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Novartis receives EU approval for cancer drug,Farydak

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Novartis has announced that the European Commission has approved Farydak (panobinostat, previously known as LBH589) capsules, in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma who have received at least two prior regimens including bortezomib and an immunomodulatory agent (IMiD).

Multiple myeloma is a cancer of the plasma cells, a type of white blood cell present in the bone marrow, and affects approximately 84,000 people in Europe. Farydak is the first HDAC inhibitor to show efficacy in multiple myeloma. As an HDAC inhibitor, its epigenetic activity may help restore cell function in patients with multiple myeloma.

The EU approval of Farydak is based on efficacy and safety data in a subgroup analysis of 147 patients who had received at least two prior regimens, including 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), evaluating Farydak in combination with bortezomib and dexamethasone against bortezomib and dexamethasone alone in patients with relapsed and/or relapsed and refractory multiple myeloma. The trial found that the median progression-free survival (PFS) benefit in this subgroup increased by 7.8 months in Farydak patients who had received prior treatment with both bortezomib and an IMiD (12.5 months; n=73), as compared to the placebo arm (4.7 months; n=74) (hazard ratio=0.47 [95% confidence interval (CI): 0.31, 0.72]).

The most common non-hematological adverse reactions included diarrhea, fatigue, nausea and vomiting. Treatment-emergent hematological toxicities included thrombocytopenia, anemia, neutropenia and lymphopenia.

"With the approval of Farydak in the European Union, we hope to address critically important treatment needs faced by the multiple myeloma community-disease progression and treatment resistance. This milestone, the approval of a first in its class treatment option for patients in need of new therapies, is the result of more than 13 years of dedicated research, which has helped us better understand the development of multiple myeloma,"said Ms Bruno Strigini, president, Novartis Oncology.

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Farydak in combination with bortezomib and dexamethasone is also approved in the US, Chile and Japan for certain patients with previously treated multiple myeloma.

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