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Approved Drugs

- On Sept. 4, the U.S. Food and Drug Administration (FDA) granted accelerated approval to **Gavreto™ (pralsetinib)** (Blueprint Medicines Corporation, blueprintmedicines.com) for adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer as detected by an FDA-approved test.
- On Aug. 20, the Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) and Amgen (amgen.com) announced that the FDA approved the expansion of the **Kyprolis® (carfilzomib)** prescribing information to include its use in combination with **Darzalex® (daratumumab) plus dexamethasone** in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.
- On Sept. 1, Bristol Myers Squibb (bms.com) announced that the FDA approved **Onureg® (azacitidine)** for the continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and who are not able to complete intensive curative therapy.
- On Oct. 2, the FDA approved the combination of **Opdivo® (nivolumab) plus Yervoy® (ipilimumab)** (Bristol-Myers Squibb, bms.com) as first-line treatment for adult patients with unresectable malignant pleural mesothelioma.
- On Sept. 8, Athena Bioscience (athenabioscience.com) announced that the FDA has approved **Qdolo™ (tramadol hydrochloride)** oral solution 5 mg/1 mL C-IV, an opioid agonist indicated in adults, for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Drugs in the News

- Ascentage Pharma (ascentagepharma.com) announced that the FDA has granted **APG-2575**, its novel Bcl-2 inhibitor, orphan drug designation for the treatment of chronic lymphocytic leukemia. The company also announced that the FDA has granted two orphan drug designations to two of the company's apoptosis-targeting assets: the MDM2-p53 inhibitor, **APG-115**, for the treatment of acute myeloid leukemia; and the Bcl-2/Bcl-xL inhibitor, **APG-1252**, for the treatment of small cell lung cancer.
- Exelixis (exelixis.com) announced the submission of supplemental new drug application (NDA) to the FDA for **Cabometyx® (cabozantinib)** in combination with Opdivo (nivolumab) for advanced renal cell carcinoma.
- CARsgen Therapeutics Co., Ltd. (carsgen.com) announced that the FDA has granted orphan drug designation to **CT041** for the treatment of gastric and gastroesophageal junction adenocarcinoma.
- RemeGen Co., Ltd. (remegen.com) announced that the FDA has granted breakthrough therapy designation for **disitamab vedotin (RC48)** for the second-line treatment of patients with human epidermal growth factor receptor 2-positive locally advanced or metastatic urothelial cancer who have also previously received platinum-containing chemotherapy treatment.
- Leap Therapeutics, Inc. (leaptx.com) announced that the FDA has granted fast track designation to **DKN-01** for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high Dickkopf-1 protein, following disease progression on or after prior fluoropyrimidine- and platinum-containing chemotherapy and, if appropriate, human epidermal receptor growth factor/neu-targeted therapy.
- ESSA Pharma Inc. (essapharma.com) announced that the FDA granted fast track designation to **EPI-7386** for the treatment of adult male patients with metastatic castration-resistant prostate cancer resistant to standard-of-care treatment.
- The FDA granted **Gavreto™ (pralsetinib)** (Blueprint Medicines Corporation, blueprintmedicines.com) priority review for the treatment of people with advanced or metastatic RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer.
- Gan & Lee Pharmaceuticals Co., Ltd. (ganlee.com/en/) announced that the FDA has granted orphan drug designation to **GLR2007** for the treatment of malignant glioma.

