PRODUCT UPDATE

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Azacitidine Approved for Myelodysplastic Syndrome

Azacitidine (Vidaza™, Pharmion, Boulder, CO) was approved by the U.S. Food and Drug Administration (FDA) for all subtypes of myelodysplastic syndromes. The approval came less than five months after Pharmion submitted its new drug application. Azacitidine previously had been approved for fast-track and orphan drug status. Myelodysplasia has five subtypes, and the FDA called azacitidine the first effective treatment for this disorder.

Azacitidine is believed to cause hypomethylation of DNA and direct cytotoxicity on abnormal hematopoetic cells in bone marrow. Azacitidine causes the death of all rapidly growing cells but has little effect on nonproliferating cells. It is excreted primarily via the kidneys.

Azacitidine may cause fetal harm and should not be given to pregnant women. Men should not father a child while receiving azacitidine. Common adverse reactions to the drug include nausea, anemia, thrombocytopenia, vomiting, fever, leukopenia, diarrhea, fatigue, erythema at the injection site, constipation, neutropenia, and ecchymosis. Infrequent but dose-limiting adverse reactions include leukopenia, thrombocytopenia, neutropenia, and fever.

The treatment regimen for azacitidine usually is 75–100 mg/m^2 subcutaneously administered daily for seven days every four weeks. Known hypersensitivity to azacitidine or mannitol is a contraindication, as is advanced malignant hepatic disease. See full prescribing information for more information. Reimbursement and financial assistance programs are available. For more information, call 866-PHARMION or visit www.vidaza.com.

New Indication Approved for Gemcitabine

The U.S. Food and Drug Administration has approved gemcitabine, in combination with paclitaxel, for first-line treatment of metastatic breast cancer. Other approved indications for gemcitabine include treatment of metastatic pancreatic cancer and use with cisplatin for the treatment of advanced non-small cell lung cancer. Phase III studies showed that gemcitabine with paclitaxel was more effective than paclitaxel alone and had manageable side effects. Patients who received the combination drugs experienced higher rates of alopecia, neutropenia, and fatigue. For more information, call 888-443-6927 or visit www.lillyoncology.com.

Atrasentan Will Be Submitted for New Drug Application

Abbott Laboratories in Abbott Park, IL, announced it will submit atrasentan (Xinlay™) for a new drug application (NDA) by the end of 2004. The drug has been granted fast-track status from the U.S. Food and Drug Administration. The NDA is based on a meta-analysis of two phase III clinical trials. Individually, each clinical trial did not show statistical significance but did show trends in favor of treatment with atrasentan. Combined, the meta-analysis demonstrates statistically significant outcomes for atrasentan over placebo.

Atrasentan is an oral, once-a-day, nonhormone, nonchemotherapy, anticancer agent. It belongs to a new class of drugs know as selective endothelin-A receptor antagonists, which antagonize the effect of one of the proteins thought to be involved in metastasis. So far, atrasentan has been studied in men with metastatic, hormone-refractory prostate cancer. It is being used in a phase III trial of men with hormone-refractory prostate cancer that is not metastatic. Researchers also are using atrasentan with other cancers such as kidney, brain, ovarian, and non-small cell lung cancer.

The most common adverse effects of atrasentan are headache, peripheral edema, and rhinitis. For more information, visit www.abbott.com.

Advisory Committee Recommends Approval of Pemetrexed

The Oncologic Drugs Advisory Committee has recommended that the U.S. Food and Drug Administration approve pemetrexed (Alimta®, Eli Lilly & Co., Indianapolis, IN) for second-line treatment of non-small cell lung cancer. Pemetrexed already is approved for the treatment of mesothelioma in conjunction with cisplatin. The committee based its recommendation on a phase III trial that found pemetrexed had similar survival and response rates to the standard treatment with docetaxel but less severe side effects. For more information, visit www.lilly.com.

