On behalf of Pfizer Oncology, I respectfully request the NCCN Breast Cancer Guidelines Panel to review the enclosed for consideration of revising the NCCN Breast Cancer Guidelines to include the updated indication for IBRANCE: IBRANCE (palbociclib) in combination with an aromatase inhibitor as initial endocrine based therapy option for postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer.

• Request for NCCN Guidelines Panel to consider review of data for a specific indication:
  On March 31, 2017 the FDA granted approval of the PALOMA-2 (A5481008) sNDA for IBRANCE. This approval updates the USPI for IBRANCE to include the confirmatory Phase 3 PALOMA-2 results and converts the accelerated approval of IBRANCE to regular approval. The updated USPI also broadens the indication of IBRANCE to include hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or fulvestrant in women with disease progression following endocrine therapy.

• Specific changes recommended within the NCCN Guidelines:
  o Currently the NCCN Guidelines list the combination of IBRANCE (palbociclib) with letrozole as first-line endocrine therapy for recurrent or stage IV disease in postmenopausal patients.

  o The recommended change is to update the NCCN Guidelines to list the combination of IBRANCE (palbociclib) with an aromatase inhibitor as first line endocrine therapy for recurrent or stage IV disease in postmenopausal patients.

• Statement of whether the submitted use is or is not FDA approved for that indication
  o The submitted use was approved by the FDA on March 31, 2017.

• Rationale for recommended change
  o The indication has been updated in the FDA approved Prescribing Information.

  IBRANCE is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
  • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or
  • fulvestrant in women with disease progression following endocrine therapy. (1)

• Citation of literature support and complete articles supporting recommended change (attached):
  1. FDA approved US Prescribing Information (March 31, 2017)
We appreciate the Panel’s thorough consideration of Pfizer’s recommendation that IBRANCE (palbociclib) in combination with an aromatase inhibitor be listed as first-line therapy for postmenopausal patients with HR+, HER2- recurrent or stage IV breast cancer.

Kind regards,

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