NEW DRUG APPROVALS

‘Breakthrough Therapy’ Zykadia For Late-Stage Lung Cancer

The FDA granted accelerated approval to ceritinib (Zykadia, Novartis) for patients with anaplastic lymphoma kinase-positive (ALK+) metastatic non–small-cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

Lung cancer, the leading cause of cancer-related deaths, will kill an estimated 159,260 Americans this year. About 85% of lung cancers are NSCLC, but only 2% to 7% of these patients are ALK+.

Ceritinib, an oral, selective ALK inhibitor, is the fourth drug designated a breakthrough therapy to receive FDA approval, which it secured four months before its Prescription Drug User Fee Act goal. The FDA also gave ceritinib priority review and orphan product designation.

In a pivotal trial that included 163 patients with metastatic ALK+ NSCLC who progressed on or were intolerant to crizotinib, ceritinib achieved an overall response rate of 54.6% (95% CI, 47–62) and a median duration of response of 7.4 months (95% CI, 5.4–10.1).

Common side effects of ceritinib include gastrointestinal symptoms such as diarrhea, nausea, vomiting, and abdominal pain. Laboratory abnormalities such as increased liver enzymes, pancreatic enzymes, and increased glucose levels were also observed.

Sources: FDA and Novartis, April 29, 2014

Cyramza for Stomach Cancer

Ramucirumab injection (Cyramza, Eli Lilly) has received FDA approval as a single-agent treatment for patients with advanced or metastatic gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after fluoropyrimidine- or platinum-containing chemotherapy.

In the phase 3 REGARD trial of 355 patients, ramucirumab (8 mg/kg by infusion every two weeks) plus best supportive care (BSC), compared with placebo plus BSC, increased the median overall survival of patients with advanced gastric cancer by 37% (5.2 months for ramucirumab vs. 3.8 months for placebo). Ramucirumab improved median progression-free survival 62% (2.1 months for ramucirumab vs. 1.3 months for placebo).

Ramucirumab’s labeling includes a boxed warning regarding an increased risk of hemorrhage, including severe and sometimes fatal events. Ramucirumab should be discontinued in patients who experience severe bleeding. The most common adverse events of any grade in the REGARD trial were hypertension, diarrhea, headache, and hyponatremia.

Ramucirumab is a vascular endothelial growth factor (VEGF) receptor 2 antagonist that specifically binds VEGF receptor 2 and blocks binding of VEGF receptor ligands VEGF-A, VEGF-C, and VEGF-D. VEGF receptor 2 is an important mediator in the VEGF pathway.

An estimated 22,000 U.S. residents will be diagnosed with gastric cancer in 2014. Source: Eli Lilly, April 21, 2014

Entyvio for Ulcerative Colitis And Crohn’s Disease

The FDA has approved vedolizumab injection (Entyvio, Takeda Pharmaceuticals America) for the treatment of adults with moderate-to-severe ulcerative colitis or Crohn’s disease when one or more standard therapies have not produced an adequate response.

Ulcerative colitis, which affects about 620,000 Americans, causes inflammation and ulcers in the large intestine’s inner lining that can lead to abdominal discomfort, gastrointestinal (GI) bleeding, and diarrhea. More than 500,000 Americans have been diagnosed with Crohn’s disease, which inflames and irritates the GI tract. Standard therapies include corticosteroids, immunomodulators, or tumor necrosis factor blockers.

In two clinical trials involving about 900 ulcerative colitis patients who had not responded adequately to standard therapies, a greater percentage of those treated with vedolizumab than placebo achieved and maintained a clinical response or clinical remission and achieved corticosteroid-free clinical remission. Among about 1,500 Crohn’s disease patients in three clinical trials who had not responded adequately to standard therapies, a greater percentage of those treated with vedolizumab than placebo achieved a clinical response, clinical remission, and corticosteroid-free clinical remission.

Vedolizumab blocks the interaction of a specific integrin receptor (expressed on circulating inflammatory cells) with a specific protein (expressed on cells in the interior wall of blood vessels), blocking migration of those circulating inflammatory cells across those blood vessels and into areas of inflammation in the GI tract.

Vedolizumab’s most common adverse effects include headache, joint pain, nausea, and fever. The most serious risks include serious infections, hypersensitivity, infusion-related reactions, and hepatotoxicity.

Sources: FDA, May 20, 2014, and Entyvio prescribing information

Epanova for Severe Hypertriglyceridemia

A formulation of omega-3-carboxylic acids (Epanova, AstraZeneca) has received FDA approval as an adjunct to diet to treat adults’ severe hypertriglyceridemia (triglyceride levels of 500 mg/dL or more). The first FDA-approved prescription omega-3 in free fatty acid form can be prescribed in daily dosages of 2 g (two capsules) or 4 g (four capsules).

FDA approval was based on a clinical development program that included the phase 3 EVOLVE (EpanoVa for Lowering Very High Triglycerides) trial. The
12-week, randomized, double-blind study evaluated the efficacy and safety of 2-g, 3-g, and 4-g daily doses of Epanova versus placebo in 399 patients with fasting triglyceride levels of at least 500 mg/dL but less than 2,000 mg/dL. Epanova demonstrated statistically significant decreases of triglycerides in all dose groups, including approximately 26% in the 2-g group and 31% in the 4-g group. Non–high-density lipoprotein-cholesterol also declined in all dose groups: approximately 8% and 10% in the 2-g and 4-g cohorts, respectively. The most common adverse events (mild and gastrointestinal) were mostly resolved during the trial.

AstraZeneca plans to conduct a large cardiovascular outcomes trial to evaluate Epanova’s safety and efficacy in combination with statin therapy in patients with mixed dyslipidemia. The company also plans to pursue development of a fixed-dose combination of Epanova and a statin.

Sources: AstraZeneca, May 6, 2014, and Omthera Pharmaceuticals, November 15, 2012

**Zontivity to Reduce Risk Of Heart Attack and Stroke**

The FDA has approved vorapaxar (Zontivity, Merck) to reduce the risk of heart attack, stroke, cardiovascular death, and the need for additional medications compared with patients who received placebo. During safety assessments in about 1,700 adults, the most common adverse reactions were itching in the mouth and ears, as well as throat irritation. The prescribing information includes a boxed warning to inform caregivers and patients that severe and sometimes life-threatening allergic reactions can occur.

