PRODUCT UPDATE

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Docetaxel Approved for Advanced Prostate Cancer Treatment

The U.S. Food and Drug Administration has approved docetaxel (Taxotere®, Aventis Pharmaceuticals, Inc., Bridgewater, NJ) in combination with prednisone as treatment for androgen-independent metastatic prostate cancer. In a pivotal phase III trial, docetaxel increased survival in men with advanced prostate cancer. Typically, men with advanced prostate cancer initially are treated with hormones. Over time, the tumor becomes less sensitive to hormone manipulation, usually in about 24–36 months.

The most common severe adverse side effects of docetaxel include immunosuppression, fatigue, diarrhea, and mouth and throat irritation. Other nonsevere side effects include alopecia, peripheral neuropathies, rash, nail changes, nausea, vomiting, and myalgias. Uncommon potentially life-threatening side effects include fluid retention, infection, and hypersensitivity reactions. For more information, visit www.aventis-us.com or call 800-981-2491.

Innovative Treatment Introduced for Hypercalcemia in Patients With Parathyroid Cancer

Parathyroid carcinoma is a rare cancer that results in an excess secretion of parathyroid hormone (PTH). Excess PTH causes hypercalcemia, which can lead to mental status changes, nausea, vomiting, constipation, bone fractures, kidney stones, and, in severe cases, coma. Management of parathyroid carcinoma is typically surgical removal of the tumor, but this treatment may not be curative and repeated surgical debulking may be required. Cinacalcet HCl (Sensipar™, Amgen Inc., Thousand Oaks, CA) is a first-in-class oral calcimimetic approved to treat elevated calcium levels in patients with parathyroid cancer as well as in patients with chronic kidney disease on dialysis. Cinacalcet HCl works by acting directly on the calcium-sensing receptor, which then downregulates PTH, thereby lowering calcium levels.

The most commonly reported side effects are nausea and vomiting. The threshold for seizures may be lowered by reducing calcium levels, but seizures have been reported infrequently, primarily in patients with a history of seizure disorders. For more information, visit www.amgen.com.

First Immune Response Modifier Is Approved to Treat Actinic Keratosis

Actinic keratosis is a precancerous skin condition that affects millions of Americans every year. Actinic keratosis looks like rough, red, scaly patches or crusts commonly found on the face or scalp. It results from chronic sun exposure. This skin condition rarely can turn into squamous cell carcinoma or more commonly can turn into basal cell carcinoma.

Imiquimod cream 5% (Aldara™, 3M Pharmaceuticals, St. Paul, MN), applied topically to actinic lesions, can clear lesions by 75% or more. In two double-blind, randomized, placebo-controlled studies, nearly half of the patients achieved complete clearance of all lesions, compared to only 3% in the placebo group.

The most commonly reported side effects were local skin reactions, including erythema; flaking, scaling, dryness, scabbing, or crusting; edema; erosion or ulceration; weeping or exudates; and itching or burning at the application site. Two percent of patients discontinued treatment because of local skin or application site reactions. For more information, visit www.aldara.com or call 877-4-AK-NEWS.

Patent Application Submitted for 4-Hydroxy Tamoxifen

Ascend Therapeutics (Herndon, VA) has applied for a patent for 4-hydroxy tamoxifen (4-OHT). 4-OHT is a derivative of tamoxifen that can be applied locally as a gel. The gel is absorbed through the skin, yielding a therapeutic dose to the local area. The gel has less systemic absorption than oral tamoxifen, thereby decreasing side effects. 4-OHT is currently in phase II clinical trials exploring its use in chemoprevention for breast cancer instead of tamoxifen. The company also is exploring its use in treating ductal carcinoma in situ.

So far, the primary side effect of 4-OHT is hot flashes, and a dose escalation study reported one complaint each of local pain, nausea, red blotches, and dizziness and two complaints of itching. Unlike with tamoxifen, no one reported menstrual disturbances, estrogen-deprivation effects, serious side effects on the uterus, or blood clots. For more information, visit www.ascendtherapeutics.com.

U.S. Food and Drug Administration Bans Ephedra

On April 12, 2004, the U.S. Food and Drug Administration (FDA) banned all sales of products containing ephedra. The FDA is asking people to stop buying and using ephedra-containing products immediately. Ephedra is a plant derivative that has been used as a dietary supplement to help people lose weight. The FDA stated that no evidence exists that ephedra is effective for anything other than short-term weight loss and that significant side effects are associated with ephedra, including hypertension and increased risk of stroke. For more information, visit www.fda.gov/oc/initiatives/ephedra/february/2004.

NEW PRODUCTS

First Rapid Oral Fluid HIV Test Is Approved

The U.S. Food and Drug Administration has approved the OraQuick® Rapid HIV-1 antibody test (OraSure Technologies, Bethlehem, PA), the first HIV test that is noninvasive. A small device with an absorbent pad at one end is swabbed around the outer gums. The devise then is placed into a vial. In about 20 minutes, the test can be read. The new test has more than 99% accuracy. This new methodology greatly increases the safety of the person performing the test because no blood is needed. If positive, the test must be confirmed with a more specific blood test. For more information, visit www.fda.gov/cber/pma/p01004710.htm or www.orasure.com or call 800-869-3538.

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