Therion Biologics Will Start Phase III Trial With a Vaccine for Treatment of Advanced Pancreatic Cancer

Therion Biologics in Cambridge, MA, announced the initiation of a pivotal clinical trial using PANVAC™-VF, a vaccine developed for the treatment of metastatic pancreatic cancer in patients who failed gemcitabine treatment. The study will enroll 250 patients, and its endpoint will be overall survival compared to palliative chemotherapy or best supportive care. This study will be conducted under a special protocol assessment. In earlier phase I trials, patients treated with the vaccine had increased survival compared to historical controls.

PANVAC-VF is designed to stimulate the immune system and destroy cancer cells that express carcinoembryonic antigen (CEA) and mucin-1. These proteins can be found on more than 90% of pancreatic tumor cells. The vaccine also contains Tricom™, a triad of costimulatory molecules that enhance and sustain an immune response against tumor cells. Treatment includes an initial priming dose followed by booster vaccinations.

Therion Biologics also is planning clinical trials in other types of cancers that are known to express CEA and mucin-1. For more information, visit www.therionbio.com.

Bedford Laboratories to Market Prochlorperazine

The U.S. Food and Drug Administration has given Bedford Laboratories in Bedford, OH, approval to market prochlorperazine edisylate injection USP. This is a generic brand of Compazine® (GlaxoSmithKline, Research Triangle Park, NC) that is indicated for the treatment of severe nausea and vomiting. In recent months, many areas of the country have had prochlorperazine in short supply. Having the generic brand available should help to ease the shortages. For full prescribing information, call 800-521-5169 or visit www.bedfordlabs.com.

Drug Warning Issued for Bevacizumab

Genentech, Inc., in South San Francisco, CA, issued a warning advising practitioners of a serious adverse event that has been associated with bevacizumab (Avastin™). "There is evidence of an increased risk of serious arterial thromboembolic events including cerebrovascular accidents, myocardial infarctions, transient ischemic attacks, and angina, related

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to the use of Avastin. The risk of fatal arterial thrombotic events is also increased. Patients who experience an arterial thromboembolic event during treatment should permanently discontinue Avastin." Patients who are at risk include those who have a history of arterial thromboembolic events prior to receiving bevacizumab, are greater than age 65, and are receiving bevacizumab. For more information, refer to the package insert or call medical information at Genentech at 800-821-8590.

To report a serious adverse event suspected to be associated with bevacizumab, call Genentech at 888-835-2555. Serious adverse events to any drug also may be reported to the U.S. Food and Drug Administration's (FDA's) MedWatch system by calling 800-FDA-1088, faxing 800-FDA-0178, visiting www.accessdata.fda.gov/scripts/medwatch, or mailing FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787.

New Diluent Required for INTRON® A

Schering-Plough in Kenilworth, NJ, announced that the diluent for INTRON® A is changing, effective immediately. The new diluent is sterile water without a preservative, provided in a 1 ml size only. The change in diluent size does not change dosing in any way. However, once INTRON A is reconstituted and given, any remaining drug must be discarded. The change in diluent does change how INTRON A is stored. Patients should inject INTRON A immediately after reconstitution, but it may be stored for as long as 24 hours at 36°–46°F. Storage of the powder before reconstitution has not changed; it also is stored at 36°–46°F. For more information, contact a representative or call customer service at 800-222-7579.

NEW PRODUCTS

Implantable Identification Chip Will Be Evaluated

VeriChip™ (VeriChip Corporation, Delray Beach, FL) is an under-the-skin radio frequency identification chip that the U.S. Food and Drug Administration (FDA) is evaluating. The chip could identify patients and access medical records. The FDA is evaluating the privacy issues surrounding VeriChip. VeriChip is about the size of a grain of rice and can be implanted under the skin on the back of the upper arm. The chip remains dormant until stimulated by a radio frequency from a scanner. The chip then emits a signal transmitting the individual's unique personal identification number.

VeriChip has other proposed uses, such as allowing access through security doors, and can be used in settings such as airports, research, or government facilities. The ID number emitted from a VeriChip can be used to access a subscriber-supplied database providing personal information. In the medical setting, the VeriChip can be used to identify a patient before a procedure or before administering a medication. For more information, call 800-970-CHIP or visit www.4verichip.com.