Source: FDA, April 17, 2014

**Sylvant for Multicentric Castleman’s Disease**

The FDA has approved siltuximab (Sylvant, Janssen Biotech) to treat patients with multicentric Castleman’s disease (MCD) who test negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

Siltuximab is an IL-6 antagonist biologic therapy administered as an intravenous infusion once every three weeks. It is the first U.S.-approved treatment for MCD, a rare blood disorder in which lymphocytes are overproduced, leading to enlarged lymph nodes. MCD can also affect lymphoid tissue of internal organs, enlarging the liver, spleen, or other organs. An estimated 1,100 to 1,300 Americans have MCD.

Overproduction of IL-6, a multifunctional cytokine produced by various cells, is considered a key mechanism in MCD. Siltuximab works by binding to IL-6.

Siltuximab’s efficacy and safety were evaluated in a multinational, randomized, double-blind, placebo-controlled pivotal study in 79 patients who had symptomatic MCD and were HIV-negative and HHV-8 negative. For siltuximab compared with placebo, durable MCD response (defined as reduction in tumor size and disease symptoms that persisted for at least 18 weeks without treatment failure) was 34% versus 0%. Tumor response for the 53 patients in the siltuximab arm was 38% versus 4% for those in the placebo arm.

The most frequent adverse reactions during siltuximab treatment were rash (28%), pruritus (28%), upper respiratory
truct infection (26%), increased weight (19%), and hyperuricemia (11%).

Source: Janssen Biotech, April 23, 2014

**Generic Approvals**

**Celecoxib**

Generic celecoxib should be available by the end of 2014, but exactly who will be selling it and when remain in dispute.

Under a settlement of patent litigation with Pfizer, Teva Pharmaceuticals USA can launch U.S. generic versions of Pfizer’s Celebrex by December 2014. U.S. sales of Celebrex were $2.2 billion in 2013, according to IMS Health.

Although key Celebrex patents expired in May 2014, Pfizer has been fighting to reinstate another patent, overturned in federal court, that would protect Celebrex until December 2015.

Teva believes it was the first to file its application to make generic celecoxib, which has tentative FDA approval. But other generics companies are suing the FDA to challenge Teva’s 180 days of exclusivity.

Watson Laboratories (a subsidiary of Actavis, which made a similar litigation-ending deal with Pfizer) argues that it is entitled to share exclusivity. And Mylan—which did not join in the Pfizer settlement—believes it should be allowed to offer celecoxib at the end of May 2014, when Pfizer’s remaining Celebrex patents expired.

Celecoxib, a nonsteroidal anti-inflammatory drug used for arthritis and acute pain, carries boxed warnings for cardiovascular and gastrointestinal risk.

Sources: Teva, April 17, 2014; Mylan, April 25, 2014; Actavis, April 28, 2014; Celebrex prescribing information

**Eszopiclone**

At least five companies now offer generic formulations of Lunesta, the Sunovion Pharmaceutical’s insomnia drug that had 2013 U.S. sales of approximately $852 million, according to IMS Health. Teva Pharmaceuticals, Mylan, Dr. Reddy’s Laboratories, Glenmark Generics, and Roxane Laboratories are selling eszopiclone CIV 1-mg, 2-mg, and 3-mg tablets in the U.S.

Sources: Teva, Mylan, and FDA, April 15, 2014; Dr. Reddy’s Laboratories and Glenmark Generics, April 16, 2014

**Rosiglitazone Maleate and Metformin Hydrochloride**

The FDA has approved Teva Pharmaceuticals’ combination type-2 diabetes treatment rosiglitazone maleate and metformin hydrochloride tablets, 2 mg (base)/500 mg, 4 mg (base)/500 mg, 2 mg (base)/1 g, and 4 mg (base)/1 g. This is the first U.S. generic version of GlaxoSmithKline’s Avandamet.

This combination of rosiglitazone, a thiazolidinedione, and metformin, a biguanide, carries boxed warnings for increased risks of congestive heart failure, myocardial infarction, and lactic acidosis. It is sold under a risk evaluation and mitigation strategy (REMS) program.

Sources: FDA, May 7, 2014, and Avandamet prescribing information

**Norelgestromin / Ethinyl Estradiol Transdermal System**

Mylan has launched Xulane (norelgestromin/ethinyl estradiol transdermal system 150/35 mcg per day), the first generic version of Janssen Pharmaceuticals’ Ortho Evra. This product is indicated for pregnancy prevention in women who elect to use a transdermal patch for contraception. Ortho Evra had U.S. sales of approximately $152.9 million in 2013, according to IMS Health.

Source: Mylan, April 16, 2014

**Atazanavir Sulfate**

The FDA has approved Teva Pharmaceuticals’ atazanavir sulfate capsules, 100 mg, 150 mg, 200 mg, and 300 mg (base), after determining them to be therapeutically equivalent to Reyataz capsules manufactured by Bristol-Myers Squibb. This is the first generic formulation of Reyataz, a protease inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Sources: FDA, April 22, 2014, and Reyataz prescribing information

**Arzerra With Chlorambucil in CLL**

The FDA has approved ofatumumab (Arzerra, GlaxoSmithKline/Genmab), a CD20-directed cytolytic monoclonal antibody, in combination with chlorambucil for the first-line treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) for whom fludarabine-based therapy is inappropriate.

In a pivotal phase 3 study, COMPLEMENT 1, ofatumumab plus chlorambucil was compared with chlorambucil alone in 447 previously untreated patients with CLL (median age, 69 years) for whom fludarabine-based therapy was considered inappropriate. Among the 221 patients randomly assigned to receive the combination, median progression-free survival was 22.4 months, compared with 13.1 months for the 226 patients assigned to receive chlorambucil alone.

Infusion reactions were seen in 67% of patients in the ofatumumab-plus-
Synribo Approved for Use At Home by CML Patients

The FDA has approved patients’ home administration of omacetaxine mepsuccinate (Synribo, Teva Pharmaceuticals) for injection, for subcutaneous use. The agency also approved a medication guide and instructions for use.

The medication is indicated for the treatment of adults with chronic or accelerated-phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors. Although its mechanism of action is not fully understood, the drug has been shown to prevent the production of the proteins Bcr-Abl and Mcl-1 in laboratory studies. These proteins are produced at increased levels by cancerous CML cells and help drive the disease.

Sources: Teva, May 5, 2014, and Synribo prescribing information

Kogenate FS in Adults With Hemophilia A

The FDA has approved antihemophilic factor VIII, recombinant (Kogenate FS, Bayer) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A.

The approval was based on data from SPINART (Secondary Prophylaxis IN Adults, a Randomized Trial), a phase 3 study in which 84 male subjects with severe hemophilia A were randomly assigned to receive Kogenate FS either as prophylaxis (25 IU/kg three times per week) or as on-demand therapy. Patients who received on-demand treatment experienced, on average, 15.2 times as many bleeds as patients receiving prophylaxis. Serious adverse reactions with Kogenate FS included systemic hypersensitivity reactions and the development of high-titer inhibitors necessitating the use of alternatives to factor VIII.

