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.millennium.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 sutent 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

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 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 guideing 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

anceComplianceRegulatoryInformation/Guidances/UCM305501.pdf.

Download HealthClips Rx Application on iTunes®

HealthClips Rx is a patient education application that offers ease of use and mobility across multiple device platforms, such as iPads®, iPhones®, and computers. Physicians can create and share educational playlists tailored to each patient. Patients can interact with HealthClips Rx content by flagging sections of video content, inserting notes for care providers, attaching files, e-mailing videos to family members, and sending data to an electronic medical record. HealthClips Rx is available on iTunes.

New Genetic Testing Available for Hereditary Cancers

Ambry Genetics now has a number of diagnostic tests for hereditary cancers using next-generation sequencing technology. The four new panels allow for a rapid analysis of multiple genes. The panels include

- BreastNext—a 14-gene panel for hereditary breast cancer
- ColoNext—a 15-gene panel for hereditary colon cancer
- OvaNext—a 20-gene panel for hereditary gynecologic cancers
- CancerNext—a 23-gene panel for a wide range of hereditary cancers.

For more information, visit www.ambrygen.com.

Gene Distinguishes Chronic Leukemia's Aggressiveness

An estimated 16,060 new cases of chronic lymphocytic leukemia (CLL) will be diagnosed in Americans in 2012, as well as 4,580 deaths (American Cancer Society, 2012). Researchers at the Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, both in Columbus, OH, examined a gene called *ZAP-70* in CLL cells for a chemical change called methylation. Patients with a slow-progressing form of CLL are more likely to have the gene in leukemia cells that are methylated. If the *ZAP-70* gene is unmethylated, patients are likely to have more aggressive disease and may need treatment immediately. Researchers involved with the study suggest that the *ZAP-70* methylation status is highly predictive and a reproducible biomarker of poor prognosis in CLL. For more information, visit http://jco.ascopubs.org/content/early/2012/05/03/JCO.2011.39.3090.short?rss=1.

American Cancer Society. (2012). *Cancer facts and figures 2012*. Retrieved from http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-031941.pdf

SAFETY CONCERNS

FDA Issues Warning About Fentanyl Patches

The FDA issued a warning about the appropriate storage, use, application, and disposal of fentanyl patches to prevent harm from accidental exposure, particularly in children. A series of 26 cases of pediatric accidental exposure to fentanyl patches reported during the past 15 years led to the warning. Ten of those cases resulted in death and 12 in hospitalization, with 16 occurring in children aged two years or younger. Risk for exposure can arise from young children being held by someone wearing a partially detached patch. Healthcare professionals are urged to educate patients and caregivers about the appropriate use and disposal of fentanyl patches. Any cases of accidental exposure should be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting program. Reports can be made at www.fda.gov/MeWatch/report.htm

PRODUCT UPDATES

New Thickening Powder Reduces Aspiration Risk

Nestle Health Science has introduced a new nonstarch-based thickening powder designed to decrease the risk of aspiration compared to thin liquids for people with dysphagia. Resource® ThickenUp® Clear is tasteless, mixes and dissolves easily, and remains clear when mixed with water. Thickening products can assist patients with swallowing difficulties to swallow more safely and keep foods and liquids from entering the lungs.

Leonard et al. (2011) showed a significant reduction in the incidence of penetration and aspiration in patients with dysphagia who consumed Resource ThickenUp Clear, which is made with xanthan gum, compared to thin liquid. An improvement in airway closure time was observed, demonstrating the ability of this thickener to enhance patient safety.

Systematic screening to identify individuals at risk of dysphagia and help improve outcomes can be done by implementing a validated dysphagia screening tool, such as the Eating Assessment Tool (EAT-10) swallowing screening tool, as a standard of care. EAT-10 is a symptom-specific, 10-question questionnaire that can be used to identify patients at risk for dysphagia. The tool does not address treatment. Referral to a speech language pathologist is recommended for additional evaluation, dietary modification, and treatment. For more information, visit www.thickenupclear.com.

Leonard, R., et al. (2011, September). *The effects of rheology and type of thickening agent on objective swallowing parameters*. Poster session presented at the 1st Congress of the European Society for Swallowing Disorders, Leiden, The Netherlands.

Calendula Cream for Irradiated Skin Distributed at Workshops

Calendula cream can protect irradiated skin after repeated radiation treatments, and is known for its helpful benefits with burns and skin irritations. My Girls™ Skin Care cream, which contains 10% calendula, is the first radiation cream to be included in the American Cancer Society's Look Good . . . Feel Better® complimentary CareKits distributed at workshops. The cream is nongreasy and enables patients to return to work after treatments without staining their clothing. My Girls Skin Care cream can be found online at www.LotsToLiveFor.com, as well as at oncology boutiques, independent pharmacy chains, and specialty mastectomy fitters.

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.

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