PRODUCT UPDATE

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Ondansetron Approved for Use in Children as Young as One Month Old

GlaxoSmithKline in Research Triangle Park, NC, has announced that ondansetron (Zofran®) was approved for use in children as young as one month old for the treatment of postoperative and chemotherapy-induced nausea and vomiting. Ondansetron previously had been approved for children as young as two years. Approval was based on a double-blind, multisite, placebo-controlled study of 670 pediatric patients from one month to two years old who were undergoing routine surgery. The study found significantly less vomiting in children who received ondansetron within five minutes following induction of anesthesia. The most commonly found adverse reactions were agitation and swelling, which occurred in less than 1% of patients.

Ondansetron also was studied in a group of patients aged six months to four years who were receiving chemotherapy. This open-label, multicenter, noncomparative trial had 75 participants. Ondansetron was found to have a higher percentage of patients who were emesis free than was expected with a placebo. One adverse event, a rash, may have been related to ondansetron. For more information, visit www.gsk.com or www.zofran.com.

RX-0201 Receives Orphan Drug Status

The U.S. Food and Drug Administration (FDA) has granted orphan drug status to Rexahn Pharmaceuticals in Rockville, MD, for the drug RX-0201. The orphan drug status was granted for the treatment of ovarian cancer, renal cell carcinoma, glioblastoma, stomach cancer, and pancreatic cancer. RX-0201 is a first-in-class drug that represses the production of Akt, a protein kinase that plays a key role in cancer progression. RX-0201 blocks the growth in tumor cells and promotes apoptosis.

Orphan drug status allows for an accelerated review process, tax advantages, and seven years of market exclusivity in the United States. The drug currently is being tested in safety and pharmacokinetics trials. For more information, visit www.rexahn.com.

Lyposomal Doxorubicin Receives Full FDA Approval

Tibotec Therapeutic, a Division of Ortho Biotech Products, L.P., in Bridgewater, NJ, has announced that the FDA has given full approval of Doxil® (doxorubicin HCl liposome) for the treatment of patients with progressive or recurrent ovarian cancer. Doxorubicin HCl liposome previously had been granted accelerated approval. Full approval has been granted after the review of a randomized phase III clinical study demonstrated the drug's benefit in relapsed ovarian cancer. Doxorubicin HCl liposome showed benefit for patients in survival, time to disease progression, and tumor response rate. For more information, call 908-541-4000 or visit www.doxil.com.

New Formulation of Oxaliplatin Is Available

Eloxatin™ (oxaliplatin, Sanofi-Synthelabo, New York, NY) is available in a new aqueous solution. The formulation has been approved by the FDA. It is now easier to prepare oxaliplatin injections; the clear, colorless, preservative-free solution does not require any reconstitution. Oxaliplatin is approved for the adjuvant treatment of patients with stage III colon cancer in combination with infusional fluorouracil and leucovorin. The solution is available in 50 mg and 100 mg doses. For more information, visit www.eloxatin.com.

Combination Treatment Receives Expanded Indication

Tositumomab and iodine-131 treatment regimen (Bexxar™, GlaxoSmithKline) has received an expanded indication from the FDA. It now is approved for CD20-antigen–expressing relapsed or refractory, low-grade, follicular, or transformed non-Hodgkin lymphoma, including patients with tositumomab-refractory non-Hodgkin lymphoma. The new indication expands the number of patients who are eligible to receive this regimen and allows the regimen to be used earlier in the disease process. For more information, call 877-423-9927 or visit www.bexxar.com.

Temozolomide Approved for Newly Diagnosed Glioblastoma

Schering-Plough in Kenilworth, NJ, has announced that temozolomide (Temodar®) received full FDA approval for the treatment of adult patients with newly diagnosed glioblastoma multiforme in combination with radiation therapy. This approval is based on data that demonstrate a significant survival advantage for patients receiving concurrent temozolomide and radiation. Temozolomide previously received approval for the treatment of refractory anaplastic astrocytoma. For full prescribing information, visit www.schering-plough.com.