Source: GlaxoSmithKline, April 17, 2014

Lipiodol for Imaging of Tumors In Hepatocellular Carcinoma

Ethiodized oil (Lipiodol, Guerbet) for injection has received FDA approval for selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC).

Lipiodol received an orphan-drug designation for management of patients with known HCC in October 2013. Approval was received shortly after the FDA accepted a new manufacturing site for Lipiodol, which has been supplied during the past three years under a temporary importation program.

Source: Guerbet, April 10, 2014

NEW FORMULATION Mercaptopurine Oral Suspension

The FDA has approved a 20 mg/mL oral suspension of mercaptopurine (Purixan, Nova Laboratories), which is indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) as part of a combination regimen.

Mercaptopurine was approved in 1953 as a 50-mg tablet, which remained the only commercially available formulation. Because of the age and weight range of children with ALL, this was not ideal: Body surface area dosing was difficult, and tablets are not the best medication for children younger than 6 years old. A suspension offers more accurate delivery and dose adjustment for children in a wide range of weights.

The approval was based on a clinical pharmacology study to assess the bioequivalence of mercaptopurine from tablets with that of the mercaptopurine oral suspension in a healthy adult population.

Source: FDA, April 29, 2014

DRUG NEWS

FDA Grants Priority Review For MK-3475 for Melanoma

The FDA will give priority review to the biologics license application for MK-3475, Merck’s investigational anti-PD-1 antibody, for the treatment of unresectable or metastatic melanoma in patients previously treated with ipilimumab.

The FDA set a Prescription Drug User Fee Act date of October 28, 2014, for the review under its accelerated approval program. The FDA previously granted MK-3475 breakthrough therapy designation for advanced melanoma. If approved by the FDA, MK-3475 has the potential to be the first anti-PD-1 antibody in a new class of immune checkpoint modulators.

By the end of 2014, Merck anticipates that the MK-3475 development program will grow to more than 24 clinical trials across 30 different tumor types in monotherapy and combination.

Source: Merck, May 6, 2014

Mydicar Termed Breakthrough Therapy for Heart Failure

The FDA has granted Mydicar (Celldon Corporation) a “breakthrough therapy” designation for reducing hospitalizations for heart failure in neutralizing antibody (NAb)-negative patients with New York Heart Association class III or IV chronic heart failure.

Mydicar is being developed as a first-in-class therapy for patients with chronic heart failure due to systolic dysfunction. It uses genetic enzyme-replacement therapy to correct deficiencies in the enzyme SERCA2a that result in inadequate pumping of the heart. Mydicar transfers the SERCA2a gene directly into cardiac muscle cells using a nonpathogenic
recombinant adeno-associated virus. In the phase 2a CUPID 1 trial, a single intracoronary infusion of high-dose Mydilyn in patients with advanced heart failure due to systolic dysfunction reduced heart failure-related hospitalizations and improved patients’ symptoms, quality of life, and key markers of cardiac function that were predictive of survival.

Source: Celladon Corporation, April 10, 2014

Orphan Drug Designations
Volasertib for Acute Myeloid Leukemia
The FDA granted an orphan drug designation to volasertib (Boehringer Ingelheim) for the treatment of acute myeloid leukemia (AML). The investigational compound is being evaluated in a phase 3 clinical trial for the treatment of patients 65 years of age or older with previously untreated AML who are ineligible for intensive remission-induction therapy.

The average age of an AML patient is 65 to 70 years. The recommended standard of care for AML is intensive chemotherapy, but many patients, because of age and comorbidities, cannot tolerate this approach. Volasertib is being investigated in this population.

Volasertib inhibits polo-like kinase (Plk) enzymes. Inhibition of Plk1, which regulates mitosis, can result in prolonged cell-cycle arrest, ultimately leading to apoptosis. Volasertib is being evaluated in clinical studies for the treatment of various solid tumors and hematological cancers.

Source: Boehringer Ingelheim, April 17, 2014

Ciprofloxacain Dry Powder for Inhalation
Bayer HealthCare’s investigational ciprofloxacain dry powder for inhalation (DPI) has received an FDA orphan drug designation for the treatment of noncystic fibrosis bronchiectasis (NCFB). Patients with NCFB suffer frequent severe acute pulmonary bacterial exacerbations, which lead to further inflammation and to airway and lung parenchyma damage.

Ciprofloxacain DPI is in development as chronic intermittent therapy for reducing the frequency of acute exacerbations in NCFB patients with bacterial respiratory pathogens. It comprises ciprofloxacain, a fluoroquinolone antibiotic, formulated into dry powder for inhalation using Novartis PulmoSphere technology and is administered with a dry powder inhaler.

Source: Bayer HealthCare, April 22, 2014

BioThrax After Anthrax Exposure
Emergent BioSolutions has received orphan drug designation for anthrax vaccine adsorbed (BioThrax) for post-exposure prophylaxis of anthrax disease resulting from suspected or confirmed exposure to Bacillus anthracis. BioThrax, the only FDA-licensed vaccine to prevent anthrax disease, is licensed for pre-exposure prophylaxis.

Source: Emergent BioSolutions, April 21, 2014

FDA to Review Psychiatric Side Effects of Chantix
An FDA advisory panel will meet October 1 to discuss the risk of serious neuropsychiatric adverse events with varenicline tartrate tablets (Chantix, Pfizer) and to review options for addressing this risk.

Chantix, a nicotinic receptor partial agonist, was approved in 2006 for use as an aid to smoking-cessation treatment. The FDA began investigating its potential adverse effects the following year.

In 2009, a boxed warning was added to the labeling for varenicline tartrate, citing a potential for serious neuropsychiatric events. The warning advises patients and caregivers that the patient should stop taking the drug and contact a health care provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are atypical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior while taking or shortly after discontinuing varenicline tartrate.

Two FDA-sponsored epidemiological studies found no significant difference in the risk of neuropsychiatric hospitalizations between varenicline tartrate and nicotine replacement therapy, but both trials had study-design limitations.

Sources: Medical Xpress and Federal Register; April 25, 2014; FDA, October 24, 2011; Chantix prescribing information

Don’t Inject Corticosteroids Into Spine’s Epidural Area, FDA Says
Injectable corticosteroids into the epidural space of the spine may cause rare but serious adverse events, including loss of vision, stroke, paralysis, and death, the FDA says. The agency is requiring the addition of a warning to the labels of injectable corticosteroids to describe the risks of such injections, which are given to treat neck and back pain and radiating pain in the arms and legs.

