tools

Approved Drugs

- On June 16, the U.S. Food and Drug Administration (FDA) approved **Ayvakit™ (avapritinib)** (Blueprint Medicines, blueprintmedicines.com) for adult patients with advanced systemic mastocytosis (SM), including patients with aggressive SM, SM with an associated hematological neoplasm, and mast cell leukemia.
- On July 9, the FDA approved **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)** (Janssen Biotech, Inc., janssen.com) in combination with pomalidomide and dexamethasone for adult patients with multiple myeloma who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor.
- On July 6, the FDA approved an expanded label for **Keytruda® (pembrolizumab)** (Merck, merck.com) as a monotherapy for the treatment of patients with locally advanced cutaneous squamous cell carcinoma that is not curable by surgery or radiation. On July 21, the FDA approved Keytruda in combination with Lenvima® (lenvatinib) (Eisai, us.eisai.com) for patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, who have disease progression following prior systemic therapy in any setting, and who are not candidates for curative surgery or radiation. On July 26, the FDA approved Keytruda for high-risk, early-stage triple-negative breast cancer in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery.
- On July 9, the FDA approved **Padcev® (enfortumab vedotin-ejfv)** (Astellas Pharma, Inc., astellas.com) for adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor 1 or programmed death ligand 1 inhibitor and platinum-containing chemotherapy or patients who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.
- On July 16, the FDA approved **Rezurock™ (belumosudil)** (Kadmon Pharmaceuticals, LLC, kadmon.com) for adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy.
- On July 1, the FDA approved **Rylaze™ (asparaginase erwinia chrysanthemi (recombinant)-rywn)** (Jazz Pharmaceuticals, jazzpharma.com) as a component of a chemotherapy regimen to treat acute lymphoblastic leukemia and lymphoblastic lymphoma in adult and pediatric patients who are allergic to the Escherichia coli-derived asparaginase products commonly used for treatment.

Drugs in the News

- Bayer (bayer.com/en/) announced the submission of a supplemental new drug application (NDA) to the FDA seeking approval of the investigational combination of the anti-cancer treatments **Aliqopa® (copanlisib)** and **rituximab**. The submission is for the treatment of patients with relapsed indolent B-cell non-Hodgkin's lymphoma and is outside the FDA accelerated approved indication for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies.
- Allogene Therapeutics, Inc. (allogene.com) announced that the FDA granted fast track designation to **ALLO-605** for the treatment of relapsed or refractory multiple myeloma.
- Ascentage Pharma (ascentagepharma.com) announced that the FDA granted an orphan drug designation to **alrizomadlin (APG-115)** for the treatment of stage IIB to IV melanoma.
- Agenus Inc. (agenusbio.com) announced that the FDA accepted its biologics license application for **balstilimab (AGEN2034)** for the treatment of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- Exelixis (exelixis.com) announced that the FDA accepted its supplemental NDA for **Cabometyx® (cabozantinib)** as a treatment for patients 12 years and older with differentiated thyroid cancer who have progressed following prior therapy and are radioactive iodine refractory (if radioactive iodine is appropriate).
- G1 Therapeutics, Inc. (g1therapeutics.com) announced that the FDA granted fast track designation to **Cosela™ (trilaciclib)** for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple-negative breast cancer.
- CNS Pharmaceuticals Inc. (cnspharma.com) announced that the FDA granted

fast track designation to **berubicin** for the treatment of patients with recurrent glioblastoma multiforme.

