PRODUCT UPDATE

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Arsenic Trioxide May Improve Survival From Leukemia

Recent results from a Cancer and Leukemia Group B phase III clinical trial showed that adult patients with acute promyelocytic leukemia (APL) who received arsenic trioxide (Trisenox®, Cephalon, Inc.) in addition to standard chemotherapy had significantly better event-free and overall survival than those who received only standard chemotherapy.

Arsenic trioxide is approved by the U.S. Food and Drug Administration (FDA) to treat APL in patients whose disease has not improved with other chemotherapy drugs or has recurred. APL is an aggressive (fast-growing) type of acute myeloid leukemia in which too many immature blood-forming cells exist in the blood and bone marrow. It usually is marked by an exchange of parts of chromosomes 15 and 17. Trisenox destabilizes lysosomes in the APL cells. It also induces a degradation of an oncogenic protein resulting from the fusion of a promyelocytic leukemia protein and the retinoic acid receptor alpha, which can lead to apoptosis of APL cells. For more information, visit www.trisenox.com.

Topical Steroid May Reduce Graft-Versus-Host Disease

Allogeneic hematopoietic stem cell transplantation can be a life-saving intervention for some patients but carries with it the risk of graft-versus-host disease (GVHD). A recently conducted study found that the drug orBec® (oral beclomethasone dipropionate [BDP], DOR BioPharma, Inc.) reduced some of the effects of gastrointestinal GVHD. BDP, a steroid, usually is formulated as a topical cream or a nasal spray used to treat skin conditions or allergies. OrBec is formulated as an oral delivery and targets the mucosa of the gastrointestinal tract.

OrBec allows larger doses of BDP to be delivered to the afflicted gastrointestinal area without systemic side effects associated with other steroids used to treat GVHD. OrBec has orphan drug status and fast-track designation from the FDA.

The gastrointestinal manifestation of GVHD occurs in approximately 60% of related donor and 70% of unrelated donor allogeneic transplant recipients. Gastrointestinal GVHD is the most common and often the most persistent manifestation of the GVHD process. Symptoms include anorexia, nausea, vomiting, diarrhea, bloody stool, cramping, epithelial cell necrosis, and, in severe cases, ulceration and exfoliation of the intestinal mucosa. For more information, visit www.dorbiopharma.com.

Liquid Form of Tamoxifen Is Now Available

Soltamox® (Cytogen Corporation) is a liquid form of tamoxifen citrate that offers an alternative to patients who are not able to swallow pills. Soltamox is the first liquid form of the hormonal breast cancer therapy tamoxifen. Soltamox is a sugar-free, colorless liquid that has a licorice flavor. Visit www.soltamoxus.com for more information.

Drug Provides Alternative for Imatinib Resistance

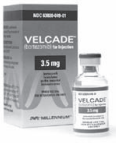
A new drug is available for patients with chronic myelogenous leukemia (CML) who develop resistance to or are refractory to imatinib mesylate (Gleevec®, Novartis Pharmaceuticals). Nilotinib (Tasigna®, Novartis Pharmaceuticals) is a tyrosine kinase inhibitor like imatinib. The use of Tasigna in patients with Philadelphia chromosome–positive CML reduced or eliminated the presence of this defective chromosome in 51% of Gleevec-resistant patients in the chronic phases of the disease and led to normalized white blood cell counts in 74% of the patients. Tasigna was developed by Novartis as a next-generation targeted therapy based on the success of Gleevec. Although most patients achieve positive results from Gleevec, a subset of patients is resistant or refractory to the drug and will benefit from Tasigna.

Tasigna is an orally available inhibitor of *BCR-ABL, c-Kit,* and platelet-derived growth factor. The drug retains half of the chemical makeup of Gleevec with the added capability of tighter binding with *BCR-ABL* to prevent cell proliferation and induce apoptosis, otherwise known as cell death. This has the effect of increasing the potency of Tasigna, with the potential to overcome Gleevec resistance. Tasigna currently is available only in clinical trials. For more information, visit www.novartis.com.

Investigational Drug May Treat Deep Vein Thrombosis

Once-weekly injections of idraparinux (sanofi-aventis), an investigational oligosaccharide, are comparable to low-molecular-weight heparin and daily vitamin K antagonist at preventing recurrent deep vein thrombosis. Results of a phase III clinical trial show that idraparinux may offer an important alternative to standard heparins and vitamin K antagonists for the treatment of life-threatening deep vein thrombosis. Idraparinux is a synthetic agent that binds to antithrombin, resulting in the inhibition of factor Xa, thereby preventing the conversion of fibrinogen into fibrin clots. Once-per-week dosing with idraparinux is just as effective and safe as traditional treatments and frees patients with deep vein thrombosis from the daily injection and continuous monitoring that would be required otherwise. For more information, visit www.sanofi-aventis.us.

