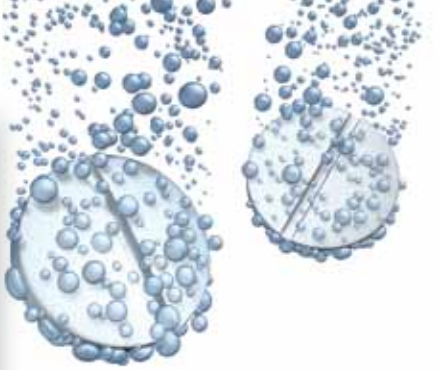
THE TOOLS

Fast Facts

New Medical Trends in 2011

- Drive Through Clinics
- Concierge Doctors
- Nurse Practitioners
- Virtual Doctors
- Holistic Medicine
- Medical Tourism
- D.I.Y. Care
- Increased use of ERs
- More Medical Specialists

Source: Red Rooster Public Relations. *www.redroosterpr.com*



ILLUSTRATION/BIGSTOCKPHOTO

[Approved Drugs]

■ Genentech, a member of the Roche Group, and Biogen Idec (*www.gene.com*) announced that the Food and Drug Administration (FDA) has approved **Rituxan® (rituximab)** as a maintenance treatment for patients with advanced follicular lymphoma who responded to initial treatment with Rituxan plus chemotherapy (induction treatment). This approval was based on data from the Phase III PRIMA study, which showed continuing Rituxan administration every two months for two years in patients who responded to initial treatment with Rituxan plus chemotherapy, nearly doubled the likelihood of them living without the disease worsening (progression-free survival) compared to those who stopped treatment.

■ Hospira, Inc. (*www.hospira.com)* announced FDA approval of **Topotecan Injection**, a generic version of Hycamtin®. Hospira's topotecan is indicated for treatment of small cell lung cancer (SCLC) sensitive disease after failure of first-line chemotherapy. The solution formulation of topotecan, with a concentration of 4 mg/4 ml, is designed to improve caregiver convenience and safety. Hospira expected the product to launch by the end of February 2011.

■ ProStrakan Inc. (*www.prostrakan-usa.com*) announced FDA approval for **Abstral (fentanyl) transmucosal tablets** to manage breakthrough pain for adults with cancer. Fentanyl immediate-release transmucosal medications are administered on the soft surfaces of the mouth (inside of the cheek, gums, tongue), or the nasal passages or throat where they dissolve and are absorbed.

Abstral is indicated for the management of breakthrough pain in patients with cancer, ages 18 and older, who already use opioid pain medication around the clock and who need and are able to safely use high doses of an additional opioid medication. Only healthcare professionals skilled in the use of Schedule II opioids should prescribe this drug product.

Abstral is available only through a Risk Evaluation and Mitigation Strategy (REMS) program, which is intended to minimize the risk of misuse, abuse, addiction, and overdose. The company expects to launch Abstral in the U.S. early in the first quarter of 2011.

[Drugs in the News]

■ Centocor Ortho Biotech Inc. (*www.centocororthobiotech.com*) submitted a new drug application (NDA) to the FDA for the investigational drug **abiraterone acetate** administered with prednisone for the treatment of metastatic advanced prostate cancer in patients who received prior chemotherapy containing a taxane.

Abiraterone acetate is an investigational oral androgen biosynthesis inhibitor being developed for the treatment of metastatic advanced prostate cancer that has developed resistance to conventional hormonal therapies (also known as castration-resistant prostate cancer).

■ Exelixis, Inc. (*www.exelixis.com*) announced that the FDA has granted orphan drug designation to **XL184 (cabozantinib)** for treatment of follicular, medullary, and anaplastic thyroid carcinoma, and metastatic or locally advanced papillary thyroid cancer.

A pivotal Phase III trial of cabozantinib is ongoing in patients with medullary thyroid cancer, and the company expects to release top-line Phase III results in the first half of 2011.

Cabozantinib, an inhibitor of tumor growth, metastasis, and angiogenesis, simultaneously targets MET and VEGFR2, key kinases involved in the development and progression of many cancers.

■ EUSA Pharma (*www.eusapharma.com*) announced that the company's biologics license application (BLA) for **Erwinase® (L-asparaginase derived from Erwinia chrysanthemi**) has been accepted for filing and awarded priority review status by the FDA. The company is seeking marketing approval for Erwinase for use in the treatment of acute lymphoblastic leukemia in patients with hypersensitivity to E. coli-derived asparaginase. Previously, the FDA awarded Erwinase orphan drug designation.

[Genetic Tests and Assays in the News]

■ Caris Life Sciences, Inc. (*www.carislifesciences.com*) announced the launch of a new **Caris Target Now™** molecular profile for ovarian cancer patients, which provides individualized molecular information to treating physicians relevant to the selection of therapies to treat this cancer.