- Erytech Pharma (erytech.com) announced that the FDA granted fast track designation to **eryaspase** for the treatment of patients with acute lymphocytic leukemia who have developed hypersensitivity reactions to *Escherichia coli*-derived pegylated asparaginase.
- Aadi Bioscience, Inc. (aadibio.com) announced that the FDA accepted its NDA and granted priority review to **Fyarro™ (sirolimus albumin-bound nanoparticles for injectable suspension, nab-sirolimus ABI-009)** for the treatment of advanced malignant perivascular epithelioid cell tumors.
- Alkermes plc (alkermes.com) announced that the FDA granted fast track designation to **nemvaleukin alfa (nemvaleukin)** for the treatment of mucosal melanoma.
- Puma Biotechnology, Inc. (pumabiotechnology.com) announced that the FDA approved a labeling supplement to the U.S. prescribing information for **Nerlynx® (neratinib)** in human epidermal growth factor receptor 2-positive early stage and metastatic breast cancer.
- Fidia Farmaceutici (fidiapharma.com/en/) announced that the FDA granted orphan drug designation to **Oncofid®-P** for the treatment of malignant mesothelioma.
- InnoCare Pharma (innocarepharma.com) announced that the FDA granted breakthrough therapy designation to **orelabrutinib** for the treatment of relapsed or refractory mantle cell lymphoma.
- Fennec Pharmaceuticals Inc. (fennecpharma.com) announced that the FDA accepted for filing the resubmission of its NDA for **Pedmark™ (a formulation of sodium thiosulfate)** for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to less than 18 years of age with localized non-metastatic solid tumors.
- Incyte (incyte.com) announced that the FDA extended the review period for the supplemental NDA for **Jakafi® (ruxolitinib)** for the treatment of adult and pediatric patients 12 years and older with steroid-refractory chronic graft-versus-host disease.
- Hutchmed Limited (hutch-med.com) announced that the FDA accepted its filing of the NDA for **surufatinib** for the treatment of pancreatic and extrapancreatic neuroendocrine tumors.
- Roche (roche.com) announced that the FDA accepted the supplemental biologics license application and granted priority review for **Tecentriq® (atezolizumab)** as adjuvant treatment following surgery and platinum-based chemotherapy for people with non-small cell lung cancer (NSCLC) whose tumors express programmed death ligand 1 greater than or equal to one percent, as determined by an FDA-approved test.
- Transcenta Holding Limited (transcenta.com) announced that the FDA granted orphan drug designation to **TST001** for the treatment of patients with gastric cancer or gastroesophageal junction.
- Roche (roche.com) announced that **Venclexta® (venetoclax)** in combination with azacitidine has been granted breakthrough therapy designation by the FDA for the treatment of adult patients with previously untreated intermediate-, high-, and very high-risk myelodysplastic syndromes based on the revised International Prognostic Scoring System.
- Novartis (novartis.com) announced that the FDA granted breakthrough therapy designation to **177Lu-PSMA-617** for the treatment of metastatic castration-resistant prostate cancer.

Devices and Assays in the News

- Foundation Medicine, Inc. (foundationmedicine.com) announced that it received approval from the FDA for **FoundationOne®CDx** to be used as a companion diagnostic for Alunbrig® (brigatinib), which is currently FDA approved for the treatment of adult patients with anaplastic lymphoma kinase-positive metastatic NSCLC as detected by an FDA-approved test. Foundation Medicine, Inc., also announced that it received approval from the FDA for **FoundationOne Liquid CDx** to be used as a companion diagnostic to aid in identifying patients with MET exon 14 skipping in metastatic NSCLC for whom treatment with Tabrecta® (capmatinib) may be appropriate.
- The FDA cleared under 510(k) designation for clinical lab use the **NYU Langone Genome Profiling of Actionable Cancer Targets (PACT)** (New York University Langone Health and Laura and Isaac Perlmutter Cancer Center, nyulangone.org and nyulangone.org/locations/perlmutter-cancer-center) to guide treatment decisions for patients who have received a cancer diagnosis.
- The FDA cleared the **OncoMate™ MSI Dx Analysis System (OncoMate™ MSI)** (Promega, promega.com) as an *in vitro* diagnostic medical device to determine microsatellite instability status in colorectal cancer tumors.
- AnchorDx (anchordx.com) was awarded breakthrough device designation by the FDA for **UriFind**, an early detection test for bladder cancer based on urine DNA methylation detection.

FDA Approves Diagnostic Agent for Lymphatic Mapping in Patients with Solid Tumors

- On June 10, Cardinal Health (cardinalhealth.com/en.html) announced that the FDA approved **Lymphoseek® (technetium Tc99m tilmanocept)**, a radioactive diagnostic agent for accurate and precise lymph node identification in pediatric patients with melanoma, rhabdomyosarcoma, or other types of solid tumors. OI