Bortezomib Receives New Indication for Lymphoma



The FDA granted approval to bortezomib (Velcade®, Millennium Pharmaceuticals, Inc.), a proteasome inhibitor, for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy. Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions, and contraindications, is available at www.fda.gov/cder/foi/label/2006/021602s010lbl.pdf.

NEW PRODUCTS

Procedure Clears Blood Clots and Reduces Deep Vein Thrombosis

A new technique safely and effectively removes blood clots in the body, which reduces risk of pulmonary embolism. The AnjioJet® Rheolytic™ Thrombectomy System and the AnjioJet Ultra Thrombectomy

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System (Possis Medical, Inc.) also relieve symptoms such as pain and swelling. The technique combines clot-dissolving drugs with a clot-removing device that breaks up clots, making them easier to "vacuum" out of veins into a catheter. The nonsurgical intervention restores blood flow to an affected limb and removes the deep vein thrombosis (DVT). The procedure often clears a clot in one treatment.

The AnjioJet systems, which were approved by the FDA in December 2006, provide the ability to administer clot-dissolving agents and remove clots in the same procedure. Opening the vein allows the blood to flow freely and resolves a majority of the symptoms and risks of DVT. For more information on the AnjioJet thrombectomy systems, visit www.possis.com.

Genetic Analysis Predicts Breast Cancer Recurrence or Metastasis

MammaPrint® (Agendia) has received FDA approval as the first microarray genetic analysis designed to aid in predicting the risk of stage I or II breast cancer recurrence or metastasis within 5–10 years. MammaPrint is an in vitro diagnostic multivariate index assay device that measures 70 gene markers in tumors. Microarray analysis is a powerful tool for simultaneously studying the patterns of behavior of large numbers of genes in biologic specimens. The results are used to calculate an index to predict the likelihood of cancer recurrence or metastasis. The test provides useful biologic information about an individual cancer that gives oncologists more information to integrate into their clinical arsenal. The information provided by the test can help guide treatment options.

The difference between MammaPrint and other genetic tests is that MammaPrint is the first microarray test that looks for 70 signals, not just one. The FDA plans to publish a special controls guidance document in spring 2007 describing types of data that should support claims for genetic profiling for breast cancer prognosis. For more information, visit www.agendia.com.

Breathing Technique May Lower Blood Pressure

Scientific evidence has proven that structured therapeutic breathing exercises, performed routinely, can significantly lower blood pressure and reduce stress naturally. RESPeRATE® (InterCure, Inc.) is a portable medical device specifically indicated as an adjunct treatment for hypertension. RESPeRATE helps lower blood pressure naturally by enabling patients to quickly harness the power of paced breathing. RESPeRATE's breathing sensor automatically analyzes apatient's individual breathing pattern and creates a personalized melody composed of two distinct inhale and exhale guiding tones. As patients listen to the melody, their bodies will respond to the external rhythm. By slowly moving the breathing rate down, patients can reach a therapeutic range, which leads to relaxation and a lowering of blood pressure. The FDA has approved RESPeRATE as an over-the-counter medical device. For more information, visit www.resperate.com.

RECALLS AND ALERTS

Patients Reported to Have Developed Virus After Taking Rituximab

The FDA is alerting health professionals and patients that some patients taking the drug Rituxan® (rituximab, Genentech, Inc.) have been reported to have developed progressive multifocal leukoencephalopathy, a fatal viral infection of the central nervous system. The patients were being treated "off-label" for systemic lupus erythematosus, an unapproved but permissible use for Rituxan. For the full FDA alert, visit www.fda.gov/bbs/topics/NEWS/2006/NEW01532.html.

NOTEWORTHY

FDA Unveils Plans for Postmarketing Program Improvements

The FDA has announced plans to overhaul its postmarketing surveillance system and improve internal and external communication capabilities. The FDA will launch a pilot program that reviews the safety of drugs that have been on the market for 18 months, and it will issue report cards on the drugs' performance. The agency will update the electronic adverse event tracking system and improve communications to the public about postmarketing drug reviews. It also will share utilization and safety information with other federal agencies. Another planned improvement is the initiation of a panel of outside experts that will discuss strategies for communication of risk issues with the public. Part of the plan reflects a commitment to improve communication among staff members who review drugs prior to their approval. The changes reflect the beginning of more stringent drug safety practices and have been called for by the Institute of Medicine's recent criticism of the FDA.

Cancer Genome Atlas Is a Step Toward Exploring Genomes in Cancer

The Cancer Genome Atlas is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of genome analysis technologies, including large-scale genome sequencing. To fulfill the mission, the National Cancer Institute and the National Human Genome Research Institute have launched the Cancer Genome Atlas Pilot Project. The project will assess the feasibility of a full-scale effort to systematically explore the entire spectrum of genomic changes involved in human cancer.

The overarching goal of the Cancer Genome Atlas is to improve healthcare providers' ability to diagnose, treat, and prevent cancer. To learn more about the Cancer Genome Atlas, visit http://cancergenome.nih.gov/index.asp.