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Approved Drugs

• Eisai Inc. (www.eisai.com/US) announced that the Food and Drug Administration (FDA) has approved **Akynzeo® (netupitant and palonosetron)** for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo is a combination oral agent that targets two critical signaling pathways associated with CINV (chemotherapy-induced nausea and vomiting) by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT3 receptor antagonist, in a single capsule for the prevention of CINV.

• The FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, www.merck.com) for the treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. Keytruda blocks a cellular pathway known as PD-1, which restricts the body's immune system from attacking melanoma cells. The drug is intended for use following treatment with ipilimumab, a type of immunotherapy. For melanoma patients whose tumors express a gene mutation called BRAF V600, Keytruda is intended for use after treatment with ipilimumab and a BRAF inhibitor, a therapy that blocks activity of BRAF gene mutations.

• Millennium: The Takeda Oncology Company (www.millennium.com) announced that the FDA has approved **Velcade® (bortezomib) for injection** for use in previously untreated patients with mantle cell lymphoma (MCL). This approval extends the utility of Velcade beyond relapsed or refractory mantle cell lymphoma, for which it has been approved since 2006.

• Medivation, Inc. (www.medivation.com) and Astellas Pharma Inc. (www.asteallas.com/en) announced that the FDA approved a new indication for the use of **Xtandi® (enzalutamide) capsules** to treat patients with metastatic castration-resistant prostate cancer (CRPC).

Drugs in the News

• The FDA has granted multiple orphan drug designations to **aldoxorubicin** (CytRx Corporation, www.cytrx.com) in three indications: glioblastoma multiforme, small cell lung cancer, and ovarian cancer. Aldoxorubicin is CytRx's modified version of the widely-used chemotherapeutic agent, doxorubicin.

• DNAtrix, Inc. (www.dnatrix.com) announced that the FDA has granted orphan drug designation for **DNX-2401**, a conditionally-replicative oncolytic adenovirus for malignant glioma.

• FDA has granted priority review status for the new drug application for **lenvatinib mesylate** (Eisai Inc., www.eisai.com) as a treatment for progressive radioactive iodine-refractory differentiated thyroid cancer.

• Taiho Oncology, Inc. (www.taihooncology.com) announced that the FDA has granted fast track designation for **TAS-102 (trifluridine and tipiracil hydrochloride)**, an oral combination anticancer drug under investigation for the treatment of refractory metastatic colorectal cancer (mCRC).

Genetic Tests and Assays in the News

• bioTheranostics, Inc. (www.biotheranostics.com) announced that its **Breast Cancer Index℠** test has been awarded Medicare coverage. The molecular genomic test quantifies risk of breast cancer recurrence and predicts which patients have a high likelihood of benefitting from extended endocrine therapy. The Medicare policy covers use of the test to predict risk of late (5 to 10 years) distant recurrence in women with early stage, estrogen receptor-positive breast cancer who are considering extended therapy but are concerned about continuing anti-hormonal therapy because of documented toxicity or possible significant patient-specific side effects. In addition to new claims, Medicare coverage and payment for the Breast Cancer Index will be made retrospectively for previously submitted claims. OI