THE TOOLS

Fast Facts

HIT System Adoption at U.S. Hospitals

- 17 percent of hospitals have computerized order entry for medications.
- 7.6 percent of hospitals have an institution-wide "basic system," defined as having electronic medical records, computerized order entry, and five other functions.
- 3 percent of hospitals have "basic systems" in only some departments, including as few as one department.
- 1.5 percent of hospitals have comprehensive health information technology systems that include intercommunicating electronic medical records, electronic clinical decision support, computerized order entry, electronic image displays, and 20 more functions.

Source: *New England Journal of Medicine.* Available online at: *http://content.nejm.org/cgi/content/full/NEJMsa0900592.*

[Approved Drugs]

■ The Food and Drug Administration (FDA) has granted full approval to **Sprycel®** (Bristol-Meyers Squibb, New York, N.Y.) for the treatment of adults in all phases of chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy, including Gleevec® (imatinib mesylate).

[Drugs in the News]

■ Delcath Systems, Inc. (New York, N.Y.) announced that the FDA has granted orphan drug designation to the drug **Alkeran® (melphalan)** for the treatment of patients with neuroendocrine tumors. The company is enrolling patients in a Phase II clinical trial. The trial will test the company's proprietary drug delivery system, known as the Delcath Percutaneous Hepatic Perfusion (PHP) System™, with ultra-high dose melphalan for the treatment of neuroendocrine tumors metastatic to the liver.

■ Arno Therapeutics, Inc. (Parsippany, N.J.) announced that the FDA has accepted the company's investigational new drug (IND) application for the use of **AR-12**, an orally available PDK1 inhibitor that blocks PI3K/Akt pathway and induces the endoplasmic reticulum stress pathway. Acceptance of the IND permits the company to initiate a Phase I clinical trial in adults with advanced or recurrent solid tumors of lymphoma for which no standard therapy is available.

■ The FDA granted orphan drug status to Antigenics Inc.'s (New York, N.Y.) **Oncophage® (vitespen)** for the treatment of glioma.

Derived from each individual's tumor, Oncophage contains the "antigenic fingerprint" of the patient's particular cancer and is designed to reprogram the body's immune system to target only cancer cells bearing this fingerprint. Oncophage has been studied in Phase III clinical trials for the treatment of kidney cancer and metastatic melanoma and is currently being investigated in a Phase II trial in recurrent glioma.

■ **Paclical®** (Oasmia Pharmaceutical, Uppsasla, Sweden) has received orphan drug designation by the FDA for the treatment of ovarian cancer. With the retinoid-based platform XR-17, Oasmia has produced a water soluble formulation of Paclitaxel (Paclical®) that does not require premedication and without the severe Cremmophor® EL-related side effects.

■ Nerviano Medical Sciences (Nerviano, Italy) announced that the FDA has approved the company's IND application for a Phase I clinical study of its **PLK-1 small molecule inhibitor** for the treatment of cancer.

■ The FDA has granted fast track designation to **SGN-35** (Seattle Genetics, Inc., Bothell, Wash.) for the treatment of Hodgkin lymphoma. SGN-35, an antibody drug conjugate, is in an ongoing trial under a special protocol assessment (SPA) from the FDA for relapsed or refractory Hodgkin lymphoma.

■ Agennix (Houston, Texas) announced that **talactoferrin alfa (talactoferrin)** has been granted fast track designation by the FDA for the first-line treatment of renal cell carcinoma (RCC) in combination with sunitinib.

Talactoferrin is a novel targeted dendritic cell recruiter and activator being studied for the treatment of several life-threatening diseases including RCC and NSCLC. Talactoferrin mediates its anti-cancer activity by targeting dendritic cells, which play an important role in activating innate and adaptive immunity.

[Devices in the News]

■ The FDA granted 510(k) clearance to .decimal, Inc. (Sanford, Fla.) for the company to release the software necessary for the delivery of **Bolus Electron Conformal Therapy (Bolus ECT™)** an advanced form of patient-specific electron therapy. Treating with Bolus ECT will be available to users of all three of the major treatment planning systems: CMS XiO™, Varian Eclipse™, and Philips Pinnacle3™. Bolus ECT can create favorable dose distributions for certain tumors of the chest wall, breast, or head and neck, when a tumor volume has spread out near the patient surface and rendered other treatment problematic for a variety of reasons.