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Approved Drugs

• The U.S. Food and Drug Administration (FDA) granted accelerated approval to **Bavencio® (avelumab)** (EMD Serono, Inc., emdserono.com) for the treatment of patients 12 years and older with metastatic Merkel cell carcinoma. Avelumab is a programmed death-ligand 1 (PD-L1) blocking human IgG1 lambda monoclonal antibody. This is the first FDA-approved product to treat this type of cancer.

• Pfizer Inc. (Pfizer.com) announced that the FDA has approved a supplemental new drug application (NDA) for its first-in-class cyclin dependent kinase 4/6 (CDK 4/6) inhibitor, **Ibrance® (palbociclib)**. Ibrance now is indicated in combination with an aromatase inhibitor, expanding on its earlier indication in combination with letrozole, as initial endocrine based therapy in post-menopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer.

• The FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com), an anti-PD-1 therapy, for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma, or who have relapsed after three or more prior lines of therapy.

• Novartis (novartis.com) announced that the FDA approved **Kisqali® (ribociclib, formerly known as LEE011)** in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer.

• The FDA expanded the approved use of **Stivarga® (regorafinib)** to include treatment of patients with hepatocellular carcinoma (liver cancer) who have been previously treated with the drug sorafenib. This is the first FDA-approved treatment for a liver cancer in almost a decade.

• The FDA granted regular approval to **Tagrisso (osimertinib)** (AstraZeneca Pharmaceuticals, LP, astrazeneca-us.com) for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy.

• Genentech (gene.com) announced that the FDA granted accelerated approval to **Tecentriq® (atezolizumab)** for the treatment of people with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin chemotherapy.

• The FDA has approved Lexicon Pharmaceuticals' (lexpharma.com) **Xermelo™ (telotristat ethyl)** for treatment for diarrhea caused by carcinoid syndrome.

• Silvergate Pharmaceuticals, Inc. (silvergatepharma.com) announced that the FDA approved **Xatemp™ (methotrexate) Oral Solution**, the first and only FDA-approved methotrexate oral solution. Xatemp is indicated for the treatment of acute lymphoblastic leukemia (ALL) and polyarticular juvenile idiopathic arthritis in pediatric patients.

• Tesaro, Inc. (tesarobio.com) announced that the FDA approved **Zejula™ (niraparib)**, a poly ADP-ribose polymerase (PARP) inhibitor, for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy.

Approved Devices

• Lifetrack Medical Systems Inc. (lifetrackmed.com) announced FDA approval of its **Lifesys™ PACS**, featuring patented RadNav™ technology, which serves as a guidance system to radiologists through its integrated decision support system and active templates.

• iCAD (icadmed.com) announced that the **PowerLook® Tomo Detection** received premarket approval from the FDA. This concurrent-read computer-aided detection solution for digital breast 3D tomosynthesis and is the latest innovation available on the PowerLook® Breast Health Solutions platform.