NEW PRODUCTS

New Bladder Cancer Kit Approved

The FDA has approved the first gene-based test for assisting in the diagnosis of bladder cancer. The UroVysion™ DNA probe assay (Vysis Inc., Downers Grove, IL) is used to detect genetic changes in bladder cells found in urine. When used in combination with cystoscopy, the UroVysion test kit can diagnose bladder cancer and monitor for disease recurrence. When combined with cystoscopy, UroVysion has a sensitivity of 97% and specificity of 96%. The company stated that UroVysion can detect bladder cancer recurrence up to six months sooner than current diagnostic methods. UroVysion also is unaffected by the presence of *bacillus Calmette-Guerin* used for the treatment of bladder cancer. For more information, visit www.urovysion.com.

DNA Testing Kits Are Available on Internet Through Physician Orders

A new genetic test kit for breast cancer, as well as other genetic tests, now is available on the Internet through DNA Direct in San Francisco, CA. A physician's order is required, and the consumer must read and sign consent forms. Consumers may select several different types of testing. Single-site testing for BRCA mutation, appropriate for people who know that a specific BRCA mutation

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that runs in their family, costs about $585. Multisite testing, appropriate for people with Ashkenazi Jewish ancestry, costs about $626. Full-sequence testing runs about $3,311 and is appropriate for people who have a family history of cancer but have not previously been tested. People should be aware that their medical insurance may cover only part of these costs, if any at all. The Web site is very easy to use and has screening information to direct people to the appropriate test. When complete, consumers receive a personalized report, and phone support is available from genetic experts. People also can speak with genetic counselors before ordering the tests to discuss the pros and cons of testing.

Critics of this type of direct consumer testing question the validity of these tests and raise concerns about the company's ability to explain very complicated results. For more information, visit www.dnadirect.com or call 877-646-0222.

MEDICARE NEWS

Medicare Offers Expanded Coverage for Off-Label Drug Use

CMS has expanded off-label use of oxaliplatin, irinotecan, bevacizumab, and cetuximab when these drugs are used in selected clinical trials. The ultimate goal is to improve the quality of cancer care to patients by facilitating research with these drugs. Medicare currently covers off-label use of some cancer drugs if they are listed in certain compendiums. For more information, visit www.medicare.gov.

Medicare Expands Coverage for Positron Emission Tomography Scans

The Centers for Medicare and Medicaid Services (CMS) will now cover positron emission tomography (PET) scans for brain, cervical, ovarian, pancreatic, small cell, lung, testicular, and other cancers when the provider participates in either a PET clinical trial that meets certain FDA requirements or when data are submitted to a database providing information about the use of PET scans. CMS's decision will help to accumulate data on the effectiveness and usefulness of PET scans in different types of cancer. Cost of the PET scan no longer will be a barrier to participation in this type of research. The PET scan database is under development and should be available within the next several months. The coverage of the cost of a PET scan will become effective once the database is established. For more information, visit http://cms.hhs.gov/coverage.

Medicare Proposes New Electronic Prescription System

As part of the Improvement and Modernization Act of 2003, Medicare is proposing a new electronic system for medication prescriptions. The system would allow for new prescriptions and prescription changes and cancellations to be completed electronically. The proposal includes a pilot project before final adoption. The goal is to provide more information to physicians at the point of service, reduce errors, and save time. When physicians order a medication electronically, the system would be able to provide information about potential drug interactions for medications that patients already were taking; alert for allergies; indicate whether the medication was covered; and list lower-cost, therapeutically equivalent alternatives. The system also eliminates problems resulting from poor handwriting. Participation in the proposed program would be optional for physicians and pharmacies but required for drug plans. The target is to have a final rule issued no later than April 2008 and for changes to take place no later than one year after that. For more information, visit www.hhs.gov/news/press/2005pres/20050127.html.