Generic Name:
Alpelisib
Trade Name:
Piqray
Company:
Novartis
Notes:

FDA approved alpelisib tablets for use in combination with the endocrine therapy fulvestrant to treat men and postmenopausal women with hormone receptor (HR)-positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer (as detected by an FDA-approved test) following progression on or after an endocrine-based regimen.

FDA also approved the companion diagnostic test, therascreen PIK3CA RGQ PCR Kit, to detect the PIK3CA mutation in a tissue and/or a liquid biopsy. Patients who are negative by the therascreen test using the liquid biopsy should undergo tumor biopsy for PIK3CA mutation testing. When breast cancer is HR positive, patients may be treated with antihormonal treatment (also called endocrine therapy), alone or in combination with other medicines, or chemotherapy.

Common adverse effects of alpelisib are high blood glucose levels, increase in creatinine, diarrhea, rash, decrease in lymphocyte count in the blood, elevated liver enzymes, nausea, fatigue, low red blood cell count, increase in lipase, decreased appetite, stomatitis, vomiting, weight loss, low calcium levels, prolonged aPTT, and hair loss.

Health professionals are advised to monitor patients taking alpelisib for severe hypersensitivity reactions and not to initiate treatment in patients with a history of severe skin reactions such as Stevens-Johnson Syndrome, erythema multiforme, or toxic epidermal necrolysis. Patients receiving alpelisib have reported severe hyperglycemia, and the safety of alpelisib in patients with type 1 or uncontrolled type 2 diabetes has not been established. Before initiating treatment with alpelisib, health professionals are advised to check fasting glucose and A1C and to optimize glycemic control. Patients should be monitored for pneumonitis/interstitial lung disease and diarrhea during treatment. Alpelisib must be dispensed with a patient Medication Guide that describes important information about the drug?s uses and risks.

Efficacy was studied in the SOLAR-1 trial, a randomized trial of 572 men and postmenopausal women with HR-positive, HER2-negative, advanced or metastatic breast cancer whose cancer had progressed while on or after receiving an aromatase inhibitor. Results from the trial showed the addition of alpelisib to fulvestrant significantly prolonged progression-free survival (median of 11 mo vs. 5.7 mo) in patients whose tumors had a PIK3CA mutation.

Medication Monitor Categories:
New Drug Approvals