Injectable corticosteroids are used to reduce swelling or inflammation. Injecting them into the epidural space of the spine has been widespread for decades, but its effectiveness and safety have not been established and corticosteroids are not FDA-approved for such use.

The FDA’s Safe Use Initiative convened a panel of experts to help define techniques for such injections that would reduce preventable harm; the panel’s recommendations have not been finalized. The FDA plans to convene an advisory meeting of external experts in late 2014 to discuss the benefits and risks of epidural corticosteroid injections.

Source: FDA, April 23, 2014

Guidelines for Women’s Routine HIV Screening
The American College of Obstetrics and Gynecology (ACOG) now recom- continued on page 405
mends human immunodeficiency virus (HIV) screening for females ages 13 to 64 years at least once in their lifetimes and annually thereafter if warranted by risk factors. Screening is also indicated after age 64 if a risk assessment indicates an ongoing risk of HIV infection (such as new sexual partners).

ACOG says repeat HIV testing should be offered at least annually to women who use injection drugs, are sex partners of injection drug users, exchange sex for money or drugs, are sex partners of HIV-infected persons, have had sex with men who have sex with men since the most recent HIV test, or have had more than one sex partner since their most recent HIV test.

In addition, obstetrician–gynecologists should encourage women and their prospective sex partners to be tested before initiating a new sexual relationship.

ACOG has joined other leading professional organizations in support of “opt-out” HIV screening. The patient is notified that HIV testing will be performed as a routine part of gynecological and obstetrical care, and written consent is not required. However, the patient is given the opportunity to decline testing.

Source: Obstetrics & Gynecology, May 2014

Extended-Release, Long-Acting Opioids Face New Safety Steps

The FDA has approved class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain. Given the serious risks posed by ER/LA opioids—even at recommended doses—the changes include new language to help health care professionals tailor their prescribing decisions based on patients’ individual needs.

ER/LA opioids are now indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. ER/LA opioid analgesics are not indicated for as-needed pain relief.

The FDA is requiring manufacturers to conduct studies of the risks of misuse, abuse, hyperalgesia, addiction, overdose, and death. The FDA is also requiring a new boxed warning to caution that chronic maternal use of ER/LA opioid analgesics during pregnancy can result in neonatal opioid withdrawal syndrome. Companies must also follow an updated ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS).

Sources: FDA, April 16, 2014, and September 10, 2013

FDA Reminds Providers To Limit Acetaminophen

Combination products that contain more than 325 mg of acetaminophen per dose should not be prescribed by health care professionals or dispensed by pharmacists, the FDA says. If pharmacists receive a prescription for a combination product with more than 325 mg of acetaminophen per tablet, capsule, or other dosage unit, the agency recommends that they contact the prescriber to discuss a product containing less acetaminophen.

The FDA no longer considers products with more than 325 mg of acetaminophen safe, and they were voluntarily withdrawn by manufacturers at the FDA’s request to protect consumers from the risk of severe liver damage that can result from taking too much acetaminophen. The FDA says there are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks of liver injury.

Sources: FDA, April 28, 2014, and January 10, 2014

TPA, Thrombus, and Bloodstream Infection

Patients whose peripherally inserted central catheters (PICCs) are flushed with tissue plasminogen activator (tPA) have three times the relative risk of developing central line–associated bloodstream infections (CLABSIs), according to a study at Boston Medical Center.

At the medical center, nurses flush PICCs with the tPA alteplase when flow is slowed or blocked. The study used tPA administration as a surrogate for line thrombosis. Patients were divided into those who did and did not receive tPA during admission when a PICC was placed. The researchers defined a CLABSI as a positive blood culture documented more than 24 hours after PICC insertion or within 72 hours of line removal.

Of the 3,723 patients in the analysis, 1,463 (39%) received tPA. Of the 46 (1.2%) who developed CLABSIs, the rate was significantly higher in those who received tPA than those who did not (2.2% vs. 0.62%). The adjusted odds of developing a CLABSI were nearly four times greater in patients with PICC lines who received tPA than those who did not. Neither primary nor secondary hypercoagulable states (such as factor V Leiden) were associated with increased tPA use.

The results support the notion that clotting in and around a central venous catheter facilitates adhesion, colonization, and infection by bacteria, the researchers say. Thrombus formation—as signaled by the need for tPA—may identify at-risk patients who need closer surveillance.


Palliative Chemotherapy May Worsen Last Days

Dying cancer patients often choose chemotherapy—even though it may make their last days more unpleasant, say researchers from Harvard and Weill Cornell Medical College.
The researchers analyzed data from Coping with Cancer, a prospective, longitudinal study of patients with advanced cancer at eight U.S. outpatient clinics. Of 386 patients, 56% were receiving palliative chemotherapy when they enrolled in the study. Those patients were more likely to choose “life-extending” care over comfort care, including chemotherapy if it might add even one week to their lives.

Patients receiving palliative chemotherapy were less likely to acknowledge that their illness was terminal compared with patients who were not receiving chemotherapy (35% vs. 49%). They were also less likely to report that they had discussed their end-of-life wishes with a physician or completed a do-not-resuscitate order.

In their last week of life, patients who received palliative chemotherapy were more likely to receive cardiopulmonary resuscitation, mechanical ventilation, or both (14% vs. 2%), to be fed through a tube (11% vs. 5%), and to be referred late to hospice (54% vs. 37%) compared with patients not on palliative chemotherapy. Palliative chemotherapy patients were also more likely to die in an intensive care unit rather than at home or another preferred place. All those factors have been associated with worse quality of life for patients at the end, more distress for caregivers, and higher costs, the researchers say. This study found no difference in survival between patients who received palliative chemotherapy and those who did not. BMJ 2014;348:g1219

**Clevidipine Rapidly Aids Heart Failure Symptoms**

Symptom onset in acute heart failure (AHF) with hypertension may be abrupt, presenting as profound dyspnea and acute pulmonary edema, say researchers for PRONTO (A Study of Blood Pressure Control in Acute Heart Failure—a Pilot Study). It’s important to control these patients’ blood pressure (BP) immediately.

Clevidipine is a rapidly acting intravenous (IV) antihypertensive with a one-minute half-life that allows rapid titration. To determine its benefits in hypertensive AHF, researchers examined data on 44 patients who received clevidipine and 41 who received standard-of-care IV antihypertensive therapy (SOC), usually nitroglycerin or nicardipine.

Clevidipine patients reached target BP range more often than SOC patients (71% vs. 37%), and sooner. They also required fewer additional IV therapies for BP management (16% vs. 51%).

