THE TOOLS

Fast Facts

Top 10 Patient Satisfaction Ratings for Medical Practice Specialties

1. Medical Oncology – 92.76
2. Gynecological Oncology – 92.39
3. Interventional Cardiology – 92.01
4. Cardiovascular Disease – 91.99
5. Optometry – 91.81
6. Hematology – 91.77
7. Geriatric Internal Medicine – 91.37
8. Gynecology – 91.32
9. Nephrology – 91.29
10. Family Medicine – 90.76

Source: Press Ganey Associates, Inc.
For more information, visit *www.pressganey.com.*

[Approved Drugs]

■ The Food and Drug Administration (FDA) approved **Afinitor® (everolimus) Tablets** (Novartis Pharmaceuticals Corporation, *www.novartis.com*) for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced, or metastatic disease.

■ The FDA approved **Sutent (sunitinib)** (Pfizer, *www.Pfizer.com*) to treat patients with progressive neuroendocrine cancerous tumors located in the pancreas that cannot be removed by surgery or that have spread to other parts of the body.

■ Centocor Ortho Biotech Inc. (*www.centocororthobiotech.com*) announced that the FDA has approved **Zytiga™ (abiraterone acetate)**, an oral, once-daily medication for use in combination with prednisone for the treatment of men with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel. Zytiga is an oral androgen biosynthesis inhibitor that works by inhibiting the CYP17 enzyme complex.

[Drugs in the News]

■ Pfizer (*www.pfizer.com*) has filed a new drug application (NDA) and been granted priority review status by the FDA for **crizotinib**, an oral first-in-class anaplastic lymphoma kinase (ALK) inhibitor. The proposed indication is for the treatment of patients with ALK-positive advanced non-small cell lung cancer. Crizotinib received orphan drug designation from the FDA in September 2010.

■ Morphotek® (*www.morphotek.com*), a subsidiary of Eisai Inc. (*www.eisai.com*), announced that the FDA has granted orphan drug designation for two of the company's investigational cancer drugs, **MORAb-004** for the treatment of soft tissue sarcoma and **MORAb-066** for the treatment of pancreatic cancer. MORAb-004 is a humanized monoclonal antibody to endosialin/tumor endothelial marker-1 (TEM-1), which is a protein that is expressed in many human malignancies, and which plays a role in tumor development. MORAb-066 is a humanized monoclonal antibody to tissue factor, which is a protein that plays an important role in blood coagulation.

PHOTOGRAPH/ISTOCKPHOTO

■ The FDA has granted orphan drug status to **NKTR-102** (Nektar Therapeutics, *www.nektar.com*) for the treatment of women with ovarian cancer. Nektar has an ongoing Phase II study for NKTR-102 that is enrolling approximately 125 patients with platinum-resistant ovarian cancer whose disease has progressed following treatment with pegylated liposomal doxorubicin (PLD) therapy. In addition, Phase III planning is also underway for NKTR-102 in ovarian cancer.

■ XTL Biopharmaceuticals, Ltd. (Herzliya, Israel) announced that the company's **rHuEPO (recombinant human erythropoietin)** drug has been granted orphan drug designation for multiple myeloma by the FDA. The drug is currently in preparations for Phase II clinical trial.

■ Genentech (*www.gene.com*), a member of the Roche Group, announced submission of an NDA for **vemurafenib (RG7204, PLX4032)** to the FDA for people with BRAF V600 mutation-positive metastatic melanoma. Vemurafenib is designed to selectively target and inhibit a mutated form of the BRAF protein found in about half of all cases of melanoma. A companion diagnostic (developed by Roche) identifies people who may be appropriate for this medicine.

[Genetic Tests and Assays in the News]

■ Genetic Technologies Limited (*www.gtglabs.com*) announced that the company has secured U.S. approval for launch of its

BREVAGen™ breast cancer test. Genetic Technologies Limited received certification of the company's Australian laboratory under the U.S. Clinical Laboratories Improvements Amendments (CLIA) (42 U.S.C. section 263a) regulated by the Centers for Medicare & Medicaid Services (CMS).

■ Arrayit Corporation (*www.arrayit.com*) announced the product launch of **OvaDx®**, the company's pre-symptomatic screening test for ovarian cancer. The microarray-based blood test measures the activation of the immune system in response to early stage ovarian tumor cell development. The test is being offered at $650 per test for research purposes only to advance the forefront of ovarian cancer research.

