tools

Approved Drugs

- On May 22, the U.S. Food and Drug Administration (FDA) approved **Alunbrig® (brigatinib)** (Takeda Pharmaceutical Company Limited, takeda.com/en-us/) for adult patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer as detected by an FDA-approved test.
- On April 8, the FDA approved **Braftovi® (encorafenib)** (Pfizer.com, pfizer.com) in combination with **Erbitux® (cetuximab)** (Bristol Myers Squibb, bms.com) for the treatment of adult patients with metastatic colorectal cancer with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy.
- On May 29, Eli Lilly and Company (lilly.com) announced that the FDA has approved **Cyramza® (ramucirumab)**, in combination with erlotinib, for the first-line treatment of people with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 mutations.
- On May 1, the FDA approved **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)** (Janssen Biotech, Inc., janssen.com) for adult patients with newly diagnosed or relapsed/refractory multiple myeloma.
- On April 21, the FDA expanded the indication of **Imbruvica® (ibrutinib)** (Pharmacyclics LLC, pharmacyclics.com) to include its combination with rituximab for the initial treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.
- On April 15, UroGen Pharma Ltd. (urogen.com) announced that the FDA granted expedited approval for **Jelmyto™ (mitomycin)** for pyelocalyceal solution, a first-in-class treatment indicated for adults with low-grade upper tract urothelial cancer.
- Merck (merck.com) announced that the FDA has approved an additional recommended dosage of 400 mg every six weeks for **Keytruda® (pembrolizumab)**, Merck's anti-PD-1 therapy, across all adult indications, including monotherapy and combination therapy.
- On April 10, the FDA approved **Koselugo® (selumetinib)** (AstraZeneca, astrazeneca.com) for pediatric patients, two years of age and older, with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas.
- On May 8, AstraZeneca (astrazeneca.com) and Merck (merck.com) announced that **Lynparza® (olaparib)** in combination with bevacizumab has been approved in the United States for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation and/or genomic instability. Patients will be selected for therapy based on an FDA-approved companion diagnostic test.
- On May 19, the FDA approved **Lynparza® (olaparib)** (AstraZeneca and Merck, astrazeneca.com and merck.com) for adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment with enzalutamide or abiraterone.
- On May 15, the FDA approved the combination of **Opdivo® (nivolumab)** plus **Yervoy® (ipilimumab)** (Bristol Myers Squibb, bms.com) as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1 (≥1%), as determined by an FDA-approved test, with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- On May 26, the FDA approved the combination of **Opdivo® (nivolumab)** plus **Yervoy® (ipilimumab)** (Bristol Myers Squibb, bms.com) and two cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- On April 20, the FDA granted accelerated approval to **Pemazyre™ (pemigatinib)** (Incyte Corporation, incyte.com) for the treatment of adults with previously treated, unresectable locally advanced, or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test.