When nitroglycerin was removed from the analysis, clevidipine and nicardipine were equally effective at reducing BP. With dyspnea, however, clevidipine had an advantage. Patients’ breathing in both groups improved markedly for the first 30 minutes after the drugs were given, but at 45 minutes clevidipine patients had greater mean visual analog scale (VAS) dyspnea improvement than SOC patients, an effect that persisted for three hours.

In PRONTO, the mean time from hospital arrival to study-drug administration was 3.2 hours for clevidipine and 2.7 hours for SOC. The marked, rapid improvement in dyspnea in both treatment groups suggests that time to treatment may be important in managing AHF patients, the researchers say. Am Heart J 2014;167:529–536

**Dabigatran Vs. Warfarin for AF**

Switching atrial fibrillation patients from warfarin to dabigatran may increase their risk of myocardial infarction (MI) in the first two months, say researchers from Aalborg University, Denmark, and City Hospital, Birmingham, England.

Using nationwide Danish databases, they identified 4,818 patients who were taking dabigatran for the first time (110 mg for 2,124 and 150 mg for 2,694), and 8,133 patients taking warfarin for the first time. They also studied a second cohort, of vitamin K antagonist–experienced patients; 1,554 switched to 110-mg dabigatran, 1,825 switched to 150-mg dabigatran, and 49,868 continued on warfarin. Warfarin users were the highest-risk group in the VKA-naïve cohort but the lowest-risk group in the VKA-experienced cohort during a mean follow-up time of 16 months.

Among the “new starters,” the analysis showed a nonsignificant trend to lower MI rates with both dabigatran doses compared with warfarin. However, among the “switchers,” overall MI rates increased significantly for both dabigatran doses within 60 days, the researchers say.

In the sensitivity analysis, the 110-mg dose had a greater effect on the MI rate when patients with previous MI were excluded. The researchers say this raises the possibility that dabigatran could be less protective against MI than warfarin.

In “real world” practice, the researchers note, clinicians may be more likely to switch problematic warfarin patients, such as those with poor adherence, to one of the novel oral anticoagulants. The potential impact on MI in switchers needs to be balanced against the magnitude of benefit from stroke prevention, reduced intracranial hemorrhage, and lower vascular mortality. Am J Med 2014;127:329–336

**FDA Allows Baxter Saline Import**

Baxter Healthcare Corp. will temporarily distribute in the U.S. 0.9% sodium chloride injection (normal saline) made in Spain. The FDA is temporarily exercising its discretion regarding the distribution of this product and Fresenius Kabi’s saline product from Norway to address a critical shortage of normal saline.

In addition, U.S.-based manufacturers—Baxter, B.Braun Medical, and Hospira—are currently producing and releasing normal saline. Baxter manufac-
Recalls

Seven Lots of Hospira Propofol
Hospira, Inc., recalled seven lots of propofol injectable emulsion, 1%, 200 mg/20 mL (10 mg/mL) due to a glass defect on the interior neck of vials, embedded metal particulates, and free-floating metal particulates that were identified during a sample inspection and subsequent analysis. Lots 29-615-DJ, 29-616-DJ, 29-617-DJ, 29-628-DJ, 29-629-DJ, and 29-630-DJ were distributed nationwide from August 2013 through December 2013 and expire May 1, 2015. To return affected products, contact Stericycle at 1-877-272-2158 Monday through Friday, 8 a.m. to 5 p.m. Eastern time.

Source: Hospira, Inc., April 17, 2014

One Lot of Hospira Marcaine
Hospira, Inc., recalled lot 34-440-DD of 0.25% bupivacaine HCl injection, USP (Marcaine) 10 mL, single-dose vial, preservative free, due to a discolored solution with visible particles embedded in the glass. Hospira attributed the embedded particulate to a supplier’s glass defect. The lot was distributed from December 2013 through January 2014. For assistance, call Stericycle at 1-877-546-7642 Monday through Friday, 8 a.m. to 5 p.m. Eastern time.

Source: Hospira, Inc., April 21, 2014

One Lot of Hospira Lidocaine
Hospira, Inc., recalled lot 31-427-DK of 1% lidocaine HCl injection, USP, due to iron oxide particulate in the solution and embedded in the glass vial. This lot, which expires in July 2015, was distributed from September 2013 through October 2013. For assistance, call Stericycle at 1-888-835-2723 Monday through Friday, 8 a.m. to 5 p.m. Eastern time.

Source: Hospira, Inc., April 18, 2014

One Lot of Cubicin
Cubicin Pharmaceuticals recalled lot 280453F of daptomycin for injection (Cubicin) after discovery of glass particles in a single vial produced by a contract manufacturer. The lot, which expires in April 2016, was shipped between March 17 and 25, 2014. Health care professionals with medical questions may contact Cubist Medical Information at 877-282-4786 between 8 a.m. and 5:30 p.m. Eastern time, Monday through Friday.

Source: Cubist Pharmaceuticals, April 18, 2014

DEVICE NEWS

Approvals

DEKA Arm System
The FDA has allowed marketing of the DEKA Arm System, the first prosthetic arm that can perform multiple, simultaneous powered movements controlled by electrical signals from electromyogram (EMG) electrodes. The arm is the same shape and weight as an adult arm.

EMG electrodes detect electrical activity caused by the contraction of muscles close to where the prosthesis is attached. The electrodes send the electrical signals to a computer processor in the prosthesis that translates them to a specific movement or movements.

The EMG electrodes in the DEKA Arm System convert electrical signals into up to 10 powered movements. The system also contains a combination of mechanisms, including switches, movement sensors, and force sensors, that cause the prosthesis to move.

Clinical information reviewed by the FDA included a Department of Veterans Affairs study in which 36 participants provided data on how the DEKA arm performed in common household and self-care tasks. Approximately 90% of study participants were able to perform activities with the DEKA Arm System that they were not able to perform with their current prosthesis, such as using keys and locks, preparing food, feeding themselves, using zippers, and brushing and combing hair.

The DEKA Arm System can be configured for people with limb loss occurring at the shoulder joint, mid-upper arm, or mid-lower arm. It cannot be configured for limb loss at the elbow or wrist joint.

Source: FDA, May 9, 2014

Inspire Upper Airway Stimulation For Sleep Apnea
The FDA has approved Inspire Medical Systems’ Inspire Upper Airway Stimulation therapy for use in patients with moderate-to-severe obstructive sleep apnea (OSA) who are unable to use continuous positive airway pressure (CPAP).

About 18 million Americans have OSA; poorly managed, it increases their risk for heart attack, stroke, weight gain, high blood pressure, heart failure, and drowsiness while driving. CPAP often works, but studies show that roughly half of patients who start CPAP do not use it consistently.

