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Approved Drugs

- Celgene Corp. *(www.celgene.com)* announced that the Food and Drug Administration (FDA) has approved **Abraxane® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension, albumin-bound)** for use in combination with carboplatin for the initial treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who are not candidates for curative surgery or radiation therapy. In 2005 Abraxane was approved for the treatment of metastatic breast cancer after failure of combination chemotherapy.

- A pediatric dosage form of **Afinitor Disperz® (everolimus)** (Novartis, *www.novartis.com*) was approved by the FDA to treat subependymal giant cell astrocytoma (SEGA). Everolimus is recommended to treat patients aged 1 year and older with tuberous sclerosis complex who are diagnosed with inoperable SEGA. Studies are under way to further evaluate the long-term safety and effectiveness of everolimus in both pediatric and adult patients with SEGA.

- The FDA approved **Bosulif® (bosutinib tablets)** (Pfizer, Inc., *www.pfizer.com*) for the treatment of chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in adult patients with resistance or intolerance to prior therapy. The recommended dose and schedule for bosutinib is 500 mg orally once daily with food.

- Bayer HealthCare *(www.bayer.com)* and Onyx Pharmaceuticals, Inc. announced that the FDA approved **Stivarga® (regorafenib)** tablets for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with currently available therapies (including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy). Stivarga is an oral multi-kinase inhibitor that inhibits various kinases without the mechanisms involved in tumor growth and progression-angiogenesis, oncogenesis, and the tumor microenvironment.

- The FDA approved **Xtandi Capsules® (enzalutamide)** (Medivation, Inc., and Astellas Pharma US, Inc.) for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. The recommended dose and schedule for enzalutamide is 160 mg orally once daily. OI

CMS Grants Temporary Add-On Payment for Voraxaze

BTG International Inc. *(www.btgplc.com)* announced that the Centers for Medicare & Medicaid Services (CMS) has granted a temporary New Technology Add-on Payment **(NTAP) for Voraxaze® (glucarpidase)**, effective Oct. 1, 2012. CMS will pay up to 50 percent of the cost of Voraxaze to hospitals in addition to the standard diagnosis-related group (DRG) reimbursement payment. NTAPs are only available for new technologies that provide a substantial clinical benefit and meet appropriate cost criterion.

CMS will provide a maximum add-on payment for Voraxaze of $45,000 per case. Along with the add-on payment, CMS has granted Voraxaze a new ICD-9 procedure code 00.95 (injection or infusion of glucarpidase).

Voraxaze received U.S. regulatory approval in January 2012 for the treatment of toxic plasma methotrexate concentrations (>1 micromole per liter) in patients with delayed methotrexate clearance due to impaired renal function.