NEW DRUGS

Provenge Immunotherapy For Prostate Cancer

The FDA has approved Sipuleucel-T (Provenge, Dendreon) for men with asymptomatic or minimally symptomatic metastatic prostate cancer that is resistant to standard hormone treatment. Cells from the patient’s own immune system are collected and then exposed to a protein that is found in most prostate cancers. This exposure triggers an enhanced immune response in the cells. The cells are then returned to the body to fight the disease. Sipuleucel-T is discussed in this month’s Pharmaceutical Approval Update column on page 345.

Source: Datamonitor, April 29, 2010

Natazia, an Oral Contraceptive

A combination oral contraceptive (Natazia, Bayer) has been approved. The tablet contains two female hormones, an estrogen (estradiol valerate [Deleges-trogen]) and synthetic progesterone (a progestin, Dienogest). This is the first four-phasic oral contraceptive marketed in the U.S. Doses of progestin and estrogen vary four times throughout each 28-day treatment cycle.

In two phase 3 studies in North America and Europe, adverse effects included irregular bleeding, breast tenderness, headaches, nausea and vomiting, increased weight, and acne. A boxed warning states that women older than 35 years of age who smoke cigarettes should not use this product.

Source: FDA, May 6, 2010

Generic Valtrex For Herpes Infections

Watson Laboratories has received the FDA’s approval of its Abbreviated New Drug Application for valacyclovir HCl tablets, USP, in 500- and 1,000-mg strengths. This product is the generic equivalent of GlaxoSmithKline’s Valtrex tablets. Valacyclovir is indicated for the treatment of cold sores (herpes labialis), initial and recurrent episodes of genital herpes in immunocompetent adults, chronic suppressive therapy of recurrence of genital herpes in immunocompetent and in HIV-infected adults, the reduction of transmission of genital herpes in immunocompetent adults, and the treatment of herpes zoster (shingles) in immunocompetent adults.

Source: Watson, May 24, 2010

Lumizyme for Pompe Disease

Alglucosidase alfa (Lumizyme, Genzyme) is now approved for patients eight years of age and older with late-onset (non-infantile) Pompe disease, a rare genetic disorder. The primary symptom is heart and skeletal muscle weakness, progressing to respiratory weakness and death from respiratory failure. Lumizyme is thought to replace a deficient enzyme, thereby reducing the accumulated glycogen in heart and skeletal muscle cells.

A boxed warning mentions the risk of anaphylaxis, severe allergic reactions, and immune-mediated reactions. Distribution will be restricted to ensure that the drug is used by the correct patient group.

The only other agent for Pompe disease available in the U.S. is Genzyme’s Myozyme, which has been in short supply. Myozyme is intended for infants and children, who usually have a more aggressive form of the disease. Patients with infantile-onset Pompe disease or patients eight years of age and younger with late-onset disease should receive Myozyme, not Lumizyme.

Source: FDA, May 25, 2010

DRUG NEWS

FDA to Study Safety Of Hormonal Therapies

Gonadotropin-releasing hormone (GnRH) agonists, which are commonly used to treat prostate cancer, have been associated with a small increased risk for diabetes, heart attack, stroke, and sudden death. Examples in this drug class include leuprolide (Eligard, Lupron, Viadur), nafarelin (Synarel), triptorelin pamoate (Trelstar), histrelin implant (Vantas), and goserelin (Zoladex), as well as several generic products.

The FDA is advising health care professionals to be aware of the potential risks and benefits before prescribing these agents. Patients should be monitored for the development of diabetes and cardiovascular disease, and cardiovascular risk factors should be managed according to current clinical practice. Patients should not stop using GnRH agonists unless they are advised to do so.

GnRH agonists suppress the production of testosterone, which is involved in the growth of prostate cancer. Androgen-deprivation therapy, which suppresses testosterone, has been shown to shrink or slow the growth of the cancer. These medications are also prescribed for women to treat endometriosis, uterine fibroids, and advanced breast cancer. Patients should not use these products for more than one year except to treat breast cancer. Some GnRH agonists are also used in children with central precocious puberty.

