PHARMACY CORNER

Drug Approved for Treatment of Basal Cell Carcinoma

The U.S. Food and Drug Administration (FDA) has approved oral vismodegib (Erivedge™) for the treatment of adult patients with locally advanced basal cell carcinoma who are not candidates for surgery or radiation and for those with metastatic disease. The drug initially was tested at Scottsdale Healthcare in Arizona.

In the United States, two million new cases of basal cell carcinoma are diagnosed each year, and Arizona has one of the highest incidences of skin cancer in the world. Most cases of basal cell cancer can be treated effectively but, in some situations, an aggressive form of cancer develops that does not respond to the standard surgical treatment.

According to Daniel Von Hoff, MD, lead investigator, "Until now, we did not have any treatments that can effectively slow the tumor growth in these patients with advanced skin cancer" (Scottsdale Healthcare, 2012, p. 1). Von Hoff is physician-in-chief at TGen and chief scientific officer at the Virginia G. Piper Cancer Center Clinical Trials at Scottsdale Healthcare, where patients with cancer receive treatment with promising new drugs.

According to Glen Weiss, MD, "The drug works by inhibiting the hedgehog pathway that is active in most basal cell cancers, preventing development, growth, and survival of certain cancer cells. Results showed a durable clinical benefit—tumor shrinkage visible on x-ray or other physical examination or improvement in symptoms without tumor growth" (Scottsdale Healthcare, 2012, p. 1.). Weiss is the director of Thoracic Oncology at Virginia G. Piper Cancer Center Clinical Trials and clinical associate professor and translational physician scientist at TGen. "In some patients there is progression to life-threatening, locally advanced or metastatic tumors. Approved as a pill to be taken once a day, we believe this new drug represents an opportunity to improve quality of life for these patients," Weiss said.

Scottsdale Healthcare. (2012). FDA approves new skin cancer drug first tested in Arizona by Scottsdale Healthcare and TGen [press release]. Retrieved from http://www.prnewswire.com/news-releases/fda-approves-new-skin-cancer-drug-first-tested-in-arizona-by-scottsdale-healthcare-and-tgen-138491769.html

Drug Targeting Gastrointestinal Cancer Receives Clearance

The FDA granted imatinib (Gleevec®) full approval as an adjuvant treatment following surgical removal of KIT (CD117)-positive gastrointestinal stromal tumors in adult patients.

The confirmatory, phase III study that led to the approval showed that patients taking imatinib for 36 months had a five-year overall survival of 92% compared to 82% for those who only took the drug for the standard 12 months of treatment (Novartis Pharmaceuticals, 2011).

The FDA approval was based on data from an international, multicenter, open-label, phase III clinical trial (Joensuu et al., 2011). Results of the study showed that 36 months of imatinib treatment significantly prolonged recurrence-free survival compared to 12 months of imatinib treatment, which was a 54% reduction in the risk of recurrence ($p < 0.0001$). In addition, 36 months of imatinib treatment resulted in a 55% reduction in the risk of death compared to one year of treatment ($p = 0.0187$) (Joensuu et al., 2011).

Joensuu, H., Eriksson, M., Hatrmann, J., Sundby Hall, K., Schutte, J., Reichardt, A., . . . Reichardt, P. (2011). Twelve versus 36 months of adjuvant imatinib (IM) as treatment of operable GIST with a high risk of recurrence: Final results of a randomized trial (SSGXVIII/AIO) [Abstract LBA1]. Retrieved from http://www.asco.org/ascov2/Meetings/Abstracts?&vmview=abst_detail_view&confID=102&abstractID=78836

Novartis Pharmaceuticals. (2011). *Gleevec® (imatinib mesylate)* [Prescribing information]. East Hanover, NJ: Author.

NOTEWORTHY

Tumor-Freezing Method Shown to Increase Survival

Minimally invasive cryoablation has been demonstrated to extend the lives of patients with cancer and is cost effective according to a study reported at the fourth annual Symposium on Clinical Interventional Oncology (Bang, Littrup, Currier, Goodrich, & Kassem, 2012).

The unpublished study included 21 patients with metastatic ovarian cancer whose tumors in the abdomen, liver, lung, and bone could not be removed surgically. Cryoablation was used to treat 48 tumors, killing 47 of them (98%). From the time of diagnosis of metastatic disease, average patient survival time was more than four years and seven months, which is significant because women whose tumors are not successfully removed surgically (as occurs in about 60% of cases, according to studies) typically survive about 7 months to 2.5 years (International Symposium on Endovascular Therapy, 2012). On average, more than three years had passed from the time of diagnosis to the first cryoablation treatment, meaning the women already had passed their expected survival time, and yet cryoablation was able to extend their survival even further. Some patients had multiple cryoablation treatments and, of 41 procedures, three major complications (7%) occurred. The complications included two deaths that were attributed to the cancer, not to the procedure.

The study also determined the treatment was cost effective, with an average price of $26,806 per life-year saved, well below the current standard of $100,000. According to Bang et al. (2012), "This procedure is often overlooked, but based on the high survival rate, cost effectiveness, consistent local control, and safety of the procedure, we should be taking a closer look at cryoablation as an option before

these women enter the latter stages of their disease" (p. 1).