- On May 15, the FDA expanded the indication of **Pomalyst® (pomalidomide)** (Celgene Corporation, celegene.com) to include treating adult patients with AIDS-related Kaposi's sarcoma after failure of highly active antiretroviral therapy and Kaposi's sarcoma in adult patients who are HIV negative.
- On May 15, the FDA approved **Qinlock™ (ripretinib)** (Deciphera Pharmaceuticals, LLC, deciphera.com), for adult patients with advanced gastrointestinal stromal tumor who have received prior treatment with three or more kinase inhibitors, including imatinib.
- On April 3, the FDA approved **Reblozyl® (luspatercept-aamt)** (Bristol Meyers Squibb, bms.com) for the treatment of anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis.
- On May 8, the FDA granted accelerated approval to **Retevmo™ (selpercatinib)** (Eli Lilly and Company, lilly.com) for the following indications: adult patients with metastatic RET fusion-positive non-small cell lung cancer; adult and pediatric patients greater than 12 years of age with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy; and adult and pediatric patients greater than 12 years of age with advanced or metastatic ZET fusion-positive thyroid cancer who require systemic therapy and who are refractory to radioactive iodine (if radioactive iodine is appropriate).
- On May 15, the FDA granted accelerated approval to **Rubraca® (rucaparib)** (Clovis Oncology, Inc., clovisoncology.com) for patients with deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
- On May 6, the FDA granted accelerated approval to **Tabrecta™ (capmatinib)** (Novartis, novartis.com) for adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping as detected by an FDA-approved test.
- On May 18, the FDA approved **Tecentriq® (atezolizumab)** (Genentech Inc., gene.com) for the first-line treatment of adult patients with metastatic non-small cell lung cancer whose tumors have high PD-L1 expression (PD-L1 stained ≥50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells covering ≥10% of the tumor area [IC ≥ 10%]), with no EGFR or ALK genomic tumor aberrations.
- On May 29, the FDA approved **Tecentriq® (atezolizumab)** in combination with **Avastin® (bevacizumab)** to treat people with the most common form of liver cancer.
- On April 22, the FDA granted accelerated approval to **Trodelvy™ (sacituzumab govitecan-hziy)** (Immunomedics, Inc., immunomedics.com) for adult patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease.
- On April 17, the FDA approved **Tukysa™ (tucatinib)** (Seattle Genetics, seattlegenetics.com) in combination with trastuzumab and capecitabine for adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- On April 29, the FDA approved **Zejula® (niraparib)** (GlaxoSmithKline, us.gsk.com/en-us) for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

Drugs in the News

- Agenus Inc. (agenusbio.com) announced that the FDA has granted Agenus fast track designation for investigation of **balstilimab (anti-PD-1)** for the treatment of cervical cancer.
- EMD Serono (emdserono.com) and Pfizer Inc. (pfizer.com) announced the submission of a supplemental biologics license application (BLA) to the FDA and breakthrough therapy designation for **Bavencio® (avelumab)** for first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted its new drug application (NDA) for **CC-486**, an investigational oral hypomethylating agent, for the maintenance treatment of adult patients with acute myeloid leukemia who achieved complete remission or complete remission with incomplete blood count recovery, following induction therapy with or without consolidation treatment, and who are not candidates for, or who choose not to proceed to, hematopoietic stem cell transplantation.
- Cellectar Biosciences, Inc. (cellectar.com) that the FDA has granted fast track designation for **CLR 131** in lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia in patients who have received two or more prior treatment regimens.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo's (daiichisankyo.com) **Enhertu® (fam-trastuzumab deruxtecan-nxki)** has been granted FDA breakthrough therapy designation for the treatment of patients with HER2-positive unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma who have received two or more prior regimens including trastuzumab and orphan drug designation for the treatment of patients with gastric cancer, including gastroesophageal junction cancer.
- AVEO Oncology (aveooncology.com) announced that it has submitted an NDA to the FDA for **Fotivda® (tivozanib)**, the company's vascular endothelial growth factor receptor tyrosine kinase inhibitor, as a treatment for relapsed or refractory renal cell carcinoma.
- Bristol Myers Squibb (bms.com) and Bluebird Bio, Inc. (bluebirdbio.com) announced the submission of a BLA to the FDA for **idecabtagene vicleucel (ide-cel; bb2121)** for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.