New Camisole Provides Options for Women After Breast Surgery

The Gentle Touch Camisole is designed for women after breast surgery. The camisole has a front opening that attaches with Velcro® and four internal pockets that can be used to hold breast forms or postsurgical drainage bulbs. The camisole comes with a lightweight temporary breast form that contains a generous amount of polyfill that can be removed to create a breast form of the appropriate size. The front opening makes reaching a venous access device easy and allows access to the breast for dressing care or postoperative radiation.

Camisoles come in white with white trim, white with pink trim, or beige with beige trim. Sizes run from small to XXXL. For more information, call 800-989-5726 or visit www.gentlet.com.

New Technology Stops Minor Bleeding Quickly

QR™ Powder (Biolife, LLC, Sarasota, FL) is a new approach to stopping bleeding that was found serendipitously. Scientist James Paterson was looking for ways to purify drinking water when he accidentally cut his hand. His hands were covered with potassium salt, which immediately stopped the bleeding. With other scientists, Paterson created a mixture of potassium salt and hydrophilic polymers. This combination stops bleeding from minor cuts and scrapes and nosebleeds within seconds by combining with a person's blood to form a scab. When applied to some minor scrapes or cuts, QR Powder may cause stinging.

The clotting effect of this product is independent of inherent clotting factors, so it works equally well on patients with clotting disorders or those on anticoagulants. The product is approved by the U.S. Food and Drug Administration and is available over the counter at retail pharmacies. For more information, visit www.biolife.com or call 800-772-7559.

Ethyl Chloride Spray Reduces Pain Associated With Venipuncture

Gebauer's Ethyl Chloride® (Gebauer Company, Cleveland, OH) is a skin refrigerant that is used topically to numb the skin for minor surgical procedures such as venipunctures. Available by prescription only, the spray is used for three to seven seconds from a distance of three to nine inches from the skin until the skin just turns white. Do not frost. The skin then is cleaned with an antiseptic, and the venipuncture or surgical procedure proceeds as usual. The product is flammable and must be kept away from open flames. The anesthetic effect rarely lasts more than a few seconds to a minute. Ethyl chloride comes in either glass bottles or aerosol cans with fine, medium, or mist sprays. A risk of cutaneous sensitization exists, but this is a rare adverse reaction. Do not use on individuals with a history of hypersensitivity. For external use only. For more information, visit www.gebauerco.com.

Safety Needles Offer Protection From Needle Sticks

Punctur-Guard® Safety Needles (ICU Medical, San Clemente, CA) are the first safety needles that use an internal blunting cannula that is engaged before the needle is withdrawn from a patient. This eliminates the risk of an accidental needle stick during the first few seconds after removing the needle from a patient. Punctur-Guard needles are available as blood collection needles and as winged sets for blood draws or infusions. To use the Punctur-Guard needle, a patient's vein is accessed as usual. When ready to remove the needle, a plastic wing is flipped from one side of the winged set to the other, engaging the blunt cannula. The needle then can be withdrawn as usual. For more information, visit www.icumed.com or call 800-824-7890. ONS

Merck & Co., Inc., Withdraws Vioxx From the Market

Merck & Co., Inc., in Whitehouse Station, NJ, voluntarily withdrew rofecoxib (Vioxx®), a nonsteroidal anti-inflamatory drug, after growing concerns about the drug causing an increased risk of cardiac events. These cardiac events include heart attacks and strokes. Rofecoxib was approved by the U.S. Food and Drug Administration (FDA) for pain and inflammation related to osteoarthritis, signs and symptoms of rheumatoid arthritis in adults and children, acute pain in adults, and menstrual pain.

The FDA reported that Merck promptly halted and then reported the findings of a study that found that patients taking the drug on a regular basis had twice the risk of a heart attack compared to patients taking a placebo. The FDA will closely monitor other drugs in the same class (cox-2 inhibitors), but at this time, no reports indicate that this is a complication of the other drugs.

All patients currently taking rofecoxib are encouraged to speak with their physicians about alternative medications. For more information, visit www.fda.gov/cder/drug/infopage/vioxx/default.htm, www.merck.com, or www.vioxx.com, or call 888-36VIOXX or 888-INFO-FDA.