tools

Approved Drugs

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

- FDA has granted accelerated approval to **Ibrance® (palbociclib)** (Pfizer, Inc., www.pfizer.com) for use in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.

- Janssen Biotech, Inc. (www.janssenbiotech.com) announced that the FDA has approved **Imbruvica® (ibrutinib)** capsules as the first therapy indicated specifically for patients with Waldenstrom's macroglobulinemia (WM), a rare, indolent type of B-cell lymphoma. This represents the fourth indication for Imbruvica since its initial approval in November 2013. Imbruvica was granted Breakthrough Therapy Designation for WM by the FDA and is being jointly developed and commercialized by Janssen and Pharmacyclics, Inc.

- Eisai, Inc. (www.eisai.com) announced that the FDA has granted approval to **Lenvima™ (lenvatinib)** to treat patients with progressive, differentiated thyroid cancer (DTC) whose disease progressed despite receiving radioactive iodine therapy (radioactive iodine refractory disease). Lenvima is a kinase inhibitor, which works by blocking certain proteins from helping cancer cells grow and divide.

- The FDA has granted accelerated approval to **Lynparza™ (olaparib)** (AstraZeneca Pharmaceuticals, www.astrazeneca.com) for women with advanced ovarian cancer associated with defective BRCA genes, as detected by an FDA-approved test. Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. It is intended for women with heavily pre-treated ovarian cancer that is associated with defective BRCA genes. The FDA approved Lynparza with a genetic test called BRCAAnalysis CDx (Myriad Genetics, Inc., www.myriad.com), a companion diagnostic that will detect the presence of mutations in the BRCA genes (gBRCAm) in blood samples from patients with ovarian cancer.

- Bristol-Myers Squibb (www.bms.com) announced that the FDA has granted accelerated approval to **Opdivo® (nivolumab)** for patients with unresectable or metastatic melanoma who no longer respond to other drugs. Opdivo works by inhibiting the PD-1 protein on cells, which blocks the body's immune system from attacking melanoma tumors. Opdivo is intended for patients who have been previously treated with ipilimumab and for melanoma patients whose tumors express a gene mutation called BRAF V600, for use after treatment with ipilimumab and a BRAF inhibitor.

- Celgene Corporation (www.celgene.com) has announced that the FDA has expanded the existing indication for **Revlimid (lenalidomide)** in combination with dexamethasone to include patients newly diagnosed with multiple myeloma.

- The FDA has approved **Somatuline® Depot Injection (lanreotide)** (Ipsen Pharma, www.ipsen.com) for the treatment of patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Genetic Tests and Assays in the News

- The FDA has granted 510(k) clearance for Agendia's (www.agendia.com) **Mamma-Print® Breast Cancer Recurrence Test in FFPE** (formalin-fixed paraffin embedded) **Tissue**. The MammaPrint FFPE test uses the same 70 genes and proprietary algorithm as the previously cleared MammaPrint Fresh. Due to the larger panel of genes, both tests provide an unambiguous result of "Low vs. High risk" for recurrence of a patient's breast cancer. OI