Source: FDA, May 4, 2010

Label Change for Vyvanse

A change to the prescribing information for Shire’s once-daily lisdexamfetamine dimesylate (Vyvanse, LDX) has been approved. LDX capsules are indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD). New data mention improved attention in adults throughout the day and into the evening. LDX was discussed in detail in the May 2010 issue of P&T.

Source: Shire, May 3, 2010
Rotavirus Vaccines in the News
FDA Revises Opinion on Vaccine

The FDA has determined that it is appropriate to resume using Rotarix (GlaxoSmithKline) and to continue prescribing RotaTeq (Merck) vaccines. These products are indicated for protection against rotavirus, a leading cause of severe diarrhea and dehydration among babies and young children.

The agency had earlier advised that Rotarix not be used in infants because a pig virus was found in the product. In May, the agency changed its decision based on laboratory and other scientific findings.

The FDA noted that both products had strong safety records, and it found no evidence that porcine circovirus (PCV1 or PCV2) posed a safety risk or caused infection or illness in humans.

Source: FDA, May 14, 2010

Vaccine Helps Lower Hospital Rates

Vaccinating infants against rotavirus has been associated with a dramatic decline in hospitalization rates for acute gastroenteritis in the U.S. Worldwide, rotavirus infection causes more than 500,000 deaths each year. RotaTeq was licensed in the U.S. and recommended for routine use in infants in 2006.

A team at the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality examined hospitalization rates for acute gastroenteritis during the rotavirus season among children younger than 5 years of age in the U.S. It was found that these rates were 16% lower in 2007 and 45% lower in 2008, compared with rates before the vaccine was introduced. During 2008, infants 0 to 2 months of age showed a 28% reduction, and infants 6 to 23 months of age had a 50% reduction. Rates among children 3 to 5 months of age and 24 to 59 months declined by 42% and 45%.

Approximately 55,000 hospitalizations for acute gastroenteritis were prevented during the 2008 rotavirus season as a result of the vaccinations. The declines also occurred among children who were too young or too old to receive the vaccine; these children might have been protected by the herd immunity resulting from vaccination of their peers.

Sources: J Infectious Dis, June 1, 2010; Science Daily, May 14, 2010

USP Panel Advises Standard Prescription Labels

To help establish universal standards for prescription medication labels, an advisory panel of the U.S. Pharmacopeial Convention (USP) has recommended consistent and simplified labeling on prescription packages. For instance, the USP stated that labels on the container should display only the most critical information in clear and concise language.

Ambiguous directions such as “take as directed” should be avoided. The drug’s purpose should be clearly stated on the label. When possible, the label should be printed in the patient’s preferred language. Medical jargon and Latin abbreviations, which can be misunderstood, should be eliminated.

Source: FDA, May 10, 2010

FDA Launches Video Series for Pharmacists

In mid-May, the FDA released “FDA Drug Info Rounds,” a new pharmacist education video series. The first program in the series is an eight-minute video focusing on single-ingredient oral colchicine, highlighting the differences between FDA-approved Colcrys (URL Pharma/Mutual) and unapproved colchicine, the public safety risks represented by unapproved drugs, and the significant scientific discoveries that led to the FDA’s approval of Colcrys. The video also serves to remind pharmacists that they should dispense FDA-approved products only. The video is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm 211975.htm.

Source: FDA, May 21, 2010

Both Tamoxifen and Raloxifene Reduce Breast Cancer Risk

Postmenopausal women with an elevated risk for breast cancer may be able to reduce their risk by taking an old standby, tamoxifen (Nolvadex, AstraZeneca) or an osteoporosis drug, raloxifene (Evista, Lilly).

Tamoxifen is more effective in reducing risk, but raloxifene is associated with fewer adverse effects. In 1998, the FDA approved raloxifene for use by women who did not have breast cancer but were at high risk for its development. In 2007, it was approved for breast cancer prevention in some high-risk postmenopausal women.

The updated analysis from the Study of Tamoxifen and Raloxifene trial (STAR) suggested that after five years of therapy, tamoxifen was better in preventing invasive breast cancer by 50%. Raloxifene cut the risk by 38%; it was 76% as effective as tamoxifen for this purpose and 78% as effective in preventing noninvasive breast cancers.