- Merck (merck.com) announced that the FDA has accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors with tissue tumor mutational burden-high mutations/megabase, as determined by an FDA-approved test, who have progressed following prior treatment and who have no satisfactory alternative treatment options.
- Novartis (novartis.com) announced that the FDA granted regenerative medicine advanced therapy designation to **Kymriah® (tisagenlecleucel)** for an investigational new indication to treat patients with relapsed or refractory follicular lymphoma.
- Merck (merck.com) announced the U.S. launch of **Ontruzant® (trastuzumab-dttb)**, as a biosimilar of the reference biologic medicine Herceptin® (trastuzumab).
- Medivir AB (medivir.com) announced that the FDA has granted orphan drug designation to **MIV-818** for the treatment of patients with hepatocellular carcinoma, the most common type of primary liver cancer.
- Marker Therapeutics, Inc. (markertherapeutics.com) announced that the FDA granted orphan drug designation to **MT-401**, a multi-tumor-associated antigen-specific T-cell product for the treatment of patients with acute myeloid leukemia, following allogeneic stem cell transplant.
- Cardiff Oncology, Inc. (cardiffoncology.com) announced that the FDA granted fast track designation to **onvansertib**, its oral and highly selective polo-like kinase 1 inhibitor, for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer.
- Precigen, Inc. (precigen.com) announced that the FDA has cleared the investigational NDA to initiate a Phase I/II trial for Precigen's **PRGN-2009**, an investigational immunotherapy utilizing the AdenoVerse™ platform designed to activate the immune system to recognize and target HPV+ solid tumors.
- Hutchison China MediTech Limited (chi-med.com) announced that the FDA has granted two fast track designations for the development of **surufatinib** for the treatment of both advanced and progressive pancreatic neuroendocrine tumors and extra-pancreatic (non-pancreatic) neuroendocrine tumors in patients who are not amenable for surgery.
- Karyopharm Therapeutics (karyopharm.com) has submitted a supplemental NDA to the FDA seeking approval for **Xpovio® (selinexor)**, its first-in-class, oral selective inhibitor of nuclear export compound, as a new treatment for patients with previously treated multiple myeloma.

Approved Genetic Tests and Assays

- Caris Life Sciences® (carislifesciences.com) announced the submission of two pre-market approval applications for **MI Exome™ CDx** and **MI Transcriptome™ CDx** to the FDA. MI Exome™ CDx, whole exome sequencing (DNA), and MI Transcriptome™ CDx, whole transcriptome sequencing (RNA), are precision medicine assays that include key companion diagnostic biomarkers with therapy claims and detect all classes of alterations, including genomic signatures for microsatellite instability, tumor mutation burden, and loss of heterozygosity.
- Myriad Genetics, Inc. (myriad.com) announced that the FDA approved the **myChoice CDx®** test for use as a companion diagnostic by healthcare professionals to identify patients with advanced ovarian cancer with positive homologous recombination deficiency status who are eligible or may become eligible for first-line maintenance treatment with Lynparza® (olaparib) in combination with bevacizumab.
- Roche (roche.com) announced FDA approval for the **cobas® HPV test** for use on the fully automated, high-throughput cobas 6800/8800 Systems. The cobas HPV test identifies women at risk for cervical cancer by detecting the presence of high-risk human papillomavirus DNA in cervical samples.
- Personal Genome Diagnostics, Inc. (personalgenome.com) received FDA clearance for **PGDx elio™** tissue complete, the first genomic profiling diagnostic kit for oncology.
- Sectra (sectra.com) has received a 510(k) clearance by the FDA for **Sectra Digital Pathology Module** when used together with Leica Biosystems' scanner AT2 DX. This enables healthcare providers to use Sectra's digital pathology solution for primary diagnostics.
- Qiagen (qiagen.com) announced launch of its novel **therascreen® BRAF V600E RGQ PCR Kit (therascreen BRAF V600E Kit)** following FDA approval as a companion diagnostic to the BRAF inhibitor Braftovi® (encorafenib), which the FDA has approved for use in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy. OI

RxVantage Virtual Meetings

This digital solution helps providers reconnect with life science experts and resources that have been severely disrupted by COVID-19-related social distancing. Seamlessly integrated into the RxVantage platform, with one click practices can turn any in-person appointment into a secure virtual meeting, equipped with two-way high-definition video, audio, and screen sharing. Virtual meetings can also be started instantly with more than 60,000 product experts, nurse educators, reimbursement specialists, or medical science liaisons who are members of the RxVantage expert community. Free for all healthcare providers. Learn more at rxvantage.com.