THE TOOLS

[Approved Drugs]

■ Novartis (East Hanover, N.J.) announced that the Food and Drug Administration (FDA) has approved **Afinitor® (everolimus) tablets** for patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent® (sunitinib) or Nexavar® (sorafenib). Afinitor belongs to a class of drugs called kinase inhibitors, which interfere with cell communication, preventing tumor growth. The drug is intended for those patients with advanced RCC who have already tried another kinase inhibitor, Sutent or Nexavar.

While Sutent and Nexavar are multiple kinase inhibitors (acting on a number of cellular targets), Afinitor works by blocking a specific protein known as the mammalian target of rapamycin or mTOR. The protein blocking action disrupts the growth, division, and metabolism of cancer cells.

■ Ferring Pharmaceuticals, USA (Parsippany, N.J.) announced the U.S. commercial availability of **degarelix for injection** (trade name pending), a new injectable gonadotropin-releasing hormone (GnRH) receptor antagonist approved by the FDA for the treatment of hormone sensitive advanced prostate cancer. Degarelix is available for order through traditional and specialty pharmacy distributors.

[Drugs in the News]

■ The FDA has cleared Cellectar, Inc.'s (Madison, Wisc.) investigational new drug (IND) application for its **(131)I-CLR1404** drug candidate for testing in patients with advanced solid malignancies. The company expects to begin Phase I clinical trials in the second quarter of 2009.

■ Arno Therapeutics, Inc. (Parsippany, N.J.) announced that the FDA accepted the company's IND application for the use of **AR-42**. The orally available, novel, potent, small molecule modifies the acetylation of histones and other molecules, and is a targeted inhibitor of the Pan-DAC and Akt pathways. HDAC inhibitors disrupt HDAC-PPI complexes and cause signaling kinase dephosphorylation.

■ The FDA has accepted and granted priority review to Genmab's

Fast Facts

PHOTOGRAPH/FOTOLIA

As genetic tests become more affordable and advanced, consumers have access to personalized medical information that can help them manage their health and make good choices for prevention and treatment. But not all genetic tests are created equal. Here are 6 questions consumers should ask about genetic tests.

1. Is the test done in a medical lab certified under CLIA, the Clinical Laboratory Improvement Amendment, which requires medical laboratories to meet standards for quality, accuracy, safety, and validity of the tests they perform?
2. Is a genetic counselor, physician, or other knowledgeable healthcare professional available to assist you in selecting tests and interpreting results?
3. Do the claims seem hard to believe? (If the claim seems too good to be true, it probably is.)
4. Are other products, such as nutritional supplements, being sold along with the test? (Caution: that could be a sign that the company's profit—not your health—is the real concern.)
5. Are you willing to be "an informed" consumer—that is, to take the time to understand what genetic testing tells you?
6. Does the provider of the service offer adequate assurances that your genetic information will be kept private and secure?

Source: *Results for Life*, an educational campaign of the American Clinical Laboratory Association, a non-profit association in Washington, D.C. For more information go to: *www.labresultsforlife.org*.

e-prescribing Tool

McKesson Specialty Care Solutions, a division of McKesson Corp., has launched a fully integrated e-prescribing solution that enables oncology and other specialty physicians to participate in the Medicare e-prescribing Incentive Program. Leveraging **RelayHealth's eScript**,™ physicians will now be able to electronically file medical renewals and refills on behalf of patients directly from Lynx Mobile,™ McKesson's charge capture and inventory management technology. Powered by eScript, the solution also incorporates Lynx TotalView™ to give practices the reporting tools necessary to track their progress towards achieving the incentives available under the Medicare e-prescribing program.

(Copenhagen, Denmark) biologics license application for **Arzerra™ (ofatumumab)** to treat patients whose chronic lymphocytic leukemia (CLL) is resistant to previous therapies. The novel, investigational, fully human monoclonal antibody targets a membrane-proximal (close to the cell surface) small loop epitope (a portion of a molecule to which an antibody binds) on the CD20 molecule of B-cells. The CD20 molecule is a key target in CLL therapy because it is expressed on most B-cells in CLL patients.

