| TOOLS |

Drugs

Cephalon, Inc., (West Chester, Pa.) has received FDA approval for a new compressed powder formulation of **ACTIQ®** (oral transmucosal fentanyl citrate) [C-II] for the management of breakthrough cancer pain in patients with malignancies who are already receiving and are tolerant to opioid therapy. The new formulation of ACTIQ is bioequivalent to the previous formulation, with dosage strengths printed on the handle tag. All doses of ACTIQ (200/400/600/800/1200/ 1600 mcg) remain available in the new formulation.

Axcan Scandipharm, Inc., (Birmingham, Ala.) has received FDA approval of **Photofrin®** (porfimer sodium) **Injection** for the ablation of precancerous lesions (high-grade dysplasia) in Barrett esophagus patients who do not undergo surgery to remove the esophagus. Photofrin is a photosensitizing agent used in photodynamic therapy. The FDA first approved Photofrin in 1998.

Genta Incorporated (Berkeley Heights, Calif.) has received FDA approval to market **Ganite™** (gallium nitrate injection) for the treatment of cancer-related hypercalcemia that is resistant to hydration. With the launch of Ganite, Genta also announced the initiation of an assistance program to facilitate patient access to Ganite treatment.

The Centers for Medicare & Medicaid Services has identified the following codes for hospitals to bill Medicare for **Bexxar®** (tositumomab and iodine I-131 tositumomab).

- **G3001,** administration and supply of tositumomab, 450 mg, for the infusion of nonradioactive tositumomab during the dosimetric step and the infusion of nonradioactive tositumomab during the therapeutic step. This code is new and will be used twice during the course of Bexxar therapy.

- **G0273**, radiopharmaceutical biodistribution, single or multiple scans on one or more days, pretreatment planning for radiopharmaceutical therapy of non- Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar dosimetric dose using iodine I-131 tositumomab. An existing code, G0273 includes all scans taken during the dosimetric step and should be billed only once, no matter how many scans are performed.

- **G0274**, radiopharmaceutical biodistribution, single or multiple scans on one or more days, pretreatment planning for radiopharmaceutical therapy of non- Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar therapeutic dose using iodine I-131 tositumomab. G0274 is an existing code.

- **CPT 77300** is an existing code for dosimetry calculation.

Faulding Pharmaceutical Co. of Paramus, N.J., has added **paclitaxel injection** to its line of oncology products. The product is equivalent to Bristol-Myers Squibb's Taxol® Injection and has several on- and off-label indications. Faulding will supply paclitaxel in 30 mg, 100 mg, and 300 mg multi-dose vials.

The FDA has granted fast track designation to Telik, Inc. (Palo Alto, Calif.) for its drug **TELCYTA™** for third-line

therapy in patients with platinum refractory or resistant ovarian cancer. The drug is currently undergoing a randomized Phase III registration clinical trial for this use.

- Advexin® (Introgen Therapeutics, Inc., Austin, Tex.) was granted fast track designation by the FDA for its effect on prolonging survival and on prolonging the time to loco-regional disease progression in patients with recurrent, unrespectable squamous cell carcinoma of the head and neck. The FDA previously granted Advexin orphan drug status in head and neck cancer.

New Products

Siemens Medical Solutions (Malvern, Pa.) has received 510(k) clearance from the FDA for its **ONCOR™ Avant-Garde Linear Accelerator.** Now commercially available in the United States, ONCOR Avant-Garde is designed to deliver advanced, high quality radiation therapy treatments in a streamlined workflow environment.

Aurora Self-Expanding Biliary Stent System by Medtronic, Inc., (Minneapolis, Minn.) has received FDA clearance. The product is designed to maintain bile flow in ducts restricted or blocked by malignant tumors.

Second Look® Digital and **Second Look® AD CAD Systems** (CADx Systems, Inc., Beavercreek, Ohio) have been granted FDA approval, allowing integration with the GE Senographe 2000D full-field digital mammography system. Mammography CAD results are available in two minutes, allowing radiologists to review the CAD results immediately at the GE Senographe® 2000D Review Workstation.

The Electron Monte Carlo (eMC) dose calculation option (Varian Medical Systems, Inc., Palo Alto, Calif.) has received 510(k) clearance for marketing from the FDA. The eMC provides enhanced planning capability for electron radiotherapy, and the eMC algorithm has been integrated to work with the Eclipse™ treatment planning system, functioning alongside other calculation algorithms for different forms of radiotherapy.

Varian Medical Systems, Inc., has also released a new version of its Eclipse™ 3D radiotherapy treatment planning software for image-guided radiotherapy using combinations of PET, CT, and MRI.

Endocare (Irvine, Calif.) has received 510(k) clearance from the FDA to market its new **Cryocare CS™ System**, an easy-to-use, flexible, and more precise minimally invasive treatment for all forms of localized prostate cancer. The system uses cryoablation, including the availability of an integrated biplane ultrasound system with precise color Doppler visualization, to simplify the procedure and reduce the overall cost outlay for the technology. Cryocare CS also incorporates Endocare's automated freezing system (AutoFreeze™), a computer operated temperature control technology that effectively freezes the prostate without compromising sensitive adjacent healthy tissues.

Signa® EXCITE™ 3.0T GE Medical Systems, Waukesha, Wisc.), an MRI system for whole body imaging, has received marketing approval by the FDA. Signa EXCITE 3.0T offers the largest patient imaging volume with a full 45 cm field-of-view imaging capability.