PRODUCT UPDATE

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New Treatment Receives Fast Track Status for Melanoma, Myeloma, and Chronic Lymphocytic Leukemia

Genasense™ (oblimersen sodium, Genta Inc., Berkley Heights, NJ) has been granted fast track and orphan drug status by the U.S. Food and Drug Administration for advanced malignant melanoma, multiple myeloma, and chronic lymphocytic leukemia. Oblimersen has a unique mechanism of action that enhances the effect of traditional chemotherapy.

Apoptosis is a normal process in which cells die. Cells that become damaged or are useless are programmed to self-destruct. Recent research has stimulated a theory that cancer may occur when the normal apoptosis process becomes inactivated, allowing cells to continue to live and reproduce despite being damaged and not functioning normally. Apoptosis can be blocked by a protein called Bcl-2. Increased levels of Bcl-2 also are thought to be a major mechanism of cancer resistance to chemotherapy. Elevated levels of Bcl-2 can be found in many types of cancer but are evident especially in hormone-refractory prostate cancer, breast cancer, and malignant melanoma. Oblimersen, an antisense drug, works at the molecular level to turn off the Bcl-2 protein before it is produced. An antisense drug is a small, modified stretch of single-strand RNA that binds to a specific section of mRNA, blocking protein production. By blocking Bcl-2 production, cancer cells become more susceptible to apoptosis, allowing traditional chemotherapy to be much more effective in causing cell death.

Antisense drugs can have a significant impact on how cancer is treated. Because this type of drug is so specific, it can target diseases without causing disruption of normal cell functions. Oblimersen is being investigated for use in conjunction with many chemotherapy drugs, including docetaxel, paclitaxel, irinotecan, gemtuzumab ozogamicin, fludarabine, imatinib, cyclophosphamide, cytosine arabinoside, rituximab, and thalidomide. Typically, oblimersen is given as a pretreatment to chemotherapy.

In a phase III trial, the addition of oblimersen to dacarbazine caused a higher incidence of neutropenia, thrombocytopenia, and constitutional symptoms (e.g., fever, nausea, headache). However, participants did not report serious adverse reactions when compared to dacarbazine alone. Other than fever, the incidence of serious adverse reactions was less than 5% and the addition of oblimersen did not affect the ability of subjects to receive the full dose of dacarbazine. For more information about the available clinical trials for oblimersen, e-mail ClinicalTrials@genta.com or call 888-864-3682. For general information, visit www.genta.com.

Tumor-Targeted Injectable Gene Therapy Receives Orphan Drug Status

Rexin-G™ (Epeius Biotechnologies, Los Angeles, CA) has been approved by the U.S. Food and Drug Administration (FDA) for orphan drug status for the treatment of pancreatic cancer. Rexin-G is the first tumor-targeted injectable gene therapy. In addition, Epeius Biotechnologies announced an agreement with the National Cancer Institute to help evaluate the activity of Rexin-G. The FDA also has approved a phase I clinical trial using Rexin-G in a hepatic arterial infusion for colorectal cancer with metastasis to the liver. For more information, visit www.epeius biotech.com, e-mail info@epeiusbiotech .com, or call 818-771-7344.

Amgen Introduces Prefilled Syringes for Darbepoetin

Darbepoetin (Aranesp™, Amgen Inc., Thousand Oaks, CA) now is available in a prefilled syringe. The advantages of the prefilled syringe include a smaller injection volume for the same dose, less preparation time, a safety needle, no need to change needles (decreasing the risk of needle sticks), and eliminated cost of syringes used when drawing from a vial. For more information, contact an Amgen representative, call 800-28-AMGEN, or visit www.amgen.com.

NEW PRODUCTS

New Test Detects Prostate Cancer Gene

The first urine test for prostate cancer now is available from Bostwick Laboratories in Richmond, VA. The test, called uPM3™, is based on detecting PCA3, a gene expressed profusely in prostate cancer. uPM3 is reported to have an 81% accuracy rate compared to the prostate-specific antigen test, which has a 47% accuracy. Patients would undergo a digital rectal prostate examination by a urologist. The digital examination causes cells from the prostate to shed into the bladder. The patient then gives a urine sample, which is sent to Bostwick Laboratories. This test can be helpful particularly in cases where the prostate-specific antigen level is rising but the biopsy is negative. For more information, call 804-288-6564.

New Breast and Prostate Cancer Diagnosis Technique Is Approved

A new scanning technique may replace the need for some biopsies for the detection of breast and prostate cancer. 3TP (three time point) is performed on a magnetic resonance imaging machine and uses contrast. Patients are scanned three times, once before receiving the contrast and twice afterward. A software package takes the images and creates a colored likeness of the scanned area. Excess red in the picture indicates malignancy, and excess blue or green indicates benign tissue. Using this technique, patients may avoid the initial biopsy and either be reassured that the tissue is benign or go straight to definitive surgery or treatment. The technique is under investigation for its effectiveness in detecting cancer in other areas, such as lung tissue. The theory behind this technique is that new blood vessels have a tendency to leak. The contrast agent will enter and clear out of a cancerous tumor faster than normal or benign tissue. The contrast agent is highlighted as it escapes the vessel walls and the intercellular spaces. Cells in a tumor are not equally distributed and have disrupted architecture yielding an uneven pattern. The software program analyzes the clearance rate of the contrast and the distribution pattern. It then assigns a color to each tiny pixel, which results in a color image of the scanned area.

In clinical trials, the 3TP system diagnosed tumors that were larger than 5 mm with nearly 100% accuracy. The overall accuracy rate was 90% for all the clinical trials, including ductal carcinoma in situ of the breast. This scanning technique can be used to monitor disease response as well as for diagnosis.

3TP currently is in beta testing but soon will be available commercially. For more information, call 631-702-2400 or e-mail JRM3TP@hamptons.com.

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