THE TOOLS

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[Approved Drugs]

■ Eli Lilly and Company (Indianapolis, Ind.) announced that the company received a fourth approval from the Food and Drug Administration (FDA) for **Alimta®(pemetrexed for injection)**. The latest approval is for Alimta as a maintenance therapy for locally advanced or metastatic non-small cell lung cancer (NSCLC), specifically for patients with a nonsquamous histology whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Alimta is not indicated for treatment of patients with squamous cell non-small cell lung cancer.

■ The FDA has approved Genentech Inc.'s (South San Francisco, Calif.) **Avastin® (bevacizumab)** plus interferon-alfa for people with metastatic renal cell carcinoma.

The approval is based on data from a global, randomized, double-blind, placebo-controlled Phase III study (AVOREN) of 649 patients with previously untreated metastatic renal cell carcinoma. The study showed patients who received Avastin plus interferon-alfa had a 67 percent increase in progression-free survival (PFS) compared with patients receiving interferon-alfa plus placebo. Median PFS was 10.2 months for patients who received bevacizumab plus interferon-alfa compared with 5.4 months for patients who received interferon-alfa alone. Patients in the bevacizumab group experienced a 30 percent decrease in tumor size compared with the 12 percent in patients assigned to interferon-alfa alone. The final analysis showed no improvement in overall survival after 444 deaths (median overall survival of 23 months in the bevacizumab plus interferon-alfa arm vs. 21 months in the interferon-alfa plus placebo arm).

■ BioDelivery Sciences International, Inc., (Raleigh, N.C.) and Meda AB (Solna, Sweden) announced FDA approval to market **Onsolis™ (fentanyl buccal soluble film)**, formerly referred to as BEMA™ Fentanyl, for the management of breakthrough pain in patients with cancer, 18 years of age or older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Onsolis is available only through a restricted distribution program called the FOCUS Program and requires prescriber, pharmacy, and patient enrollment.

[Drugs in the News]

■ The FDA has accepted for review the new drug application (NDA) for **APF530** (A.P. Pharma, Inc., Redwood City, Calif.) for potential treatment of

Fast Facts

How Consumers Feel about Their Healthcare Plans

- Fifty-three percent are satisfied with their health plan—an increase from 44 percent in 2008. Satisfaction is highest among enrollees in Medicare (70 percent) and military health programs (67 percent), lowest among individual policy holders (45 percent).
- Forty-six percent say they would recommend their health plan to others.
- Cost is the reason the uninsured lack coverage. Forty-five percent of the uninsured say it is too expensive to purchase healthcare coverage.
- Seventeen percent of insured consumers say they switched insurance companies or plans in the past year, an increase from 13 percent in 2008. Lower premiums and co-pays (29 percent) and job changes (25 percent) were major reasons for changes.
- Four in 10 say they would like to customize their insurance product by selecting benefits and features from a menu, knowing the cost would reflect what they choose. The desire to customize is higher among the uninsured (57 percent), lower among Medicare enrollees (36 percent).
- Customizable features that consumers consider most important include prescription coverage (81 percent), dental coverage (69 percent), waiver of referrals to specialists (67 percent) and pre-authorizations (60 percent), and a wide provider network (60 percent).
- Familiarity with and the reputation of the insurance company is important to three in five consumers.

Source: Deloitte Center for Health Solutions. Health Care Consumerism—Opportunities and Challenges for Health.

chemotherapy-induced nausea and vomiting. APF530 is a long-acting formulation of granisetron that utilizes the company's proprietary Biochronomer™ drug delivery system. Based on the Prescription Drug User Fee Act, the FDA has issued an action date of March 18, 2010.

■ CyDex Pharmaceuticals, Inc., (Lenexa, Kansas) announced that the FDA has accepted the company's investigational new drug application (IND) for a clinical study of **Captisol-Enabled® melphalan HCL (CDX-353)**. In December 2008, CyDex received orphan-drug designation from the FDA for melphalan "as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation."