- Bristol Myers Squibb (bms.com) and bluebird bio, Inc. (bluebirdbio.com) announced that the FDA has accepted for priority review their biologics license application (BLA) 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.
- AstraZeneca (astrazeneca.com) announced that the FDA has accepted a supplemental BLA for **Imfinzi® (durvalumab)** and has also been granted priority review for a new four-week, fixed-dose regimen for treatment in the approved indications of non-small cell lung cancer and bladder cancer.
- ImmunoGen, Inc. (immunogen.com) announced that the FDA has granted breakthrough therapy designation for **IMGN632** for the treatment of patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm.
- Alphamab Oncology (alphamabonc.com/en/) announced that the FDA has granted orphan drug designation to **KN046** for the treatment of thymic epithelial tumors.
- Oncopeptides (oncopeptides.se/en) announced that the FDA has granted priority review for the NDA seeking approval of **melflufen (INN melphalan flufenamide)** in combination with dexamethasone for the treatment of adult patients with multiple myeloma whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody.
- The FDA has awarded rare pediatric disease designation for diffuse intrinsic pontine glioma and orphan drug designation for treatment of malignant glioma to **OKN-007**, an investigational drug discovered at the Oklahoma Medical Research Foundation and being developed by Oblato, Inc.
- Athenex, Inc. (athenex.com) announced that the FDA has accepted for filing the NDA and granted priority review for **oral paclitaxel and encequidar (Oral Paclitaxel)** for the treatment of metastatic breast cancer.
- Kazia Therapeutics Limited (kaziatherapeutics.com) announced that the FDA has awarded rare pediatric disease designation to **paxalisib (formerly GDC-0084)** for the treatment of diffuse intrinsic pontine glioma, a rare and highly aggressive childhood brain cancer.
- Kazia Therapeutics Limited (kaziatherapeutics.com) announced that the FDA has granted fast track designation to **paxalisib (formerly GDC-0084)** for the treatment of glioblastoma, the most common and most aggressive form of primary brain cancer.
- Precision BioSciences, Inc. (precisionbiosciences.com) announced that the FDA has granted fast track designation to **PBCAR0191**, the company's lead investigational allogeneic chimeric antigen receptor T cell therapy for the treatment of advanced B-cell precursor acute lymphoblastic leukemia.
- EMD Serono (emdgroup.com/en) announced that the FDA has accepted and granted priority review to the NDA for **tepotinib** for the treatment of 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.
- G1 Therapeutics, Inc. (g1therapeutics.com) announced that the FDA has accepted the NDA and granted priority review to **trilaciclib** for small cell lung cancer patients being treated with chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA has accepted an NDA for **umbralisib (TGR-1202)** as a treatment for patients with previously treated marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and follicular lymphoma who have received at least two prior systemic therapies.
- Pfizer Inc. (pfizer.com) announced that the FDA has accepted and granted priority review to the supplemental NDA for **Xalkori® (crizotinib)** for the treatment of pediatric patients with relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase-positive.
- Mersana Therapeutics, Inc. (mersana.com) announce that the FDA has granted fast track designation for **XMT-1536** for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received up to three prior lines of systemic therapy or patients who have received four prior lines of systemic therapy regardless of platinum status.
- Kite Pharma (kitepharma.com) announced that it has submitted a supplemental BLA to the FDA for **Yescarta® (axicabtagene ciloleucel)** for the treatment of relapsed or refractory follicular lymphoma and marginal zone lymphoma after two or more prior lines of systemic therapy.

Approved Genetic Tests and Assays

- The FDA approved Foundation Medicine, Inc.'s (foundationmedicine.com) **FoundationOne®Liquid CDx**, a comprehensive pan-tumor liquid biopsy test with multiple companion diagnostic indications for patients with advanced cancer. FDA approval includes companion diagnostic claims for Rubraca® (rucaparib) and three tyrosine kinase inhibitors for non-small cell lung cancer.
- Genetron Holdings Limited (en.genetronhealth.com) announced that its blood-based next-generation sequencing test **HCCscreen™** has been granted breakthrough device designation by the FDA for early detection of hepatocellular carcinoma in individuals who are designated to be at high risk for hepatocellular carcinoma due to chronic hepatitis B virus infection and/or liver cirrhosis.
- The FDA has granted premarket approval to Thermo Fisher Scientific's (thermofisher.com/us/en/home.html) **Oncomine Dx Target Test** as a companion diagnostic to identify patients with RET fusion-positive metastatic non-small cell lung cancer who are candidates for Gavreto™ (pralsetinib). OI