PHARMACY CORNER

Drug Approved for First-Line Head and Neck Cancer

Cetuximab (Erbitux®) has been approved by the U.S. Food and Drug Administration (FDA) in combination with standard chemotherapy (a platinum plus 5-fluorouracil) for first-line treatment of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN).

Cetuximab, a chimeric monoclonal antibody, targets and inhibits the activity of epidermal growth factor receptors (EGFRs). EGFRs commonly are overexpressed in tumor cells such as those found in SCCHN, and although cetuximab is not given as a cytotoxic chemotherapy agent, its benefits are seen in the inhibition of tumor cell proliferation.

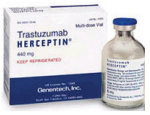
Approval was based on the results of the Erbitux in First-Line Treatment of Recurrent or Metastatic Head and Neck Cancer (EXTREME) trial. The phase III trial (N = 442) demonstrated improvements in overall survival (OS) by 37% ($p = 0.034$) and progression-free survival (PFS) by 67% ($p < 0.001$) when cetuximab was added to standard chemotherapy. Patients in the cetuximab arm (n = 222) experienced an OS of 10.1 months compared to 7.4 months with the chemotherapy-alone arm (n = 220). PFS was 5.5 months with cetuximab versus 3.3 months without.

The chemotherapy regimen used in both arms of EXTREME gave physicians the option of administering either carboplatin (AUC 5) or cisplatin (100 mg/m^2) as platinum agents via IV on day 1, along with 5-flurouracil (1,000 mg/m^2 per day) given as a continuous infusion during days 1 through 4.

Cetuximab also is approved as first-line therapy in combination with radiation therapy for nonmetastatic head and neck cancer. For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm278957.htm.

Trastuzumab May Work Subcutaneously

Research is ongoing regarding the possibility of making trastuzumab (Herceptin®) available as a subcutaneous injection. Trastuzumab, a monoclonal antibody, has been a game-changer since its initial approval in 1998 by providing a targeted strategy for treating breast cancers that overexpressed HER2 receptors. Currently, trastuzumab is available only as a 30-minute IV infusion.



Halozyme Therapeutics, Inc. has developed a subcutaneous formulation of trastuzumab, and the Roche-funded phase III HannaH trial (N = 596) compared the safety and efficacy of traditional IV trastuzumab versus the Halozyme-developed subcutaneous product. According to Halozyme, results were comparable. One proposed advantage of subcutaneous administration is reduced administration time (about five minutes compared to a 30-minute IV infusion). For more information, visit http://bit.ly/tjkATh.

NOTEWORTHY

Study Reaffirms Links Between Alcohol and Breast Cancer

A study by Chen, Rosner, Hankinson, Colditz, and Willett (2011) confirmed prior studies linking alcohol to breast cancer. The authors noted that moderate alcohol consumption over a lifetime moderately increases the risk for invasive breast cancer. The authors cited data from the Nurses Health Study that examined the relationship of alcohol consumption and the occurrence of invasive breast cancer among female nurses (N = 105,986) from 1980–2008. By the study's end, 7,690 cases of invasive breast cancer were diagnosed, and data from this observational study indicated a growing risk as alcohol consumption increased.

The authors did not note that the type of alcoholic beverage made a difference; rather, it was the quantity that mattered. Relative risk increased about 10% for every 10 grams of average daily intake of alcohol. For those drinking, on average, only three to six drinks a week, the risk for invasive breast cancer increased 15%.

Typically, the standard alcoholic beverage serving has about 14 grams of alcohol, with a 12-ounce beer, a 5-ounce glass of wine, and 1.5 ounces of 80-proof liquor containing roughly the same amount of alcohol. One of the reasons alcohol is believed to increase breast cancer risk is that alcohol consumption stimulates the production of estrogen—a key hormone in many breast cancers.

Chen, W.Y., Rosner, B., Hankinson, S.E., Colditz, G.A., & Willett, W.C. (2011). Moderate alcohol consumption during adult life, drinking patterns, and breast cancer risk. *JAMA, 306,* 1884–1890. doi:10.1001/jama.2011.1590

Smokers Require More Help With Quitting

Based on the 2010 National Health Information Survey (NHIS), according to the Centers for Disease Control and Prevention (CDC), the desire of smokers to "kick the habit" is high, but methods to improve success with cessation are underused.