Only 5% to 20% of patients who could benefit from the drugs take them, perhaps because women perceive uterine cancers, clotting problems, and cataracts as barriers to tamoxifen use.

For women at an increased risk for breast cancer but not at risk for blood clots or uterine cancer, both drugs may be good choices. If a woman is at risk for these problems, raloxifene might be better, although tamoxifen is more effective. Women with osteoporosis might consider raloxifene.

Although the study included only postmenopausal women, tamoxifen has been...
effective in treating breast cancer in premenopausal women as well.Raloxifene is approved for use only after menopause. High-risk premenopausal women who have had a hysterectomy and who have no history of blood clots might consider tamoxifen.

Each drug costs about $140 per month, or $8,400 for five years. In comparison, treating one case of early breast cancer can cost $50,000 to $120,000.

Sources: Cancer Prev Res, April 2010; WebMD, April 20, 2010

Unstable Blood Pressure Raises Risk of CVD

The risk of cerebrovascular disease (CVD) appears to be higher among people with fluctuating blood pressure (BP) values who also have hypertension. CVD, which includes stroke and other disorders affecting blood vessels in the brain, is associated with cognitive decline and disability in older adults. Elevated BP can cause CVD and has been associated with poorer cognitive function and the risk of Alzheimer’s disease.

Researchers at Columbia University studied 686 older adults without dementia. BP measurements were taken during three study visits at 24-month intervals. Structural magnetic resonance imaging was also used to detect CVD. Participants were divided into four groups, depending on whether they had high BP, low BP, high BP fluctuations, or low BP fluctuations between visits.

Subjects in the two high BP groups had either hypertension or prehypertension; those in the other two groups had BP that was considered normal. Over the three-year period, elevated BP and alterations in BP were associated with CVD. Either factor was independently associated with an increased risk, and subjects with higher average BP and more fluctuations had more CVD than those with either condition alone.

In general, participants with the highest BP and fluctuation levels were most likely to receive antihypertensive medications, suggesting that a lack of treatment compliance might be one cause of the variations. The researchers recommended that managing BP fluctuations, even in older adults with normal BP, could be beneficial in reducing CVD risk and in enhancing cognition in the elderly.

Source: Arch Neurol 2010;67(5):564–569

Prompt Checkups Mean Lower Rehospitalization Rates For Heart Failure Patients

It is common for patients to have to return to the hospital after they have been treated for heart failure. Early follow-up after hospitalization may help to reduce readmission rates and to ensure that patients receive the right care after they are discharged.

On average, nearly 20% of the one million heart failure patients admitted to hospitals each year are readmitted within one month. Heart failure is the leading cause of those readmissions, which cost Medicare $17 billion each year overall and amount to 20% of all Medicare payments.

A recent study involved more than 30,000 Medicare patients at 252 hospitals. More than half of the hospitals failed to follow up with patients for a week after discharge, even though most of these frail patients were taking a mix of prescriptions, dosages, or both. Patients who were checked on promptly after discharge were about 15% less likely to need rehospitalization within 30 days.

Readmission rates varied dramatically; one hospital had a low rate (fewer than 16% of patients), whereas the last-ranking hospital readmitted 34% of its heart failure patients within 30 days.

Sources: JAMA 2010;303(17):1716–1722; USA Today, May 5, 2010

More Evidence for Bar Codes

A study was conducted at Brigham and Women’s Hospital in Boston to assess rates of errors before and after implementation of bar-code technology. Errors that involved early or late administration of medications were classified as timing errors; all others were classified as non-timing errors. Two clinicians reviewed the errors to determine their potential to harm patients and categorized those that could be harmful as potential adverse drug events.

After reviewing 14,041 medication administrations and 3,082 order transcriptions, the researchers noted 776 non-timing errors in drug administration on hospital units that did not use a bar-code electronic medication administration record (bar-code eMAR) system (error rate, 11.5%), compared with 495 such errors on units that did use it (a 6.8% error rate). This difference represented a 41.4% relative reduction in errors.

The rate of potential adverse drug events (other than those associated with timing errors) fell from 3.1% without the use of the technology to 1.6% with its use, representing a 50.8% relative reduction. The rate of timing errors in medication administration fell by 27.3%, although the rate of potential adverse drug events associated with timing errors did not change significantly.

