tools

Approved Drugs

- The U.S. Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin**) (Seattle Genetics, seattlegenetics.com) for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation consolidation.

- Endo Pharmaceuticals Inc., (endo.com) and BioDelivery Sciences International, Inc. (bdsi.com), announced that the FDA has approved **Belbuca™ (buprenorphine) buccal film** for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Belbuca is expected to be commercially available in the U.S. during the first quarter of 2016.

- The FDA approved Amgen's (amgen.com) biologics license application for **Imlygic™ (talimogene laherparepvec)**, a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

- The FDA granted accelerated approval for **Keytruda® (pembrolizumab)** (Merck, merck.com) to treat patients with metastatic non-small cell lung cancer (NSCLC) whose disease has progressed after other treatments and with tumors that express a protein called PD-L1. Keytruda is approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test.

- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA approved **Lonsurf® (trifluridine and tipiracil)**, formerly known as TAS-102, for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.w

- The FDA approved **Onivyde™ (irinotecan liposome injection)** (Merrimack Pharmaceuticals, merrimack.com) in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas whose disease has progressed following gemcitabine-based therapy.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA granted accelerated approval to **Opdivo® (nivolumab**) in combination with ipilimumab for the treatment of patients with BRAF V600 wild-type, unresectable, or metastatic melanoma.

- The FDA has approved **Promacta® for oral suspension (eltrombopag)** (Novartis, novartisoncology.com) for the treatment of thrombocytopenia in pediatric patients one year and older with chronic immune idiopathic thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

- TESARO, Inc. (tesarobio.com) announced that the FDA approved **Varubi™ (rolapitant)** in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

- Bristol-Myers Squibb Company (bms.com) announced that the FDA approved **Yervoy® (ipilimumab) 10 mg/kg** for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection including total lymphadenectomy.

- The FDA approved Janssen Product's (janssen.com) **Yondelis® (trabectedin)**, a chemotherapy for the treatment of specific soft tissue sarcomas—liposarcoma and leiomyosarcoma—that are unresectable or metastatic. This treatment is approved for patients who previously received chemotherapy that contained anthracycline.

Drugs in the News

- Eli Lilly and Company (lilly.com) announced that the FDA granted breakthrough therapy designation to **abemaciclib**, a cyclin-dependent kinase 4 and 6 inhibitor, for patients with refractory hormone-receptor-positive (HR+) metastatic breast cancer.

- The FDA granted fast track designation to Pfizer's (pfizeroncology.com) **avelumab**, an investigational fully human anti-PD-L1 IgG1 monoclonal antibody, for the treatment of metastatic Merkel cell carcinoma, a rare and aggressive type of skin cancer.

- Blueprint Medicines (blueprintmedicines.com) announced that the FDA granted orphan drug designation to its novel drug candidate **BLU-554** for the treatment of hepatocellular carcinoma (HCC).

- Bionomics Limited (bionomics.com) announced that its IND submission for **BNC101** passed FDA review. Bionomics plans to initiate a Phase I clinical trial in patients with metastatic colon cancer and in patients with metastatic pancreatic cancer prior to Dec. 31, 2015.

- The FDA granted fast track designation to Can-Fite BioPharma's (can-fite.com) drug candidate **CF102** as a second line treatment for HCC.

- Janssen Research & Development, LLC (janssenrnd.com) announced that the FDA accepted for priority review the biologics license application (BLA) for **daratumumab** as a treatment for patients with multiple myeloma who are refractory to both a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who have received three or more prior lines of therapy, including a PI and an IMiD.

- The FDA accepted for priority review the BLA for **Empliciti (elotuzumab)** (Bristol-Myers Squibb Company, bms.com and AbbVie, abbvie.com). This investigational signaling lymphocyte activation molecule-directed immunostimulatory antibody is for the treatment of multiple myeloma as combination therapy in patients who have received one or more prior therapies.

- Boehringer Ingelheim (us.boehringer-ingelheim.com) announced that the FDA has accepted filing applications for **Gilotrif® (afatinib)** for the treatment of patients with advanced squamous cell carcinoma of the lung progressing after treatment with first-line chemotherapy.

- A supplemental new drug application (sNDA) for **Imbruvica® (ibrutinib)** (Janssen Biotech Inc., janssenbiotech.com) was submitted to the FDA for front-line use in patients with chronic lymphocytic leukemia.

- The FDA granted breakthrough therapy designation to Pfizer Inc.'s (pfizer.com) investigational antibody-drug conjugate **inotuzumab ozogamicin** for acute lymphoblastic leukemia.

- Amgen (amgen.com) announced that the FDA accepted for priority review the sNDA of **Kyprolis® (carfilzomib) for Injection** for patients with relapsed multiple myeloma. The sNDA is designed to expand the current indication to include Kyprolis in combination with dexamethasone for patients who have received at least one prior therapy.

- The FDA has granted orphan drug designation to **LOXO-101** (Loxo Oncology, Inc., loxooncology.com) for the treatment of patients with soft tissue sarcoma.

- Bristol-Myers Squibb Co. (bms.com) announced that the FDA granted breakthrough therapy status to its immunotherapy drug **Opdivo® (nivolumab)** as a potential treatment for kidney cancer patients.

- The FDA has granted orphan drug designation to Tocagen's (tocagen.com) lead immuno-oncology product, **Toca 511 & Toca FC**, for the treatment of glioblastoma.

Approved Devices

- EIZO Inc. (eizo.com) announced that it has received FDA 510(k) clearance for breast tomosynthesis for its 5 megapixel monochrome medical monitor, the **RadiForce GX540.**

- The FDA has granted 510(k) clearance to Orfit Industries' (orfit.com) **HP Pro Solution**, a versatile immobilization system for use in brain and head and neck treatments in proton therapy.

- Royal Philips (philips.com) announced that it has received 510(k) clearance from the FDA to market its **Spectral Diagnostic Suite (SpDS)**, a set of advanced visualization and analysis tools designed for the Philips IQon Spectral CT to deliver enhanced spectral viewing and advanced clinical applications capabilities.

Devices in the News

- Lightpoint Medical (lightpointmedical.com) announced that the **LightPath™ Imaging System** is now CE marked, enabling the launch of the device in Europe. The LightPath Imaging System is the first approved medical device for intra-operative molecular imaging in the world. The technology provides the potential for optical imaging of numerous cancer types. Commercial launch in the United States is planned for 2016.

Genetic Tests and Assays in the News

- Dako (agilent.com) announced that the FDA has approved the new diagnostic **PD-L1 IHC 28-8 pharmDx** that can identify PD-L1 expression levels on the surface of non-small cell lung cancer tumor cells and provide information on the survival benefit with Opdivo® (nivolumab) for patients with non-squamous NSCLC.