Smoking has been known to be extremely addictive and dangerous to one's health for decades. In addition, quitting smoking is well known to improve health symptoms and reduce fatality risk from cardiac events, strokes, and cancer. Smoking-related illness creates an unsustainable burden to the healthcare system and, combined with losses of productivity, is estimated to cost the nation $193 billion each year. That burden, along with the recognized magnitude of lost lives from tobacco use, has motivated research directed at strategies to assist smokers to stop using tobacco products.

In the 2010 NHIS, an encouraging 69% of current adult smokers indicated a desire to quit, and about 52% had attempted to quit in the past year. That highlights, however, the addictive nature of nicotine—more than half of adult smokers attempted to quit, but failed.

As healthcare professionals with knowledge of the consequences of smoking, nurses are in a key position to assist and support smokers in cessation strategies. Somewhat surprisingly, of the 2010 NHIS participants who were smokers, only 48% reported having been advised to quit smoking by a healthcare provider in the prior year. That demonstrates an area in need of improvement. The CDC recommends that smokers be offered cessation advice

at every visit with a healthcare provider, and those desiring to quit should be offered evidence-based counseling and, as appropriate, medications to increase their chance of successful enduring cessation.

The 2010 NHIS revealed that a large number of smokers attempting to quit in the past year (68%) did so without the benefit of evidence-based strategies. Oncology nurses can serve an important role in providing smokers with information regarding strategies that work.

The 2010 NHIS was administered to more than 27,000 adults in the United States. The prevalence of smoking is continuing to decline, perhaps demonstrating the effectiveness of efforts to reduce affordability and social acceptability. Local, state, and federal laws have increased the costs of tobacco products to consumers, and many businesses as well as local governments have enforced smoking restrictions. In 1965, about 42% of adults reported themselves as smokers; by 2010, that rate dropped to less than one in five (19%).

In 2010, about $25 billion was collected by the states as part of the 1998 tobacco industry settlement with the states. According to the Campaign for Tobacco-Free Kids (CTFC), only a fraction of this money is directed toward cessation programs, and $25 billion pales in comparison to the revenue generated by tobacco companies. State-by-state comparisons of how settlement dollars are spent, as well as many links to information regarding tobacco legislation, can be found on the CTFC Web site (www.tobaccofreekids.org).

To view the CDC report, visit www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a2.htm?s_cid=mm6044a2_w.

PRODUCT UPDATE

Umbilical Cord Stem Cells Add to Transplantation Options

For patients requiring unrelated donor hematopoietic progenitor stem cell (HPC) transplantations, umbilical cord HPCs (HPC-Cs) may be a viable option. The FDA has approved the use of HEMACORD (HPCs derived from cord blood) as unrelated donor tissue in the allogeneic HPC transplantation setting following myeloablative preparative regimens.

As with more traditional HPC transplantations, wherein cells are derived from bone marrow or apheresed tissue, HPC-C transplantations are very high-risk procedures that warrant a careful consideration of the risks versus benefits. Preparatory regimens (e.g., high-dose myeloablating chemotherapy) and subsequent administration of HPC-Cs should occur only in settings with the necessary qualified personnel, appropriate equipment, and emergency procedures in place.

Fatal infusion reactions can occur from reactions to agents used in the preparation of harvested HPCs. Chief among those is dimethyl sulfoxide, an additive to HPC products that prevents crystallizing damage to cells as they are cryopreserved and later thawed for infusion.

Graft-versus-host disease is expected universally, but it can lead to fatal complications as the donor immune system attacks the host (person receiving transplantation) during and following engraftment. Graft failure, where the transplantation fails to take hold and grow into a functioning immune system, also is a very real risk that can result in fatality. For more information, view the HEMACORD package insert at http://1.usa.gov/vt0FID.

Caring for patients preparing for, undergoing, or having received a stem cell transplantation requires a specialized knowledge set beyond that of the basic oncology nurse. If interested in learning more about blood and marrow stem cell transplantations, a good place to start is the Oncology Nursing Society's Blood and Marrow Special Interest Group virtual community at http://bloodmarrow.vc.ons.org. The Oncology Nursing Society also offers the Fundamentals of Blood and Marrow Transplant webcourse at www.ons.org/CourseDetail.aspx?course_id=86.

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Oncology Update

This feature provides readers with newsworthy information about new treatments, clinical trials, and oncology care, in addition to drug approvals, product recalls, and safety updates. For more information, contact Associate Editor Diane M. Otte, RN, MS, OCN®, at otte.diane@mayo.edu.