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Approved Drugs

• Seattle Genetics, Inc. (www.seattlegenetics.com) announced that the Food and Drug Administration (FDA) has approved **Adcetris® (brentuximab vedotin)** for the treatment of patients with classical Hodgkin lymphoma at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation consolidation. Adcetris is an antibody-drug conjugate directed to CD30, which is expressed in classical HL and systemic anaplastic large cell lymphoma (ALCL), as well as other lymphoma subtypes. This is the third indication for the drug, which was granted accelerated FDA approval in August 2011 for two other indications: treatment of Hodgkin lymphoma patients who fail autologous transplant or who fail at least two prior multi-agent chemotherapy regimens and are not autologous transplant candidates, and treatment of systemic ALCL patients who fail at least one prior multi-agent chemotherapy regimen.

• FDA has approved AstraZeneca's (www.astrazeneca.com) drug **Iressa® (gefitinib)** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. This approval of gefitinib is being approved concurrently with a labeling expansion of the *theracreen*® EGFR RGQ PCR Kit, a companion diagnostic test for patient selection.

• **Odomzo® capsules (sonidegib)**, Novartis Pharmaceuticals Corporation, (www.us.novartis.com), has received FDA approval for the treatment of patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

CMS Expands Medicare Anti-Cancer Treatment Compendia List

On Aug. 12, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a decision adding Wolters Kluwer *Lexi-Drugs*® to the list of compendia in Chapter 15, section 50.4.5 of the Medicare Benefit Policy Manual, for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia.

Drugs in the News

• ZIOPHARM Oncology, Inc. (www.ziopharm.com) announced that the FDA has granted orphan drug designation for **Ad-RTS-hIL-12 + veledimex** in the treatment of patients with malignant glioma. Ad-RTS-hIL-12 is a novel gene therapy candidate for the controlled expression of IL-12, a critical protein for stimulating an anti-cancer T cell immune response.

• The FDA has granted orphan drug designation to Novogen Limited (**www.novogen.com**) for its chemotherapy candidate drug, **Anisina (ATM-3507)**. The drug is for neuroblastoma.

• ASLAN Pharmaceuticals (www.aslanpharma.com) announced that the FDA has granted orphan drug designation to its pan-HER inhibitor **Varlitinib (ASLAN001)** for cholangiocarcinoma, a rare and very aggressive form of bile duct cancer.

• Cleave Biosciences (www.cleavebio.com) announced that its lead drug candidate, **CB-5083**, has been granted orphan drug designation by the FDA for the treatment of multiple myeloma. CB-5083 is an oral inhibitor of p97, a critical enzyme that controls various aspects of protein homeostasis. Cleave is currently evaluating CB-5083 in two Phase I studies, including one in patients with multiple myeloma, and one in patients with solid tumor malignancies.

• The FDA has granted NanoSmart Pharmaceutical (www.nanosmartpharma.com) orphan drug designation for a second drug product that uses NanoSmart's proprietary drug delivery platform. The drug product is a formulation of **dactinomycin** for the treatment of Ewing's sarcoma.

• The FDA has granted PNP Therapeutics (www.pnptherapeutics.com) orphan drug status for **Gedeptin™** (adenoviral vector expressing *E. coli* purine nucleoside phosphorylase gene) for the intratumoral treatment of anatomically accessible oral and pharyngeal cancers, including cancers of the lip, tongue, gum, floor of mouth, salivary gland, and other oral cavities.

• Valor Biotherapeutics, LLC, (www.valorbio.com) announced that the FDA has approved an investigational new drug (IND) for **IGN002**. The approved IND is a key step in allowing Valor to begin a Phase I clinical study of IGN002 in patients with non-Hodgkin lymphoma (NHL).

• **ImMucin** (Vaxil Bio, www.vaxilbio.com) has been granted FDA orphan drug designation for the treatment of multiple myeloma (MM). ImMucin is an immunotherapeutic treatment that educates the MM patient's immune system to attack MM cancer cells via a specific domain, termed signal peptide, of the tumor marker MUC1.

