THE TOOLS

[Drugs in the News]

■ GlaxoSmithKline and Genmab (London, U.K., and Copenhagen, Denmark) announced submission of a biologics license application (BLA) to the FDA for **Arzerra™ (ofatumumab)** to treat patients whose chronic lymphocytic leukemia (CLL) is resistant to previous therapies. If approved, ofatumumab would be the first anti-CD20 monoclonal antibody available for this patient population.

■ Amgen Inc. (Thousand Oaks, Calif.) announced FDA acceptance of a BLA for **denosumab**, an investigational RANK ligand inhibitor. The indications for which Amgen is seeking FDA approval are treatment and prevention of postmenopausal osteoporosis (PMO) in women, and treatment and prevention of bone loss in patients undergoing hormone ablation for either prostate or breast cancer. Denosumab is the first fully human monoclonal antibody in late stage clinical development that specifically targets RANK Ligand, an essential regulator of osteoclasts (the cells that break down bone).

■ The FDA granted TransMolecular, Inc., (Cambridge, Mass.) orphan drug designation for the company's anti-cancer compound **^{131}I-TM601** for the treatment of Stage IIb-IV melanoma. The drug candidate is currently in a Phase I/II clinical trial for the treatment of recurrent malignant melanoma. The company had previously received orphan drug designation for ^{131}I-TM601 in malignant glioma, as well as for the non-radiolabeled version of TM601 for the treatment of malignant glioma.

■ ChemGenex Pharmaceuticals Limited (Melbourne, Australia, and Menlo Park, Calif.) announced that the FDA has granted orphan drug designation to **omacetaxine** for the treatment of myelodysplastic syndromes (MDS).

Omacetaxine mepesuccinate is a first-in-class cetaxine with established clinical activity as a single agent in a range of hematological malignancies. Omacetaxine has a novel mechanism of action, and induces apoptosis by inhibition of protein synthesis, particularly Mcl-1. As omacetaxine acts independently of tyrosine kinase inhibitors, it has therapeutic advantages for patients who have developed resistance to tyrosine kinase inhibitor therapy. Omacetaxine is administered subcutaneously.

■ The FDA has granted BTG plc (London, U.K.) orphan drug designation for its drug **OncoGel™** (paclitaxel) for the treatment of brain cancer.

■ Seattle Genetics, Inc., (Bothell, Wash.) announced that **SGN-35** has been granted orphan drug designation by the FDA for the treatment of anaplastic large cell lymphoma (ALCL). This designation is in addition to the SGN-35 orphan drug designation for Hodgkin lymphoma previously received from the FDA. The company plans to initiate a pivotal trial of SGN-35 for Hodgkin lymphoma and a Phase II clinical trial for ALCL during the first quarter of 2009.

SGN-35 is an antibody-drug conjugate (ADC) comprising an anti-CD30 monoclonal antibody attached by an enzyme cleavable linker to a potent, synthetic drug payload, monomethyl auristatin E (MMAE), using the company's proprietary technology. The ADC is designed to be stable in the bloodstream, but to release MMAE upon internalization into CD30-expressing tumor cells, resulting in a targeted cell-killing effect.

Epocrates Rx Pro®

Oncologists using BlackBerry devices can subscribe to the Epocrates Rx Pro® premium application featuring Epocrates ID® infectious disease treatment guide, and an IV compatibility checker. More than 600 alternative medicine monographs are available for clinicians whose patients are taking supplements, such as grape seed or St. John's Wart, which can negatively interact with prescription medications. To date, Epocrates subscribers using a BlackBerry device have had free access to critical prescribing information including drug dosing, adverse reactions, interactions, and pricing.

PHOTOGRAPH/BIGSTOCKPHOTO

[Devices in the News]

■ IMRIS Inc., (Winnipeg, Canada) announced that the FDA has cleared the company's **3 Tesla**

IMRISneuro for sale in the United States. IMRISneuro is now available with either a 1.5 Testa (1.5T) or a 3 Tesla (3T) magnet. Both systems provide IMRIS' patented technology and utilize 70 cm wide bore advanced magnetic resonance imaging systems from Siemens.