■ Sagent Pharmaceuticals, Inc., (Schaumburg, Illinois) announced that the company has launched **ondansetron in 5% dextrose injection in premix bags**, an antiemetic and selective 5-HT3 receptor antagonist used to prevent nausea and vomiting caused by chemotherapy. Sagent, a specialty pharmaceutical company, will offer ondansetron in 5% dextrose injection in 32 mg per 50 mL single dose premix bags.

Sagent Pharmaceuticals, Inc., has also launched **fludarabine phosphate for injection, USP** and **epirubicin hydrochloride injection**. Fludarabine for injection, USP will be offered in 50 mg single-use vials. Epirubicin hydrochloride injection will be offered in 50 mg per 25 mL and 200 mg per 100 mL single-dose vials.

■ Hospira, Inc., (Lake Forest, Illinois) announced FDA approval and launch of the company's **oxaliplatin injection**. Hospira's oxaliplatin injection is one of the first generic versions of this drug to come in solution form. Hospira will initially offer oxaliplatin in 50 mg and 100 mg single-use vials

■ AstraZeneca (Wilmington, Delaware) announced submission of an NDA to the FDA for an investigational drug **vandetanib 100 mg** for use in combination with chemotherapy for the treatment of advanced non-small cell lung cancer in patients previously treated with one prior anti-cancer therapy. The submission is supported by data from Phase III clinical studies evaluating the safety and efficacy of vandetanib 100 mg in combination with chemotherapy. Pending approval, the treatment will be marketed as **Zactima™**.

[Devices in the News]

■ The FDA granted clearance for Hologic, Inc.'s (Bedford, Mass.) **R2™ DigitalNow™ HD software application**. The R2™ DigitalNow™ HD software is the only FDA-cleared application intended to process digitized screen-film mammograms for comparison purposes. The software adapts each digitized film image to a selected contrast and tissue intensity that models a digital mammography system. It also embeds a series of look-up tables in the image that allow Integrated Healthcare Enterprise (IHE) mammography conformant workstations to draw out less evident regions of density within digitized films.

■ Elekta (Anaheim, Calif.) announced the company's CMS Software has received FDA 510(k) clearance for the **VMAT enhancement to Monaco**, an advanced IMRT treatment planning solution. Monaco with VMAT can optimize single or multiple non-coplanar arcs simultaneously, providing the flexibility and control needed for complex treatment plans. Reducing planning time and increasing clinical throughput, arc plans can be delivered with a single button push at the linear accelerator console, gantry directions automatically sorted, and control points seamlessly integrated into a single deliverable arc sequence.

Label Change to Erbitux and Vectibix

New label information on the cancer treatment Erbitux® (cetuximab) will state there is no evidence that the drug works on a minority of colon cancer patients with a specific genetic mutation. Eli Lilly and Company and Bristol-Myers Squibb Company announced that the addition to the drug's label will state that studies have not shown that Erbitux helps patients whose tumors have a mutated gene, or biomarker, called *KRAS*.

Amgen Inc. announced a similar label change for its cancer drug Vectibix® (panitumumab). Both Erbitux and Vectibix block the epidermal growth factor receptor, preventing cells from growing and expanding.

Lilly Widens Income Eligibility for Patient Assistance Programs

On Aug. 1, 2009, Lilly USA adjusted the income eligibility for its most widely used patient assistance programs to allow enrollment of eligible patients with incomes at or less than 300 percent of the U.S. Federal Poverty Level. As an example, the new yearly eligible income limit for a family of two corresponds to approximately $44,000. Previously, the income eligibility limit was set at 200 percent of the Federal Poverty Level.

The company is broadening the income eligibility in response to concerns expressed by patients who have experienced strained financial circumstances—such as job loss and loss of insurance coverage—due to the recent economic downturn.

Patients who believe they qualify for any of Lilly's patient assistance programs, or whose financial situation has changed from their last tax filing or application to Lilly's programs, may contact the applicable patient assistance program or visit *www.lilly.com/responsibility/programs* for more information.