Transcription errors occurred at a rate of 6.1% on units without the technology, but they were completely eliminated on units that used it.

Bar-code eMAR substantially reduced the rate of errors in transcribing prescriptions and administering drugs and helped to prevent adverse events.

Although errors were not eliminated, the technology was considered an important intervention for improving medication safety.

Similar Suicide Risks For Different Antidepressants

Adults have about the same risk of experiencing suicidal thoughts or attempting suicide when they begin to take antidepressants, regardless of which drug class is used. In a study conducted at Brigham and Women’s Hospital and Harvard Medical School in Boston, the lead author suggested that psychiatrists could base their choice on what works best for the patient rather than what is considered to be safest. However, labels for all of these drugs now carry a boxed warning about an increased likelihood of suicidal thoughts and behaviors.

To investigate whether any one drug or drug class might be more dangerous than another, researchers studied data on nearly 300,000 adults taking antidepressants between 1997 and 2005. Among the 287,543 men and women in the study, 751 attempted suicide and 104 committed suicide. No difference in risk was found between the various drug classes, including selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine (Prozac, Lilly) or sertraline (Zoloft, Pfizer) or older agents such as tricyclic antidepressants. Risks also were similar in comparisons of individual SSRIs. A similar study of 10- to 18-year-olds, published in the Journal of Pediatrics, also found no difference in suicide risk among antidepressants.

It remains unclear why antidepressants might increase suicide risk. Clinicians, therefore, should be vigilant in monitoring patients after prescribing any antidepressant agent.

Sources: Pediatrics, April 12, 2010 (online); Arch Gen Psychiatry, May 2010; Reuters Health, May 4, 2010

Mild Stroke Deserves Lifesaving Therapy

Patients who have had a severe stroke are given tissue-plasminogen activator (t-PA) as a matter of course, but patients with mild stroke usually do not receive this agent because of the notion that they might improve spontaneously and might not benefit from intravenous (IV) thrombolysis. However, researchers from the University of Medicine and Dentistry of New Jersey and the University of Minnesota conducted a retrospective review of 52 patients with acute ischemic stroke who received IV t-PA and concluded that giving IV t-PA after a mild stroke might improve clinical outcomes. Given the small sample size and the lack of long-term follow-up, the study should be considered hypothesis-generating, say the researchers. They recommend prospective studies to ascertain whether increasing the scope of therapeutic IV recombinant t-PA treatment is beneficial and safe for mild stroke.

Source: J Stroke Cerebrovasc Dis 2010; 19:116–120

Opioid Errors Are Common

Errors are common in opioid prescribing: in one study, 70% of patients received at least one incorrect prescription for an opioid agent. Researchers at Cleveland Clinic Taussig Cancer Center assessed 238 patients: 52 with non-cancer diagnoses and 186 with cancer. Of those patients with cancer, 117 had cancer pain—and 82 patients were subject to medication errors involving opioids. Errors were detected, encompassing strategy, conversion, rotation, titration, and the use of adjuvant analgesics. The most common mistakes were failing to order around-the-clock opioids for patients with constant pain and failing to treat or prevent opioid adverse effects. Multiple errors were more common among female patients, although the difference did not reach statistical significance.

The problems stem from both the system and the operator, the team suggests. Not ordering around-the-clock agents, for instance, might reflect poor assessment, difficulty in titrating the dose as an initial strategy, an underestimation of pain severity, or inadequate knowledge about opioid prescribing and pharmacology. Failure to recognize and appropriately treat different temporal pain patterns, such as constant versus intermittent or incident pain versus non-incident pain, can also lead to poor pain management and the mislabeling of pain as refractory. For incident pain, for example, patients require a different dosing strategy that includes titrating rescue doses, not increasing the around-the-clock dose.

In another study, the most significant errors in the use of oral morphine for terminal cancer patients occurred in dose titration and in the management of side effects. These problems were also observed in the authors’ own study, at rates of 9% and 15%, respectively. Because their patients were referred from multiple specialties, the problem transcends any one specialty. A pain management consultation effectively identified and corrected the dosing errors.

Opioids are discussed in greater detail in the article by David Craig on page 324.