Inspire therapy is a fully implanted system consisting of three components: a small generator, a sensing lead, and a stimulation lead. The single external component is a handheld remote used to turn the therapy on before bed and off upon waking.

When activated, Inspire therapy senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep. In contrast to other surgical options for OSA, Inspire therapy does not require removal or permanent alteration of facial or airway anatomy. The less invasive procedure should result in a shorter recovery time.

Patients implanted with Inspire therapy who participated in the STAR (Stimulation Therapy for Apnea Reduction) pivotal clinical trial experienced a 68% reduction in apnea events, a 70% reduction in oxygen desaturation events, and significant improvements in daytime functioning as...
measured by two validated questionnaires.

Source: Inspire Medical Systems, May 1, 2014

**PerClot Topical Hemostatic Powder**

CryoLife has received FDA 510(k) clearance for PerClot Topical, a hemo-
static powder composed of polysaccha-
ride granules that is meant to be used as a topical dressing for the temporary treatment of mild bleeding.

PerClot Topical can be used with surgical wounds (postoperative, donor sites, dermatological, etc.), cuts and lac-
erations, and mild bleeding from topical ear, nose, and throat surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites.

PerClot Topical is ready to use, requires no mixing, and does not need special handling or storage. Preclinical evaluations have shown its effectiveness to be comparable to current popular sur-
gical hemostatic materials.

Source: CryoLife, April 29, 2014

**HPV DNA Test**

The FDA has given the green light to the first agency-approved human papil-
ломavirus (HPV) DNA test for women 25 years of age and older that can be used alone to help a health care professional assess the need for additional diag nostic testing for cervical cancer. The test can also provide information about the patient’s future risk for cervical cancer.

Using a sample of cervical cells, the cobas HPV test (Roche Molecular Sys-
tems) detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18 while concurrently detecting 12 other types of high-risk HPVs.

Women who test positive for HPV 16 or HPV 18 should have a colposcopy, while women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy. Health care professionals should use the cobas HPV test results together with other information, such as the patient screening history and risk factors, and current professional guidelines.

The FDA approved the cobas HPV test in 2011 for use in conjunction with or as a follow-up to a Pap test, which examines cervical cells for changes that might become cervical cancer. The new approval expands the test’s indication to include use as either a co-test or a prima ry cervical cancer screening test. How ever, it does not change medical practice guidelines for cervical cancer screening.

Source: FDA, April 24, 2014

**Indications Added for Medtronic Pacemakers and Defibrillators**

The FDA has approved Medtronic’s revised labeling for two cardiac resyn-
chronization therapy pacemakers (CRT-Ps) and eight cardiac resynchroni-
zation therapy defibrillators (CRT-Ds), expanding the indication for use to patients with atrioventricular (AV) block and less severe heart failure (HF).

The devices provide electrical impulses through implanted leads to the heart’s right ventricle (RV) and left ventricle (LV). A clinician programs the impulse timing, synchronizing the patient’s heart to improve cardiac function for HF patients. The RV leads used with CRT-D devices can deliver high-voltage energy to defibrillate the heart in the event of ventricular arrhythmia.

The FDA previously approved the devices for patients with more severe HF as evaluated by their physicians using specific criteria. Patients with less severe HF who are already indicated to receive RV pacing are now eligible to receive a device that will pace both sides of their hearts.

The expanded approval was based on data from a clinical study that compared death, HF-related urgent care visits, and increases in left ventricular end systolic volume index (LVESVI) in subjects who received either left and right ventricular pacing or RV pacing alone. Of 918 participants, 831 received a CRT-P device and 227 received a CRT-D device. Cardiac resynchronization therapy provided by CRT-P and CRT-D devices resulted in a 27% reduction in death, HF-related urgent-care visits, and increases in LVESVI compared to RV pacing alone.

The expanded device approvals are for the Consulta CRT-P, Consulta CRT-D, Syncra CRT-P, Maximo II CRT-D, Concerto II CRT-D, Viva XT CRT-D, Viva S CRT-D, Protecta CRT-D, Protecta XT CRT-D, and Brava CRT-D.

Source: FDA, April 10, 2014

**Boston Scientific Defibrillators and Heart Failure Devices**

Boston Scientific Corporation has received FDA approval for its latest gen eration of defibrillators and heart failure devices, including the Dynagen Mini and Inogen Mini implantable cardioverter defibrillators (ICDs) and the Dynagen X4 and Inogen X4 cardiac resynchronization therapy defibrillators (CRT-Ds).

ICDs in the Mini family are up to 20% smaller by volume and up to 24% thinner than competitors’ devices; the size is a particular benefit to patients with a small frame. The X4 line of quadripolar CRT-Ds offers 70% more pacing options to address high capture thresholds and phrenic nerve stimulation effectively, along with industry-leading battery capacity.

Source: Boston Scientific, April 15, 2014

**Limit Urged on Laparoscopic Power Morcellation Use**

The FDA is discouraging the use of laparoscopic power morcellation for hys-
terectomy or myomectomy because it poses a risk of spreading unsuspected cancerous tissue beyond the uterus.
Laparoscopic power morcellation uses a medical device to divide uterine tissue into smaller pieces so it can be removed through a small incision in the abdomen. Based on an analysis of available data, the FDA has determined that approximately one in 350 women who are undergoing hysterectomy or myomectomy unknowingly have uterine sarcoma. Performing laparoscopic power morcellation on these women might spread the cancerous tissue within the abdomen and pelvis, significantly worsening the odds of long-term survival.

The FDA will convene a meeting of its Obstetrics and Gynecological Medical Devices Panel to discuss laparoscopic power morcellation. The agency anticipates the discussion will include whether a boxed warning related to the risk of spreading cancer should be added to the labeling for laparoscopic power morcellators.

Source: FDA, April 17, 2014

Avoid GenStrip Blood Glucose Test Strips, FDA Advises

The FDA has advised diabetes patients and health care professionals to stop using GenStrip Blood Glucose Test Strips. At an inspection earlier this year that was documented in an April 2014 warning letter, the FDA found that manufacturer Shasta Technologies lacked many requirements of a quality system. Without such a system, the FDA believes the strips could report incorrect blood glucose levels, which in turn could lead to inappropriate or delayed treatment. To date, the FDA said, the company has been unwilling to voluntarily recall the test strips, which are advertised for use with LifeScan OneTouch glucose meters.

The test strips have been manufactured and distributed since March 2013 and are available through online retailers and retail pharmacies.

