THE TOOLS

[Approved Drugs]

■ GlaxoSmithKline (London, U.K.) announced that the Food and Drug Administration (FDA) has approved **Arzerra (ofatumumab)** for patients with chronic lymphocytic leukemia (CLL). Arzerra is approved for patients with CLL whose cancer is no longer being controlled by other forms of chemotherapy. Arzerra is a monoclonal antibody that binds to a specific protein found on the surface of both normal and malignant B cells, making the cells more susceptible to immune system attack.

■ The FDA has approved **Istodax® (romidepsin)** for injection for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy. Istodax interferes with processes required for cell replication. Istodax is manufactured by Gloucester Pharmaceuticals Inc., (Cambridge, Mass.).

[Drugs in the News]

■ Apogenix GmbH (Heidelberg, Germany) announced that the FDA has granted orphan drug designation to **APG101** for the treatment of glioblastoma multiforme (GBM).

■ AEterna Zentaris Inc., and Keryx Biopharmaceuticals, Inc., announced that the FDA has granted fast track designation to **perifosine (KRX-0401)** for the treatment of relapsed/refractory multiple myeloma. Perifosine is a novel oral anticancer agent that modulates several key signal transduction pathways, including Akt, MAPK, and JNK that have been shown to be critical for the survival of cancer cells.

PHOTOGRAPH/COMSTOCK

■ The FDA has granted orphan drug designation to **TNFerade™** (GenVec, Inc., Gaithersburg, Md.) for the treatment of pancreatic cancer. TNFerade, which has not yet been approved for use, is an adenovector, or DNA carrier, which contains the gene for tumor necrosis factor-alpha (TNF-alpha), an immune system protein with potent and well-documented anti-cancer effects, for direct injection into tumors. After administration, TNFerade stimulates the production of TNF-alpha in the tumor.

[Devices in the News]

■ Boston Scientific Corporation (Natick, Mass., and London) announced FDA 510(k) clearance and CE Mark approval to market its **WallFlex® Fully Covered Esophageal Stent** for the treatment of malignant esophageal strictures (obstructions) caused by tumors in patients with resectable or non-resectable esophageal cancer. The WallFlex Fully and Partially Covered Stents employ a proprietary Permlume® silicone covering designed to prevent tumor ingrowth, seal concurrent esophageal strictures and help reduce food impaction.

Fast Facts

Top 10 Healthcare Reform Principles

1. Value and cost
2. Wellness and patient responsibility
3. Electronic systems
4. New form of reimbursement
5. Evidence-based medical decision-making
6. Universal coverage
7. Level the playing field
8. Primary care
9. Measurement and public reporting
10. Accountable care organizations

Source. The Camden Group. *The Camden Quarterly.* Volume XII, No. 3, 2009.

Medicare Administrator Establishes Reimbursement Code for MammaPrint®

Agendia (Huntington Beach, Calif., and Amsterdam, The Netherlands) announced that Palmetto GBA, California's Part B Medicare administrator, has established coding guidelines for the company's MammaPrint test. The coding guidelines are available on the Centers for Medicare & Medicaid Services (CMS) website at: *www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=30376&lcd_version=5&show=all.*

MammaPrint is the only breast cancer recurrence test cleared by the FDA. FDA clearance under the *in vitro* diagnostic multivariate index assay (IVDMIA) guidelines requires clinical and analytical validation and reporting systems to ensure that patient safety and efficacy are addressed. All MammaPrint tests are conducted in Agendia's CLIA-accredited service laboratory.