tools

Approved Drugs

- Helsinn (helsinn.com) announced that the U.S. Food and Drug Administration (FDA) has approved the intravenous formulation of **Akynzeo® (netupitant/palonosetron)** for patients experiencing chemotherapy-induced nausea and vomiting. The FDA has approved Akynzeo IV in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.
- Eli Lilly and Company (lilly.com) announced that the FDA has granted approval for a new indication for **Alimta® (pemetrexed for injection) in combination with carboplatin and Keytruda® (pembrolizumab)** for the initial treatment of patients with metastatic nonsquamous non–small cell lung cancer (NSCLC), irrespective of PD-L1 expression status.
- The FDA has approved Janssen Pharmaceutical Companies of Johnson & Johnson's (janssen.com) **Darzalex® (daratumumab) in combination with Velcade® (bortezomib), melphalan, and prednisone (VMP)** for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- Mylan N.V. (mylan.com) and Biocon Ltd. (biocon.com) announced that the FDA has approved **Fulphila™ (pegfilgrastim-jmbd)**, a biosimilar to Neulasta® (pegfilgrastim). Fulphila has been approved to reduce the duration of febrile neutropenia in patients treated with chemotherapy in certain types of cancer.
- The FDA has approved Novartis's (novartis.com) **Kymriah® (tisagenlecleucel) suspension for intravenous infusion** for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Kymriah is not indicated for the treatment of patients with primary central nervous system lymphoma.
- Bristol-Myers Squibb Company (bms.com) announced that the FDA has approved **Opdivo® (nivolumab)** 3 mg/kg plus **Yervoy® (ipilimumab)** 1 mg/kg (injections for intravenous use) as the first immuno-oncology combination therapy for previously untreated patients with intermediate- and poor-risk advanced renal cell carcinoma.
- The FDA has approved Pfizer, Inc.'s (pfizer.com) **Retacrit ® (epoetin alfa-epbx)**, a biosimilar to Epogen® and Procrit® (epoetin alfa), for the treatment of anemia due to chronic kidney disease in patients on dialysis and not on dialysis, use of zidovudine in patients with HIV infection, and the effects of concomitant myelosuppressive chemotherapy. It is also approved for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery.
- Clovis Oncology's (clovisoncology.com) **Rubraca® (rucaparib)**, a poly ADP-ribose polymerase inhibitor, has received FDA approval for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- The FDA has approved **Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)** (Novartis Pharmaceuticals Corporation, novartis.com) for the treatment of anaplastic thyroid cancer that cannot be removed by surgery or has spread to other parts of the body and has a type of abnormal gene, BRAF V600E (BRAF V600E mutation positive).
- AstraZeneca (astrazeneca.com) announced that the FDA has approved **Tagrisso® (osimertinib)** for the first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions or exon 21 L858R mutations), as detected by an FDA-approved test.
- The FDA has approved **Tavalisse™ (fostamatinib disodium hexahydrate tablets)** (Rigel Pharmaceuticals, Inc., rigel.com) for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.
- Sun Pharmaceutical Industries Ltd. (sunpharma.com) and Churchill Pharmaceuticals, LLC (churchillpharma.com) announced that the FDA has approved **Yonsa® (abiraterone acetate)**, a novel formulation in combination with methylprednisolone, for the treatment of patients with metastatic castration-resistant prostate cancer.

This was updated with a correction July 19, 2018.

