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Approved Drugs

- On September 24, the Food and Drug Administration (FDA) approved **Copiktra™ (duvelisib)** (Verastem, Inc., verastem.com) for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma after at least two prior therapies. It also received accelerated approval for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies.
- On August 27, AbbVie Inc. (abbvie.com) announced that the FDA approved **Imbruvica® (ibrutinib)** plus rituximab for the treatment of adult patients with Waldenström's macroglobulinemia.
- On August 17, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, nonsquamous non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR) or ALK genomic tumor aberrations.
- On August 16, the FDA approved **Lenvima® (lenvantinib)** (Eisai Inc., eisai.com) for first-line treatment of patients with unresectable hepatocellular carcinoma. Approval was based on an international, multicenter, randomized, open-label, noninferiority trial conducted in 954 patients with previously untreated, metastatic, or unresectable hepatocellular carcinoma.
- On September 28, the FDA approved **Libtayo® (cemiplimab-rwlc)** (Sanofi, sanofi.com, and Regeneron, regeneron.com) for the treatment of patients with metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.
- On September 13, the FDA approved **Lumoxiti™ (moxetumomab pasudotox-tdfk)** (AstraZeneca, astrazeneca.com) for the treatment of adult patients with relapsed or refractory hairy cell leukemia who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog.
- On August 17, Bristol-Myers Squibb Company (bms.com) announced that the FDA has approved **Opdivo® (nivolumab)** for patients with metastatic small cell lung cancer whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy.
- On September 27, the FDA approved **Vizimpro® (dacomitinib)** (Pfizer Inc., pfizer.com) for the first-line treatment of patients with metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Approved Devices

- Roche (roche.com) announced that it has received approval from the FDA for the **cobas® EGFR Mutation Test v2** as a companion diagnostic test for Iressa.®
- On August 16, the FDA approved the **Dako PD-L1 IHC 22C3 PharmDx Assay** (Dako North America, Inc., agilent.com) as a companion diagnostic to select patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible for treatment with Keytruda.®

Drugs in the News

- Medsenic SAS (medsenic.com) announced that the FDA has granted orphan drug designation to **Arscimed® (arsenic trioxide)** for the treatment of graft-versus-host disease.
- Aslan Pharmaceuticals (aslanpharma.com) announced that the FDA has granted orphan drug designation to **ASLAN003** for the treatment of acute myeloid leukemia.
- Aravive Biologics, Inc. (aravive.com) announced that the FDA has granted fast track designation to **AVB-S6-500** as a potential treatment for platinum-resistant recurrent ovarian cancer.
- Cellectar Biosciences, Inc. (cellectar.com) announced that the FDA has granted rare pediatric disease designation to **CLR 131** for the treatment of osteosarcoma, a rare pediatric cancer.
- Rafael Pharmaceuticals, Inc. (rafaelpharma.com) announced that the FDA has granted orphan drug designation to **CPI-613** for the treatment of peripheral T-cell lymphoma.
- Janssen Pharmaceuticals (janssen.com) announced that a new drug application (NDA) has been submitted to the FDA,

seeking approval of **erdafitinib** for the treatment of patients with locally advanced or metastatic urothelial cancer and certain fibroblast growth factor receptor genetic alterations whose tumors have progressed after prior chemotherapy.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA accepted the company's biologics license application (BLA) for **Empliciti™ (elotuzumab)** in combination with pomalidomide and low-dose dexamethasone for the treatment of patients with relapsed/refractory multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor.
- Merck & Co., Inc. (merck.com) announced that the FDA has accepted and granted priority review for a new supplemental BLA seeking accelerated approval for **Keytruda® (pembrolizumab)** for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
- Merck & Co., Inc. (merck.com) also announced that the FDA has accepted and granted priority review for a new supplemental BLA seeking approval for **Keytruda® (pembrolizumab)** for first-line treatment of locally advanced or metastatic nonsquamous or squamous NSCLC in patients whose tumors express PD-L1 (tumor proportion score ≥1%) without EGFR or ALK genomic tumor aberrations.
- Amgen (amgen.com) announced that the FDA has approved a supplemental NDA to expand the prescribing information for **Kyprolis® (carfilzomib)** to include a once-weekly dosing option in combination with dexamethasone for patients with relapsed or refractory multiple myeloma.
- Loxo Oncology, Inc. (loxooncology.com) announced that the FDA has granted breakthrough therapy designation to **LOXO-292**, a selective RET inhibitor, for the treatment of patients with metastatic, RET-fusion-positive NSCLC who require systemic therapy and have progressed following platinum-based chemotherapy and an anti-PD-1 or anti-PD-L1 therapy and for the treatment of patients with RET-mutant medullary thyroid cancer who require systemic therapy, have progressed following prior treatment, and have no acceptable alternative treatment options.
- Y-mAbs Therapeutics, Inc. (ymabs.com) announced that the FDA has granted breakthrough therapy designation to **naxitamab**, in combination with GM-CSF, for the treatment of high-risk neuroblastoma refractory to initial therapy or with incomplete response to salvage therapy in patients older than 12 months of age with persistent refractory disease limited to bone marrow with or without evidence of concurrent bone involvement.
- OBI Pharma, Inc. (obipharma.com) announced that the FDA has granted orphan drug designation for **OBI-3424** for the treatment of acute lymphoblastic leukemia (ALL).
- Clovis Oncology, Inc. (clovisoncology.com) announced that the FDA has granted breakthrough therapy designation to **Rubraca® (rucaparib)** as a monotherapy treatment of adult patients with BRCA1/2-mutated metastatic castration-resistant prostate cancer who have received at least one prior androgen receptor-directed therapy and taxane-based chemotherapy.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that the FDA has accepted its NDA with priority review seeking accelerated approval for **selinexor** as a new treatment for patients with penta-refractory multiple myeloma.
- Bristol-Myers Squibb Company (bms.com) announced that the FDA accepted has its supplemental BLA for **Sprycel® (dasatinib)** in combination with chemotherapy for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome-positive ALL.

Genetic Tests and Assays in the News

- On September 28, the FDA permitted marketing of the **clonoSEQ® assay** (Adaptive Biotechnologies, adaptivebiotech.com), a next-generation sequencing-based test for minimal residual disease in patients with ALL or multiple myeloma.
- On August 8, PapGene, Inc. (papgeneinc.com) announced that it had received breakthrough device designation from the FDA for the **PapGene test**, a multi-analyte liquid biopsy test that uses a combination of circulating tumor DNA and protein biomarkers to detect the presence of cancer in average-risk, asymptomatic individuals over the age of 65.

Devices in the News

- Qiagen N.V. (qiagen.com) announced that the FDA has approved a PMA Supplement, expanding the labeling claim of the ***therascreen*® EGFR RGQ PCR Kit** to allow its use as a companion diagnostic with Pfizer's Vizimpro® for first-line treatment of patients with NSCLC with EGFR exon 19 deletions or an exon 21 L858R mutation. OI

FDA Expands Use of Gardasil®9

On October 5, the FDA approved a supplemental application for **Gardasil9 (Human Papillomavirus 9-valent Vaccine, Recombinant)** (Merck & Co., Inc., merck.com), expanding the approved use of the vaccine to include individuals aged 27-45 years.

FDA Updates Prescribing Information for Keytruda® and Tecentriq®

Prescribing **Keytruda (pembrolizumab)** (Merck & Co., Inc., merck.com) and **Tecentriq (atezolizumab)** (Genentech, Inc., gene.com) now requires the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible.