PRODUCT UPDATE

Valerie Burger, RN, MA, MS, OCN®
Associate Editor

PHARMACY CORNER

Investigational Immunotherapy Targets Cancer Antigen

An investigational immunotherapy that targets an antigen produced by non-small cell lung cancer (NSCLC) appears to reduce the risk of recurrence when used as adjuvant therapy with surgery.

Results of the multicenter proof-of-principle trial with the fusion protein–derived agent MAGE-A3 antigen-specific cancer immunotherapy (ASCI) have set the stage for a global phase III trial that will involve more than 2,000 patients.

MAGE-A3 is a tumor-specific antigen that is expressed in a variety of cancers, including NSCLC, head and neck cancer, and bladder cancer, with no expression in normal cells. This novel cancer immunotherapy is developed using tumor-specific antigens, delivered as highly purified recombinant proteins. MAGE-A3 ASCI is an investigational compound and currently is not approved for use in any indication in any country.

The immunotherapy works somewhat like a vaccine. The target is tumor specific, so normal cells do not experience adverse effects. The agent is very well tolerated and, in the clinical trial, resulted in minimal grade 1 or 2 side effects, consisting of injection site irritation and fatigue.

The initial trial involved 182 patients with stage IB or II NSCLC. All patients had tumors that expressed MAGE-A3, an antigen produced by 35%–50% of early NSCLC.

Proof-of-principle studies are an early stage of clinical drug development when a compound has shown potential in animal models and early safety testing. The proof-of-principle or proof-of-concept step often links between phase I and phase II studies. These small-scale studies are designed to detect a signal that the drug is active on a pathophysiologically relevant mechanism as well as provide preliminary evidence of efficacy for a clinically relevant end point.

For more information on MAGE-A3 ASCI, visit www.gsk.com.

New Pancreatic Drug May Treat Neuroendocrine Tumors

Carcinoid tumors and pancreatic islet cell lesions appear to be sensitive to treatment with the investigational drug RAD001 or everolimus (Certican®, Novartis). RAD001

is a mammalian target of rapamycin (mTOR) inhibitor, a key regulatory kinase. It currently is used as an immunosuppressant to prevent rejection of organ transplants.

An intracellular protein, mTOR acts as a central regulator of multiple signaling pathways (e.g., insulin-like growth factor, epidermal growth factor, platelet-derived growth factor, vascular endothelial growth factor, amino acids) that mediate abnormal growth, proliferation, survival, and angiogenesis in cancer. RAD001 is an oral kinase inhibitor that specifically blocks the mTOR protein. By inhibiting cell proliferation, cellular bioenergetics, and angiogenesis, RAD001 may have a direct effect on cancer cells.

Neuroendocrine tumors have very few effective treatment options, and RAD001 could be a new option for treating them. For more information on RAD001 and other investigational drugs from Novartis, visit www.novartisoncology.com.

Treatment for Kidney Cancer With Torisel Can Prolong Survival

The drug Torisel™ (temsirolimus, Wyeth Pharmaceuticals) prolongs survival in patients with metastatic renal cell carcinoma. The U.S. Food and Drug Administration (FDA) approved Torisel for the treatment of advanced renal cell carcinoma based on a study that showed that use of the drug prolonged survival. Torisel inhibits mTOR kinase, a protein that regulates cell proliferation, cell growth, and cell survival, and is the first drug of its kind to be approved for treatment of cancer.

The safety and effectiveness of Torisel were shown in a clinical trial of 626 patients divided into three groups. One group received Torisel alone, another received a comparison drug called interferon alfa, and a third received a combination of Torisel and interferon.

The group of patients who received Torisel alone showed a significant improvement in overall survival, with a median overall survival of 10.9 months versus 7.3 months for patients treated with the interferon alone. Progression-free survival increased from 3.1 months for patients receiving interferon to 5.5 months for patients receiving Torisel. When compared with interferon alone, the combination of Torisel and interferon did not result in a significant increase in overall survival.

The most common adverse reactions, occurring in at least 30% of Torisel-treated patients, were rash, fatigue, mouth sores, nausea, edema, and loss of appetite. The most common laboratory abnormalities were high blood sugar, elevated blood lipids and triglycerides, elevated liver and kidney blood tests, and low red cell, white cell, and platelet counts.

For more drug information, visit www.wyeth.com. In the United States, Torisel will be available prior to FDA approval through the Expanded Access Program (EAP). For more information about the Torisel EAP in the United States, call 800-234-8423. Additional information about temsirolimus may be obtained at www.clinicaltrials.gov.

NEW PRODUCTS

Tumor Paint Can Be Used to Locate Cancer

A tumor paint developed by researchers at Seattle Children's Hospital Research Institute and Fred Hutchinson Cancer Research Center will help surgeons see where a tumor begins and ends more precisely by illuminating cancerous cells.

The paint is a scorpion-derived peptide called chlorotoxin that is linked to the molecular beacon Cy5.5. Until now, surgeons have had no way to see tumors "live" during surgery.

Cy5.5 is a fluorescent molecular beacon that emits photons in the near-infrared spectrum and can be visualized in the operating room with the aid of infrared glasses. The illumination gives surgeons a better chance of removing cancerous cells during surgery without injuring surrounding healthy tissue.

Cy5.5 is applicable to many cancers but is especially helpful to surgeons operating on brain tumors because approximately 80% of malignant cancers recur at the edges of the surgical site. Not only would the tumor

Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.*

Digital Object Identifier: 10.1188/07.ONF.1222-1224

paint reveal whether any bits of tumor were left behind, but it also would help them avoid removing normal tissue.

Tumor painting has been tested successfully in mice, and the pilot safety trials are complete. Researchers now are preparing the necessary toxicity studies before seeking approval from the FDA to begin clinical trials.

The original article can be viewed at http://cancerres.aacrjournals.org/cgi/content/full/67/14/6882.

Spectrometry Helps Identify Cancer

Using techniques borrowed from physics and chemistry, researchers have identified a pattern in the blood of patients with NSCLC that predicts their response to drugs that target the epidermal growth factor receptor.

The use of mass spectrometry to classify NSCLC actually reveals which patients may benefit from the tyrosine kinase inhibitors erlotinib (Tarceva®, OSI Pharmaceuticals) and gefitinib (Iressa®, AstraZeneca).

Mass spectrometry is used most generally to find the composition of a physical sample by generating a mass spectrum representing the sample components. Latest research has used mass spectrometry to analyze cancer tissue samples and specimens of normal lung tissue. From that, researchers derived a "signature" of 25 proteins associated with better survival, which they then tested in a blinded fashion against a validation set. The signature of the sample allows certain determinations to be made about it.

Researchers used the technique to analyze blood samples of patients who had been treated with gefitinib and found a spectrum that allowed them to classify patients into those who did well on the drug and those who did poorly.

The process may be an important means of determining who will benefit from targeted therapies and who will benefit from other methods of treatment.

Soft Garments Provide Adjuvant Therapy

Patients who undergo cancer treatment may experience skin pain, including inflammation, peeling, swelling, redness, and wet and dry desquamation. Patients can develop skin rashes as well as itching, dryness, and cracking.

A new fabric can help provide adjunctive therapy in soothing the skin of affected patients with cancer. DermaSmart® (Milliken & Company) is a 100% microfiber fabric clinically proven to reduce itching, burning, redness, and peeling. The fabric offers an additional method of symptom relief for patients with sensitive or compromised skin.

DermaSmart garments are made of a silky, soft, breathable fabric designed to calm inflamed, sensitive skin. Its lightweight jersey knit construction allows for smooth comfort against the skin, helping to relieve the painful symptoms better than 100% cotton. In addition, DermaSmart garments have a moisture management system to wick excess perspiration and disperse it through the fabric to help the garment dry quickly, keeping patients dry and comfortable throughout the day and night. To ensure no additional irritation, DermaSmart garments do not have tags and feature flat seams.

To order, call toll free at 888-445-5468 or visit the Web site at www.DermaSmart.com.

RECALLS AND ALERTS

Oral Moisturizer Is Recalled

Gebauer is recalling several lots of Salivart® Oral Moisturizer. Salivart is an aerosol that is used to lubricate and moisten the oral tissue of patients who are suffering from dry mouth. Lot numbers involved in the recall are 06AA001, 06AA002, 06AA003, 06AA004, 06AA005, and 06AA006 with expiration dates of June 2008 through October 2008 and ship dates from September 11, 2006, through January 10, 2007. Gebauer is recalling the product because some cans of Salivart do not meet the company's specifications for aerobic microorganisms and mold. Anyone in possession of the recalled product should stop using it and dispose of it immediately. Gebauer Customer Service can be reached at 800-321-9348.

Glycerin Could Be Contaminated

The FDA warned pharmaceutical manufacturers, suppliers, drug repackers, and healthcare professionals who compound medications using glycerin of the importance of ensuring that the glycerin used is not contaminated with diethylene glycol (DEG), a known poison used in antifreeze and as a solvent. Although the FDA has no reason to believe that the supply of glycerin in the United States is contaminated with DEG, it is aware of reports from other countries over the past several years in which DEG-contaminated glycerin has caused human deaths. The FDA emphasizes the importance of testing glycerin for DEG because of the serious nature of this potentially fatal problem. The FDA issued guidance to industry, recommending methods of testing glycerin and other controls to identify any contamination with DEG before using glycerin in the manufacture or preparation of pharmaceutical products.

Diabetes Drug Has Potential Safety Issues

The FDA informed healthcare professionals of a potential safety issue related to Avandia® (rosiglitazone, GlaxoSmithKline). An ongoing analysis of safety data for the treatment of type 2 diabetes mellitus using Avandia showed differing rates of ischemic cardiovascular events with potential mortality, including heart attack or heart-related adverse events, relative to other drugs used to treat diabetes. The clinical studies reviewed to date vary with respect to their populations, treatment regimens, and length of follow-up. Based on the data, the risk of ischemic cardiovascular events when using Avandia remains unclear. Prescribers should continue to carefully make individualized treatment decisions for patients with diabetes mellitus. Read the complete 2007 safety summary, including a link to the FDA news release and prescribing information, at www.fda.gov/medwatch/safety/2007/safety07.htm#Avandia.

Drug Warning Label Now Includes Potential Renal Failure

Novartis and the FDA notified healthcare professionals of changes to the warnings and adverse reactions sections of the product labeling for EXJADE® (deferasirox), an oral drug used to treat chronic iron overload caused by repeated blood transfusions. Cases of acute renal failure, some with fatal outcomes, have been reported following the postmarketing use of Exjade. Most of the fatalities occurred in patients with multiple comorbidities and those in advanced stages of their hematologic disorders. In addition, postmarketing reports noted cytopenias, including agranulocytosis, neutropenia, and thrombocytopenia, in patients treated with Exjade. The relationship of those episodes to treatment with Exjade is uncertain. Most of the patients had preexisting hematologic disorders that frequently are associated with bone marrow failure. Furthermore, cases of leukocytoclastic vasculitis, urticaria, and hypersensitivity reactions (including anaphylaxis and angioedema) were reported.

Healthcare professionals should monitor serum creatinine in patients who are at increased risk of complications, have preexisting renal conditions, are older, have comorbid conditions, or are receiving medicinal products that depress renal function. Blood counts also should be monitored regularly and treatment should be interrupted in patients who develop unexplained cytopenia. Read the complete 2007 safety summary,

including a link to the manufacturer's healthcare professional letter, regarding this issue at www.fda.gov/medwatch/safety/2007/safety07.htm#Exjade.

NOTEWORTHY

National Cancer Institute Launches New Program

The National Cancer Institute (NCI), part of the National Institutes of Health, has launched a three-year pilot phase of a new program that will help bring state-of-the-art cancer care to patients in community hospitals across the United States.

The National Community Cancer Centers Program (NCCCP) is designed to encourage the collaboration of private practice medical, surgical, and radiation oncologists with close links to NCI research and the network of 63 NCI-designated cancer centers principally based at large research universities. Building on this expanded network, NCCCP sites will explore ways of sharing information via electronic medical records to further enhance patient care. Evidence from a wide range of studies suggests that patients with cancer diagnosed and treated in a setting of coordinated multispecialty care and clinical research may live longer and have a better quality of life.

The pilot program will research new and enhanced ways to assist, educate, and treat the needs of underserved populations, including older adults, patients from rural and inner-city areas, patients with low incomes, and racial and ethnic groups with unusually high cancer rates.