Source: FDA, April 30, 2014

FDA Proposes Stricter Pelvic Mesh Rules

The FDA has issued proposed orders to address risks associated with surgical mesh used for transvaginal repair of pelvic organ prolapse (POP). If finalized, the orders would reclassify surgical mesh for transvaginal POP from a moderate-risk (class II) to a high-risk (class III) device and require manufacturers to submit a premarket approval application for the agency to evaluate the treatment’s safety and effectiveness.

In POP, internal structures that support the pelvic organs become so weak, stretched, or broken that the organs drop from their normal position and bulge into the vagina. Women with POP often experience pelvic discomfort; disruption of their sexual, urinary, and defecatory functions; and a reduction in quality of life.

Surgical mesh is used to provide additional support when repairing weakened or damaged tissue. Many mesh products come in kits that include instruments specifically designed to aid in the insertion, placement, fixation, and anchoring of mesh in the body. Instruments provided in these kits would be reviewed as part of the regulatory submission for the mesh product. Instruments are also provided separately from the mesh implant, and the FDA is proposing that this instrumentation be reclassified from low risk (class I) to moderate risk (class II).

Surgical mesh indicated for surgical treatments of stress urinary incontinence, abdominal POP repair with mesh, hernia repair, and other non-urogynecological indications is not part of the proposed order.

Source: FDA, April 29, 2014

FDA Proposes Expedited Access For Medical Devices

The FDA has proposed a program to provide earlier access to high-risk medical devices that are intended to treat or diagnose patients with serious conditions whose medical needs are unmet by current technology.

The “expedited access premarket approval application for unmet medical needs for life threatening or irreversibly debilitating diseases or conditions” is being called the EAP program by the FDA. EAP features earlier, more interactive engagement with FDA staff and a collaboratively developed plan for collecting the data to support approval.

While existing device programs have focused on reducing the time for the premarket review, the EAP program also seeks to reduce the time associated with product development. The agency expects most devices that enter the program will be in the pre-clinical trial phase.

To be eligible, the device must be intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition. It must meet one of these criteria: 1) no approved alternative exists; 2) it is a breakthrough technology that provides a clinically meaningful advantage over existing technology; 3) it offers a significant, clinically meaningful advantage over existing approved alternatives, or 4) its availability is in the patient’s best interest. The device must also have an acceptable FDA-approved data development plan.

Source: FDA, April 22, 2014

Recalls

Alere Test Strips

Alere Inc. recalled test strips used to monitor warfarin’s effect on blood clotting after some strips provided erroneous results. Nine serious adverse events have been reported; three described bleeding associated with deaths.

The Alere INRatio2 PT/INR Professional Test Strip provided significantly different test results compared with laboratory tests of the international normalized ratio (INR), which measures how long it takes blood to clot. The Alere
continued from page 409

product’s results were 3.1 to 12.2 INR units lower than the lab results, reflecting therapeutic or near-therapeutic INR levels when the actual levels were outside of the therapeutic range.

The cause of the problem has not been determined. Alere advised customers to stop using the INRatio2 PT/INR Professional Test Strip (PN 99008G2) and will transition customers to the Alere INRatio PT/INR Test Strip (PN 100139). The recall does not affect the Alere INRatio PT/INR Test Strip (PN 100071). Customers with questions can call Alere at 844-292-5373.

Source: Alere Inc., May 6, 2014

Baxter Sigma Spectrum Infusion Pumps

Baxter Healthcare Corporation is recalling its Sigma Spectrum Infusion Pumps with Master Drug Library after receiving more than 3,500 reports of “system error” malfunctions that included nine severe but nonfatal adverse events.

The System Error 322 “Link Switch Error (low)” problem occurs when the pump improperly determines that its closed door is open. The pump stops the infusion, an alarm sounds, and a light flashes. A clinician must reset the alarm, reprogram the pump, and confirm the infusion is running properly.

The affected products (models 35700BAX and 35700ABB) were manufactured from July 1, 2005, through January 15, 2014, and distributed from February 20, 2013, through January 15, 2014. Customers should contact Baxter at 1-800-356-3454 (option 1) Monday through Friday, 7 a.m. to 7 p.m. Eastern time.

Source: FDA, May 1, 2014

HeartWare Ventricular Assist System

HeartWare is recalling the HeartWare Ventricular Assist System after reports that the driveline connector locking mechanism failed to engage as a result of a faulty manufacturing assembly process, which could cause the pump to stop.

The system (also called the HeartWare Ventricular Assist Device) is a bridge to cardiac transplantation in patients at risk of death from advanced heart failure. The recall involves catalog numbers 1100 through 1104 and number 1205 and serial numbers HW001 to HW 11270 and HW20001 to HW 20296. They were manufactured from March 6, 2006, through October 17, 2013, and distributed from March 17, 2006, through November 29, 2013.

Health professionals should promptly arrange a follow-up visit with any patient who has the affected device to inspect the driveline connector.

Source: FDA, April 29, 2014

Covidien Embolization and Retrieval Device

Covidien is recalling some Pipeline Embolization Devices and Alligator Retrieval Devices because the coating applied to the delivery wire to ease friction could come off, potentially leading to embolic occlusion in the cerebral vasculature.

Covidien discovered the issue through internal product testing and has not received reports of patient injuries. The recall affects 32 Pipeline Embolization Devices in 17 lots and 621 Alligator Retrieval Devices in 43 lots manufactured and distributed from May 2013 to March 2014.

Covidien is arranging for replacements. For information, contact Covidien Customer Service at 1-800-716-6700 Monday through Friday, 7 a.m. to 7 p.m. Central time, or e-mail CustomerServiceUS@Covidien.com.

Source: Covidien, April 11, 2014, and FDA, April 22, 2014

ARKON Anesthesia Delivery System

Spacelabs Healthcare is recalling the Arkon Anesthesia System with version 2.0 software due to a software defect that may cause the system to stop working and require manual ventilation of patients. In addition, plugging a cellphone or other USB device into one of the four USB ports for charging may cause the system to stop working.

Sixteen units were distributed to hospitals in North Carolina and South Carolina with serial numbers ARKN-000011, ARKN-000016, ARKN-000017, and ARKN-000019 through ARKN-000031. They were manufactured and distributed from March 18, 2013, through June 17, 2013.

Spacelabs is contacting customers to schedule a software update that may resolve this issue. For information, contact Spacelabs Healthcare at 1-800-522-7025; select 2 for Technical Support.

Source: FDA, March 10, 2014

Hospira Acclaim Infusion Pumps

Hospira recalled Abbott Acclaim and Hospira Acclaim Encore infusion pumps after customers reported broken door assemblies that could lead to delayed or excessive infusions. Closed properly, the door helps ensure the tubing is seated correctly so therapy flows to the patient.

