**NEW DRUG APPROVALS**

**Opdivo for Melanoma**

Nivolumab injection (Opdivo, Bristol-Myers Squibb) has received the FDA’s accelerated approval for the treatment of patients with unresectable or metastatic melanoma that has progressed after treatment with specific medications.

Nivolumab is a monoclonal antibody that binds to the programmed death-1 (PD-1) receptor and blocks its interaction with ligands PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response. It is indicated for intravenous treatment of patients with disease progression after treatment using ipilimumab (Yervoy, Bristol-Myers Squibb) and, in cases of BRAF V600 mutation-positive disease, a BRAF inhibitor. Accelerated approval was based on the tumor response rate and the durability of response.

Nivolumab is associated with immune-mediated pneumonitis, colitis, hepatitis, nephritis, renal dysfunction, hypothyroidism, hyperthyroidism, and embryofetal toxicity, among other adverse reactions.

Nivolumab’s efficacy was evaluated in a single-arm, noncomparative planned interim analysis of the first 120 patients who received the drug with at least six months’ follow-up in CheckMate-037, a pivotal, randomized, phase 3 clinical trial in advanced melanoma that had progressed on ipilimumab and (if BRAF mutation-positive) a BRAF inhibitor. CheckMate-037 compared nivolumab 3 mg/kg (n = 268), administered every two weeks, with chemotherapy (n = 102) consisting of the investigator’s choice of either single-agent dacarbazine 1 g/m² every three weeks or the combination of carboplatin AUC 6 every three weeks plus paclitaxel 175 mg/m² every three weeks. The primary endpoint was the objective response rate (ORR).

In the interim analysis of 120 nivolumab-treated patients, 76% had advanced metastatic disease; 18% had a history of brain metastases. Their median age was 58 years, and 22% were BRAF V600 mutation-positive. Nivolumab achieved a 32% response rate (38 of 120). Four patients (3%) showed a complete response, and 34 (28%) showed a partial response. Of these 38 patients 87% had ongoing responses ranging from 2.6-plus to 10-plus months. Responses to nivolumab were demonstrated in patients with or without the BRAF mutation.

In CheckMate-037, serious adverse events (AEs) occurred in 41% of the patients treated with nivolumab. The most frequent grade-3 and grade-4 AEs (reported in 2% to less than 5% of patients) included abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. The most common AE was rash (21%).

Sources: Bristol-Myers Squibb and FDA, December 22, 2014

**Viekira Pak for Hepatitis C**

The FDA has approved Viekira Pak (AbbVie) to treat patients with chronic hepatitis C virus genotype 1 infection, including those with cirrhosis.

Viekira Pak contains three new drugs—ombitasvir, paritaprevir, and dasabuvir—that work together to inhibit the growth of hepatitis C virus (HCV). It also contains ritonavir, an older drug that is used to increase blood levels of paritapre- vir. Viekira Pak can be used with or without ribavirin but is not recommended for patients with decompensated cirrhosis.

Viekira Pak was evaluated in six clinical trials enrolling 2,308 participants with chronic HCV infection with and without cirrhosis. In different trials, participants were randomly assigned to receive Viekira Pak or placebo. Viekira Pak with or without ribavirin, or Viekira Pak with ribavirin for 12 or 24 weeks.

Sustained virological responses (SVRs) at 12 weeks in multiple populations, including those considered difficult to treat, ranged from 91% to 100% among participants who received Viekira Pak at the recommended dosing (two ombitasvir/paritaprevir/ritonavir 12.5-mg/75-mg/50-mg tablets once daily and one dasabuvir 250-mg tablet twice daily). The most common side effects were feeling tired, itching, feeling weak or lacking energy, nausea, and trouble sleeping.

Viekira Pak was the fourth medication approved by the FDA in roughly a year to treat chronic HCV infection, joining simprevir (Olysio, Janssen), November 2013; sofosbuvir (Sovaldi, Gilead), December 2013; and ledipasvir/sofos- buvir (Harvoni, Gilead), October 2014.

Three days after the FDA approved Viekira Pak, Express Scripts announced that it had made the medication its exclusive National Preferred Formulary option for patients with genotype 1 HCV. Soon afterward, CVS Health agreed to include only Gilead’s Harvoni and Sovaldi on its main formularies, and Anthem (Express Script’s largest customer) agreed to make Harvoni its primary option for patients with genotype 1 HCV. In all three cases, patients may obtain the nonformulary competitors under limited circumstances.

Discounts to the drugs’ high list costs are believed to be key factors in the agreements, but details were not disclosed.

Sources: FDA, December 19, 2014; Express Scripts, December 22, 2014; and FiercePharma, January 5, 2015, and January 9, 2015

**Lynparza for Ovarian Cancer**

Olaparib (Lynparza, AstraZeneca Pharmaceuticals) has won accelerated FDA approval for women with advanced, heavily pretreated ovarian cancer associated with defective BRCA genes as detected by an FDA-approved test.

Olaparib is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. It is the first of a new class of drugs
for treating ovarian cancer. The FDA approved a companion genetic test called BRACAnalysis CDx (Myriad Genetics Laboratories, Inc.) that will detect the presence of mutations in the BRCA genes (gBRCAm) in blood samples from ovarian cancer patients. The test can identify patients who may be candidates for treatment with olaparib.