Source: J Pain Symptom Manage 2010; 39:702–711

Heart Patients Question Need for Medications

In a study at Duke University, one-third of patients reported a negative change in their opinions about heart drugs in the first year after their hospitalization for acute coronary syndrome.

In the study, 812 patients completed two surveys, one at three months after hospital discharge and the second survey at 12 months. The patients rated the perceived necessity of taking prescribed medications and their concerns about potential adverse consequences of taking the medication. Higher values indicated...
greater necessity or concern.

At both 3 and 12 months, 74% of the patients had a score higher than the midpoint for perceived necessity of heart medications. Only 9% shifted from a high necessity score to a low score. Half of the patients had a score lower than midpoint for concern about their prescribed regimens, but 21% shifted from a low concern to a high concern score.

The only factors significantly associated with a decrease in perceived necessity were not having a cardiologist as the primary care provider and non-persistence with lipid-lowering therapy. Factors associated with statistically significant increases in concern were depression, the patient’s perception that the health care practitioner was not listening carefully, being discharged from the hospital with seven or more drugs, and not receiving instructions at discharge. Because a patient’s beliefs about medications have a significant influence on adherence, understanding and addressing changes in perception may help them stick with their regimens.

Source: Am Heart J 2010;159:561–569

Drug-Interaction Changes For Protease Inhibitors

Package inserts for all approved protease inhibitors (PIs), which are used to treat HIV infection, are now updated to reflect important drug interactions. These interactions are a common obstacle for patients receiving antiretroviral therapy. PIs compete with other drugs for enzymes that regulate drug levels in the body. This can result in elevated blood levels of one or more drugs (leading to more side effects) or lower blood levels of medications (decreasing the effectiveness of treatment).

Sildenafil (Revatio, Pfizer), a version of the erectile dysfunction drug Viagra, is prescribed to treat pulmonary arterial hypertension (PAH). Patients with HIV infection who are using PIs should not use sildenafil under any circumstances.

Bosentan (Tracleer, Actelion) and tadalafil (Adcirca, Eli Lilly), also indicated for PAH, should be used cautiously. (Tadalafil, when used as Cialis, is also prescribed to treat erectile dysfunction.) The dose of bosentan and tadalafil may need to be adjusted when combined with PIs. Bosentan should not be used with the PI atazanavir (Reyataz, Bristol-Myers Squibb) if a ritonavir (Norvir, Abbott) booster is not also included.

Salmeterol, a component of Advair and Serevent (GlaxoSmithKline), is often used to treat asthma, chronic obstructive pulmonary disease, and seasonal allergies. It should not be combined with PIs.

Alfuzosin (Uroxatral, Sanofi-Aventis), a therapy for benign prostatic hyperplasia, should not be taken with PIs.

Colchicine (Colcrys, URL Pharma/Mutual), indicated for treating and preventing gout and for treating familial Mediterranean fever, may require dose adjustments, depending on the PI used.

Sources: FDA; www.aidsmeds.com, April 28, 2010; www.pharmpro.com, May 6, 2010

High-Dose Aspirin for Migraine

Aspirin, at a single dose of 900 to 1,000 mg, has been found to reduce migraine headache pain within two hours for more than half of people who took it.

In a Cochrane review of 13 studies including 4,222 participants, formulations of aspirin 900 mg, together with 10 mg of metoclopramide (Reglan, Schwarz), an antiemetic, were better than placebo at reducing associated nausea, vomiting, photophobia, and phonophobia.

Researchers compared differences in response rates for aspirin alone or aspirin plus an antiemetic versus placebo or another active agent. Migraine pain was reduced from moderate or severe to no pain in 25% of participants within two hours with a single dose of 900 to 1,000 mg of aspirin alone compared with placebo. Pain was reduced to no worse than mild in 52% of participants. Aspirin alone reduced symptoms of nausea, vomiting, photophobia, and phonophobia, but aspirin plus metoclopramide helped decrease nausea and vomiting yet produced no greater degree of pain relief.

A boxed warning for metoclopramide mentions the risk of its long-term or high-dose use. Chronic use of metoclopramide has been linked to tardive dyskinesia, even after the drug is no longer taken.

Source: Cochrane Database Syst Rev 2010(4), Art. No.: CD008041

RESEARCH NEWS

Do Analgesics Decrease Cancer Risk in Women?

