BioSpectrum the business of Bio & Health Sciences

Novartis' blood cancer drug gets FDA nod

25 February 2015 | News | By BioSpectrum Bureau

Novartis' blood cancer drug gets FDA nod

Novartis has announced that the US Food and Drug Administration (US FDA) has approved Farydak (panobinostat, previously known as LBH589) capsules in combination with bortezomib and dexamethasone. It has been approved for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory (IMiD) agent.

Farydak has been shown to extend the progression-free survival (PFS) benefit of the standard-of-care therapy in this patient population. It was approved under accelerated approval based on PFS. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The FDA has approved a risk evaluation and mitigation strategy (REMS) for Farydak.

This FDA approval is based on efficacy and safety data in a pre-specified subgroup analysis of 193 patients who had received prior treatment with both bortezomib and an IMiD during the Phase III, randomized, double-blind, placebo-controlled, multicenter global registration trial, called PANORAMA-1 (PANobinostat ORAl in Multiple MyelomA). The trial found that the median PFS benefit increased in Farydak patients who had received prior treatment with both bortezomib and an IMiD (10.6 months; n=94), as compared to the placebo arm (5.8 months; n=99) (hazard ratio=0.52 [95 percent confidence interval (CI): 0.36, 0.76]).

The most common adverse reactions (incidence >= 20 percent) in clinical studies are diarrhea, fatigue, nausea, peripheral edema, decreased appetite, pyrexia and vomiting. The most common non-hematologic laboratory abnormalities (incidence >= 40 percent) are hypophosphatemia, hypokalemia, hyponatremia and increased creatinine. The most common hematologic laboratory abnormalities (incidence >= 60 percent) are thrombocytopenia, lymphopenia, leukopenia, neutropenia, and anemia.

"Novartis is committed to developing innovative first-in-class therapies for patients who need treatment options. Farydak represents a new drug class in multiple myeloma, providing these patients with an important treatment approach for this

difficult-to-treat cancer," said Mr Bruno Strigini, president, Novartis Oncology.