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New Products

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FDA OK'S NEW IRINOTECAN INDICATION

The Food and Drug Administration has approved CAMPTOSAR® (irinotecan hydrochloride injection) as first-line therapy for the treatment of patients with metastatic colorectal cancer in combination with 5-fluorouracil/leucovorin (5-FU/LV).

The FDA approval is based on data from two prospective Phase III studies that demonstrated the potential of CAMPTOSAR to prolong patients' lives when used in combination with 5-FU/LV as a first-line therapy for metastatic colorectal cancer compared with 5-FU/LV alone. These studies, conducted primarily in North America and Europe, demonstrated significantly prolonged median survival and significantly longer time to tumor progression for the regimen of CAMPTOSAR and 5FU/LV compared with 5FU/LV alone.

For additional product information, contact Pharmacia Corp. 1-800-253-8600, ext. 38244 (for health care practitioners).

VIADUR™ TREATS ADVANCED PROSTATE CANCER

ALZA Corporation and Bayer Corporation have entered into a commercialization agreement for Viadur™ (leuprolide acetate implant), a once-yearly implant for the palliative treatment of advanced prostate cancer, developed by ALZA.

Viadur, which received marketing approval from the FDA in March 2000, provides continuous, 12-month testosterone suppression with a single treatment. It is the first approved product to incorporate ALZA's proprietary DUROS® implant technology. Testosterone suppression or hormonal therapy is commonly used for the palliative treatment of advanced stages of prostate cancer.

According to the American Cancer Society, in the year 2000 an estimated 180,400 new cases of prostate cancer will be diagnosed, and approximately 31,900 men will die from this disease in the U.S. For more information, contact Mary Sawyers of Bayer Corporation, 203-812-3321.

NEW OPTION TO TREAT INOPERABLE LIVER CANCER

RadioTherapeutics has received FDA approval to market its RF System for the ablation of nonresectable liver lesions.

Consisting of the RF 2000™ Radiofrequency Generator and family of LeVeen™ Needle Electrodes, the RF Ablation System provides radiofrequency (RF) energy to heat and destroys soft tissue.

The RadioTherapeutics RF Ablation System addresses the significant need for an alternative or complementary procedure for liver lesions that cannot be removed surgically due to their size, number, or location. Of the approximately 2 million cases of liver cancer that occur worldwide each year, only 10 percent can be treated surgically, and few respond to chemotherapy, according to RadioTherapeutics.

The RadioTherapeutics RF Ablation System can be used in open surgical procedures, as well as less invasive laparoscopic or percutaneous procedures, expanding the number of patients who can receive this technique.

Direct inquiries to Gary Curtis at 408-745-3200.

FDA CLEARS NEW SOFTWARE FOR CANCER RADIOTHERAPY

Varian Medical Systems, Inc., has received FDA 510(k) clearance on its SomaVision™ software for planning and simulating cancer radiotherapy treatments. SomaVision 6.0 is a key component in Varian Medical Systems' new fully integrated Generation 6 system of hardware and software products for cancer radiotherapy, including the new Intensity Modulated Radiation Therapy (IMRT).

The SomaVision software compiles diagnostic images from CT scans into 3-D images of tumors within patient anatomies. It allows radiation oncologists to visualize and simulate treatment plans on their computer screens in order to optimize beam placement so that proper doses are delivered to tumors with minimal exposure and complications for surrounding healthy tissue. It is ideal for IMRT and 3-D conformal treatments where the radiation beam is precisely sculpted to the tumor size, shape and location.

For more information, contact Varian Medical Systems' customer service center at 1-800-544-4636.

DEVICE ASSISTS WITH BREAST SELF-EXAMINATION

Women's Health Products, a privately owned company, is now marketing the patented, Aware™ Breast Self-Examination Pad, which has been cleared by the FDA to assist women with their monthly breast self-examinations.

The Aware pad consists of two ten-inch polyurethane circles with a silicone lubricant sealed in between. During clinical development, researchers found that the pad demonstrated increased sense of touch by reducing friction between the fingers and the breast.

For more information, call 212-527-8815, or visit www.AwareBSE.com.