tools

Approved Drugs

• Genentech (*www.gene.com,* a member of the Roche Group) announced Food and Drug Administration (FDA) approval of **Perjeta™ (pertuzumab) injection** for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer (mBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Pertuzumab is a recombinant humanized monoclonal antibody that targets the extracellular dimerization domain (Subdomain II) of HER2, and thereby blocks ligand-dependent heterodimerization of HER2 with other HER family members, including EGFR, HER3, and HER4.

This approval is based on data from a Phase III study, which showed that people with previously untreated HER2-positive mBC who received the combination of Perjeta, Herceptin, and docetaxel chemotherapy lived a median of 6.1 months longer without their cancer getting worse (progression-free survival, or PFS) compared to Herceptin plus docetaxel chemotherapy (median PFS 18.5 months vs. 12.4 months).

• The FDA approved **Votrient™ (pazopanib)** (GlaxoSmithKline, plc, *www.gsk.com*) to treat patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The efficacy of pazopanib for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.

The approval is based on a randomized, double-blind, placebo-controlled, multicenter Phase III PALETTE study in patients with metastatic STS who had received prior chemotherapy, including anthracycline.

Votrient is a pill that works by interfering with angiogenesis. The recommended dose and schedule of pazopanib is 800 mg orally once daily, administered without food (at least 1 hour before or 2 hours after a meal).

Drugs in the News

• Ambit Biosciences (*www.ambitbio.com*) and Teva Pharmaceutical Industries Ltd. (*www.tevapharm.com*) announced clearance of an investigational new drug application (INDA) with the FDA for **CEP-32496**, a noval BRAF (V600E) kinase inhibitor. CEP-32496 is a small molecule kinase inhibitor of V600E mutated BRAF.

• Bayer HealthCare (*www.bayer.com*) announced submission of a new drug application (NDA) to the FDA seeking approval for the oral multi-kinase inhibitor **regorafenib** for the treatment of patients with metastatic colorectal cancer (mCRC). The submission is based on the results of the CORRECT study, an international, multicenter, randomized, double-blind, placebo-controlled Phase II study that enrolled 760 patients with mCRC whose disease had progressed during or within three months following the last administration of approved standard therapies.

Assays and Genetic Tests in the News

• Agendia (*www.agendia.com*) announced the launch of the company's **ColoPrint microarray-based 18-gene expression signature** for predicting the risk of distant recurrence for stage II colon cancer patients who have undergone surgery.

• Quest Diagnostics (*www.questdiagnostics.com*) launched the **Quest Diagnostics Thyroid Cancer Mutation Panel**, a new molecular test designed to help physicians determine if a thyroid gland is cancerous and requires surgical removal. The new panel identifies mutations of the molecular markers *BRAF, V600E, RAS, RET/PTC,* and *PAX8PPAR gamma,* which are associated with papillary and follicular thyroid cancer.

In addition the company has introduced the **Quest Diagnostics Thyroglobulin (Tg) Post-Treatment Monitoring Test** to aid in monitoring for recurrence of cancer following surgery.

Approved Devices

• Devicor® Medical Products, Inc. (*www.devicormedical.com*) announced the commercial launch of the **Mammotome® *elite* Biopsy System**, a tetherless single insertion, multiple sample,

vacuum-assisted biopsy (VAB) device featuring proprietary TruVac™ vacuum technology. Unlike devices that rely on automated syringes, *elite* provides a vacuum that achieves nearly the same suction power of the traditional Mammotome VAB system, enabling the device to capture large, high-quality tissue samples.

In March, the company received FDA 510(k) clearance for the Mammotome *elite* Biopsy System, which will be used to aid in the detection and treatment of breast cancer in ultrasound-guided breast and axillary lymph node biopsies.

- Mevion Medical Systems, Inc. (*www.mevion.com*) received FDA 510(k) clearance for the company's **MEVION S250 Proton Therapy System**. The MEVION S250 Proton Therapy System provides the same precise, non-invasive treatment advantages and capabilities of complex, large, and costly proton therapy systems but with higher patient throughput, significantly reduced footprint, improved reliability, and lower implementation and operational costs.

- Ventana Medical Systems, Inc. (*www.ventana.com*), a member of the Roche Group, received 510(k) clearance from the FDA for the **VENTANA Companion Algorithm p53 (DO-7) image analysis application** using the VENTANA iScan Coreo Au scanner and VIRTUOSO software. Ventana is currently the only company offering an FDA-cleared p53 image analysis algorithm for determining p53 expression levels in breast cancer patients. In addition, the company offers FDA-cleared algorithms for HER2 (4B5), PR (1E2), and Ki-67 (30-9).

- ViewRay Incorporated (*www.viewray.com*) has received FDA 510(k) premarket notification clearance for its MRI-guided radiation therapy system. The **ViewRay System** features a unique combination of radiotherapy delivery and simultaneous magnetic resonance imaging for the treatment of cancer. OI

Doxil C.A.R.E.S. Physician Access Program Initiates Open Enrollment

Janssen Products, LP, announced the initiation of an open enrollment process for the Doxil® C.A.R.E.S. Physician Access Program. In a May 9, 2012, letter, Rob Bazemore, President, Janssen Products, LP, announced that, "Returning a reliable supply of Doxil to the marketplace remains our top priority. We are able to re-open enrollment at this time because some physician allocation requests have changed and freed up product for reallocation. Other physicians indicated Doxil earmarked for patients in the program is no longer needed, or they opted patients out of the program. We've met the needs of all physicians who submitted enrollment forms for their patients during the recent Doxil C.A.R.E.S. Physician Access Program re-enrollment process and this latest assessment has allowed us to re-open enrollment for patients not currently enrolled." For more information, call 1.866.298.5774. Beginning July 1, providers administering Doxil and billing Medicare should begin using the temporary HCPCS code that CMS has assigned specific to Doxil (Q2048), and discontinue use of code J9001.

New Mobile Apps Launched

- Eli Lilly and Company (*www.lillyoncology.com*) has launched a searchable clinical trial mobile application for oncology healthcare professionals. The app—available for Apple iPad and iPhone, as well as RIM's BlackBerry and Google's Android platforms—allows healthcare professionals to search oncology trials that are enrolling new patients by disease state, molecule being studied, study phase, country, state, and keyword.

The mobile app provides details on all global oncology trials. The app's functionality provides a mechanism for healthcare professionals to contact Lilly Oncology for additional details on its trials, as well as a third-party contact for non-Lilly clinical trials.

Details for downloading the clinical trial app are available on a new website, *LillyOncologyPipeline.com*.

- Velos, Inc., (*www.velos.com*) has released **Velos Aversi**, an iPad app for clinicians in oncology and bone marrow transplantation. The app is designed to record, track, and export patient adverse events and graft-versus-host-disease at point-of-care in hospital and ambulatory care settings. The app is available for download from the Apple App Store.