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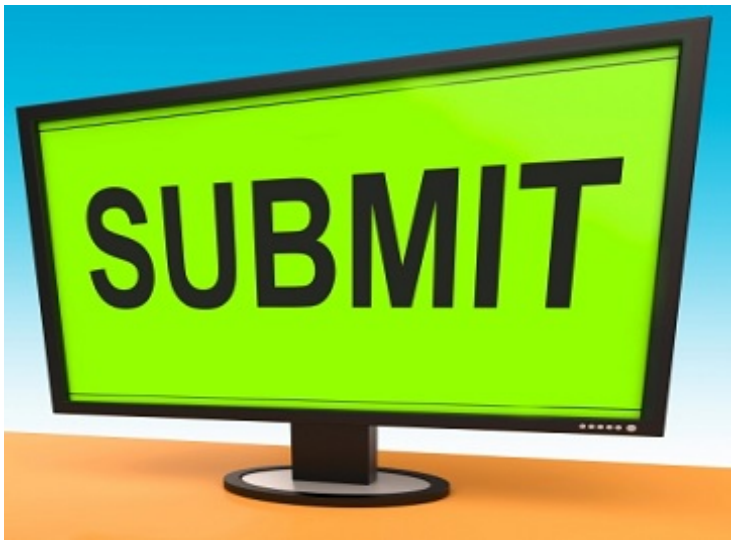

Pfizer has announced that it has completed the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (US FDA) for palbociclib. This NDA requests FDA approval of palbociclib, in combination with letrozole, for the treatment of post-menopausal women with estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer who have not previously received systemic treatment for the disease.

The submission is based on the final results of PALOMA-1, a randomized Phase 2 trial comparing palbociclib and letrozole versus letrozole alone in a group of patients in an advanced stage.

The regulatory body handed the drug a breakthrough therapy designation for its first-line systemic treatment of women with advanced or metastatic ER+, HER2- breast cancer. This designation was based on interim data from the PALOMA-1 trial.

"This submission marks an important milestone for Pfizer and palbociclib, and a potential advancement for women with advanced breast cancer," said Mr Garry Nicholson, president, Pfizer Oncology.