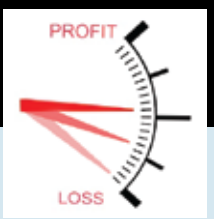
Fast Facts



Trends in Community-based Medical Oncology Practices

- Oncology practices are expanding to bring in more doctors under one roof—the average number of oncologists per practice increased between 2005 and 2007 from 2.9 to 4.3.
- The number of new patient visits to each oncologist increased by 22 percent, from an average of 300 in 2005 to 388 in 2007.
- Revenue per oncologist fluctuated, averaging $5,250 per patient in the second year of the survey and $4,082 per patient most recently.
- The average profit per oncologist per patient steadily declined, from $987 in 2005 to $654 in 2006 to just $89 in 2007.
- Percentage of overall revenue spent on drugs has increased 18 percent in two years.

Source: *Onmark 3rd Annual Benchmarking Survey*, Onmark— now part of McKesson Specialty.

[Approved Drugs]

PHOTOGRAPH/FOTOLIA

■ The Food and Drug Administration (FDA) has approved Eli Lilly and Company's (Indianapolis, Ind.) **Alimta® (pemetrexed for injection)** for use, in combination with cisplatin, in the first-line treatment of locally advanced and metastatic non-small cell lung cancer (NSCLC) for patients with nonsquamous histology. Alimta is *not* indicated for treatment of patients with squamous NSCLC.

The Alimta approval is based on a Phase III study that evaluated Alimta plus cisplatin (AC arm) versus Gemzar® (gemcitabine HCl for injection) plus cisplatin (GC arm). Based on the same data, the FDA also approved a change to the second-line indication. Alimta is indicated as a single agent for the treatment of patients with locally advanced or metastatic nonsquamous NSCLC after prior chemotherapy. Alimta is *not* indicated for treatment of patients with squamous cell NSCLC.

■ Eisai Inc. and its partner Helsinn Healthcare SA (Woodcliff Lake, N.J.) announced the FDA has approved a new oral formulation of **Aloxi® (palonosetron hydrochloride)** for the prevention of chemotherapy-induced nausea and vomiting. Aloxi capsules 0.5 mg for oral administration are indicated for the prevention of acute nausea and vomiting following initial and repeat courses of moderately emetogenic chemotherapy. A single 0.5 mg Aloxi capsule is administered approximately one hour prior to the start of chemotherapy.

■ Amgen Inc. (Thousand Oaks, Calif.) announced that the FDA has approved **Nplate™ (romiplostim)**, the first and only platelet producer for the treatment of thrombocytopenia in splenectomized and non-splenectomized adults with chronic immune thrombocytopenic purpura. Nplate works by raising and sustaining platelet counts, representing a novel approach for the long-term treatment of this chronic disease.

■ The FDA has approved Eisai Corporation's (Woodcliff Lake, N.J.) supplemental biologics license application (sBLA) for **Ontak® (denileukin diftitox) solution for intravenous injection** for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the interleukin (IL)-2 receptor (CD25+). A separate efficacy supplement that included data from patients with cutaneous T-cell lymphoma whose malignant cells did not test positive for the CD25 component of the IL-2 receptor received a complete response letter. The FDA's action marks the conversion of an accelerated approval indication to full approval and is based on data from a randomized, double-blind, placebo-controlled Phase III clinical trial that evaluated the overall clinical effectiveness and safety of Ontak in certain patients with cutaneous T-cell lymphoma.

■ The FDA has approved **Sancuso® (granisetron transdermal system)**, a skin patch that provides up to five consecutive days of control of nausea and vomiting for patients receiving a moderately and/or highly nausea-inducing chemotherapy regimen. The transdermal system (ProStrakan Group PLC, Bedminster, N.J.) delivers granisetron, its active component and an established inhibitor of nausea and vomiting, through a thin layer of adhesive that attaches the patch to the skin. The medicine is then released slowly and continuously into the bloodstream for up to five consecutive days.

[Drugs in the News]

■ **Amrubicin** (Celgene Corporation, Summit, N.J.) has been granted fast track designation by the FDA for the treatment of small cell lung cancer after first-line chemotherapy. A third-generation, synthetic anthracycline analogue, Amrubicin is a potent topoisomerase II inhibitor and is being studied as a single agent and in combination with anti-cancer therapies for a variety of solid tumors, including lung cancer.

■ The FDA has granted orphan designation to Celator Pharmaceuticals' (Princeton, N.J.) **CPX-351(Cytarabine: Daunorubicin) Lipsome Injection** for the treatment of actue myeloid leukemia.