Affected Abbott Acclaim infusion pumps (list number 12032) were manufactured from February 1998 to November 1998 and distributed from November 1998 through February 2004. Affected Hospira Acclaim Encore infusion pumps (list number 12237) were manufactured from February 1997 to February 2010 and distributed from July 1999 through November 2013. For information, contact Hospira Global Complaint Management at 1-800-441-4100 Monday through Friday from 8 a.m. to 5 p.m. Central time.

Source: FDA, May 5, 2014

Hospira Gemstar Docking Station

Hospira has recalled GemStar Docking Stations (list number 13075) used with GemStar infusion pumps due to two potential malfunctions. The docking station provides an alternate power source to the pump.
When the docking station is used with a GemStar Phase 3 pump (list number 13000, 13100, or 13150), the pump might fail to power up. When a GemStar Phase 3 or GemStar Phase 4 pump (list number 13086, 13087, or 13088) is used with both a docking station and an external battery pack (list number 13073), the pump may display error code 11/003 and sound an audible alarm, indicating excessive input voltage. The pump will stop the infusion if it measures an external voltage input of more than 3.6 volts.

The products have been distributed since February 2002. Users seeking assistance can contact Stericycle at 1-866-792-5451, Monday through Friday, from 8 a.m. to 5 p.m. Eastern time.

Sources: FDA and Hospira, May 2, 2014

Datascope Corp./MAQUET
Intra-Aortic Balloon Pumps

Datascope Corp./MAQUET is recalling intra-aortic balloon pumps (IABPs) due to the risk that mechanical failure of a fan assembly could cause the power supply to overheat, shutting down the pump without warning. The IABP inflates and deflates an intra-aortic balloon to provide temporary support to the left ventricle. The recall covers IABPs sold under the Datascope Corp. System 98/98XT (part numbers 0998-00-0446-xx, 0998-UC-0446-xx, 0998-00-0479-xx, and 0998-UC-0479-xx), CS100/CS100i (part numbers 0998-00-3013-xx, 0998-UC-3013-xx, 0998-00-3023-xx, and 0998-UC-3023-xx) brand names.

Approximately 12,360 affected units were manufactured or installed during service calls between January 1, 2003, and June 30, 2011. They can be used while awaiting replacement fan assemblies. For information, contact Datascope Corp./MAQUET’s Technical Support Department at 1-800-777-4222 (press 3), Monday through Friday from 8 a.m. to 6 p.m. Eastern time.

Source: Datascope Corp./MAQUET, May 9, 2014

NEW MEDICAL DEVICES

Marvin M. Goldenberg, PhD, RPh, MS

Name: BioFlow DuraMax Chronic Hemodialysis Catheter
Manufacturer: AngioDynamics, Latham, New York
Approval Date: March 7, 2014
Purpose: The BioFlo DuraMax hemodialysis catheter is indicated for attaining blood access for hemodialysis and apheresis.
Description: The catheter is inserted percutaneously into an adult’s internal jugular or subclavian veins for more than 30 days. It comes in nine lengths to help reduce the risk of arterial insufficiency. An angled venous tip and unique guidewire lumen position the guidewire in the center of the leading edge of the distal tip, providing superior over-the-wire performance and improved ease of insertion. The curved tip of the catheter reduces vein wall apposition and risk of arterial insufficiency. A 3-cm tip stager reduces recirculation rates.

In vitro blood-loop model test results demonstrated that the catheter had 90% less thrombus accumulation on its surface on average compared with noncoated conventional catheters based on platelet count, and 83% less thrombus accumulation on its surface compared with a heparin-coated dialysis catheter. In addition, results of an in vivo sheep study with a 31-day insertion time showed comparable thrombus resistance characteristics to a heparin-coated dialysis catheter.

Benefit: Thrombosis and occlusions may occur within 24 hours after insertion and are prevalent in up to 40% of chronic dialysis patients. This is the first dialysis catheter with Endexo technology, creating a catheter material more resistant to the accumulation of blood components compared with noncoated conventional catheters.

Source: www.angiodynamics.com

Name: Simplexa HSV 1 and 2 Direct Molecular Test
Manufacturer: Focus Diagnostics, a division of Quest Diagnostics, Madison, New Jersey, and Cypress, California
Approval Date: March 24, 2014
Purpose: This is the first molecular test to be cleared by the FDA for the qualitative detection and differentiation of herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) in cerebrospinal fluid from patients suspected of HSV central nervous system infection, including encephalitis.

Description: The test uses real-time polymerase chain reaction technology, which can detect viral or bacterial DNA or RNA, as well as genetic material from other analytes, eliminating the need for costly and time-consuming nucleic acid extraction. Nucleic acid extraction can take up to 90 minutes, while the Simplexa test turns results around in an hour.

The Simplexa HSV 1 and 2 Direct Molecular Test uses a special process that eliminates nucleic acid extraction, resulting in rapid turnover of results after providing a specimen for testing. It runs on the company’s 3M Integrated Cycler testing platform.

Benefit: Encephalitis is an inflammation of the brain often caused by the herpes simplex or other viruses. HSV encephalitis occurs in all ages and during all seasons, with HSV-1 encephalitis more common in adults and HSV-2 encephalitis more common in newborn infants. The availability of this test will enable health...
Care providers to make more informed therapeutic decisions in a timely manner for patients suffering from encephalitis.


**Name:** Camino Flex Ventricular Catheter

**Manufacturer:** Integra LifeSciences, Plainsboro, New Jersey

**Approval Date:** April 4, 2014

**Purpose:** The ventricular catheter may be used during magnetic resonance imaging (MRI) scans.

**Description:** The device contains a sensor that measures directly at the source and is designated for use with the Integra’s Camino monitor. The system provides continuous monitoring of intracranial pressure (ICP) in the ventricles under normal circumstances, as well as when cerebrospinal fluid (CSF) flow can’t be determined accurately or when there is a blood clot. The device’s multilumen design allows for ICP monitoring and draining of CSF.

The Camino Monitor is configured to integrate both tunneled and bolted advanced monitoring technologies, which measure ICP in either the parenchyma or ventricle space. The Camino Monitor is portable and ergonomically designed, and incorporates strain gauge and fiber optic monitoring technologies. It features up to five days of patient ICP data trending and has a large, highly visible touchscreen interface.

**Benefit:** Before FDA approval of this device, Integra’s 1.5 and 3.0 catheter was MRI conditional. With approval, patients can undergo neuromonitoring scans with Camino Flex without having the catheter removed. This is beneficial for patients whose management protocol includes both drainage of CSF and follow-up imaging.

**Source:** http://investor.integralife.com