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New Products

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FDA OKS SCREENING TEST FOR GASTRIC CANCER/ULCERS

The Food and Drug Administration (FDA) has given approval to Trinity Biotech PLC for marketing its Uni-Gold™ H. pylori one-step test, which screens for the presence of IgG antibodies to the bacterium Helicobacter pylori. H. pylori bacterium is believed to be the causative agent in 60 percent of gastric cancers, as well as in more than 90 percent of duodenal ulcers and 70 percent of gastric ulcers. It has been classified by the World Health Organization (WHO) as a definitive carcinogen for gastric cancer.

Trinity Biotech's Uni-Gold H. pylori test facilitates the rapid assessment of patients presenting with the symptoms of gastric or duodenal ulcers. The company states that it is a quick, efficient, and inexpensive alternative to endoscopy, which is invasive and requires a specialist to administer. The Trinity test is said to be simple to perform, is cost effective, and brings the diagnosis to the immediate point-of-care market.

For further information, contact Jonathan O'Connell, 800-603-8076; e-mail: joconnell@trinitybiotech.ie.

FDA CLEARS POINT-OF-CARE USE FOR BLOOD TESTING

The CARESIDE Analyzer™ blood-testing system, which already cleared the FDA for licensed laboratory use, has received additional FDA approval for point-of-care use. This system allows patients to have their blood drawn and tested at their "point-of-care"—whether they are at a physician's office, a health clinic, or other health care facility.

This point-of-care FDA clearance means that health care providers can use the CARESIDE Analyzer to obtain blood test results and report them to their patients within 15 minutes of drawing a blood sample from the patient. Physicians who equip their offices with the CARESIDE Analyzer no longer need to send patients or their blood samples to outside laboratories and wait days for results.

This clearance also means that properly trained, non-technical personnel can operate the CARESIDE Analyzer, eliminating the need for a lab specialist to oversee each test. Thus, the CARESIDE Analyzer increases efficiency of medical offices.

The clearance was based upon a demonstration that both licensed lab personnel and non-technical personnel were capable of obtaining equivalent results after receiving appropriate training. CARESIDE provides the training, which usually takes a few hours, to its clients.

The CARESIDE Analyzer currently has FDA clearance for 36 tests in the categories of chemistry, electrochemistry, and coagulation. Immunochemistry testing is expected to be available in 2000.

CARESIDE, Inc. of Culver City, Calif., developed and markets the product. For more information, contact Jim Koch, CARESIDE, Inc., 310-338-6767.

FDA APPROVES CELEBREX™ FOR PATIENTS WITH FAP

The FDA has approved Celebrex™ (celecoxib capsules) as an oral adjunct to usual care (e.g., endoscopic surveillance and surgery) for patients with familial adenomatous polyposis (FAP). This is a rare and devastating hereditary disease that left untreated almost always leads to colorectal cancer.

Celebrex, the only COX-2 specific inhibitor indicated for the treatment of both osteoarthritis and adult rheumatoid arthritis, is the first pharmacologic agent to be indicated to reduce the number of adenomatous colorectal polyps in patients with FAP.

A six-month, 83-patient clinical trial, sponsored by the National Cancer Institute's Division of Cancer Prevention in collaboration with Searle, is the largest randomized, double-blind, placebo-controlled trial to date in FAP. The clinical study demonstrated that an oral dose of Celebrex 400 mg twice a day significantly reduced the number of adenomatous colorectal polyps by an average of 28 percent —compared to a 5 percent reduction with placebo. In the FAP trial, common side effects were diarrhea and dyspepsia.

The study was conducted at the University of Texas, MD Anderson Cancer Center in Houston, as well as at St. Mark's Hospital in London, the center for one of the world's premier registries of FAP patients.

Since the current trial did not include a cancer endpoint, the effect of Celebrex on the development of cancer has not yet been established. Searle and Pfizer will conduct further studies to assess the clinical benefit of Celebrex in this setting.

For additional information on Celebrex and FAP, call 212-229-8478.