■ Tigris Pharmaceuticals, Inc. (Bonita Springs, Fla.) announced that the FDA has accepted the company's IND application for its **geranylgeranyltransferase inhibitor (GGTI-2418)**. GGTI-2418 is a synthetic peptidomimetic inhibitor of geranylgeranyltransferase I (GGTase I) that induces apoptosis by downregulating several pivotal oncogenic and tumor survival pathways. The FDA's acceptance of the company's IND will allow the company to open a Phase I study evaluating the safety of GGTI-2418 during the first quarter of 2009.

■ Vion Pharmaceuticals, Inc. (New Haven, Conn.) announced the filing of a new drug application (NDA) with the FDA for **Onrigin (larmustine) Injection** as a single agent for remission induction treatment for patients 60 years of age or older with de novo poor-risk acute myeloid leukemia (AML). The company requested priority review for the application. Onrigin (laromustine) Injection, formerly known as Cloretazine® (VNP40101M), is a novel alkylating agent.

[Devices in the News]

■ Xoft, Inc. (Sunnyvale, Calif.) announced FDA clearance for a **skin and surface treatment applicator** for use with the **Axxent Electronic Brachytherapy (eBx) System** to deliver surface brachytherapy, including Intraoperative Radiation Therapy (IORT). This latest FDA clearance allows the applicator to be used on any external or internal surface of the body where radiation therapy is indicated. Previously cleared for accelerated treatment of early stage breast cancer and endometrial and rectal cancers, the Axxent System is also cleared for use in the treatment of surface cancers or conditions where radiation therapy is indicated.

■ Neuisys Imaging System Solutions, LLC (Greensboro, N.C.) announced that the FDA has granted 510(k) clearance of the **NeuViz 16 Multi-Slice Computed Tomography (CT) System**. The NeuViz 16 is developed by Philips Newsoft Medical Systems, a joint venture between Royal Phillips Electronics of the Netherlands and Neusoft Corporation of China.

■ The FDA has granted Serica Technologies, Inc. (Medford, Mass.) 510(k) clearance for its **SeriScaffold™** silk-based, long-term bioresorbable scaffold technology. The SeriScaffold platform technology has the potential to provide a new solution as an off-the-shelf, long-term bioresorbable scaffold for support and repair of weakened or damaged connective tissue. According to the company, SeriScaffold could be used as a tissue repair scaffold for the approximately 60,000 women who annually undergo reconstructive procedures resulting from illnesses such as breast cancer. The SeriScaffold platform technology provides a unique, natural, protein-based alternative to synthetic materials and graft products harvested from human or animal cadaver tissue.

[Genetic Tests and Assays in the News]

■ The FDA approved the first DNA test that identifies two types of human papillomavirus (HPV) that cause the majority of cervical cancers among women in the United States. **Cervista HPV 16/18** (Third Wave Technologies Madison, Wisc.) detects the DNA sequences for HPV type 16 and HPV 18 in cervical cells. Differentiating these HPV types gives healthcare professionals more information on a patient's risk of subsequently developing cervical cancer. A positive Cervista 16/18 test result indicates whether HPV type 16, 18, or both types are present in the cervical sample.

The FDA also approved the **Cervista HPV HR** test, which is the second DNA test that detects essentially all of the high-risk HPV types in cervical cells samples. The Cervista HPV HR test uses a method similar to the Cervista HPV 16/18 to detect the DNA sequences of these HPV types.

In women age 30 and older or women with borderline cytology, the Cervista HPV 16/18 test can be used together with cytology and the Cervista HPV HR test to assess risk of cervical disease.

Totect® Kit with New Price Option

TopoTarget USA, Inc. (Rockaway, N.J.) announced it is offering a new lower-priced option for a complete **Totect® (dexrazoxane for injection)** emergency kit for the treatment of anthracycline extravasation (AEV). The new Totect kit will be priced at $6,500 for the full three-day emergency treatment. In addition, effective February 1, 2009, TopoTarget USA, Inc. will ensure that a kit purchased at the new lower price option has at least 16-months of product life. Therefore, if a kit purchased from a Totect authorized distributor has less than 16-months of shelf life, TopoTarget USA, Inc. will provide one free replacement kit should a kit expire before use.