[Approved Drugs]

- The Food and Drug Administration (FDA) granted accelerated approval to **Adcetris (brentuximab vedotin)** (Seattle Genetics, Inc., *www.seagen.com*) for two indications: to treat patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemoptherapy regimens in patients who are not ASCT candidates and to treat patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.

- The FDA granted accelerated approval to **crizotinib (Xalkori capsules)** (Pfizer, Inc., *www.pfizer.com*) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The FDA approved the **Vysis ALK Break-Apart FISH Probe Kit** (Abbott Molecular, Inc., *www.abbott.com*) concurrently with the crizotinib approval. This companion diagnostic test is designed to detect rearrangements of the ALK gene in NSCLC.

- Janssen Pharmaceuticals, Inc. (*www.janssenpharmaceuticalsinc.com*) announced FDA approval of **Nucynta® ER (tapentadol extended-release tablets)**, an oral analgesic taken twice daily for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Tapentadol is a centrally-acting synthetic analgesic. The tapentadol molecule is classified as Schedule II of the Controlled Substances Act. Nucynta (tapentadol immediate-release tablets) was approved by the FDA on Nov. 20, 2008, for the relief of moderate to severe acute pain in patients 18 years of age or older.

- The FDA approved new indications for **Prolia® (denosumab)** (Amgen, *www.amgen.com*) as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor (AI) therapy for breast cancer and as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for non-metastatic prostate cancer. In patients with prostate cancer, Prolia also reduced the incidence of vertebral fractures.

  Denosumab is a monoclonal antibody that binds to RANKL, a protein involved in the formation, function, and survival of osteoclasts, the cells responsible for bone resorption.

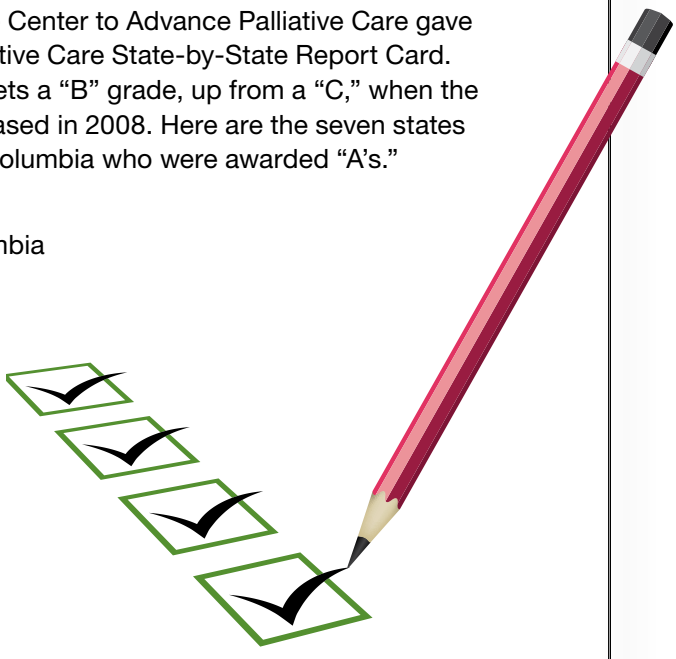
- The FDA approved **vemurafenib tablets (Zelboraf)** (Hoffmann-La Roche Inc., *www.roche.com*) for the treatment of patients with unresectable or metastatic melanoma with the $BRAF^{V600E}$ mutation as detected by an FDA-approved test. The approval was based primarily on an international, randomized, open-label trial in patients with previously untreated metastatic or unresectable melanoma with the $BRAF^{V600E}$ mutation as detected by the cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.). This companion diagnostic test was approved by the FDA concurrently with vemurafenib's approval.

Fast Facts

The Distinguished Honor Roll

In October 2011, the Center to Advance Palliative Care gave to Congress a Palliative Care State-by-State Report Card. The nation overall gets a "B" grade, up from a "C," when the report was first released in 2008. Here are the seven states and the District of Columbia who were awarded "A's."

