have not yet been treated with endocrine therapy.

“The addition of palbociclib to letrozole provides a novel treatment option to women diagnosed with metastatic breast cancer,” said Richard Pazdur, MD, director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research, in a press release. “The FDA is committed to expediting marketing approval of cancer drugs through our accelerated approval regulations.”

The randomized phase II trial that led to the approval included 165 postmenopausal patients with metastatic ER-positive, HER2-negative breast cancer assigned to either letrozole plus palbociclib or letrozole alone. Patients received a 125-mg daily dose of palbociclib and a 2.5-mg daily dose of letrozole.

Treatment with palbociclib led to an improved progression-free survival (20.2 months vs 10.2 months). Overall survival data are not yet available.

Results of this trial were originally presented at the 2014 American Association for Cancer Research Annual Meeting.

Common adverse events among patients treated with palbociclib included decreased appetite, nausea, vomiting, diarrhea, alopecia, anemia, fatigue, leukopenia, neutropenia, thrombocytopenia, stomatitis, epistaxis, asthenia, peripheral neuropathy, and upper respiratory infection.

Palbociclib is also being studied in two phase III trials: PALOMA-2 is testing palbociclib with

letrozole and fulvestrant in late-stage metastatic breast cancer patients who have failed endocrine therapy, and PENELOPE-B is testing palbociclib in combination with standard endocrine therapy in hormone receptor–positive breast cancer patients with residual disease after neoadjuvant chemotherapy and surgery.

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