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