The regular use of aspirin and other analgesics may reduce estrogen levels, which could contribute to a decreased risk of breast or ovarian cancer. A significant inverse association was observed between concentrations of several estrogens and the use of aspirin, aspirin plus non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs), and all analgesics combined. The results suggest that postmenopausal women who use aspirin and other analgesics may have lower estrogen levels than non-users.

In 740 postmenopausal women who participated in the Nurses’ Health Study, the frequency of all analgesic use was inversely associated with estradiol, free estradiol, estrone sulfate levels, and the estradiol-to-testosterone ratio. Whether the use of aspirin and other NSAIDs is related to a reduced breast cancer risk is still unresolved.

In another report, aspirin use after a diagnosis of breast cancer appeared to reduce the risk of recurrence and death.

Sources: Cancer Epidemiol Biomarkers Prev 19(4), April 2010; American Cancer Society, March 10, 2010
**DEVICES IN THE NEWS**

**Alair System for Severe Asthma**

The Alair Bronchial Thermoplasty System (Asthmatx, Inc.) has been approved to treat severe, persistent asthma in adults 18 years of age and older whose asthma is not well controlled with inhaled corticosteroids or long-acting beta-agonist agents. Alair is designed to reduce the number of severe attacks on a long-term basis.

Radiofrequency energy is used to heat lung tissue in a controlled manner, reducing the thickness of smooth muscle in the airways and improving the ability to breathe. Patients need several sessions to target various areas in the lungs.

Possible side effects include wheezing, chest tightness or pain, partially collapsed lung, hemoptysis, anxiety, headaches, nausea, and a risk of asthma attacks during treatment.

Alair is not indicated for patients who have a pacemaker, an internal defibrillator, or another implantable electronic device; for those with sensitivities to lidocaine, atropine, or benzodiazepines; for those who have had changes to their corticosteroid regimen 14 days before the proposed treatment; and for those who have had changes to their corneal transplant.

The FDA is requiring a five-year post-approval study to evaluate the long-term safety and effectiveness of the device.

Sources: Bronchial Thermoplasty, www.bfiorasthma.com, April 27, 2010; Medical News Today, April 28, 2010

**Assay Detects Chagas Disease**

The FDA has approved a second test to screen blood, tissue, and organ donors for a blood-borne parasite that causes Chagas disease, a potentially fatal parasitic infection. The assay detects antibodies to *Trypanosoma cruzi* in serum or plasma specimens obtained from donors of whole blood and blood components and from other living donors. Cadaveric donors may also be used.

Approximately 300,000 people in the U.S. have Chagas disease, which is spread mainly by blood-sucking insects infected with *T. cruzi*. It can also be spread via blood transfusions and organ transplants and from pregnant women to their unborn children. Since 2007, 1,000 donors with *T. cruzi* infection have been identified.

Source: FDA, April 30, 2010

**Device Recalls**

**Lifepak 15 Monitor/Defibrillator.** Physio-Control, Inc., has issued a class I recall of its Lifepak 15 Monitor/Defibrillator, which is used in emergencies to monitor heart rhythms and to treat cardiac arrest. The device was recalled because of the possibility of a power malfunction, such as turning on by itself, not turning on, not allowing itself to be turned off, or requiring an operator to turn the power back on. Customers should keep the device in service and test it according to the instructions. These instruments were made between March 26 and December 15, 2009.

Source: FDA, April 22, 2010

**Colleague Infusion Pumps.** The FDA has ordered Baxter to recall and destroy all Colleague Volumetric Infusion Pumps in the U.S. because of a long-standing failure to correct serious problems. As many as 200,000 pumps may be affected. Baxter has been ordered to reimburse customers for the value of the devices and to help find replacements.

Source: FDA, May 3, 2010

**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Levia Personal Targeted Phototherapy

**Manufacturer:** Lerner Medical Devices, Inc., Los Angeles, Calif.

**Approval Date:** March 5, 2010

**Purpose:** Levia is a non-drug option without the potential systemic side effects of pharmaceutical treatments. It is an ultraviolet B (UVB) light source with light-beam attachments. It is indicated for the treatment of small areas of the skin, scalp psoriasis, vitiligo, atopic dermatitis, eczema, and seborrheic dermatitis, including dandruff. The device is recommended for use six to 12 weeks after surgery, and patients can use it in the home.