THE TOOLS

CPX-351 is a liposomal formulation of cytarabine and daunorubicin delivered in a 5:1 molar ratio shown to be strongly synergistic in preclinical studies.

■ Ortho Biotech (Bridgewater, N.J.) announced submission of a supplemental new drug application (sNDA) to the FDA for the combination of **Doxil® (doxorubicin HCl liposome injection)** and **Taxotere® (docetaxel)** for the treatment of women with advanced breast cancer who have received prior anthracycline treatment.

■ Novartis (East Hanover, N.J.) announced that **Gleevec® (imatinib mesylate) tablets** has been granted priority review status by the FDA as the first therapy to be reviewed for use after surgery in kit-positive gastrointestinal stromal tumors (GIST). The Gleevec submissions are based on data from a Phase III study of more than 700 GIST patients who had surgery to remove their tumors. The results showed a dramatic 89 percent reduction in risk of kit-positive GIST returning after surgery (adjuvant setting) in patients treated with Gleevec versus placebo.

■ **MP-470** (SuperGen, Dublin, Calif.), an experimental treatment for brain cancer, has been granted orphan drug designation by the FDA. The company is developing the drug to treat glioblastoma multiforme. MP-470 is being evaluated in Phase I trials both as a single agent and in combination with chemotherapy in patients with solid tumors, a Phase Ib study in patients with glioblastoma multiforme is planned.

■ OncoGenex Pharmaceuticals (Bothell, Wash., and Vancouver, B.C., Canada) announced that **OGX-011**, also known as custirsen sodium, received fast track designation from the FDA in combination with doxetaxel for progressive metastatic cancer. OGX-011 is currently completing five Phase II clinical studies in prostate, lung, and breast cancer, and is designed to inhibit the production of a specific protein, clusterin, associated with treatment resistance.

■ Novartis (East Hanover, N.J.) announced that **RAD001 (everolimus)** has been granted priority review by the FDA. The designation is based on the drug's potential to become the first therapy to demonstrate significant benefit in patients with advanced kidney cancer after failure of standard treatment. RAD001, an oral once-daily inhibitor of mTOR, is an investigational drug being studied in multiple tumor types.

[Devices in the News]

■ GE Healthcare (Princeton, N.J.) announced that the FDA has approved **AdreView® (Iobenguane I 123 Injection)**, a molecular imaging agent for the detection of rare neuroendocrine tumors in children and adults. AdreView provides high-quality images that allow physicians to detect tumors, both at the time of initial diagnosis and at later examinations when relapse or recurrence is suspected.

■ CMS, Inc., an Elekta Company, (St. Louis, Mo.) has received FDA 510(k) clearance for its new **Atlas-Based Autosegmentation (ABAS)** product. ABAS is a software application that produces an estimate of the anatomy boundary contours needed to create a radiation treatment plan. A stand alone, vendor neutral product that communicates using standard DICOM file formats for both input and output, ABAS is compatible with any radiation treatment planning system that can read standard DICOM RT structure set files.

■ Baxter International Inc. (Deerfield, IL) introduced the company's latest container of the Aviva platform—the **500 mL Aviva Container system**. This flexible, functional, closed-system container will provide healthcare professionals with a more versatile container to help meet the needs of sensitive patient populations, such as neonatal, pediatric, and oncology patients.

FDA Approves Expanded Uses for Gardasil®

In September 2008, the FDA announced approval of the vaccine Gardasil for the prevention of vaginal and vulvar cancer caused by Human Papillomavirus (HPV) types 16 and 18 in girls and women ages 9 to 26. These two HPV types cause 70 percent of cervical cancers, and are known to also cause some vulvar and vaginal cancers, but the percentages are not well defined. The FDA originally approved Gardasil in 2006 for girls and women ages 9 to 26 for the prevention of cervical cancer caused by HPV types 16 and 18, precancerous genital lesions caused by HPV types 6, 11, 16, and 18, and genital warts caused by HPV types 6 and 11.

[Genetic Tests and Assays in the News]

■ DiagnoCure Oncology Laboratories (West Chester, Pa.), a wholly-owned subsidiary of DiagnoCure Inc., announced that it has received the U.S. CLIA certification required for the company to launch its new laboratory developed **Previstage™ GCC Colorectal Cancer Staging Test**.

■ Agendia (Huntington Beach, Calif., and Amsterdam, The Netherlands) announced the launch of **TargetPrint®**, a new diagnostic test that allows physicians to quantitatively determine the gene expression levels of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) in breast cancer biopsies. TargetPrint runs on Agendia's new High Density Chip, which received FDA market clearance in August 2008.