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

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