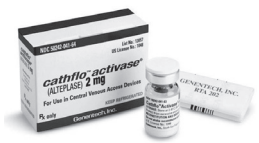
Sandra A. Mitchell, ARNP, MScN, AOCN®
Associate Editor

PHARMACY CORNER

Agent to Restore Central Venous Catheter Function Approved

Genentech (South San Francisco, CA) has received U.S. Food and Drug Administration approval for its thrombolytic agent Cathflo™ Activase® (alteplase) for the restoration of function to central venous access devices.



Each year in the United States, an estimated five million central venous catheters are placed to provide patients with life-saving medications and critical treatment. Up to 25% of these catheters may become occluded or blocked. As many as 60% of occlusions are caused by thrombosis, the formation of a blood clot within or on the tip of the catheter that obstructs the flow of fluids into or out of the body. Current treatments include surgical removal and replacement of the venous access device, which can be uncomfortable, expensive, and potentially risky. The approval of Cathflo Activase addresses the need for a safe and effective method to restore the function of occluded central venous catheters.

Cathflo Activase is a thrombolytic enzyme (serine protease) that promotes fibrin-enhanced conversion of plasminogen to plasmin. The enzyme binds to fibrin in a thrombus and converts the entrapped plasminogen to plasmin, thereby initiating local fibrinolysis. In phase III trials, Cathflo Activase was 88% effective in restoring flow to catheter lines. Nurses should avoid using excessive pressure when instilling Cathflo Activase, as force could rupture the catheter or expel the clot into circulation. Little, if any, Cathflo Activase reaches systemic circulation in normal use. Cathflo Activase is available in a 2 mg single-patient-use vial.

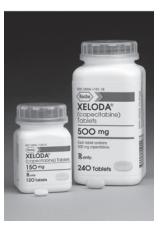
For more information on Cathflo Activase, contact Genentech at 800-821-8590 or visit the Genentech Web site at www.genentech.com.

Description of products does not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.*

Combination Therapy Approved for Metastatic Breast Cancer

Roche (Nutley, NJ) announced that the U.S. Food and Drug Administration has approved oral Xeloda® (capecitabine) in combination with infusions of Taxotere® (docetaxel, Aventis Pharmaceuticals, Bridgewater, NJ) for patients with metastatic breast cancer refractory to anthracycline therapy. Xeloda belongs to a class of drugs called the fluoropyrimidines. It works through enzymatic activation to the chemotherapeutic agent 5-fluorouracil (5-FU). The human body produces the enzyme thymidine phosphorylase (TP), which converts Xeloda into 5-FU. TP is higher at the tumor site than surrounding normal tissue. Taxotere works independently to interrupt tumor cell mitosis.

In a phase III study of 511 patients, the combination of Xeloda and Taxotere extended survival (14.5 months versus 11.5 months) compared with Taxotere alone. In addition, the combination demonstrated superior tumor response and slowed disease progression (6.1 months versus 4.2 months) when compared to Taxotere monotherapy. The combination of Xeloda and Taxotere caused more adverse events than Taxotere alone, including diarrhea, stomatitis, hand-foot syndrome, nausea, and vomiting. These events were manageable with appropriate medical intervention and dose interruptions. Dose reductions decreased the overall incidence of adverse events in subsequent cycles. Patients with severe diarrhea should be monitored carefully and given fluid and electrolyte replacement if they become dehydrated. The incidence of grade 3 or 4 treatment-related adverse events is greater in patients older than 60 receiving Xeloda in combination with docetaxel. Patients receiving Taxotere alone experienced a higher incidence of neutropenic fever, myalgia, and arthralgia.



Xeloda is contraindicated in patients with severe renal impairment or hypersensitivity to 5-FU. Dose reduction is recommended for patients with moderate renal impairment. Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (international normalized ratio [INR] or prothrombin time) monitored frequently to adjust the anticoagulant dose accordingly. A clinically important Xeloda-warfarin drug-drug interaction was demonstrated in a clinical pharmacology trial. Altered coagulation parameters or bleeding, some leading to death, have been reported in patients taking Xeloda concomitantly with coumarin-derivative anticoagulants, such as warfarin and phenprocoumon. Patients taking phenytoin concomitantly with Xeloda should be monitored carefully for plasma phenytoin levels and may require phenytoin dose reduction.

