tools

Approved Drugs

- The Food and Drug Administration (FDA) has approved **Azedra® (iobenguane I 131)** (Progenics Pharmaceuticals, Inc., progenics.com) for adult and pediatric patients (12 years and older) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.
- Genentech (gene.com), a member of the Roche Group, announced that the FDA has approved **Avastin® (bevacizumab)** for patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by single-agent bevacizumab, for stage III or IV disease after initial surgical resection.
- The FDA has approved **Braftovi™ (encorafenib) + Mektovi® (binimetinib)** (Array BioPharma, Inc., arraybiopharma.com) in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.
- Merck (merck.com) announced that the FDA has granted accelerated approval to **Keytruda® (pembrolizumab)** for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma or who have relapsed after two or more prior lines of therapy. The FDA has also approved **Keytruda** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (combined positive score ≥ 1) as determined by an FDA-approved test.
- The FDA has approved **Mircera (methoxy polyethylene glycol-epoetin beta)** (Vifor Pharma Inc., viforpharma.com) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
- The FDA has approved **Mulpleta® (lusutrombopag)** (Shionogi Inc., shionogi.com) for the treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure.
- Pfizer (pfizer.com) announced that the FDA has approved **Nivestym™ (filgrastim-aafi)** as a biosimilar for Neupogen® (filgrastim) for the treatment of chemotherapy-induced febrile neutropenia, acute myeloid leukemia, patients with cancer receiving bone marrow transplant, peripheral blood progenitor cell collection and engraftment, and severe chronic neutropenia.
- The FDA has approved **Poteligeo® (mogamulizumab-kpkc)** (Kyowa Kirin, kyowa-kirin.com) for adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.
- Agios Pharmaceuticals (agios.com) announced that the FDA has approved **Tibsovo® (ivosidenib)** for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test.
- The FDA has granted regular approval to **Venclexta® (venetoclax)** (AbbVie Inc., abbvie.com, and Genentech Inc., gene.com) for patients with chronic lymphocytic leukemia or small lymphocytic lymphoma, with or without 17p deletion, who have received at least one prior therapy.
- The FDA has approved **Xtandi® (enzalutamide)** (Astellas Pharma Inc., astellas.us) for patients with castration-resistant prostate cancer (CRPC). This approval broadens the indicated patient population to include patients with both non-metastatic CRPC and metastatic CRPC.
- The FDA has granted accelerated approval to **Yervoy® (ipilimumab)** (Bristol-Myers Squibb Company Inc., bms.com) for use in combination with Opdivo® (nivolumab) for the treatment of patients 12 years of age and older with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Drugs in the News

- Compugen Ltd. (cgen.com) has announced that that FDA has cleared Bayer AG's (bayer.com) investigational new drug application for **BAY 1905254**, an immuno-oncology therapeutic antibody targeting the ILDR2 protein in patients with advanced solid tumors.
- AbbVie (abbvie.com) announced that the FDA has accepted for priority review a supplemental new drug application (sNDA) for **Imbruvica® (ibrutinib) in combination with Rituxan® (rituximab)**

as a new treatment option for Waldenström's macroglobulinemia, a rare and incurable form of blood cancer.

- Merck (merck.com) announced that the FDA has accepted for review an sBLA for **Keytruda® (pembrolizumab)** in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous non–small cell lung cancer, regardless of PD-L1 expression.
- Amgen (amgen.com) announced that the FDA has approved the sNDA to add the positive overall survival data from the Phase III ASPIRE trial to the U.S. Prescribing Information for **Kyprolis® (carfilzomib)**. Data added to the label showed that Kyprolis, lenalidomide, and dexamethasone significantly reduced the risk of death by 21 percent and extended overall survival by 7.9 months versus lenalidomide and dexamethasone alone in patients with relapsed or refractory multiple myeloma.
- The FDA has accepted Bristol-Myers Squibb Company's (bms.com) sBLA for **Opdivo® (nivolumab)** plus low-dose **Yervoy® (ipilimumab)** for the treatment of first-line advanced non–small cell lung cancer in patients with tumor mutational burden ≥ 10 mutations per megabase.
- The FDA has accepted for filing and granted priority review designation to Pfizer Inc.'s (pfizer.com) NDA for **talazoparib**. The submission is based on results from the EMBRACA trial, which evaluated talazoparib versus chemotherapy in patients with germline (inherited) BRCA-mutated, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Talazoparib is an investigational, once-daily, oral poly-ADP ribose polymerase inhibitor.
- Roche (roche.com) announced that the FDA has granted breakthrough therapy designation for **Tecentriq® (atezolizumab) in combination with Avastin® (bevacizumab)** as a first-line treatment for people with advanced or metastatic hepatocellular carcinoma.
- AbbVie (abbvie.com) submitted an sNDA to the FDA for **Venclexta® (venetoclax) in combination with a hypomethylating agent or in combination with low-dose cytarabine** for the treatment of newly diagnosed patients with acute myeloid leukemia who are ineligible for intensive chemotherapy.

Approved Devices

- CIVCO Radiotherapy (civcort.com) and its partner Adaptiiv (adaptiiv.com) announced that they have received 510(k) clearance from the FDA to market Adaptiiv's **3D bolus software**, a customized personal medical device that uses 3D printing in the treatment of cancer.
- **PAXMAN® Scalp Cooling System** (paxmanusa.com) has been cleared by the FDA for use during treatment of patients with solid tumors. The system has been indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors such as: ovarian, breast, colorectal, bowel, and prostate cancer.
- The FDA has approved the Magtrace and Sentimag Magnetic Localization System, also known as the **Sentimag® System** (Endomagnetics Ltd., endomagnetics.com/sentimag), for detection during sentinel lymph node biopsy procedures to identify specific lymph nodes, known as sentinel lymph nodes, for surgical removal.
- Sensus Healthcare (sensushealthcare.com) announced that it has been granted 510(k) clearance by the FDA to market the **SRT-100+**, its next-generation superficial radiation therapy system for the noninvasive treatment of nonmelanoma skin cancer and keloids.

Genetic Tests and Assays in the News

- The FDA has approved Roche's (roche.com) **cobas® HPV Test** to be used as the first-line screening test for cervical cancer in women 25 and older using cervical specimens collected in SurePath preservative fluid, a collection medium commonly used for Pap tests. OI

New Indications for Kisqali®

The FDA expanded the indication for **Kisqali (ribociclib)** (Novartis, novartis.com) in combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor–positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. The FDA also expanded the indication of Kisqali in combination with fulvestrant for the treatment of postmenopausal women with hormone receptor–positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

Correction to July–August 2018 *Oncology Issues*

Text was dropped on page 16 in the Tools Department. The correct entry should read: "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." This correction has been made in the online version of the journal. The Editors apologize for the error.