- District of Columbia
- Maryland
- Minnesota
- Nebraska
- Oregon
- Rhode Island
- Vermont
- Washington



Source: CAPC. America's Care of Serious Illness: A State-by-State Report Card on Access to Palliative Care in Our Nation's Hospitals. Available online at: *http://www.capc.org/reportcard.*

ILLUSTRATIONS/ISTOCKPHOTO

THE TOOLS

[Devices in the News]

- FDA 510(k) clearance has been granted to .decimal, Inc. (*www.dotdecimal.com*), a manufacturer of patient-specific medical devices for radiation therapy, to market the company's **electron apertures for use with Varian treatment machines**. These devices are now available to radiation oncology centers across the U.S. and Canada. Electron apertures are medical devices required for the targeted delivery of electrons to patients in radiation therapy. By providing custom-made electron apertures to radiation oncology centers, .decimal® helps these facilities reduce the cost of maintaining an onsite mold room, which can add to the department's or facility's costs.

- IRIS International, Inc. (*www.proiris.com*) announced FDA 510(k) clearance for the company's **NADiA® ProsVue™** prognostic cancer test. NADiA ProsVue slope is indicated for use as a prognostic marker in conjunction with clinical evaluation as an aid in identifying those patients at reduced risk for recurrence of prostate cancer for the eight-year period following prostatectomy. NADiA ProsVue is an *in-vitro* diagnostic assay for determining rate of change of serum total prostate specific antigen (tPSA) over a period of time.

  A retrospective clinical study of 304 patients evaluated the slope of three successive ProsVue tests over a period of at least 10 months after a prostatectomy to identify prostate cancer patients with no evidence of disease or clinical progression. Recurrence of disease was determined by positive imaging, biopsy results, or prostate-cancer-related death. NADiA ProsVue is a prognostic prostate cancer marker and is not intended for the diagnosis or for the monitoring of prostate cancer.

[Diagnostic Tests and Assays in the News]

- The **VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody (H. pylori)** (Ventana Medical Systems, *www.ventana.com*) is the first *H. pylori* antibody to receive 510(k) FDA clearance. Developed by Ventana Medical Systems, Inc., a member of the Roche Group, the VENTANA H. pylori antibody, when used in immunohistochemical (IHC) staining, aids in the detection of *Helicobacter pylori*, a bacterium linked to chronic gastritis, ulcers, and stomach cancer.

- Ambry Genetics (*www.ambrygen.com*) introduced the company's new **CancerArray™** project and services utilizing aCGH technology. The Ambry CancerArray is a high resolution chromosome analysis approach to detect copy number variants without the need and additional cost for independent karyotyping or single gene deletion/duplication analysis. The high-resolution exon-focused 180K array offers genome-wide probe coverage with higher probe density coverage in over 400 known cancer-associated genes. The array enhances the resolution in these functionally important cancer regions.

- Fujirebio Diagnostics (*www.fdi.com*) has received FDA 510(k) clearance to market the company's HE4 Test in an algorithm called **ROMA™ (HE4 EIA + ARCHITECT CA 125 II™)** to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy on surgery.

  The ROMA (Risk of Ovarian Malignancy Algorithm) test uses results from simple blood tests, CA 125 and HE4, to identify patients presenting with adnexal mass as high or low likelihoodfor finding malignancy on surgery. Combiningphysician assessment with the independently validated ROMA algorithm enables physicians to identify those patients at high likelihood of malignancy who should have their surgery performed by a gynecologic oncologist.

  Precaution: ROMA (HE4 EIA + ARCHITECT CA 125 II™) should not be used without an independent clinical/radiological evaluation and is *not* intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of ROMA carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

- **Vysis CLL FISH Probe Kit** (Abbott Molecular, Inc., *www.abbott.com*), a new *in vitro* diagnostic test to aid in determining the prognosis of patients with chronic lymphocytic leukemia (CLL), has received 510(k) clearance from the FDA. It is the first FDA-cleared CLL test to aid in prognosis. The test detects genetic abnormalities in lymphocytes.

  The Vysis CLL FISH Probe Kit includes a panel of five individual FISH probes intended to detect deletion of the LSI TP53, LSI ATM, and LSI D13S319 probe targets and gain of the D12Z3 sequence in peripheral blood specimens from untreated patients with B-cell CLL. The assay may be used to dichotomize CLL (the 13q-,+12, or normal genotype group versus the 11q- or 17p- group) and may be used as an aid in determining disease prognosis in combination with additional biomarkers, morphology, and other clinical information.

  The Vysis CLL FISH Probe Kit is not intended for use in selection of therapy or in monitoring of residual disease.