• Takeda Pharmaceutical Company Limited (www.takeda.com) has submitted a new drug application (NDA) to the FDA for **ixazomib**, an investigational oral proteasome inhibitor for the treatment of patients with relapsed and/or refractory multiple myeloma.

• KaloBios Pharmaceuticals, Inc. (www.kalobios.com) announced that the FDA has cleared the company's IND application for **KB003**, an anti-GM-CSF monoclonal antibody (mAb), in patients with chronic myelomonocytic leukemia (CMML). The acceptance of this IND allows KaloBios to initiate an open-label Phase I study designed to evaluate the safety, pharmacokinetics, and clinical activity of KB003 in previously treated CMML patients.

• Amgen (www.amgen.com) has submitted a supplemental new drug application (sNDA) to the FDA for **Kyprolis® (carfilzomib) for Injection** to seek an expanded indication for the treatment of patients with a form of blood cancer, relapsed multiple myeloma, who have received at least one prior therapy. Kyprolis currently has accelerated approval in the U.S. for the treatment of patients with relapsed multiple myeloma as a monotherapy.

• The FDA has granted breatkthrough designation to **Lenvima™ (lenvatinib)** (Eisai Inc., www.eisai.com/US), a multiple receptor tyrosine kinase inhibitor, for the investigational use in patients with advanced or metastatic renal cell carcinoma (RCC) who were previously treated with a vascular endothelial growth factor (VEGF)-targeted therapy.

• Delcath Systems, Inc. (www.delcath.com) announced that the FDA has granted orphan drug designation for **melphalan** for the treatment of cholangiocarcinoma (a tumor in the bile duct that arises within the liver).

• BioDelivery Sciences International, Inc. (www.bdsi.com) announced that the FDA has approved an sNDA for a new formulation of **Onsolis® (fentanyl buccal soluble film)** for the management of breakthrough pain in patients with cancer who are opioid tolerant.

• The FDA has granted fast track designation to **Toca 511** and **Toca FC** (Tocagen Inc., www.tocagen.com) for the treatment of recurrent high grade glioma, which includes glioblastoma and anaplastic astrocytoma.

Devices in the News

• Medrobotics Corporation (www.medrobotics.com) has received FDA market clearance to sell its **Flex® Robotic System** in the U.S.

• Elekta's (www.elekta.com) **Leksell Gamma Knife® Icon™ radiosurgery** system has received 510(k) clearance from the FDA.

Genetic Tests and Assays in the News

• Roche (www.roche.com) has submitted its **cobas® EGFR Mutation Test v2** for premarket approval to the FDA as a companion diagnostic test for **AZD9291**, an AstraZeneca investigational therapy for NSCLC patients with an acquired resistant mutation.

• The **Ventana ALK (D5F3) CDx Assay** (Ventana Medical Systems, Inc., www.ventana.roche.com) has received FDA approval as a companion diagnostic to aid in the identification of patients for Pfizer's FDA-approved targeted therapy, Xalkori® (crizotinib). OI

Online Course on Male Oncofertility

This free online video course for the oncology community explores male fertility preservation. The course includes interviews with a testicular cancer survivor, as well as experts in the oncology, reproductive medicine, and cryogenics fields. The objective is to help oncology providers feel comfortable in having the fertility risk conversation with their pediatric, adolescent, and young adult cancer patients to maximize the opportunity for fertility preservation. Learn more at www.oncofertu.org.

Favorable Medicare Final Coverage Decision for the Polaris® Test

On Aug. 13, 2015, Myriad Genetics, Inc. (www.myriad.com) announced that Noridian, the Medicare Administrative Contractor (MAC) for Myriad, has issued a final local coverage determination (LCD) for **Prolaris®**, a prognostic test for assessing the aggressiveness of prostate cancer. This decision follows a final LCD decision from Palmetto GBA on Jan. 15, 2015. The final LCD is posted to the Medicare Coverage Database on the Centers for Medicare & Medicaid Services website with an effective date of Oct. 15, 2015, and provides Medicare coverage for prostate cancer patients defined as low and very low risk by the National Comprehensive Cancer Network (NCCN).