■ Clarient, Inc. (*www.clarientinc.com*) has launched the **Insight® Dx**

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Mammostrat® Breast Cancer Recurrence Test, a patented test designed to help quantify the likelihood of recurrence of breast cancer following surgery and initial treatment.

The Mammostrat test employs a set of five biomarkers that can be identified visually on a patient's tumor specimen by using immunohistochemistry. Those biomarkers are then analyzed using a mathematical algorithm to generate an assessment of risk for cancer recurrence. The Mammostrat test can be performed on small biopsy samples, and results are typically delivered in as little as 48 to 72 hours.

■ Signal Genetics, Inc. (*www.signalgenetics.com*) announced the launch of **Myeloma Prognostic Risk Signature™ (MyPRS™)**, the company's molecular test for individuals diagnosed with multiple myeloma. MyPRS analyzes and applies an algorithm to a defined number of relevant genes to determine the gene expression profile associated with the patient's condition. The gene expression profiling allows physicians to gain a predictive view of their patient's prognosis, enabling personalized treatment options.

■ HistoRx, Inc. (*www.historx.com*) announced the launch and first commercial sale of clinical diagnostic assays based on AQUA® Technology. Genoptix, Inc. (*www.genoptix.com*), a specialized laboratory service provider, is launching **NexCourse® BCa by AQUA technology**, a suite of breast cancer assays based on quantitative immunohistochemistry.

[Devices in the News]

■ Accuray Inc. (*www.accuray.com*) announced FDA 510(k) clearance to market **Lung Optimized Treatment**, a new component of the CyberKnife® VSI™ System. Lung Optimized Treatment offers the accuracy and steep dose fall off required to safely treat lung tumors, even those close to nearby critical structures. Simulation and comparison workflows, combined with unique tracking modes, allow the clinician to select from multiple, non-invasive options, providing lung SBRT patients the optimal non-invasive treatment option, regardless of tumor location.

■ Boston Scientific Corporation (*www.bostonscientific.com*) announced FDA approval of **Renegade® HI-FLO™ Fathom® Pre-Loaded System** for selective access and delivery of diagnostic, embolic, and therapeutic materials into the peripheral vasculature. The system will primarily be used by interventional radiologists for minimally invasive procedures to treat uterine fibroids and liver cancer. The system will be available in eight configurations to suit a broad range of peripheral embolization procedures.

■ Tomophase Corporation (*www.tomophase.com*) announced that the company has received FDA 510(k) clearance to market **Tomophase Optical Coherence Tomography Imaging System (OCTIS™)**. OCTIS is comprised of a single-use disposable optical catheter and imaging console. Initially OCTIS will be deployed for tissue imaging of airways and lungs, followed by diagnostics and therapeutic applications.

■ Elekta (*www.elekta.com*) has received FDA 510(k) clearance for its **XiO® treatment planning software** to plan spot scanning, a proton therapy delivery method that involves constructing a highly conformal dose to the tumor by using thousands of small individual beamlets instead of a single large beam. This approach enables intensity-modulated proton therapy (IMPT). XiO, the company's 3D/IMRT treatment planning platform, offers proton therapy centers another option to plan proton deliveries. XiO provides tools to facilitate rapid positioning of spots to construct the dose to the tumor, in addition to a proven dose calculation algorithm to optimize each beam.

■ Hologic, Inc., (*www.hologic.com/en/*) announced the company has received FDA approval for its **Selenia Dimensions (Dimensions 3-D)** digital breast tomosynthesis system. Unlike prior-generation mammography systems, which generate two-dimensional images, breast tomosynthesis produces three-dimensional images that are intended to reveal the inner architecture of the breast, free from the distortion typically caused by tissue shadowing or density. The images are displayed on a standard diagnostic workstation for review by the radiologist.

Dimensions 3-D software is a purchasable option on existing Selenia Dimensions 2-D systems. Enabling the 3-D capability on a Dimensions 2-D system involves a software key and adjusting a PC-board setting. There is no need for new hardware.

[Vaccines in the News]

■ **Gardasil Approved for Prevention of Anal Cancer**
The FDA has approved the vaccine **Gardasil** for the prevention of anal cancer and associated precancerous lesions due to the human papillomavirus (HPV) types 6, 11, 16, and 18 in people ages 9 through 26 years.

Gardasil is already approved for the same age population for the prevention of cervical, vulvar, and vaginal cancer and the associated precancerous lesions caused by HPV types 6, 11, 16, and 18 in females. It is also approved for the prevention of genital warts caused by types 6 and 11 in both males and females.

■ BioSante Pharmaceuticals (*www.biosantepharma.com/*) has received orphan drug designation for the company's melanoma cancer vaccine in the treatment of stage IIb to IV melanoma from the FDA's Office of Orphan Products Development.