The most common severe side effects associated with Taxotere include low blood cell count, fluid retention, hypersensitivity, nausea, and diarrhea. These side effects generally are reversible and manageable. A premedication regimen with corticosteroids is recommended to prevent or reduce hypersensitivity and fluid retention. Taxotere is not appropriate therapy for patients with significant liver impairment.

Xeloda (2,500 mg/m^2) is administered to patients twice daily on days 1–14, and patients receive a Taxotere (75 mg/m^2) infusion on day one of each 21-day treatment cycle.

For more information on Xeloda, contact Roche at 800-526-6367 or visit the Xeloda Web site at www.xeloda.com.

GliaSite Radiation Therapy System Receives Marketing Clearance

GliaSite® (Proxima Therapeutics Inc., Alpharetta, GA) Radiation Therapy System (RTS) for brain tumors has received marketing clearance from the U.S. Food and Drug Administration. GliaSite RTS is an internal radiation system that uses a balloon catheter filled with Iotrex™, a liquid radiation source, that is inserted into the cavity created by surgical removal of a malignant brain tumor. The primary benefit of internal radiation is the delivery of high-dose radiation directly to the tumor bed and its margins (where the tumor is most likely to recur) while minimizing the dose received by healthy, nontargeted brain tissue. The treatment can be used to deliver radiation to recurrent brain tumors or to provide a boost dose following external beam radiation for initial tumor occurrences.

During tumor resection surgery, the neurosurgeon positions the balloon portion of the GliaSite catheter within the cavity created by

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tumor removal. The injection port at the other end of the catheter is fixed on top of the skull and concealed underneath the skin. When the patient recovers from surgery, a combination of Iotrex (the liquid radiation source) and saline is injected into the catheter to fill the balloon. The Iotrex dwells for three to seven days and delivers the prescribed dose of radiation. At the end of this period, the Iotrex is withdrawn and the balloon catheter is removed during a brief surgical procedure. The balloon catheter incorporates a dual-balloon configuration for greater safety. The inner balloon serves as a reservoir for Iotrex, and the outer balloon is a safety reservoir in the event that the inner balloon is compromised. The Iotrex solution is available in 1 ml unit doses. Each unit dose provides a minimum of 150 mCi of radiation.

In a National Cancer Institute-sponsored trial of patients who completed the catheter implant procedure and radiation therapy with GliaSite RTS, no patients required reoperation for necrosis. Complications were consistent with those reported for standard brain tumor treatments. Conformance of the resection cavity to the balloon surface was excellent, regardless of tumor shape and size, and, in all cases, GliaSite RTS delivered the prescribed dose to the targeted area. Median survival currently is more than 14 months.

For more information, contact Proxima Therapeutics Inc. at 866-776-9462 or visit its Web site at www.proximatherapeutics.com.

Marketing Approvals Announced for Generic Thiotepa, Dacarbazine, and Paclitaxel Injection Products

Bedford Laboratories, a division of Ben Venue Laboratories (Bedford, OH), has received approval from the U.S. Food and Drug Administration (FDA) to market paclitaxel injection, thiotepa for injection, and dacarbazine for injection. These products are equivalent to Taxol® Injection (Bristol-Myers Squibb, New York, NY), Thioplex® (Immunex, Seattle, WA), and DTIC-Dome® (Bayer Corporation, Pittsburgh, PA). The FDA also has approved an injectable paclitaxel product from Mylan Laboratories (Pittsburgh, PA).

Paclitaxel injection is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. The therapy also is indicated for the treatment of breast cancer. Thiotepa for injection is used for the palliation of a wide variety of neoplastic diseases. Dacarbazine for injection is indicated in the treatment of metastatic malignant melanoma and as second-line therapy in combination with other agents in the treatment of Hodgkin's disease.

For more information, contact Bedford Laboratories at 800-521-5169 or visit its Web site at www.bedfordlabs.com. Mylan Laboratories can be contacted at 412-232-0100 or www.mylanlabs.com.

