

## PHARMACY CORNER

### Drug Shows Promise in Nonmetastatic Prostate Cancer

In a poster discussion session at the American Society of Clinical Oncology meeting in Chicago, IL, Daniel George, MD, of Duke University Medical Center discussed updated results from a phase II study of orteronel, a selective oral 17,20-lyase inhibitor dosed without prednisone in patients with nonmetastatic castrate-resistant prostate cancer and rising prostate-specific antigen (PSA). The primary objective of the study was to determine the percentage of patients achieving a PSA reduction to 0.2 ng/ml or less (undetectable levels) after three months. The study included 39 patients and showed the following results.

- 16% of patients experienced PSA 0.2 ng/ml or less at three months, and 32% experienced it as their best response.
- 32% experienced a decline in PSA of 90% or greater at three months and 61% experienced such a decline as their best response.
- 76% experienced a decline in PSA of 50% or greater at three months and 84% experienced such a decline as their best response.
- Median time to PSA progression was 14.8 months.
- With a median follow-up of seven cycles (8.3 months), only three patients developed metastatic disease; freedom from metastases was 97% at 6 and 12 months, and median time to metastases was not reached.

For more information, visit [www.milennium.com](http://www.milennium.com).

### Trial Announced for Patients With First-Line Kidney Cancer

Advanced renal cell carcinoma (RCC), or kidney cancer, is the ninth most commonly diagnosed cancer in the United States (U.S. Cancer Statistics Working Group, 2010). Worldwide estimates predict more than 250,000 diagnoses and more than 100,000 deaths from the disease each year (Cancer Research UK, 2011). RCC accounts for more than 90% of all kidney cancers (American

Cancer Society, 2012). AVEO Oncology and Astellas Pharma, Inc. plan to initiate a new clinical study, TAURUS (Tivozanib use versus sunitinib in advanced RCC: Patient preference). The TAURUS study will enroll patients from the United States and western Europe to further define the tolerability profile of tivozanib and understand the role it could play in treatment of first-line advanced kidney cancer compared to a standard-of-care drug. TAURUS is a randomized, double-blind, crossover-controlled, multicenter phase II study comparing tivozanib to sunitinib in about 160 patients with advanced RCC who have received no prior systemic therapy. The primary objective of the study is to compare patient preference after receiving tivozanib and sunitinib in sequence. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a phase III clinical study in advanced RCC have been reported; tivozanib also is being evaluated in other tumors.

American Cancer Society. (2012). Kidney cancer (adult) renal cell carcinoma overview. Retrieved from <http://www.cancer.org/Cancer/KidneyCancer/OverviewGuide/kidney-cancer--adult--renal-cell-carcinoma-overview-what-is-kidney-cancer>

Cancer Research UK. (2011). Cancer worldwide: The global pictures. Retrieved from <http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common>

U.S. Cancer Statistics Working Group. (2010). United States cancer statistics: 1999-2007 incidence and mortality Web-based report. Retrieved from <http://www.cdc.gov/cancer/npcr/uscs/2007/about.htm>

and Radiation Epidemiology study were analyzed. Breast cancer incidence by age 50 among women treated with chest radiation for a childhood cancer was 24% compared to 31% for carriers of *BRCA1* mutations. Hodgkin lymphoma survivors treated with higher doses of radiation had an incidence of 30% (Moskowitz et al., 2012).

The Children's Oncology Group has recommended that women treated with radiation of 20 Gy or higher to the chest have annual mammography and breast magnetic resonance imaging starting at age 25 years or eight years after radiation, whichever occurs later. Women receiving lower doses of chest radiation also were at risk for breast cancer and may benefit from breast cancer screenings.

Moskowitz, C.S., Chou, J.F., Wolden, S.L., Bernstein, J.L., Malhotra, J., Friedman, D.N., . . . Oeffinger, K.C. (2012, June). *New insights into the risk of breast cancer in childhood cancer survivors treated with chest radiation: A report from the Childhood Cancer Survivor Study (CCSS) and the Women's Environmental Cancer and Radiation Epidemiology (WECARE) Study*. Abstract presented at the American Society of Clinical Oncology Annual Meeting, Chicago, IL.

### New Trial Design to Accelerate Breast Cancer Drug Approvals

Patients with early-stage breast cancer typically have to wait years to receive new cancer drugs. The U.S. Food and Drug Administration (FDA) has drafted regulatory guidance describing a new way of conducting breast cancer drug trials that will reduce the time and cost of getting new treatments to patients. The draft guidance establishes a potential new pathway for accelerated approval of drugs tested prior to surgical removal of tumors in certain high-risk patients with localized, early-stage disease. Trials using specific genetic signatures (biomarkers) are incorporated into a trial design that allows for measuring the relative benefit of treating patients with different tumor profiles with a specific drug and guiding treatment assignments for subsequent trial participants. The trials can test new treatments with fewer participants and in half the usual time, lowering costs. To read the draft guidance, visit [www.fda.gov/downloads/Drugs/Guid](http://www.fda.gov/downloads/Drugs/Guid)

## NOTEWORTHY

### Childhood Treatment Affects Future Breast Cancer Risk

Women treated with chest radiation for childhood cancer are at increased risk for breast cancer, a risk comparable to women with *BRCA* mutations. Data from more than 1,200 female childhood cancer survivors participating in the Childhood Cancer Survivor Study and 4,570 female first-degree relatives of women participating in the Women's Environmental Cancer