**Description:** Levia incorporates software for the physician to control dosimetry. Two beam-delivery attachments ensure precise delivery of UVB light to specific areas of the skin and scalp to be treated: LiteSpot is used to treat plaques on the body, and LiteBrush is designed for hard-to-treat scalp psoriasis. Under a physician’s supervision, patients can use the light-beam attachments to deliver targeted UVB light within the spectral band of 300 to 320 nanometers (nm) to areas of the affected skin. The targeted UVB light is named UVB-Select.

Each attachment fits interchangeably into the handpiece and directs unobstructed UVB light to specific areas. The quartz fiber-optic bristles of the LiteBrush bypass the hair barrier to deliver light directly onto the scalp or other hair-bearing areas. The specially designed, rounded tips of the bristles spread light over the contact points on the scalp, bypassing the hair and delivering the therapeutic UVB light directly to the areas that need it.

The LiteSpot incorporates optical technology in directing the UVB light, which is generated by an enhanced lamp with special optical coatings. A precise UVB dose is delivered directly to psoriasis plaques without illuminating uninvolved skin, which is often a problem with conventional phototherapy devices.

**Benefit:** Patients can treat themselves...
rapidly and safely with this nonsystemic therapy. In clinical trials, Levia was effective for more than 85% of patients with psoriasis. Built-in controls enable physicians to determine a specific regimen to maximize compliance and outcomes for each patient. The compact design makes the device easy and comfortable to handle. An instruction manual and a quick reference guide are provided, and a sheet allows patients to try each attachment on UV-sensitive material before treating the skin.

Precautions: To protect their eyes from UVB light, patients and any other people in the room must wear safety goggles with side shields during treatment sessions. Safety gloves must also be worn when patients and others are handling the attachments to protect the unaffected areas of the hands during phototherapy.

Source: www.mylevia.com

Name: Vitala Continence Control Device
Manufacturer: ConvaTec Ostomy Care, Inc., Skillman, N.J.
Approval Date: April 10, 2010
Purpose: This pouchless ostomy device functions by sealing against the stoma to prevent the release of stool while permitting gases to vent through an integrated, deodorizing filter. When the device is in use, stool is stored inside the body so that patients do not need to wear an ostomy pouch.
Description: The single-use, disposable disc is worn with the ConvaTec Natura skin barrier, which measures 1.75 to 2.25 inches.
Benefit: Patients can manage their colostomy without the need for a pouch, belt, or irrigation for up to eight hours. A discreet low profile also helps to minimize the presence of the ostomy, making it less noticeable. Easy to apply and remove, a built-in expandable container prevents soiling during removal. The waterproof device can be worn during bathing, showering, or swimming.

Sources: www.convatec.com; www.medicalnewstoday.com/articles/185035.php

Name: Sysmex XT-4000i Automated Hematology Analyzer
Manufacturer: Sysmex America, Inc., Mundelein, Ill.
Approval Date: April 2, 2010
Purpose: The analyzer can detect circulating immature granulocytes, which may serve as an early indicator of acute infection, leukemia, anemia, an inflammatory response, or a myeloproliferative disorder.
Description: The XT-4000i is a new model in the XT Series and is intended for use mainly in medium-sized hospitals. Fluorescent flow cytometry and advanced cell-counting methods enable the delivery of rapid, reliable results, essential in patient diagnosis and therapeutic monitoring.
Benefit: The device has sophisticated capabilities for blood analysis and a high processing capacity, equivalent to a 25% increase over the preceding models in the XT series. Blood cells in cerebrospinal and pleural fluids can be analyzed, and the hemoglobin content of reticulocytes can be quantified. This capability is an established parameter in the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative guidelines for assessing the initial iron status of patients with chronic kidney disease who are receiving hemodialysis as well as IV iron replacement.

Compared with traditional analyzers, the Sysmex XT-4000i provides enhanced testing versatility, more comprehensive data, and more targeted analyses.
Sources: www.sysmex.com; www.medicalnewstoday.com/articles/184248.php