THE TOOLS

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[Approved Drugs]

■ **Campath (alemtuzumab)** (Genzyme Corp., Cambridge, Mass.) has received a new indication from the USP DI compendium for treatment of B-cell chronic lymphocytic leukemia, first-line monotherapy for progressive disease.

■ GlaxoSmithKline (Philadelphia, Pa.) announced that the Food and Drug Administration (FDA) has approved **Tykerb® (lapatinib) in combination with Xeloda® (capecitibine)** for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. The drug is the first targeted, once-daily oral treatment option for this patient population.

Tykerb is a small molecule that inhibits the tyrosine kinase components of the EGFR (ErbB1) and HER2 (ErbB2) receptors.

[Drugs in the News]

■ Eli Lilly and Company (Indianapolis, Ind.) has submitted a new drug application (NDA) to the FDA for **Evista® (raloxifene HCl)** for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis and postmenopausal women at high risk for breast cancer. Evista is currently indicated for the treatment and prevention of osteoporosis in postmenopausal women.

■ Nuvelo, Inc., (San Carlos, Calif.) has been granted two separate FDA fast track designations for **rNAPc2**. The first fast track designation is for first-line treatment of metastatic colorectal cancer to improve progression-free survival and overall survival when added to Avastin®-containing 5-flurourocil (5-FU)-based chemotherapy regimens. The other is for second-line treatment of metastatic colorectal cancer to improve progression-free survival and overall survival when added to 5-FU-based chemotherapy regimens.

The drug is currently being studied in a Phase II clinical trial in subjects with metastatic colorectal cancer. Recombinant nematode anticoagulant protein c2 (rNAPc2) interferes with the tissue factor/factor VIIa/factor Xa protease complex. This complex has been shown to play a role in activating the cellular signaling events leading to metastasis and angiogenesis in a variety of cancers.

■ Sunesis Pharmaceuticals, Inc., (South San Francisco, Calif.) has filed an investigational new drug (IND) application with the FDA for **SNS-314**, a targeted small molecule that selectively inhibits the Aurora kinases. Aurora kinases are key enzymes involved in cancer cell growth and division, and have a central role in the abnormal growth and proliferation of tumor cells.

■ Roche (Nutley, N.J.) announced submission of a supplemental new drug application (sNDA) to the FDA for the use of **Xeloda® (capecitabine)** in combination with oxaliplatin—XELOX—with or without Avastin® (bevacizumab) in the treatment of metastatic colorectal cancer.

■ Exelis, Inc., (South San Francisco, Calif.) has submitted three INDs to the FDA. The first IND is for **XL147**, an orally available small molecule inhibitor of phosphoinositide-3 kinase (P13K). Activation of P13K is a frequent event in human tumors, promoting tumor cell growth, survival, and resistance to chemotherapy and radiotherapy. Inactivation of P13K has been shown to inhibit growth and induce apoptosis in tumor cells.

Fast Facts

Clinical Trials and Lung Cancer Patients—Their Bottom Line

- More than 80 percent of cancer patients said they were unaware of available and appropriate clinical trials at the time they were exploring treatment options
- 69 percent of cancer patients said they would be very or somewhat interested in participating in a clinical trial if they still required treatment and a new drug was being developed
- 79 percent of cancer patients learned about a clinical trial from their physician
- 26 percent of cancer patients read about a clinical trial online
- Top two reasons patients cited for not participating in clinical trials: fear of side effects (40 percent) and fear of receiving a placebo or sugar pill (30 percent).

Source: A study of 600 patients and oncologists conducted by the Lung Cancer Alliance, a non-profit organization dedicated to patient support and advocacy for people living with, or at risk for, lung cancer. The study was made possible with the support of AstraZeneca.

The second IND is for **XL418**, an inhibitor of protein kinase B (PKB or AKT) and S6 Kinase (S6K), key components of the phosphoinosotide-3 kinase (P13K) signaling pathway. Activation of these kinases is a frequent event in human tumors, promoting cell growth, survival, and resistance to chemotherapy and radiotherapy.

