tools

Approved Drugs

- On February 28, the U.S. Food and Drug Administration (FDA) approved **Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)** injection for subcutaneous use (Genentech Inc., gene.com) for the treatment of human epidermal growth factor receptor-2 (HER2) overexpressing breast cancer.
- On February 15, the FDA approved **Keytruda® (pembrolizumab)** (Merck & Co. Inc., merck.com) for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
- On February 25, the FDA approved **Lonsurf® (trifluridine and tipiracil)** (Taiho Oncology, taihooncology.com) for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and, if appropriate, HER2/neu-targeted therapy.
- On March 8, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, gene.com) plus **Abraxane® (nab-paclitaxel)** (Celgene, celgene.com) for the frontline treatment of patients with unresectable locally advanced or metastatic PD-L1-positive triple-negative breast cancer.
- On March 19, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, gene.com) in combination with chemotherapy (carboplatin and etoposide) for the first-line treatment of adults with extensive-stage small cell lung cancer.
- On March 11, Pfizer Inc. (Pfizer.com) announced that the FDA approved **Trazimera™ (trastuzumab-qyyp)**, a biosimilar to Herceptin, for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Drugs in the News

- Moleculin Biotech, Inc. (moleculin.com) announced that it has submitted a request for fast track designation with the FDA for **Annamycin** for the treatment of relapsed or refractory acute myeloid leukemia.
- Aptose Biosciences Inc. (aptose.com) announced that the FDA has completed their review and granted investigational new drug acceptance for **CG-806** for patients with chronic lymphocytic leukemia or non-Hodgkin lymphomas.
- Heron Therapeutics, Inc. (herontx.com) announced that the FDA has approved a supplemental new drug application (NDA) for **Cinvanti® (aprepitant)** injectable emulsion to expand its administration to a two-minute intravenous injection beyond the approved 30-minute intravenous infusion.
- Ziopharm Oncology, Inc. (ziopharm.com) announced that the FDA has granted fast track designation for its **Controlled IL-12 program (Ad-RTS-hIL-12 plus veledimex)** for the treatment of recurrent or progressive glioblastoma multiforme in adults.
- Bayer (bayer.com) and Orion Oyj (orion.fi) have submitted an NDA for **darolutamide** for the treatment of patients with nonmetastatic castration-resistant prostate cancer.
- Atossa Genetics, Inc. (atossagenetics.com) announced that the FDA has approved the use of **endoxifen** for "expanded access" as a postmastectomy treatment in premenopausal patients with estrogen receptor-positive breast cancer.
- Eureka Therapeutics (eurekatherapeutics.com) announced that the FDA has cleared its investigational NDA for **ET140202 ARTEMIS T-cell therapy** for patients with hepatocellular carcinoma who are positive for alpha-fetoprotein.
- Janssen (janssen.com) announced that it had submitted a supplemental biologics license application (BLA) to the FDA seeking approval of **Darzalex® (daratumumab)** in combination with lenalidomide and dexamethasone for the treatment of newly diagnosed patients with multiple myeloma who are ineligible for autologous stem cell transplant.

  The company also submitted a supplemental BLA to the FDA seeking approval of **Darzalex** in combination with bortezomib, thalidomide, and dexamethasone for newly diagnosed patients with multiple myeloma who are eligible for autologous stem cell transplant.
- Imbrium Therapeutics (imbriumthera.com) announced that the FDA has granted orphan drug designation to **etoposide toniribate**, a novel topoisomerase II inhibitor, for the treatment of relapsed refractory biliary tract cancer.

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- Celgene (celgene.com) announced that the FDA has accepted the company's NDA and granted priority review for **fedratinib** for the treatment of patients with myelofibrosis, a bone marrow disorder that disrupts the body's normal production of blood cells.
- The FDA has granted priority review to **Keytruda® (pembrolizumab)** (Merck & Co. Inc., merck.com) in combination with axitinib as a frontline treatment for advanced renal cell carcinoma.

  The company also announced that the FDA has accepted and granted priority review for a new supplemental BLA for Keytruda as monotherapy for the treatment of patients with advanced small cell lung cancer whose disease has progressed after two or more lines of prior therapy.
- Selvita (selvita.com) announced that the FDA has accepted its investigational new drug application for **SEL120**, a CDK8inhibitor for patients with acute myeloid leukemia or high-risk myelodysplastic syndrome.
- The FDA has granted priority review to **Tibsovo® (ivosidenib)** (Agios Pharmaceuticals Inc., agios.com) for first-line treatment of patients with acute myeloid leukemia with an isocitrate dehydrogenase mutation who are not eligible for standard therapy.

  The FDA also granted breakthrough therapy designation to **Tibsovo** in combination with azacytidine for the treatment of newly diagnosed acute myeloid leukemia with an isocitrate dehydrogenase mutation in adult patients who are 75 years old or older or who have comorbidities that preclude use of intensive induction chemotherapy.
- Imbrium Therapeutics L.P. (imbriumthera.com) announced that the FDA has granted orphan drug designation for **tinostamustine** for the treatment of T-cell prolymphocytic leukemia.
- Roche (roche.com) announced that it has submitted a supplemental NDA to the FDA for **Venclexta® (venetoclax) plus Gazyva® (obinutuzumab)** for patients with previously untreated chronic lymphocytic leukemia and coexisting medical conditions.

Approved Devices

- **Paige.AI** (paige.ai), a computational pathology start-up focused on developing artificial intelligence tools for pathologists for clinical diagnosis, announced that it has been granted breakthrough device designation by the FDA.
- ViewRay (viewray.com) announced that the company has received 510(k) clearance from the FDA to market new soft tissue visualization capabilities for its MRIdian **SmartVISION MRI** system.

Genetic Tests and Assays in the News

- Roche (roche.com) announced that the FDA has approved the **VENTANA PD-L1 (SP142) Assay** as the first companion diagnostic to aid in identifying patients with triple-negative breast cancer who are eligible for treatment with Tecentriq® plus Abraxane®. OI