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Approved Drugs

- On Nov. 16, the U.S. Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin)** (Seattle Genetics, Inc., seattlegenetics.com) injection in combination with chemotherapy for adult patients with certain types of peripheral T-cell lymphoma.
- On Nov. 20, the FDA approved **Daurismo™ (glasdegib)** (Pfizer, Inc., pfizer.com) in combination with low-dose cytarabine for newly diagnosed acute myeloid leukemia in patients who are 75 years old or older or who have comorbidities that preclude intensive induction chemotherapy.
- On Nov. 6, the FDA approved **Empliciti® (elotuzumab)** (Bristol-Myers Squibb Company, bms.com) injection for intravenous use in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.
- On Oct. 30, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) in combination with carboplatin and either paclitaxel or nab-paclitaxel as first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC).
- On Nov. 9, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) for patients with hepatocellular carcinoma who have been previously treated with sorafenib.
- On Oct. 23, the FDA approved **Khapzory™ (levoleucovorin)** (Spectrum Pharmaceuticals, Inc., sppirx.com) for injection for rescue after high-dose methotrexate therapy in patients with osteosarcoma; diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination; and the treatment of patients with metastatic colorectal cancer in combination with fluorouracil.
- On Nov. 2, the FDA granted accelerated approval to **Lorbrena® (lorlatinib)** (Pfizer, Inc., pfizer.com) for patients with ALK metastatic NSCLC whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease.
- On Oct. 16, the FDA approved **Talzenna™ (talazoparib)** (Pfizer Inc., pfizer.com) for patients with deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer.
- On Dec. 6, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, Inc., gene.com) in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- On Nov. 28, the FDA approved **Truxima™ (rituximab-abbs)** (Celltrion Inc., celltrion.com) as the first biosimilar to Rituxan® (rituximab) for patients with CD20-positive, B-cell non-Hodgkin's lymphoma to be used as a single agent or in combination with chemotherapy.
- On Nov. 2, the FDA approved **Udenyca™ (pegfilgrastim-cbqv)** (Coherus BioSciences, Inc., coherus.com) to decrease the chance of infection as suggested by febrile neutropenia in patients with nonmyeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia.
- On Nov. 21, the FDA granted accelerated approval to **Venclexta® (venetoclax)** (AbbVie Inc., abbvie.com, and Genentech, Inc., gene.com) in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia in adults who are age 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.
- On Nov. 26, the FDA granted accelerated approval to **Vitrakvi® (larotrectinib)** (Loxo Oncology Inc., loxooncology.com, and Bayer, bayer.com) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment.
- On Nov. 28, the FDA approved **Xospata® (gilteritinib)** (Astellas Pharma US Inc., astellas.com) for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia with an FLT3 mutation as detected by an FDA-approved test.

Approved Devices

- On Oct. 16, Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are eligible for treatment with Talzenna.™
- On Dec. 7, iCAD Inc. (icadmed.com) announced that the FDA has cleared **ProFound AI™**, a cancer detection software for digital breast tomosynthesis, for commercial sale and clinical use in the United States.

Devices in the News

- Aethlon Medical, Inc. (aethlonmedical.com) announced that it has received breakthrough device designation from the FDA for the advancement of the **Aethlon Hemopurifier®**, a single-use device indicated for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy and with cancer types in which exosomes have been shown to participate in the development or severity of the disease.

Drugs in the News

- The FDA has accepted for a review a supplemental new drug application (sNDA) for **Doptelet® (avatrombopag)** (Dova Pharmaceuticals, dova.com) for the treatment of chronic immune thrombocytopenia in patients who have had an insufficient response to a previous treatment.
- AbbVie Inc. (abbvie.com) announced that the FDA has accepted its sNDA for priority review for **Imbruvica® (ibrutinib) in combination with Gazyva® (obinutuzumab)** in previously untreated adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.
- Incyte Corporation (incyte.com) announced that the FDA has accepted for priority review the sNDA for **Jakafi® (ruxolitinib)** for the treatment of patients with acute graft-versus-host disease who have had an inadequate response to corticosteroids.
- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA has accepted and granted priority review for its sNDA for **Lonsurf® (trifluridine/tipiracil, TAS-102)** as a treatment for patients with previously treated its advanced or metastatic gastric adenocarcinoma, including cancer of the gastroesophageal junction.
- Loxo Oncology, Inc. (loxooncology.com) announced that the FDA has granted breakthrough therapy designation to **LOXO-292**, a selective RET inhibitor, for the treatment of patients with advanced RET fusion-positive thyroid cancer who require systemic therapy, have progressed following prior treatment, and have no acceptable alternative treatment options.
- AstraZeneca (astrazeneca.com) and Merck & Co., Inc. (merck.com) announced that the FDA has granted orphan drug designation to **Lynparza® (olaparib)** for the treatment of pancreatic cancer.
- AstraZeneca (astrazeneca.com) and Merck & Co., Inc. (merck.com) also announced that the FDA has accepted an sNDA and granted priority review for the approval of **Lynparza® (olaparib)** as a maintenance treatment in patients with newly diagnosed, BRCA-mutated advanced ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy.
- Mirati Therapeutics, Inc. (mirati.com) announced that it has submitted an investigational new drug application with the FDA to initiate a Phase I/II trial with the initial goal of evaluating the safety, tolerability, and pharmacokinetics of **MRTX849** in patients with advanced solid tumors.
- Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted an NDA and granted priority review for **quizartinib** for the treatment of adult patients with relapsed/refractory FLT3-ITD acute myeloid leukemia.
- Genentech, Inc. (gene.com) announced that the FDA has accepted the company's supplemental biologics license application and granted priority review for **Tecentriq® (atezolizumab)** plus chemotherapy (Abraxane®) for the initial (first-line) treatment of unresectable locally advanced or metastatic triple-negative breast cancer in people whose disease expresses the PD-L1 protein, as determined by PD-L1 biomarker testing.
- Genentech, Inc. (gene.com) also announced that the FDA has accepted the company's supplemental biologics license application and granted priority review for **Tecentriq® (atezolizumab)** in combination with carboplatin and etoposide (chemotherapy) for the initial (first-line) treatment of patients with extensive-stage small cell lung cancer.
- UroGen Pharma Ltd. (urogen.com) announced that the FDA has granted breakthrough therapy designation to **UGN-101 (mitomycin gel)** for instillation for the treatment of patients with low-grade upper tract urothelial cancer.

Genetic Tests and Assays in the News

- Roche (roche.com) announced the global launch of the **VENTANA pan-TRK Assay**, a pan-TRK immunohistochemistry assay that identifies wild-type and chimeric infusion proteins while measuring the prevalence of TRK in tumor tissue.
- The **LeukoStrat® CDx FLT3 Mutation Assay** (Invivoscribe Technologies, Inc., invivoscribe.com), a diagnostic used to detect the FLT3 mutation in patients with acute myeloid leukemia, has been approved for an expanded indication as a companion diagnostic with Xospata (gilteritinib).