■ The FDA has approved the **cobas HPV (Human Papillomavirus) Test** (Roche, *www.roche.com*), which identifies women at highest risk for developing cervical cancer. The cobas HPV Test is the only FDA-approved cervical cancer screening test that allows HPV 16 and 18 genotyping concurrently with high-risk HPV testing. It individually identifies genotypes 16 and 18, the two highest-risk HPV genotypes responsible for more than 70 percent of cervical cancer cases, while simultaneously detecting 12 other high-risk HPV genotypes.

■ Transgenomic, Inc. (*www.transgenomic.com*) announced the launch of kits for high sensitivity mutational analysis of the *BRAF* and *PIK3CA* genes. These new kits complement the company's existing kits for detecting mutations in *K-RAS*, expanding Transgenomic's range of its **SURVEYOR® Scan** mutation detection kit product line.

■ NextGen Sciences Inc. (*www.nextgensciences.com*) announced the launch of its **plasmabreast25 multiplex protein assay**, targeting breast cancer biomarker discovery and qualification. The assay simultaneously measures 25 human plasma proteins that are thought to have potential as biomarkers in breast cancer.

[Abbott Files New Diagnostic Test with FDA]

■ Abbott (*www.abbott.com*) announced filing of a premarket approval application to the FDA for a new molecular diagnostic test designed to detect abnormal gene rearrangements in non-small cell lung cancer (NSCLC) tumors. The test is a combination product to be used with Pfizer's crizotinib, an oral first-in-class anaplastic lymphoma kinase (ALK) inhibitor. The new Abbott test uses fluorescence *in situ* hybridization technology (FISH) and is designed to detect rearrangements of the 2p23 chromosome of the ALK gene. These genetic abnormalities have been implicated in the development of NSCLC, lymphoma, and neuroblastoma.

[Devices in the News]

■ Brainlab (*www.brainlab.com*) has received 510(k) clearance from the FDA for the company's **HybridArc™ radiosurgery planning solution**. This software package will enable healthcare professionals to increase the efficiency of existing linear accelerator radiosurgery hardware and offer fast, high-precision volumetric arc radiosurgery treatment without the need for costly hardware upgrades.

■ The **HypothermX™ HX100 device** (EMIT Corporation) has received FDA 510(k) clearance. The portable fluid warming device designed to warm intravenous fluids, blood, or blood products infused into a patient to prevent or treat trauma, environmental, procedure related, or induced hypothermia. Heating is accomplished via a flameless hydrocarbon combustion process.

■ MEDRAD, Inc. (*www.medrad.com*), a business of Bayer HealthCare, announced the launch of the next generation **Intego™ PET Infusion System**, which features a new design that is 38 percent smaller, power-driven, and includes enhancements to technologist workflow. The Intego PET Infusion System remains the only FDA-cleared device for automated, controlled infusion of F18-FDG and F18-NaF, the most common PET diagnostic imaging agents used in oncology.

■ MIM Software Inc. (*www.mimsoftware.com*) announced FDA clearance for **MIM Symphony**™ as a brachytherapy treatment planning system for permanent seed implants. Key to the MIM Symphony software is the new ReSlicer™ tool. For treatments requiring needle insertions that are not precisely perpendicular to the imaging plane, ReSlicer allows images to be quickly and easily reoriented, ensuring accurate planning and dosimetry for otherwise complicated plans.

■ The FDA has approved the **NovoTTF-100A System** (Novocure, *www.novocure.com*), a new device to treat adults with glioblastoma multiforme that recurs or progresses after receiving chemotherapy and radiation therapy. Patients should not use the NovoTTF-100A System if they have an implanted medical device or skull defect, or have a known sensitivity to conductive hydrogels, such as those used with electrocardiograms. The NovoTTF-100A System is not intended to be used in combination with other cancer treatments. The device should only be used after other treatments have failed.

■ Sectra (*www.sectra.com*) announced that the company has received FDA clearance for its digital mammography system, **Sectra MicroDose Mammography**.™ The Sectra MicroDose counting technology reduces the radiation dose by half of that used by other digital or film-based systems. Unlike traditional analog and digital mammography modalities, which require a higher dose of radiation to ensure image quality, Sectra MicroDose Mammography detects X-ray photons individually. Images are delivered with 25 megapixels, which is two to four times higher resolution than that of other digital systems.