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Pfizer has announced that the US Food and Drug Administration (US FDA) has granted accelerated approval of IBRANCE (palbociclib), in combination with letrozole, for the treatment of postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer, as initial endocrine-based therapy for their metastatic disease.

This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The confirmatory Phase III trial, PALOMA-2, is fully enrolled.

IBRANCE was reviewed and approved under the FDA's Breakthrough Therapy designation and Priority Review programs.

The IBRANCE new drug application was based on the final results of the Phase 2 PALOMA-1 trial. The most frequently reported adverse event for IBRANCE plus letrozole in PALOMA-1 was neutropenia.

"I am proud of the clinical program for IBRANCE, which was discovered in Pfizer laboratories, and the innovation we are able to bring forward to the breast cancer community. The registration trial showed that, compared to letrozole alone for first-line treatment of ER+/HER2- advanced breast cancer, IBRANCE in combination with letrozole almost doubled the time before tumor progression,1 delaying the need for later-line therapies including other hormonal agents and chemotherapies." said Mr Ian Read, chairman and CEO, Pfizer.

"FDA approval of IBRANCE marks a pivotal milestone that demonstrates the strength of our science, provides an important medicine to patients in need, and underscores the contributions our Company can make to society," he added.