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Approved Drugs

- On Nov. 25, Y-mAbs Therapeutics, Inc. (ymabs.com) announced that the U.S. Food and Drug Administration (FDA) approved **Danyelza® (naxitamab-gqgk)** in combination with granulocyte-macrophage colony-stimulating factor for the treatment of pediatric patients one year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.
- On Dec. 1, the FDA approved **Gallium 68 PSMA-11 (Ga 68 PSMA-11)** (University of California, Los Angeles, ucla.edu and the University of California, San Francisco, ucsf.edu), the first drug for positron emission tomography imaging of prostate-specific membrane antigen positive lesions in men with prostate cancer.
- On Dec. 1, the FDA approved **Gavreto™ (pralsetinib)** (Blueprint Medicines, blueprintmedicines.com) for adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer who require systemic therapy or RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine refractory (if radioactive iodine is appropriate).
- On Oct. 14, the FDA extended the approval of **Keytruda® (pembrolizumab)** (Merck, merck.com) for the following indications: adult patients with relapsed or refractory classical Hodgkin's lymphoma and pediatric patients with refractory classical Hodgkin's lymphoma or classical Hodgkin's lymphoma that has relapsed after two or more lines of therapy.
- On Nov. 13, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 as determined by an FDA-approved test.
- On Oct. 16, the FDA granted regular approval to **Venclexta® (venetoclax)** (AbbVie Inc., abbvie.com and Genentech Inc., gene.com) in combination with azacitidine, decitabine, or low-dose cytarabine for newly diagnosed acute myeloid leukemia in adults 75 years or older or who have comorbidities precluding intensive induction chemotherapy.

Drugs in the News

- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced the submission of a biologics license application (BLA) to the FDA seeking approval of **amivantamab** for the treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.
- Apexigen, Inc. (apexigen.com) announced that the FDA has granted orphan drug designation status to **APX005M** for the treatment of esophageal and gastro-esophageal junction cancer and for the treatment of pancreatic cancer.
- Rafael Pharmaceuticals, Inc. (rafael-pharma.com) announced today that FDA has granted fast track designation to **CPI-613® (devimistat)** for the treatment of metastatic pancreatic cancer.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo's (daiichisankyo.com) **Enhertu® (trastuzumab deruxtecan)** received FDA acceptance of its supplemental BLA and has also been granted priority review in the United States for the treatment of patients with human epidermal growth factor receptor 2-positive metastatic gastric or gastro-esophageal junction adenocarcinoma.
- Aprea Therapeutics, Inc. (aprea.com) announced that the FDA has granted fast track designation for **eprenetapopt** in the treatment of patients with TP53-mutant acute myeloid leukemia.
- BridgeBio Pharma, Inc. (bridgebio.com) announced that the FDA has accepted its new drug application (NDA) for **infigratinib** for individuals with cholangiocarcinoma or cancer of the bile ducts.
- Regeneron Pharmaceuticals, Inc. (regeneron.com) announced that the FDA has accepted for priority review its supplemental BLA for PD-1 inhibitor **Libtayo® (cemiplimab-rwlc)** to treat patients with first-line locally advanced or metastatic non-small cell lung cancer with greater than or equal to 50 percent PD-L1 expression.
- ADC Therapeutics SA (adctherapeutics.com) announced that the FDA has accepted its BLA and granted priority review status for **Lonca (loncastuximab tesirine)** for the treatment of relapsed or refractory diffuse large B-cell lymphoma.

