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Approved Drugs

- On April 12, the Food and Drug Administration (FDA) granted accelerated approval to **Balversa™ (erdafitinib)** (Janssen Pharmaceutical Companies, janssen.com) for patients with locally advanced or metastatic urothelial carcinoma, with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
- On May 14, Pfizer Inc. (pfizer.com) announced that the FDA approved **Bavencio® (avelumab)** plus **Inlyta® (axitinib)** for the first-line treatment of patients with advanced renal cell carcinoma.
- On May 10, the FDA approved **Cyramza® (ramucirumab)** (Eli Lilly and Co., lilly.com) as a single agent for hepatocellular carcinoma in patients who have an alpha fetoprotein ≥400 ng/mL and have been previously treated with sorafenib.
- On April 4, the FDA announced that it is extending the indication of **Ibrance® (palbociclib)** (Pfizer Inc., pfizer.com) capsules in combination with specific endocrine therapies for hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in male patients.
- On May 24, the FDA approved **Jakafi® (ruxolitinib)** (Incyte Corporation, incyte.com) for the treatment of adult and pediatric patients ≥12 years of age with steroid-refractory acute graft-versus-host disease.
- On May 3, the FDA approved **Kadcyla® (ado-trastuzumab emtansine)** (Genentech Inc., gene.com) for use as an adjuvant treatment option for patients with HER2-positive early breast cancer who have residual invasive disease following neoadjuvant treatment with trastuzumab (Herceptin) and chemotherapy.
- On April 11, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co. Inc., merck.com) for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation or for patients with metastatic NSCLC.
- On April 19, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co. Inc., merck.com) plus axitinib for the first-line treatment of patients with advanced renal cell carcinoma.
- On June 10, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co. Inc., merck.com) for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma.
- On May 24, the FDA approved **Piqray® (alpelisib)** (Novartis Pharmaceuticals Corp., novartis.com) in combination with fulvestrant for postmenopausal women and men with hormone receptor-positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.
- On June 10, the FDA granted accelerated approval to **Polivy™ (polatuzumab vedotin-piiq)** (Genentech Inc., gene.com) in combination with bendamustine and a rituximab product for adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies.
- On May 28, the FDA approved **Revlimid® (lenalidomide)** (Celgene Corp., celgene.com) in combination with a rituximab product for previously treated follicular lymphoma and previously treated marginal zone lymphoma.
- On May 2, the FDA approved **Tibsovo® (ivosidenib)** (Agios Pharmaceuticals, Inc., agios.com) for the treatment of newly diagnosed acute myeloid leukemia with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy.

Drugs in the News

- Bayer HealthCare Pharmaceuticals, Inc. (bayer.us) announced that the FDA has granted breakthrough therapy designation for **Aliqopa™ (copanlisib)** for the treatment of adult patients with relapsed marginal zone lymphoma who have received at least two prior therapies.
- Moleculin Biotech, Inc. (moleculin.com) announced that the FDA has granted fast track designation to **Annamycin** for the treatment of relapsed or refractory acute myeloid leukemia.
- Aprea Therapeutics (aprea.com) announced that the FDA has granted fast track designation to **APR-246** for the treatment of patients with myelodysplastic syndromes who have a TP53 mutation.

The FDA also granted orphan drug designation to APR-246 for the treatment of myelodysplastic syndromes.

- Autolus Therapeutics plc (autolus.com) announced that the FDA has granted orphan drug designation to **AUTO3**, autologous enriched T-cells genetically modified with a retroviral vector to express two chimeric antigen receptors targeting CD19 and CD22, for the treatment of acute lymphoblastic leukemia.
- Biosight Ltd. (biosight-pharma.com) announced that the FDA has granted orphan drug designation to **BST-236**, an investigational novel antimetabolite, for the treatment of acute myeloid leukemia.
- Cellectar Biosciences, Inc. (cellectar.com) announced that the FDA has granted fast track designation for **CLR 131** for the fourth-line or later treatment of patients with relapsed or refractory multiple myeloma.
- Bayer HealthCare Pharmaceuticals, Inc. (bayer.us) announced that the FDA has accepted the new drug application and granted priority review to **darolutamide** for the treatment of non-metastatic castration-resistant prostate cancer.
- Janssen Pharmaceutical Companies (janssen.com) announced that the FDA has granted priority review for the supplemental biologics license application for the use of **Darzalex® (daratumumab)** in combination with bortezomib, thalidomide, and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are candidates for autologous stem cell transplant.
- Janssen Pharmaceutical Companies (janssen.com) announced that it has submitted a supplemental new drug application to the FDA seeking approval of a new indication for **Erleada® (apalutamide)** for the treatment of patients with metastatic castration-sensitive prostate cancer.
- Intensity Therapeutics, Inc. (intensitytherapeutics.com) announced that the FDA has granted fast track designation to **INT230-6** for the treatment of patients with relapsed or metastatic triple-negative breast cancer who have failed at least two prior lines of therapy.
- CytoDyn Inc. (cytodyn.com) announced that the FDA has granted fast track designation to **leronlimab (PRO140)** for use in combination with carboplatin for the treatment of patients with CCR5-positive metastatic triple-negative breast cancer.
- Sierra Oncology (sierraoncology.com) announced that the FDA has granted fast track designation to **momoletinib** for the treatment of patients with intermediate/high-risk myelofibrosis who have previously received a JAK inhibitor.
- Molecular Templates, Inc. (mtem.com) announced that the FDA has accepted its investigational new drug application for **MT-5111**, an engineered toxin body targeting HER2-positive solid tumors.
- Viracta Therapeutics, Inc. (viracta.com) announced that the FDA has granted orphan drug designation to **nanatinostat** in combination with the antiviral valganciclovir for the treatment of post-transplant lymphoproliferative disorder, plasmablastic lymphoma, and angioimmunoblastic T-cell lymphoma.
- Poseida Therapeutics Inc. (poseida.com) announced that the FDA has granted orphan drug designation to **P-BCMA-101** an autologous CAR-T therapy for the treatment of relapsed and/or refractory multiple myeloma.
- Celgene Corporation (celgene.com) announced that the FDA has granted breakthrough therapy designation to **Pomalyst® (pomalidomide)** for the treatment of patients with human immunodeficiency virus-positive Kaposi's sarcoma who have previously received systemic chemotherapy, as well as patients with human immunodeficiency virus-negative Kaposi's sarcoma.
- On May 29, the FDA approved the addition of overall survival data in labeling for **Xospata® (gilteritinib)** (Astellas Pharma US, Inc., astellas.com), indicated for adult patients who have relapsed or refractory acute myeloid leukemia with an FLT3 mutation as detected by an FDA-approved test.

Approved Devices

- Novocure (novocure.com) announced that the FDA has approved the **NovoTTF-110L System** in combination with pemetrexed plus platinum-based chemotherapy for the first-line treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma.

Devices in the News

- Natera, Inc. (natera.com) announced that the FDA has granted breakthrough device designation for the **Signatera™** test for use in the postsurgical detection and quantification of circulating tumor DNA in the blood of patients previously diagnosed with certain types of cancer and in combination with certain drugs.

Approved Genetic Tests and Assays

- On April 12, the FDA approved the ***therascreen*® FGFR RGQ RT-PCR Kit** (Qiagen, qiagen.com) as a companion diagnostic for patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations.
- Agilent Technologies Inc. (agilent.com) announced that the FDA has approved the **PD-L1 IHC 22C3 pharmDx assay** as a companion diagnostic to identify a broader range of patients with stage III or metastatic NSCLC for first-line treatment with pembrolizumab. OI