Drugs in the News

- BioAtla, LLC (bioatla.com) announced that FDA has cleared the investigational new drug application (NDA) for **BA3021 (CAB-ROR2-ADC)** in patients with solid tumors.
- Calithera Biosciences, Inc. (calithera.com) announced that the FDA has granted fast track designation to **CB-839 in combination with cabozantinib** for the treatment of patients with metastatic renal cell carcinoma who have received one or two prior lines of therapy, including at least one vascular endothelial growth factor tyrosine kinase inhibitor or the combination of nivolumab and ipilimumab.
- The FDA has accepted for priority review the biologics license application (BLA) for **cemiplimab (REGN2810)** (Regeneron Pharmaceuticals, Inc., regeneron.com; Sanofi, sanofi.com) for the treatment of patients with metastatic cutaneous squamous cell carcinoma or patients with locally advanced cutaneous squamous cell carcinoma who are not candidates for surgery.
- Amneal Pharmaceuticals, Inc. (amneal.com.) has received FDA approval on its abbreviated NDA for **cyclophosphamide for injection USP**, the company's AP-rated therapeutic equivalent to Cytoxan.®
- The FDA has accepted Pfizer Inc.'s (pfizer.com) NDA and granted priority review for **dacomitinib**, a pan-human EGFR tyrosine kinase inhibitor, for the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR-activating mutations.
- Debiopharm International SA (debiopharm.com) announced that the FDA has granted fast track designation to **Debio 1347**, an FGFR 1-3 inhibitor, for the treatment of patients with unresectable or metastatic tumors with a specific FGFR gene alteration.
- The FDA has granted priority review to the NDA from Verastem Inc. (verastem.com) for its lead product candidate, **Duvelisib,** a first-in-class oral dual inhibitor of phosphoinositide 3-kinase-delta and phosphoinositide 3-kinase-gamma. Verastem is seeking full approval for this drug for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma and accelerated approval for the treatment of relapsed or refractory follicular lymphoma.
- Curis, Inc. (curis.com) announced that the FDA has granted fast track designation for the development of **fimepinostat (formerly CUDC-907)** in adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy.
- Astellas Pharma, Inc. (astellas.com) announced that the company has submitted an NDA to the FDA for marketing approval of **gilteritinib** for the treatment of adult patients with FLT3 mutation-positive (FLT3mut+) relapsed or refractory acute myeloid leukemia.
- The FDA has accepted for review a supplemental BLA from Merck (merck.com) for **Keytruda® (pembrolizumab)**. The application seeks approval for Keytruda in combination with Alimta® (pemetrexed) and platinum chemotherapy (carboplatin or cisplatin) as a first-line treatment for patients with metastatic NSCLC.
- Loxo Oncology, Inc. (loxooncology.com) announced that FDA has accepted the company's NDA and granted priority review for **larotrectinib** for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an NTRK gene fusion.
- The FDA has granted orphan drug designation to Lin BioScience (linbioscience.com) for its targeted therapy **LBS-007** to treat acute lymphoblastic leukemia.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that the FDA has granted fast track designation to the company's oral selective inhibitor of nuclear export compound **selinexor** for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy.
- The FDA has granted priority review to a supplemental BLA for **Tecentriq® (atezolizumab)** (Genentech, gene.com) to be used **in combination with Avastin® (bevacizumab), carboplatin, and paclitaxel** for the first-line treatment of patients with metastatic nonsquamous NSCLC.
- Taiwan Liposome Company, Ltd. (tlcbio.com) announced the submission of an investigational new drug application with the FDA to initiate a Phase I/II, open label, dose-escalation clinical trial of **TLC178**, a NanoX™ liposomal formulation of the anticancer drug vinorelbine, in pediatric rhabdomyosarcoma patients.

Approved Devices

- Agfa (agfahealthcare.com) announced that it has received FDA 510(k) clearance for its **DR 800 multipurpose imaging system**. The device offers one solution for radiography, fluoroscopy, and advanced clinical applications.
- The FDA has granted 510(k) clearance to Exact Imaging (exactimaging.com) for its **FusionVu™ application on the ExactVu micro-ultrasound system**. FusionVu allows urologists to perform either cognitive fusion via Cognitive Assist™ or micro-ultrasound/MR fusion on the ExactVu high-resolution platform.

Genetic Tests and Assays in the News

- Cancer Genetics, Inc. (cancergenetics.com) announced that it has received 510(k) clearance from the FDA for its **Tissue of Origin (TOO®) test**, a microarray-based gene expression test that analyzes a tumor's genomic information to help identify its origin, which is valuable in classifying metastatic, poorly differentiated, or undifferentiated cancers. OI