- Ipsen (ipsen.com) announced that the FDA has granted fast track designation for **Onivyde® (irinotecan liposome injection)** as a second-line monotherapy treatment of small cell lung cancer.
- Bristol Myers Squibb (bms.com) and Exelixis, Inc. (exelixis.com) announced that the FDA has accepted the supplemental BLA and supplemental NDA, respectively, for **Opdivo® (nivolumab) in combination with Cabometyx® (cabozantinib)** for patients with advanced renal cell carcinoma.
- PMV Pharmaceuticals, Inc. (pmvpharma.com) announced that the FDA has granted fast track designation to **PC14586** for the treatment of patients with cancer with locally advanced or metastatic solid tumors that have a p53 Y220C mutation.
- PTC Therapeutics, Inc. (ptcbio.com) announced that the FDA has granted **PTC596** orphan drug designation and fast track designation for the potential treatment of leiomyosarcoma. Furthermore, the FDA has granted **PTC596** a rare pediatric disease designation and orphan drug designation for the potential treatment of diffuse intrinsic pontine glioma.
- RhoVac (rhovac.com) announced that the FDA granted fast track designation to **RV001**, the company's prostate cancer drug candidate.
- Surface Oncology (surfaceoncology.com) announced that the FDA has granted fast track designation to **SRF388** for the treatment of patients with hepatocellular carcinoma, or liver cancer, who have been previously treated with standard therapies, such as vascular endothelial growth factor targeted agents and programmed death ligand blockade.
- AstraZeneca (astrazeneca.com) announced it received acceptance from the FDA for its supplemental NDA and has also been granted priority review for **Tagrisso® (osimertinib)** for the adjuvant treatment of patients with early stage (IB, II, and IIIA) EGFR-mutated non-small cell lung cancer after complete tumor resection with curative intent.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA has granted fast track designation to the combination of **ublituximab and umbralisib** for the treatment of adult patients with chronic lymphocytic leukemia. The company has initiated a rolling submission of a BLA to the FDA requesting approval of **ublituximab** and **umbralisib** for the treatment of patients with chronic lymphocytic leukemia.
- Zymeworks Inc. (zymeworks.com) announced that the FDA has granted breakthrough therapy designation for **zanidatamab** in patients with previously treated human epidermal growth factor receptor 2 gene-amplified biliary tract cancer.

Approved Genetic Tests and Assays

- 4D Path (4dpath.com) announced that the FDA granted breakthrough device designation for its patented computer-aided cancer diagnostic and precision oncology platform, which has demonstrated promise of significant improvements over the existing standard of care.
- Roche (roche.com) announced FDA approval of expanded claims for the **cobas® EGFR Mutation Test v2** as a companion diagnostic for a broader group of therapies in the treatment of non-small cell lung cancer. This claim expansion allows the test to be used as a companion diagnostic for all five currently FDA-approved EGFR tyrosine kinase inhibitor therapies targeting EGFR mutations L858R and exon 19 deletions in accordance with the approved therapeutic product labelling.
- enGene Inc. (engene.com) announced that the FDA has granted fast track designation to **enGene for EG-70**, the company's lead investigational non-viral gene therapy, for the treatment of patients with Bacille Calmette-Guerin-unresponsive non-muscle-invasive bladder cancer.
- The FDA approved the next-generation sequencing-based **FoundationOne®CDx** test (Foundation Medicine, Inc., foundationmedicine.com) as a companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase (NTRK) genes NTRK1, NTRK2, and NTRK3 in DNA isolated from tumor tissue specimens from patients with solid tumors eligible for treatment with Vitrakvi® (larotrectinib).
- Foundation Medicine, Inc. (foundationmedicine.com) announced that the FDA approved **FoundationOne® Liquid CDx** for three new companion diagnostic indications to help match patients who may benefit from treatment with specific FDA-approved targeted therapies. The new indications are for Piqray® (alpelisib) in advanced or metastatic breast cancer; Rubraca® (rucaparib) in advanced ovarian cancer; and Alecensa® (alectinib) in a certain type of metastatic non-small cell lung cancer. The FDA also approved a label expansion for FoundationOne Liquid CDx to report additional select copy number alterations and genomic rearrangements and an expanded indication to identify patients with BRCA1, BRCA2, and/or ATM alterations in metastatic castration-resistant prostate cancer who may be appropriate for treatment with Lynparza® (olaparib).
- MiR Scientific (mirscientific.com) announced that it has received FDA breakthrough device designation for its **miR Sentinel™ PCC4 Assay (miR Sentinel Prostate Test)**.
- Agilent Technologies Inc. (agilent.com) announced that it has received FDA approval for the use of **PD-L1 IHC 22C3 pharmDx** as an aid in identifying patients with triple-negative breast cancer for treatment with Keytruda® (pembrolizumab).

AI Tools

- Ezra (ezra.com) announced that it has received FDA 510(k) premarket authorization for its artificial intelligence (AI), designed to decrease the cost of magnetic resonance imaging-based cancer screening, assisting radiologists in their analysis of prostate magnetic resonance imaging scans. It is the first prostate AI to be cleared by the FDA.
- Braid Health (braid.health/www) secured FDA clearance for its AI-powered diagnostic collaboration software, improving diagnostic access and reducing costs for large healthcare systems, urgent care clinics, and retail clinics. The Braid mobile application allows providers and radiologists to access, review, and annotate images and share results with patients in real time from any mobile device. OI