The 3T IMRISneuro provides high quality advanced imaging techniques for surgical planning such as diffusion tensor imaging (DTI), functional MRI, and spectroscopy, as well as superior quality vascular imaging in a robust platform specifically designed for use in an operating room.

■ **CELL-DYN Emerald™** (Abbott, Abbott Park, Ill.) has received 510(k) clearance from the FDA. A compact, hematology instrument, CELL-DYN Emerald has automated features designed to help laboratories improve productivity and reduce costs, including: 1) a touch-screen monitor to simplify operations, 2) one-button start-up, 3) low reagent consumption, 4) automatic cleaning and shut-down features, and 5) barcode-labeled reagents. With this device, CBC results are completed in 60 seconds and reported in an easy-to-read format with histograms representing white blood cells, red blood cells, and platelets.

■ The FDA issued 510(k) marketing clearance for the **Evident™ Microwave (MW) Ablation System** (Covidien, Boulder, Colo.), intended for use in the ablation of nonresectable liver tumors. This new system offers a procedural option for patients who are not candidates for surgical resection and have few remaining treatment options.

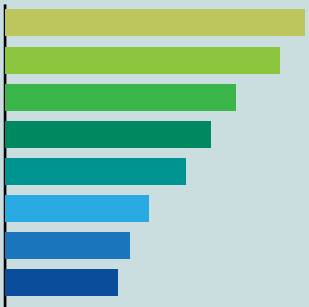
The Evident MW Ablation System is intended for the coagulation of soft tissue during percutaneous laparoscopic and open surgical procedures. The system uses microwave energy, emanating from the feed point of the radiating section of an antenna, to cause coagulation of the tissue. The microwave energy creates heat by generating friction through the vibration of water molecules. With microwave ablation, there is no current flow through the patient, eliminating the need for grounding pads.

[Genetic Tests and Assays in the News]

■ Pathwork Diagnostics, Inc., (Sunnyvale, Calif.) launched an additional version of the **Pathwork® Tissue of Origin Test** that has the capability of analyzing formalin-fixed, paraffin-embedded (FFPE) tissue specimens. This molecular test, which aids in the diagnosis of tumors with uncertain origins, is now available as a service through the CLIA-certified Pathwork Diagnostics Laboratory. The Pathwork Diagnostics Laboratory is now able to process and analyze both FFPE and frozen tissue specimens. Upon specimen receipt, Pathwork runs the microarray test on the specimens, and a staff pathologist interprets the test results and provides a comprehensive clinical report to the physician.

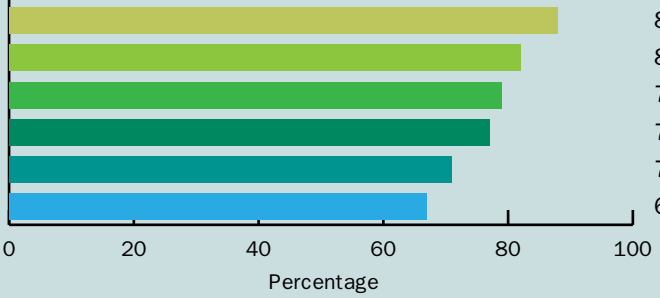
Fast Facts

Most Common Reasons for Not Using Clinical Guidelines



48% The diagnosis was not completely determined
44% I was not aware of any relevant clinical guidelines
37% It was not convenient
33% I did not agree with them
29% I did not think they would produce the desired outcome
23% My office did not have the technology to properly implement them
20% I was not being reimbursed for activities related to guideline implementation
18% They conflicted with how I currently practice medicine

Factors That would be Likely to Increase Use of Guidelines



88% The findings are relevant to the way I practice medicine
82% It was written by credible sources
79% It has a sound methodology (e.g., risk adjusted)
77% It is considered independent of commercial interests
71% It is highly recommended
67% The approach is shown to be cost effective

Source: Harris Interactive, *Healthcare News*. Vol. 8, No. 4, Feb. 25, 2008