tools

Approved Drugs

• The Food and Drug Administration (FDA) has approved **Aloxi® (palonosetron HCl) injection** (Eisai Inc., www.eisai.com/US) for the prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy, in children aged 1 month to less than 17 years.

• Eli Lilly and Company (www.lilly.com) announced that the FDA has approved **Cyramza™ (ramucirumab)** for use as a single agent for the treatment of patients with advanced or metastatic, gastric or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior treatment with fluoropyrimidine- or platinum-containing chemotherapy.

• The FDA has approved a 20 mg/ml oral suspension of **Purixan™ (mercaptopurine)** (NOVA Laboratories Limited, www.novalabs.co.uk). Purixan is indicated for the treatment of patients with acute lymphoblastic leukemia as part of a combination regimen.

• Teva Pharmaceutical Industries Ltd. (www.tevapharm.com) announced that the FDA has approved **Synribo® (omacetaxine mepesuccinate)** for injection, for subcutaneous use, to include home administration; the agency also approved a related Medication Guide and Instructions for Use.

• The FDA has approved a new indication for **Vectibix® (panitumumab)** (Amgen, www.amgen.com) for use in combination with FOLFOX, as first-line treatment in patients with wild-type *KRAS* metastatic colorectal cancer (mCRC). The FDA also approved the **Therascreen® KRAS RGQ PCR Kit** (Qiagen, www.qiagen.com) as a companion diagnostic for Vectibix. Vectibix is not indicated for the treatment of patients with *KRAS*-mutant mCRC or for whom *KRAS* mutation status is unknown.

• Novartis (www.novartisoncology.com) announced FDA approval of **Zykadia™ (certinib)** for patients with a certain type of late-stage non-small cell lung cancer.

Drugs in the News

• The FDA has granted orphan drug designation to **ADXS-HPV** (Advaxis, Inc., www.advaxis.com) for the treatment of Stage II-IV invasive cervical cancer. ADXS-HPV is an immunotherapy that is designed to target cells expressing the HPV gene E7.

• OncoMed Pharmaceuticals Inc., (www.oncomed.com) announced that **Demcizumab (anti-DLL4, OMP-21M18)** has received FDA orphan drug designation for the treatment of pancreatic cancer.

• The FDA has granted orphan drug designation to **Selinexor (KPT-330) oral** (Karyopharm Therapeutics Inc., www.karyopharm.com) for the treatment of acute myeloid leukemia.

Approved Devices

• Olympus (www.medical.olympusamerica.com) announced the commercial availability of its 510(k) cleared, next-generation **Endocapsule 10 System** for small bowel capsule endoscopy procedures; **BF-P190 and BF-XP190 bronchoscopes** for peripheral and small anatomy bronchoscopy; and **GIF-1TH190 gastrointestinal videoscope** for endoscopy or endoscopic surgery use within the upper digestive tract.

• GE Healthcare (www.gehealthcare.com) announced FDA approval and the U.S. launch of their new breast imaging technology, the **Invenia™ ABUS**.

Generic Version of Paraplatin® Injection Launched

Mylan Inc. (www.mylan.com) has launched **Carboplatin Injection**, 50 mg/5 ml, in multi-dose vials, a generic version of Bristol-Myers Squibb's Paraplatin Injection.

Genetic Testing Registry

In response to continued advances in genomic technology and genetic medicine, the National Institutes of Health has developed the Genetic Testing Registry, a free online resource, to provide physicians, researchers, and patients with detailed and accurate information about genetic and genomic tests. www.ncbi.nlm.nih.gov/gtr.