APPROVED DRUGS

• Genentech *(www.gene.com)*, a member of the Roche Group, announced the Food and Drug Administration (FDA) has approved **Erivedge™ (vismodegib) capsules** for the treatment of adults with metastatic basal cell carcinoma (BCC) or with locally advanced BCC that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

Vismodegib inhibits the Hedgehog pathway, an important embryonic developmental pathway. Reproductive toxicology studies in rats demonstrated that vismodegib exposure during organogenesis results in embryo-fetal death at higher exposures and severe birth defects at exposures within the range achieved with the recommended human dose.

The recommended dose and schedule for vismodegib is 150 mg orally daily.

• The FDA has granted regular approval for **Gleevec™ (imatinib mesylate tablets)** (Novartis Pharmaceuticals, *www.novartis.com*) for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumors (GIST). Accelerated approval for this indication was granted in December 2008. Labeling is also revised to include the results of a randomized trial demonstrating that recurrence-free survival (RFS) and overall survival (OS) were improved by continuing adjuvant imatinib therapy to 36 months.

The recommended dose of imatinib for adjuvant treatment is 400 mg/day administered with meals daily for three years. The optimal duration of treatment is not known.

• The FDA approved **Inlyta (axitinib tablets)** (Pfizer, Inc. *www.pfizer.com*), a kinase inhibitor, for treatment of patients with advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. The approval is based on data from the Phase III AXIS trial, which demonstrated that Inlyta significantly extended progression free survival (PFS) [HR=0.67, 0.54-0.81, P<0.0001] with a median PFS of 6.7 months (95% CI: 6.3,8.6) compared with 4.7 months (95% CI: 4.6,5.6) for those treated with sorafenib, a current standard of care for this patient population. This improvement in PFS was greater in the cytokine-pretreated subgroup compared to the sunitinib-pretreated subgroup.

• The FDA approved **glucarpidase injection (Voraxaze®)** (BTG International Ltd., *www.btgplc.com*) for the treatment of toxic plasma methotrexate concentrations (> 1µmol/L) in patients with delayed methotrexate clearance due to impaired renal function. Glucarpidase is not indicated for use in patients who exhibit the expected clearance of methotrexate (plasma methotrexate concentrations within 2 standard deviations of the mean methotrexate excretion curve specific for the dose of methotrexate administered) or those with normal or mildly impaired renal function because of the potential risk of subtherapeutic exposure to methotrexate.

• Millennium: The Takeda Oncology Company *(www.millennium.com)* announced that the FDA has approved a supplemental new drug application for **Velcade® (bortezomib),** which updates the label to include the subcutaneous method of administration in all approved indications: multiple myeloma and mantel cell lymphoma after at least one prior therapy.

DRUGS IN THE NEWS

• Pinnacle Biologics, Inc. (*www.pinnaclebiologics.com*) announced that the company has received orphan drug designation for **Photofrin® (porfimer sodium)** as adjuvant therapy to surgery in treatment of malignant pleural mesothelioma.

• ZIOPHARM Oncology, Inc. *(www.ziopharm.com)* announced that the FDA has accepted its investigational new drug application (INDA) for the oral dosing of **palifosfamide (Zymafos® or ZIO-201).** Palifosfamide is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide.

• Circadian Technologies Ltd. *(www.circadian.com.au)* announced that the company's wholly-owned subsidiary, Vegenics Pty Ltd., has received approval

EP Tracker Now Available

Fulcrum Methods *(www.fulcrummethods.com)* announced release of **EP Tracker™**, a SaaS-based (software-as-a-service-based) interactive tool that helps centrally administer the lifelong process of individual EP registration and reporting and attestation. Hospitals, healthcare systems, and medical groups can use EP Tracker to ensure affiliated eligible professionals (EPs) have properly registered for and successfully completed requirements to qualify for meaningful use incentives. The tool tracks EP funds receipt by year and program, EP funds flow, and EP funds assignment. EP Tracker was developed and designed in conjunction with users of Fulcrum Methods' Meaningful Use Assessment Tool.

for its INDA to initiate clinical trials of **VGX-100** in cancer patients with solid tumors. The first Phase I trial will study VGX-100 in patients with a variety of late-stage cancers. VGX-100 is a human antibody that acts against the human VEGF-C protein. Treatment for cancers, particularly glioblastoma and metastatic colorectal cancers, are the first target indications for VGX-100.

DEVICES IN THE NEWS

- Hologic, Inc. *(www.hologic.com)* announced FDA approval of the company's **Cervista HTA (high throughput automation) System** for use with Hologic's previously approved human papillomavirus (HPV) HR test. The company's HPV HR test uses Hologic's proprietary Invader technology to detect 14 high-risk types of HPV that are associated with cervical cancer and precancerous lesions.

- Varian Medical Systems *(www.varian.com)* announced updated control software, which received FDA 510(k) clearance in November, that adds a **High Intensity Mode** to the company's **Clinac® and Trilogy®** machines, enabling dose delivery rates of up to 2400 monitor units per minute—double their former highest output. Varian also received FDA clearance for the **Pivotal™ Care Solution Prone Breast Treatment,** an innovation that allows patients to be treated on their stomachs rather than their backs.

- The FDA has granted Royal Phillips Electronics *(www.healthcare.philips.com/us_en/)* 510(k) clearance for the company's first commercially available whole body positron emission tomography/magnetic resonance (PET/MR) imaging system, the **Ingenuity TF PET/MR.**

- MIM Software Inc. *(www.mimsoftware.com)* announced that Mobile MIM™ has received its second FDA 510(k) clearance for release of its new version, **Mobile MIM 3.0.** Mobile MIM is now cleared for diagnostic X-ray and ultrasound viewing, as well as radiation treatment plan review and approval. Mobile MIM 3.0 is available on the Apple® App Store(SM).

- The FDA has granted Translational Sciences Corporation *(www.transcicorp.com)* 510(k) clearance for commercialization of the company's **OncoTrac™ medical imaging software.** OncoTrac is designed for efficient quantitative assessment of treatment response of metastatic tumors, including breast, lung, colorectal, prostate, and lymphoma. OncoTrac products provide a structured workflow solution for cancer practitioners and researchers to report precise measurement of solid and metastatic tumors for routine clinical care and cancer drug trials. As a vendor-neutral platform, OncoTrac software architecture is suitable for use in daily radiology practice, and can be easily integrated into most existing PACS environments without any product customization.

- RaySearch Laboratories AB *(www.raysearchlabs.com)* announced that version 2.5 of the company's RayStation® treatment planning system has been released for clinical use in the U.S. and Europe. **RayStation 2.5** includes all of RaySearch's optimization algorithms for VMAT, IMRT, and 3D-CRT along with a comprehensive set of tools for traditional 3D-CRT planning. The new version includes improvements of RaySearch's unique multi-criteria optimization (MCO) solution for IMRT.

- Veran Medical Technologies *(www.veranmedical.com)* announced the release of its **SPiN Drive™ platform upgrade** for bi-planar virtual fluoroscopy view used to navigate multiple planes simultaneously. This advancement enables physicians to view the location of the Always-On Tip Tracked™ instrument in a fluoro-like view without any radiation being delivered to the patient, physician, or staff.

- The FDA has granted Konica Minolta Medical Imaging USA *(www.konicaminolta.com/medicalusa)* 510(k) clearance for the company's **Xpress CR Digital Mammography upgrade.** The clearance specifically applies to the company's CP1M 18 x 24 and 24 x 30 cassettes and the use of the CS 3 control station with the REGIUS 190 and 210 readers. OI