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Approved Drugs

- On December 16, the U.S. Food and Drug Administration (FDA) approved **Adstiladrin® (nadofaragene firadenovec-vncg)** (Ferring Pharmaceuticals, ferring.com) for adult patients with high-risk, Bacillus Calmette-Guérin unresponsive, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors.

- On January 19, the FDA approved **Brukinsa® (zanubrutinib)** (BeiGene, beigene.com) for the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma.

- On December 16, the FDA approved the targeted imaging agent **Cytalux® (pafolacianine)** (On Target Laboratories, ontargetlabs.com) for use in lung cancer surgery.

- On January 27, the FDA granted accelerated approval to **Jaypirca® (pirtobrutinib)** (Eli Lilly and Company, lilly.com) for the treatment of relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a BTK inhibitor.

- On January 26, the FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com) for adjuvant treatment following resection and platinum-based chemotherapy for Stages IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC).

- On December 12, the FDA granted accelerated approval to **Krazati® (adagrasib)** (Mirati Therapeutics, mirati.com) for the treatment of adult patients with KRAS-G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy.

- On December 22, the FDA granted accelerated approval to **Lunsumio™ (mosunetuzumab-axgb)** (Genentech, gene.com) for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

- On January 27, the FDA approved **Orserdu™ (elacestrant)** (Stemline Therapeutics, stemline.com) for the treatment of postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, with disease progression following at least one line of endocrine therapy.

- On December 19, Eagle Pharmaceuticals (eagleus.com) announced that the FDA approved an additional indication for **Pemfexy® (pemetrexed injection) in combination with pembrolizumab and platinum chemotherapy** for the initial treatment of patients with metastatic, non-squamous, NSCLS with no EGFR or ALK genomic tumor aberrations.

- On December 1, the FDA approved **Rezlidhia® (olutasidenib)** (Rigel Pharmaceuticals, rigel.com) for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible IDH1 mutation, as detected by an FDA-approved test.

- On December 9, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, gene.com) for the treatment of adult and pediatric patients (2 years of age and older) with unresectable or metastatic alveolar soft part sarcoma.

- On February 3, the FDA approved **Trodelvy® (sacituzumab govitecan-hziy)** (Gilead Sciences, gilead.com) for the treatment of patients with unresectable, locally advanced or metastatic, HR-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer, who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

- On January 19, the FDA granted accelerated approval to **Tukysa® (tucatinib)** (Seagen, seagen.com) **in combination with trastuzumab** for the treatment of RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

- On December 14, the FDA approved the updated labeling for **Xeloda® (capecitabine)** tablets (Genentech, gene.com).

Drugs In the News

- Mirati Therapeutics (mirati.com) announced that the FDA granted breakthrough therapy designation to **adagrasib in combination with cetuximab** for the treatment of patients with KRASG12C-mutated, advanced colorectal cancer, whose cancer has progressed following prior treatment with chemotherapy and an anti-VEGF therapy.

- Blueprint Medicines (blueprintmedicines.com) announced that the FDA accepted the supplemental new drug application for **Ayvakit® (avapritinib)** for the treatment of adults with indolent systemic mastocytosis.

- Bicycle Therapeutics (bicycletherapeutics.com) announced that the FDA granted fast track designation to **BT8009** to treat adult patients with previously treated locally advanced or metastatic urothelial cancer.

- Checkpoint Therapeutics (checkpointtx.com) announced the submission of a biologics license application (BLA) to the FDA for the approval of **cosibelimab** as a treatment for patients with metastatic cutaneous or locally advanced squamous cell carcinoma, who are not candidates for curative surgery or radiation.

- Genentech (gene.com) announced that the FDA accepted and granted priority review to the BLA for **glofitamab** to treat people with relapsed or refractory large B-Cell lymphoma.

- Seagen (seagen.com), Astellas Pharma (https://www.astellas.com/us/), and Merck (merck.com) announced that the FDA accepted for priority review the supplemental BLAs for **Padcev® (enfortumab vedotin-ejfv) and Keytruda** for the use of these two agents in combination for the treatment of patients with locally advanced or metastatic urothelial cancer, who are not eligible to receive cisplatin-containing chemotherapy.

- Fennec Pharmaceuticals (fennecpharma.com) announced that the FDA granted orphan drug exclusivity to **Pedmark® (sodium thiosulfate)** to reduce the risk of ototoxicity, or hearing loss, associated with cisplatin use in pediatric patients one month of age and older with localized, non-metastatic solid tumors.

- Mesoblast Limited (mesoblast.com) announced that it resubmitted to the FDA a BLA for **remestemcel-L** for the treatment of children with steroid-refractory, acute graft-versus-host disease.

- Syndax Pharmaceuticals (syndax.com) announced that the FDA granted breakthrough therapy designation to **revumenib** for the treatment of adult and pediatric patients with relapsed or refractory acute leukemia harboring a KMT2A rearrangement.

- Janssen (janssen.com) announced the submission of a BLA to the FDA for **talquetamab** for the treatment of patients with relapsed or refractory multiple myeloma.

- Syros Pharmaceuticals (syros.com) announced that the FDA granted fast track designation to **tamibarotene (formerly SY-1425)** for the treatment of higher-risk myelodysplastic syndrome.

Devices and Assays in the News

- Geneoscopy (geneoscopy.com) announced that it submitted a premarket approval application to the FDA for its non-invasive, stool-based, at-home screening test to detect colorectal cancer and advanced adenomas in average-risk individuals.

- Agilent Technologies (agilent.com) announced that the FDA approved **Agilent Resolution ctDx FIRST** as a companion diagnostic to identify patients with advanced NSCLC with KRAS G12C mutations who may benefit from treatment with Krazati™ (adagrasib).

- Foundation Medicine (foundationmedicine.com) announced that the FDA approved the **FoundationOne®Liquid CDx** as a companion diagnostic to identify patients with ROS1-positive NSCLC or patients with NTRK fusion-positive solid tumors, who do not have a tissue sample available and may be appropriate for treatment with Rozlytrek® (entrectinib) (Genentech, gene.com). This device was also approved by the FDA as companion diagnostic to identify patients with NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitutions and are appropriate for treatment with a group of current and future EGFR tyrosine kinase inhibitors (TKI) approved by the FDA for this indication.

- Guardant Health (guardanthealth.com) announced that the FDA approved the **Guardant360® CDx** liquid biopsy test as a companion diagnostic to identify individuals with advanced or metastatic breast cancer with ESR1 mutations who may benefit from treatment with Orserdu.

- Burning Rock (us.brbiotech.com) announced that the FDA granted breakthrough device designation to its **OverC™ Multi-Cancer Detection Blood Test.**

- Datar Cancer Genetics (datarpgx.com) announced that the FDA granted breakthrough device designation to **TriNetra™-Glio**, a blood test to help in the diagnosis of brain tumors. OI