tools

Approved Drugs

• Egalet Corporation (egalet.com) announced that the U.S. Food and Drug Administration (FDA) has approved **Arymo™ ER (morphine sulfate) extended-release (ER) tablets C-II** for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

• The FDA has approved Janssen Biotech's (janssen.com) **Imbruvica® (ibrutinib)** for the treatment of patients with marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy.

• Teva Pharmaceuticals (tevapharm.com) announced the availability of its **levoleucovorin (Fusilev®) generic for injection**, used to treat toxic effects of methotrexate in people who have received methotrexate to treat bone cancer.

• The FDA granted accelerated approval to Bristol-Myers Squibb's (bms.com) **Opdivo® (nivolumab)** for treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy.

• Celgene Corporation (celgene.com) announced that the FDA has expanded the existing indication for **Revlimid® (lenalidomide)** 10 mg capsules to include use for patients with multiple myeloma as maintenance therapy following autologous hematopoietic stem cell transplant.

Drugs in the News

• Immune Design (immunedesign.com) announced that the FDA has granted orphan drug designation for its investigational intratumoral therapy, **G100**, for the treatment of follicular non-Hodgkin's lymphoma.

• The FDA has cleared Glenmark Pharmaceuticals' (glenmarkpharma.com/usa) investigational new drug (IND) application to initiate a Phase I study of its lead candidate, **GBR 1302-BEAT™**, in patients with HER2+ cancers.

• The FDA has accepted for review a supplemental new drug application (sNDA) for Pfizer's (pfizer.com) CDK 4/6 inhibitor, **Ibrance® (palbociclib)**. The sNDA supports the conversion of the accelerated approval of Ibrance in combination with letrozole to regular approval and includes data from the Phase III PALOMA-2 trial, which evaluated Ibrance as initial therapy in combination with letrozole for postmenopausal women with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+, HER2-) metastatic breast cancer.

• Pfizer Inc. (pfizer.com) announced that a biologics license application (BLA) for **inotuzumab ozogamicin (CMC-544)** has been accepted for filing and granted priority review by the FDA. Inotuzumab ozogamicin is being evaluated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

• The FDA has accepted for review Merck's (merck.com) supplemental BLA (sBLA) for **Keytruda® (pembrolizumab)**, the company's anti-PD-1 therapy, plus chemotherapy (pemetrexed plus carboplatin) for the first-line treatment of patients with metastatic or advanced non-squamous non-small cell lung cancer (NSCLC) regardless of PD-L1 expression and with no EGFR or ALK genomic tumor aberrations. The FDA also accepted for review two additional sBLAs for patients with locally advanced or metastatic urothelial cancer, a type of bladder cancer. Specifically, the application for first-line use was accepted and granted priority review for the treatment of these patients who are ineligible for cisplatin-containing therapy. The application for second-line use was also accepted and granted priority review for these patients with disease progression on or after platinum-containing chemotherapy.

• Kura Oncology, Inc. (kuraoncology.com) announced that the FDA accepted the company's IND application to begin Phase I clinical testing of **KO-947**, its small molecule inhibitor of extracellular-signal-regulated kinases 1 and 2 (ERK1/2) as a treatment for cancers in which the mitogen activated protein kinase (MAPK) pathway

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is dysregulated. Additionally, Kura announced nomination of **KO-539**, an orally-available small molecule inhibitor of the menin-MLL interaction, as a development candidate for the treatment of mixed lineage leukemias, a genetically-defined subset of the two most common forms of acute leukemia, acute myeloid leukemia, and acute lymphoblastic leukemia.

• Mylan N.V. (mylan.com) and Biocon Ltd. (biocon.com) announced that the FDA has accepted Mylan's BLA for **MYL-1401O**, a proposed biosimilar trastuzumab, for filing through the 351(k) pathway. This product is a proposed biosimilar to branded trastuzumab, which is indicated to treat certain HER2-positive breast cancers.

• The FDA has granted priority review for Tesaro, Inc.'s (tesarobio.com) NDA for **niraparib**, a PARP inhibitor that is being evaluated as a potential new treatment option for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following response to platinum-based chemotherapy.

• Bayer (bayer.us) announced that the FDA has granted priority review status for the sNDA for **Stivarga® (regorafenib) tablets** for the second-line systemic treatment of patients with hepatocellular carcinoma.

• Genentech (gene.com) announced that the FDA has accepted the company's sBLA and granted priority review for **Tecentriq® (atezolizumab)** for the treatment of people with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin chemotherapy, and are either previously untreated (first-line) or have disease progression at least 12 months after receiving chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant).

• The FDA accepted the sNDA for filing from Novartis (novartis.com), and granted priority review for the expanded use of **Zykadia® (ceritinib)** as a first-line treatment for patients with metastatic NSCLC whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The FDA also granted breakthrough therapy designation to Zykadia for the first-line treatment of patients with ALK+ metastatic NSCLC with metastases to the brain.

Devices in the News

• The FDA allowed marketing of the **AeroForm device** (AirXpanders, airxpanders.com), a new tissue expander system for soft tissue expansion in two-stage breast reconstruction following mastectomy and in the treatment of underdeveloped breasts and soft tissue deformities. A patient uses a dose controller to independently inflate the expander. The device is a wireless tissue expander for patients who choose to have reconstructive surgery following a mastectomy. OI

Expanded Access Program for Niraparib

Tesaro, Inc. (tesarobio.com) has opened an expanded access program (EAP) in the U.S. for its investigational poly ADP ribose polymerase (PARP) inhibitor, **niraparib**. The agent is now available to treat patients who meet certain criteria with a serious disease or condition who cannot participate in a controlled clinical trial. The EAP is available for eligible women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum-based chemotherapy.