tools

Approved Drugs

• Genentech (gene.com) announced that the U.S. Food and Drug Administration (FDA) has approved **Avastin® (bevacizumab)**, either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin alone, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

• The FDA has approved Janssen Biotech's (janssen.com) **Darzalex® (daratumumab)** in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

• Merck & Co., Inc. (merck.com) announced that the FDA has approved **Keytruda® (pembrolizumab)** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test. This approval also expands the indication in second-line treatment of lung cancer to include all patients with PD-L1-expressing NSCLC.

• The FDA has approved Eli Lilly and Company's (lillyoncology.com) **Lartruvo™ (olaratumab injection, 10 mg/mL)**, in combination with doxorubicin, for the treatment of adults with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

• The FDA has granted accelerated approval to Clovis Oncology's (clovisoncology.com) **Rubraca® (rucaparib)** for women with advanced ovarian cancer who have been treated with two or more chemotherapies and whose tumors have a specific gene mutation (deleterious BRCA) as identified by an FDA-approved companion diagnostic test.

• Genentech (gene.com) announced that the FDA has approved **Tecentriq® (atezolizumab)** for the treatment of people with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities.

Drugs in the News

• The FDA has granted orphan drug designation to Ability Pharmaceuticals' (abilitypharma.com) **ABTL0812** for the treatment of pancreatic cancer. ABTL0812 is an oral targeted anticancer compound that inhibits the PI3K/Akt/mTOR pathway.

• EMD Serono Inc. (emdserono.com) announced that the FDA has accepted for priority review the biologics license application (BLA) for the anti-PD-L1 IgG1 monoclonal antibody **avelumab**. This review relates to avelumab's proposed use in patients with metastatic Merkel cell carcinoma, based on tumor response results from the JAVELIN Merkel 200 trial.

• The FDA has accepted for review the new drug application (NDA) for ARIAD Pharmaceuticals' (ariad.com) investigational oral anaplastic lymphoma kinase (ALK) inhibitor, **brigatinib**, in patients with metastatic ALK-positive (ALK+) NSCLC who have progressed on crizotinib.

• Arog Pharmaceuticals, Inc. (arogpharma.com) announced that the FDA has granted fast track designation for **crenolanib** for the treatment of patients with unresectable or metastatic gastrointestinal stromal tumors (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRα) D842V mutation.

• The FDA has granted fast track designation to Daiichi Sankyo Company's (daiichisankyo.com) investigational HER2-targeting antibody drug conjugate, **DS-8201**, for the treatment of HER2-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with HER2-targeted therapies including ado-trastuzumab emtansine (T-DM1).

• Pfizer Inc. (pfizer.com) announced that the FDA has accepted for review a supplemental NDA for its CDK 4/6 inhibitor, **Ibrance® (palbociclib)**. The supplemental NDA supports the conversion of the accelerated approval of Ibrance in combination

with letrozole to regular approval and includes data from the Phase III PALOMA-2 trial, which evaluated Ibrance as initial therapy in combination with letrozole for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) metastatic breast cancer.

• Merck (merck.com) announced that the FDA accepted for review the supplemental biologics license application (BLA) for **Keytruda® (pembrolizumab)** for the treatment of previously treated patients with advanced microsatellite instability-high cancer.

• The FDA has granted priority review to **LEE011 (ribociclib)** (Novartis, novartis.com) as first-line treatment of postmenopausal women with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer in combination with letrozole.

• Mylan (mylan.com) and Biocon Ltd. (biocon.com) announced submission of Mylan's BLA for **MYL-1401O**, a proposed biosimilar to trastuzumab, which is indicated to treat certain HER2-positive breast and gastric cancers.

• The FDA has granted orphan drug designation to Boston Biomedical's (bostonbiomedical.com) lead investigational compound, **napabucasin**, for the treatment of pancreatic cancer.

• Boehringer Ingelheim (boehringer-ingelheim.us) announced that the FDA has granted orphan drug designation to **nintedanib** for the treatment of mesothelioma.

• The FDA has granted priority review for Tesaro, Inc.'s (tesarobio.com) NDA for **Niraparib**. Niraparib, formerly known as MK-4827, is an orally active and potent poly (ADP-ribose) polymerase, or PARP, inhibitor that is being evaluated as a potential new treatment option for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following response to platinum-based chemotherapy.

• Novartis (novartis.com) announced that the FDA has granted priority review to the NDA for **PKC412 (midostaurin)** for the treatment of acute myeloid leukemia in newly-diagnosed adults with an FMS-like tyrosine kinase-3 (FLT3) mutation, as well as for the treatment of advanced systemic mastocytosis.

• Bayer (bayer.us) has submitted a supplemental NDA to the FDA for **Stivarga® (regorafenib) tablets** for the second-line systemic treatment of patients with unresectable hepatocellular carcinoma.

• The FDA has granted orphan drug designation to AbbVie's (abbvieoncology.com) **veliparib**, an oral PARP inhibitor, being investigated in combination with chemotherapies, such as carboplatin and paclitaxel, or radiation for the treatment of advanced NSCLC.

• Astellas Pharma Inc. (astellas.com/en) and Pfizer Inc. (pfizer.com) announced that the FDA has approved a supplemental NDA to update the U.S. product labeling for **Xtandi® (enzalutamide) capsules** to include new clinical data versus bicalutamide from the TERRAIN study. The data demonstrate improvement in radiographic progression-free survival in patients with metastatic castration-resistant prostate cancer who were treated with enzalutamide compared to patients who were treated with bicalutamide.

Approved Devices

• Exact Imaging (exactimaging.com) has received FDA 510(k) clearance for its **ExactVu™ micro-ultrasound system**, which performs targeted prostate biopsies.

• The FDA had approved ZDi Solutions' (zdirad.com) **Z-System™** patient positioning device for proton therapy and conventional radiation therapy. The system is comprised of the Z-Box™, Z-Square™, and Z-Tilt™.

• Biostage, Inc. (biostage.com) announced that its **Cellspan™ Esophageal Implant** was granted FDA orphan drug designation to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury, or congenital abnormalities.

Approved Genetic Tests & Assays

• Roche (roche.com) announced FDA approval of the **Ventana ALK (D5F3) CDx Assay** for use on the Ventana BenchMark ULTRA automated slide stainer. The assay is a companion diagnostic to aid in the identification of ALK-positive lung cancer patients who are eligible for treatment with Pfizer's FDA-approved therapy Xalkori® (crizotinib).

The FDA has also approved Roche's **Ventana PD-L1 (SP142) Assay** as a complementary diagnostic to identify PD-L1 expression levels in patients considering treatment with the FDA-approved Roche cancer immunotherapy Tecentriq® (atezolizumab) for previously treated metastatic NSCLC. The PD-L1 (SP142) assay is also indicated to identify patients with urothelial cancer who may benefit from treatment with Tecentriq. OI

Label Change for Tarceva®

The FDA modified the indication for **Tarceva (erlotinib)** (Astellas Pharm Global Development Inc., astellas.com/en) for treatment of NSCLC to limit use to patients whose tumors have specific EGFR mutations. The labeling change applies to patients with NSCLC receiving maintenance or second or greater line treatment. These indications will be limited to those patients whose tumors have EGFR exon 19 deletions or exon 21 L858R substitution mutations as detected by an FDA-approved test. The first-line indication previously was limited to patients with EGFR exon 19 deletions or exon 21 substitution mutations.