Bang, H.J., Littrup, P.J., Currier, B.P., Goodrich, D.J., & Kassem, M. (2012). Cryoablation of metastatic ovarian cancer for local tumor control: Improved survival and estimated cost effectiveness. Retrieved from http://www.iset.org/oncology/images/stories/Abstracts/abs3.pdf

International Symposium on Endovascular Therapy. (2012). Tumor-freezing treatment gives ovarian cancer patients extra time [press release]. Retrieved from http://www.isetnews.org/omk.php?pid=1751&sid=S20120409073321 24RP7H&pr=1826

Cancer Nutrition Program Unveils Home Food Shipments

Proper nutrition is essential to the well-being and quality of life for patients with cancer. Medco Health Solutions, Inc., and TherapEase Cuisine™, an online resource nutrition program for patients with cancer, now are providing a delivery service to patients' homes.

According to Milayna Subar, MD, "The science of cancer care is evolving, and our support for patients with complex drug regimens must also evolve" (Luddy, 2012, p. 1). Subar is the national practice leader of the Medco Oncology Therapeutic Resource Center. "Patients on certain chemotherapy or radiation treatments may have difficulty eating as a result of nausea, mouth soreness, or a metallic taste after certain chemotherapy treatments that can just make food taste bad; complications of cancers may make it difficult to swallow; and many cancer patients lose weight leading to cancer cachexia" (p. 1).

TherapEase Cuisine was launched in 2010 and provides personalized online nutritional counseling and meal planning from registered dietitians who specialize in oncology. Patients who use the service can generate a customized meal plan and order foods contained in the plan.

For more information about TherapEase Cuisine, visit www.therapeasecuisine.com.

Luddy, J.L. (2012). TherapEase Cuisine™, Medco's cancer nutrition program, expands capabilities to food shipments directly to patients' homes [press release]. Retrieved from http://news.therapeasecuisine.com/pr/te/document/Medco_TherapEaseCuisine_press_release_1_23_12.pdf

SAFETY CONCERNS

Study Identifies Nursing Risk for Blood Exposure

A new study by the International Healthcare Worker Safety Center at the University of Virginia showed that nurses experience blood exposure on their skin or in their eyes, nose, or mouth at the rate of one in two nurses at least once a month when inserting a peripheral IV catheter (Jagger, Perry, Parker, & Phillips, 2011).

The study looked at the practices of 379 nurses nationwide who place IV catheters. The risk of infection from pathogens such as HIV, hepatitis B, hepatitis C, and methicillin-resistant *Staphylococcus aureus* (MRSA) can result from such exposure. The study shows nurses are at risk for exposure to blood pathogens in 128 of 100,000 IV catheter insertions. The Centers for Disease Control and Prevention define at-risk blood exposure as "contact of mucous membrane (MME) or exposed skin (chapped, abraded, or afflicted with dermatitis) with blood, tissue, or other body fluids that are potentially infectious" (BD Medical, 2012, p. 1).

However, respondents in the study did not routinely report these exposures, saying they did not think the exposure was significant enough to report, they were too busy, or they were concerned about others' perceptions. Of the total mucous membrane exposures sustained by respondents in the study, 69% were not reported.

According to Janine Jagger, PhD, MPH, "The use of safety IV catheters has helped reduce needlestick exposures. This study demonstrates the need to consider technology and precautions to reduce the risk of all sources of blood exposure" (BD Medical, 2012, p. 1). Jagger is the director of the International Healthcare Workers Safety Center at the University of Virginia.

Study respondents said they unexpectedly came into contact with blood in a patient's room (on bed rails, bedside trays, or pump touchpads) an average of 3.55 times per month, or almost once a week. Pathogens in blood residue on these surfaces can be transferred to healthcare workers, housekeeping staff, and visitors who might come in contact with those surfaces.

For those healthcare workers concerned about keeping safe from needlestick injuries and blood exposure, Benton Dickinson has launched its latest innovation in safety peripheral IV catheter technology: the BD Insyte™ Autoguard™ BC with blood control technology. This device has been proven to reduce the risk of blood exposure by 95% compared to a nonblood control IV catheter (Onia et al., 2011).

For more information about the BD Insyte Autoguard, visit www.bd.com/infusion/products/ivcatheters/autoguard/iag.asp.

BD Medical. (2012). Study shows nurses are exposed to risks from blood exposure during insertion and removal of peripheral IV catheter [press release]. Retrieved from http://www.bizjournals.com/prnewswire/press_releases/2012/03/07/NY65345

Jagger, J., Perry, J., Parker, G., & Phillips, E.K. (2011). Nursing 2011 survey results: Blood exposure risk during peripheral IV catheter insertion and removal. *Nursing, 41*(12), 45–49. doi:10.1097/01.NURSE.0000407678.81635.62

Onia, R., Eshun-Wilson, I., Arce, C., Ellis, C., Parvu, V., Hassman, D., & Kassler-Taub, K. (2011). Evaluation of a new safety peripheral IV catheter designed to reduce mucocutaneous blood exposure. *Current Medical Research and Opinion, 27*, 1339–1346. doi:10.1185/03007995.2011.581275

Description of products does not indicate or imply endorsement by the *Oncology Nursing Forum* or the Oncology Nursing Society. Diane M. Otte, RN, MS, OCN®, can be reached at otte.diane@mayo.edu, with copy to editor at ONFEditor@ons.org.

Digital Object Identifier: 10.1188/12.ONF.317-318