Pfizer seeks early approval for breast cancer drug

May 16 2014, by The Associated Press

Pfizer Inc. says the Food and Drug Administration will let the drugmaker apply for approval of its heavily touted experimental breast cancer medicine based on midstage patient testing results.

That means New York-based Pfizer won't need bigger, very expensive, late-stage patient studies for palbociclib (pal-boh-SEYE'-klihb) to be approved.

The company says that after discussions with the FDA, the final results of a study called PALOMA-1 will be sufficient for review. The FDA last year designated palbociclib a breakthrough therapy, which speeds up the testing and approval process.

Pfizer says that by the third quarter, it will apply for approval to use palbociclib, together with a drug to prevent breast cancer recurrence called Femara, or letrozole, as an initial treatment for postmenopausal women with a certain type of advanced breast cancer.