MID-ENERGY LEVEL LINEAR ACCELERATOR GETS FDA OK

The Oncology Care Systems Group of Siemens Medical Systems has received FDA's 510(k) premarket clearance to sell, distribute and market a mid-energy range PRIMUS™ medical linear accelerator for radiation therapy. The new accelerator uses the advanced

engineering technologies widely acknowledged in the Siemens PRIMUS and PRIMART™ accelerators and expands them to the full range of energies, creating a fully modular product line.

"The mid-energy level PRIMUS offers a cost-effective solution for routine clinical radiotherapy treatments," said Patrick Boyle, vice president and division manager of Siemens Oncology Care Systems. "A key advantage is its ability to provide fast delivery of intensity modulated radiation therapy (IMRT), an advanced cancer treatment that facilitates the delivery of complex doses of radiation to tumors, including tumors near vital organs or other sensitive areas, while minimizing radiation to healthy tissue. Availability of the most frequently used photon and electron energies in a single machine provides flexible treatment capabilities to many radiotherapy departments."

For further information, contact Siemens Oncology Care Systems Group in Concord, Calif., at 925-246-8200; or visit their web site at http://www.sms.siemens.com/ocsg.

FDA APPROVES NEW DIGITAL MAMMOGRAPHY SYSTEM

GE Medical Systems has received FDA approval to begin marketing the GE Senographe 2000D, a fully digital mammography system. The GE Senographe 2000D is designed to generate digital mammographic images that can be used for screening and diagnosis of breast cancer. This digital mammographic system can be used in the same clinical applications as traditional film-based mammographic systems.

Direct inquiries to GE Medical Systems, 262-544-3530; charles.young@med.ge.com.

New Publications and Online Resources

NCI FINDS CHANGES IN PATTERNS OF CANCERS

The National Cancer Institute's (NCI) new *Atlas of Cancer Mortality in the United States, 1950-1994* shows the geographic patterns of cancer death rates in more than 3,000 counties across the U.S. in more than four decades.

For the first time, maps are presented for both white and black populations, since earlier mortality statistics lacked data that would permit a separation of blacks from the nonwhite category.

In addition, the patterns for liver cancer and for biliary tract cancer are shown for the first time. Previous disease classification schemes did not permit separate analyses of these cancers.

The report shows that significant changes in the geographic patterns of certain cancers—lung, prostate, breast and colon cancer—have occurred.

The greatest changes are seen with lung cancer. The national lung cancer rate among white men rose from 39 per 100,000 during 1950-69 to 69 per 100,000 during 1970-94. The highest rates now occur among white men in the South, among white women in the far West, and among blacks in northern urban areas.

An interactive version of the data in the new atlas is now available on the Internet at http://www.nci.nih.gov/atlas.

To order a single printed copy of the atlas, call NCI's Cancer Information Service at 1-800-4-CANCER.

DEATH AND DYING AT ABOUT.COM

About.com offers a section on Death and Dying, which includes a set of links to resources for professionals who work with the bereaved or the dying. For example, there are links to sites aimed at explaining the influence of cultural differences in relationship to grief work, dying, and funeral rituals. There are also links to articles on advance directives, grief assessment, and alternative therapies.
Visit: http://dying.miningco.com.

MATCHING PATIENTS WITH DRUG TRIALS

US Oncology (http://www.aori.com) has created SecureNet, an extranet system that eases the match of patients and clinical trials, reports the November 1999 *Medicine on the Net*.

More than 300 oncologists in 17 states who are part of US Oncology are connected to SecureNet. Combined, they treat more than 80,000 newly diagnosed patients each year.

To use the SecureNet Trial Matching System, oncologists first create patient profiles by completing a secure questionnaire. That information, and any updates, is maintained in the patient profile database. When a pharmaceutical company contacts US Oncology about a new trial, the information is entered into the clinical trial database. At least once a day, an application searches the two databases. When it finds a match between drug company criteria and patient, it immediately notifies the patient's doctor via e-mail.