The third IND is for **XL518**, a novel anticancer compound. XL518 is a potent and specific inhibitor of MEK, a key component of the RAS/RAF/MEK/ERK pathway. Inappropriate activation of this pathway is a prevalent feature of tumor cells and drives tumor growth and survival. Activation of the pathway occurs as a result of mutations in RAS in approximately 30 percent of all human tumors, and in B-RAF in 60 percent of melanomas.

■ Cell Therapeutics, Inc., (Seattle, Wash.) announced that **Xyotax™ (paclitaxel poliglumex)**, a novel biologically-enhanced version of Taxol®, qualifies for FDA fast track designation for the treatment of PS2 (poor performance status) women with first-line advanced non-small cell lung cancer. The company recently filed a special protocol assessment (SPA) with the FDA for the design of its Phase III trial of Xyotax for women with advanced non-small cell lung cancer. The trial, PGT306, will focus exclusively on women with normal estrogen levels, the subset where Xyotax

demonstrated the greatest survival advantage in the STELLAR trials. The trial is expected to enroll 300 poor performance status women who have advanced stage non-small cell lung cancer and have not received prior chemotherapy.

The company also submitted a SPA to the FDA for **PGT307**, a Phase III trial of combination therapy for women with advanced lung cancer. The trial will study Xyotax in combination with carboplatin versus paclitaxel/carboplatin in female non-small cell lung cancer patients with performance status of 0, 1, or 2. The enrollment target is 450 patients with an interim analysis planned in the first half of 2008.

[Genetic Tests, Assays, and Vaccines in the News]

■ GlaxoSmithKline (Philadelphia, Pa.) has submitted a biologics license application (BLA) for **Cervarix®** (human papillomavirus vaccine, AS04 adjuvant-adsorbed), its cervical cancer candidate vaccine, to the FDA. If licensed, the vaccine will be indicated for the prevention of cervical cancer and precancerous lesions associated with the most common cancer-causing human papillomavirus types.

■ Genzyme Genetics recently launched its **IgV_H Mutation Analysis assay** for patients with chronic lymphocytic leukemia. IgV_H is an independent prognostic marker that can be used to segregate patients within all stages of chronic lymphocytic leukemia. Studies show that chronic lymphocytic leukemia patients with mutation in their IgV_H gene have a longer median survival (293 months) than chronic lymphocytic leukemia patients without these mutations (117 months). Approximately 50 to 70 percent of patients with B-cell chronic lymphocytic leukemia have evidence of these mutations.

[Devices in the News]

■ Polymedco, Inc., (Cortlandt Manor, N.Y.) has introduced the **BTA stat® test**, a point-of-care technology for the early detection of recurrent bladder cancer. The test is a single-step, rapid imunochromatographic assay for bladder tumor-associated antigen in voided urine. The specificity of the BTA stat® test was 93 to 95 percent in patients with non-genitourinary diseases and cancers and healthy individuals tested as part of a multi-center study. Requiring five drops of urine, the result is delivered in only five minutes. The BTA stat test requires one voided urine sample and no sample preparation.

■ Varian Medical Systems (Palo Alto, Calif.) has received 510(k) clearance from the FDA to market an updated brachytherapy applicator set designed specifically for intraluminal treatment of cancer of the esophagus. The **Esophagus Bougie Set™** can now be used with Varian's full range of VariSource® and GammaMed® HDR (high-dose rate) afterloaders.

The applicator set has been designed to ensure an optimal distance from the source to the tissue being treated. The set is equipped with Bougies (slender, cylindrical instruments inserted into the esophagus) in four different diameters, facilitating the centered source position in the esophagus and optimizing the distance to the tissue to be treated.

■ Diamics (Novato, Calif.) announced that it received 510(k) clearance from the FDA to market its proprietary **CerCol Cervical Sample Collection System**. The CerCol Cervical Collector is intended for the collection of cervical cytology material and its transfer for Pap analysis.