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Approved Drugs

- On November 15, the US Food and Drug Administration (FDA) approved **Augtyro® (repotrectinib)** (Bristol Myers Squibb, bms.com) for patients with locally advanced or metastatic, ROS1-positive non-small cell lung cancer (NSCLC).

- On November 8, the FDA approved **Fruzaqla® (fruquintinib)** (Takeda Pharmaceuticals, Inc., takeda.com) for adult patients with metastatic colorectal cancer who received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-VEGF therapy; and, if the tumor is *RAS* wild-type and it is medically appropriate, an anti-EGFR therapy.

- On December 13, the FDA approved **Iwilfin® (eflornithine)** (US WorldMeds, usworldmeds.com) to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

- On December 1, the FDA granted accelerated approval to **Jaypirca® (pirtobrutinib)** (Eli Lilly and Company, lilly.com) for adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy that included a Bruton tyrosine kinase (BTK) inhibitor and a BCL2 inhibitor.

- On January 12, 2024, the FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com) given in combination with chemoradiotherapy for patients with International Federation of Gynecology and Obstetrics 2014 stage III-IVA cervical cancer. On November 16, the FDA approved **Keytruda in combination with fluoropyrimidine- and platinum-containing chemotherapy** for the first-line treatment of adults with locally advanced, unresectable or metastatic, HER2-negative (HER2–) gastric or gastroesophageal junction adenocarcinoma. On November 7, the FDA revised the existing indication of **Keytruda in combination with trastuzumab, fluoropyrimidine, and platinum-containing chemotherapy** for the first-line treatment of patients with locally advanced, unresectable or metastatic, HER2-positive gastric or gastroesophageal junction adenocarcinoma. On October 31, the FDA approved **Keytruda in combination with gemcitabine and cisplatin** for patients with locally advanced, unresectable or metastatic biliary tract cancer.

- On November 27, the FDA approved **Ogsiveo® (nirogacestat)** (SpringWorks Therapeutics, Inc., springworkstx.com) for adult patients with progressing desmoid tumors who require systemic treatment. This is the first approved treatment for desmoid tumors.

- On December 15, the FDA approved **Padcev® (enfortumab vedotin-ejfv)** (Astellas Pharma Inc., astellas.com) in **combination with Keytruda (pembrolizumab)** (Merck, merck.com) for patients with locally advanced or metastatic urothelial cancer.

- On November 16, the FDA approved **Truqap® (capivasertib)** (AstraZeneca Pharmaceuticals, astrazeneca.com) **in combination with fulvestrant** for adult patients with hormone receptor-positive (HR+)/HER2–, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

- On December 14, the FDA approved **Welireg® (belzutifan)** (Merck, merck.com) for patients with advanced renal cell carcinoma following a PD-1 or PD-L1 inhibitor and a tyrosine kinase inhibitor that targets VEGF.

- On November 16, the FDA approved **Xtandi® (enzalutamide)** (Astellas Pharma Inc., astellas.com) for patients with nonmetastatic, castration-sensitive prostate cancer with biochemical recurrence who are at high risk for metastasis.

Drugs In the News

- Oxford BioTherapeutics (oxford-biotherapeutics.com) announced that the FDA has granted fast track designation to **BI 764532** for the treatment of patients with advanced or metastatic, large-cell neuroendocrine carcinoma of the lung expressing DLL3 whose disease has progressed following at least 1 prior line of treatment including platinum-based chemotherapy.

- Bristol Myers Squibb (bms.com) announced that the FDA has accepted the supplemental biologics license application (BLA) for **Breyanzi® (lisocabtagene maraleucel)** to expand its current indication to include the

treatment of adult patients with relapsed or refractory CLL or SLL who received a prior BTK inhibitor and a BCL2 inhibitor.

- CG Oncology, Inc. (cgoncology.com) announced that the FDA has granted both fast track designation and breakthrough therapy designation for **cretostimogene grenadenorepvec** in patients with high-risk, Bacillus Calmette-Guérin-unresponsive, nonmuscle invasive bladder cancer with carcinoma in situ with or without Ta or T1 (papillary) tumors.

- Seagen Inc. (seagen.com) and Astellas Pharma Inc.(astellaspharma.com) announced that the FDA accepted for priority review a supplemental BLA for **Padcev® (enfortumab vedotin-ejfv) in combination with Keytruda (pembrolizumab)** for the treatment of adult patients with locally advanced or metastatic urothelial cancer.

- Daiichi Sankyo (daiichisankyo.com) and Merck (merck.com) announced that the FDA has accepted and granted priority review to the BLA for **patritumab deruxtecan** (HER3-DXd) for the treatment of adult patients with locally advanced or metastatic, *EGFR*-mutated NSCLC who were previously treated with 2 or more systemic therapies.

- RemeGen Co. Ltd. (remegen.com) announced that the FDA granted fast track designation to **RC88** for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, and primary peritoneal cancers.

- ProfoundBio (profoundbio.com) announced that the FDA has granted fast track designation for **rinatabart sesutecan** (Rina-S; PRO1184), a FRα-targeted antibody-drug conjugate, for the treatment of patients with FRα-expressing, high-grade, serous or endometrioid, platinum-resistant ovarian cancer.

- Janssen Pharmaceutical (jnj.com) announced the submission of a supplemental BLA to the FDA for **Rybrevant® (amivantamab-vmjw) in combination with carboplatin and pemetrexed** for the treatment of patients with locally advanced or metastatic NSCLC with *EGFR* exon 19 deletions or L858R substitution after disease progression on or after osimertinib.

- SELLAS Life Sciences Group, Inc. (sellaslifesciences.com) announced that the FDA has granted fast track designation to **SLS009** (formerly GFH009) for the treatment of patients with relapsed/refractory acute myelocytic leukemia.

- SonALAsense (sonalasense.com) announced that the FDA has granted fast track designation to the development program of **SONALA-001** in combination with the INSIGHTEC Exablate 4000 Type-2 device for the treatment of patients with diffuse intrinsic pontine glioma.

- eFFECTOR Therapeutics, Inc. (effector.com) announced that the FDA has granted fast track designation for **zotatifin in combination with fulvestrant and abemaciclib** (ZFA triplet) as second- or third-line therapy for the treatment of adult patients with estrogen receptor-positive/HER2-, advanced or metastatic breast cancer with disease progression following endocrine therapy and treatment with a CDK4/6 inhibitor.

Devices and Assays

- Geneseeq Technology Inc. (geneseeq.com) announced that its multicancer early detection solution **CanScan™** has been granted breakthrough device designation by the FDA.

- On November 20, the FDA approved **FoundationOne®CDx** (Foundation Medicine, foundationmedicine.com) as a companion diagnostic for **Truqap™ (capivasertib) in combination with Faslodex® (fulvestrant)** for the treatment of adult patients with HR+/HER2–, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy. OI