NEW PRODUCTS

Camera in a Pill Allows Imaging of Lower Small Intestine

The U.S. Food and Drug Administration has approved a swallowable video capsule for use in diagnosing disorders in the small intestine. The Given® Diagnostic Imaging System (Given Imaging, Atlanta, GA) consists of the M2A™ Swallowable Imaging Capsule, the Given® Data Recorder worn on a belt around the waist to receive signals transmitted by the capsule, and the RAPID™ Workstation equipped with software that processes, edits, and saves the data and video images. When swallowed, the capsule takes pictures inside the small intestine to assist in cancer diagnosis and supplement endoscopy and radiology. Conventional tests often are unable to reach all the way through the 20-foot small bowel, and patients without a diagnosis sometimes have to resort to exploratory surgery.

When swallowed, the camera takes two pictures per second as it is pushed by peristalsis through the stomach and intestine. The digital images are transmitted to the wireless recorder via an array of antennae placed on the patient's body. The computer workstation subsequently acquires and processes the data, allowing the images to be viewed as a video or as still pictures. Patients can continue daily activities during the examination, and the camera leaves the body with the feces. The camera is enclosed in a one-inch, single-use capsule and contains an eight-hour battery that lasts long enough to photograph the small intestine, but not the large intestine. Each capsule costs about $450. The data recorder and computer workstation cost about $20,000.

In the United States, Given Imaging tested the camera in 20 patients suspected of suffering from small intestine disease. All of the patients previously had undergone multiple gastrointestinal endoscopies and radiological procedures to identify the source of their disorders, but had not received conclusive diagnoses. The camera detected physical abnormalities in 12 patients (60%), while traditional endoscopy detected similar abnormalities in 7 patients (35%). In five cases, the system also was able to identify sources of bleeding that were beyond the reach of traditional enteroscopes. Over half of the patients said they preferred the less-invasive camera procedure over enteroscopy. The main advantage of the camera is that it enables analysis of the lower part of the small intestine, a procedure not possible with an endoscope. However, fiber optic endoscopes also may provide better image detail, and the camera cannot be stopped or controlled to take detailed pictures of the folds in the small intestine. The M2A capsule is not appropriate for patients with known or suspected intestinal obstruction, fistula, or stricture, as the capsule may become stuck and, in rare circumstances, cause death.

For more information, contact Given Imaging at 800-448-3644 or visit its Web site at www.givenimaging.com.

Bone Marrow/Stem Cell Transplant Video Provides Patient Education

The National Bone Marrow Transplant Link (Southfield, MI), a nonprofit organization committed to providing education and support to people challenged by bone marrow or stem cell transplantation, has created a video to help patients prepare for what they will face when undergoing transplantation. The film, titled *The New Normal*, presents the insight of six transplant survivors ranging in age and background and from two to 10 years post-transplant. *The New Normal* can help patients overcome their fears by providing an idea of what to expect with a bone marrow or stem cell transplant and offering information, inspiration, and hope to patients and caregivers. For more information on this complimentary video, contact the National Bone Marrow Transplant Link at 800-546-5268 or via e-mail at nbmtlink@aol.com.

Unrelated Donor Stem Cell Transplantation Guide Update Published

The National Marrow Donor Program (NMDP) (Minneapolis, MN) has published the *2001 Medical Professionals' Guide to Unrelated Donor Stem Cell Transplantation*. The 38-page publication, now in its third edition, was designed specifically for use by medical professionals to help explain the process and timelines associated with locating unrelated marrow donors, blood stem cell donors, and umbilical cord blood units. The publication also contains a section on outcomes, based on disease status at the time of transplant. All data show that transplants performed in earlier disease stages tend to have better results. Information on separate pediatric outcomes is new with this edition.

More than four million volunteer donors have been recruited since NMDP began operations in 1987. NMDP is the largest and most diverse registry of potential volunteer marrow and blood stem cell donors in the world, and 34,000 new volunteers sign up each month. As the number of donors has grown, so has the number of successful matches. Free copies of the guide are available through the NMDP office of patient advocacy. To request a copy, contact NMDP at 888-999-6743 or visit its Web site at www.marrow.org.