

Pfizer breast cancer drug to get FDA priority review

October 13 2014

Pfizer said Monday an experimental breast cancer treatment will be given an accelerated review by US regulators, speeding up the process for potential approval.

The US Food and Drug Administration has granted priority review for palbociclib, which would treat certain postmenopausal women with advanced [breast cancer](#), the US pharmaceutical giant said.

Under the priority review status, the FDA accelerates the review time from 10 months to a goal of six months, with a decision on approval expected by April 13, 2015, it said.

In April, Pfizer said a clinical trial had shown palbociclib slows the growth of advanced cancer.

Administered with another drug already on the market, letrozole, an aromatase inhibitor, the treatment stops cancer growth for 20 months on average, it said.

The experimental treatment is aimed at postmenopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) [advanced breast cancer](#) who have not received previous systemic treatment for their advanced disease.

"If approved as a first-line therapy in combination with letrozole, palbociclib will be an important new option for the thousands of women

in the US who are living with [metastatic breast cancer](#)," said Garry Nicholson, president of Pfizer Oncology, in a statement.

Pfizer, which lost its global number-one status to Swiss rival Novartis, is searching for new drugs to renew growth. In recent years, patents have expired on most of its blockbusters—drugs that have a billion dollars in annual sales—and the company is facing stiff competition from generic versions.

Shares in Dow member Pfizer were down 0.1 percent at \$29.10 in midday trade in New York.

© 2014 AFP

Citation: Pfizer breast cancer drug to get FDA priority review (2014, October 13) retrieved 18 April 2024 from <https://medicalxpress.com/news/2014-10-pfizer-breast-cancer-drug-fda.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--