In a study, 137 participants with gBRCAm-associated ovarian cancer received olaparib; 34% experienced an objective response for an average of 7.9 months.

Common side effects included nausea, fatigue, vomiting, diarrhea, dysgeusia, dyspepsia, headache, decreased appetite, nasopharyngitis, cough, arthralgia, musculoskeletal pain, myalgia, back pain, dermatitis, and abdominal pain. Serious side effects included the development of myelodysplastic syndrome, acute myeloid leukemia, and lung inflammation.

The most common laboratory abnormalities were increased creatinine, increased mean corpuscular volume elevation, decreased hemoglobin, decreased lymphocytes and neutrophils, and decreased platelet levels.

Source: FDA, December 19, 2014

**Namzaric for Dementia Of the Alzheimer’s Type**

The FDA has approved a fixed-dose combination of extended-release memantine hydrochloride and donepezil hydrochloride (Namzaric, Actavis/Adamas Pharmaceuticals) to treat moderate-to-severe dementia of the Alzheimer’s type in patients stabilized on those two medications.

Namzaric (formerly MDX-8704) is a once-daily oral capsule for patients taking the N-methyl-D-aspartate receptor antagonist memantine (10 mg twice daily or 28 mg extended-release [ER] once daily) and the acetylcholinesterase inhibitor donepezil (10 mg). The capsules can be opened so the contents can be sprinkled on food to facilitate dosing for patients who have difficulty swallowing.

Memantine ER/donepezil will be available in two dosage strengths, 28/10 mg and 14/10 mg for patients with severe renal impairment.

ER memantine is the active ingredient in Namenda XR (Forest Pharmaceuticals), which is indicated for the treatment of moderate-to-severe dementia of the Alzheimer’s type. Donepezil is the active ingredient in Aricept (Eisai/Pfizer), which is indicated for the treatment of mild-to-severe dementia of the Alzheimer’s type.

The efficacy and safety of coadministered ER memantine and acetylcholinesterase inhibitors (AChEIs), including donepezil, were based on a randomized, double-blind, placebo-controlled study of 677 outpatients receiving a stable dose of AChEIs. This study was not conducted with Namzaric, but its bioequivalence with coadministered ER memantine and donepezil was demonstrated. Approximately 68% of patients randomly assigned to receive either ER memantine 28 mg or placebo were taking donepezil as the AChEI at baseline and throughout the study. The results showed statistically significant improvement in cognition and global function for patients treated with Namenda XR 28 mg plus an AChEI at baseline and throughout the study. The primary endpoint was clinical response 24 to 32 days after the initiation of therapy. The primary analysis was conducted in the microbiological intent-to-treat population. The clinical cure rates were 83% for ceftolozane/tazobactam with metronidazole and 87.3% for meropenem.

The most common adverse events for ceftolozane/tazobactam across trials included nausea, headache, and diarrhea.

Ceftolozane is a cephalosporin and tazobactam is a beta-lactamase inhibitor.

Sources: FDA and Cubist Pharmaceuticals, December 19, 2014, and Zerbaxa prescribing information

**Savaysa to Prevent Clotting**

The FDA has approved edoxaban (Savaysa, Daiichi Sankyo Company), an oral, once-daily selective factor-Xa inhibitor, to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (NVAF). The drug is also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) after five to 10 days of initial
therapy with a parenteral anticoagulant. The approval is based on the ENGAGE AF-TIMI 48 and Hokusai-VTE studies. ENGAGE AF-TIMI 48, a randomized, double-blind, double-dummy, phase 3 trial, compared edoxaban (in two dosing strategies) with warfarin in 21,105 NVAF patients at moderate-to-high risk of thromboembolic events for a median of 2.8 years. Edoxaban was associated with significantly fewer major bleeding events compared with warfarin (hazard ratio [HR], 0.80). For edoxaban compared with warfarin in the approved population, the trial found lower rates of intracranial hemorrhage (0.5% versus 1.0% per year, respectively) and a significant increase in gastrointestinal bleeding events (1.8% versus 1.3% per year, respectively).

Hokusai-VTE was an event-driven, randomized, double-blind, parallel-group, phase 3 trial comparing edoxaban to warfarin for reducing the rate of recurrence of symptomatic venous thromboembolism (VTE) events (including DVT, PE, and VTE-related death) in 8,292 patients with acute symptomatic DVT, PE, or both. Symptomatic recurrent VTE occurred in 3.2% of participants taking edoxaban compared with 3.5% of those taking warfarin.

The most common side effects in clinical trials were bleeding and anemia. A boxed warning notes that edoxaban is less effective in atrial fibrillation patients with a creatinine clearance greater than 95 mL per minute, that premature discontinuation increases the risk of stroke, and that spinal or epidural hematomas may occur in patients who are receiving anesthesia injected around the spine or undergoing spinal puncture.

Sources: Daiichi Sankyo Company and FDA, January 9, 2015

**Xtoro for Swimmer’s Ear**
The FDA has approved finafloxacin otic suspension (Xtoro, Alcon Laboratories) to treat acute otitis externa, commonly known as swimmer’s ear. Xtoro, a fluoroquinolone antimicrobial, is an eardrop indicated to treat acute otitis externa caused by *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Its safety and efficacy were primarily established in two clinical trials in which 1,234 participants between the ages of 6 months and 85 years were randomly assigned to receive Xtoro or its vehicle. Clinical cure was achieved if the ear tenderness, redness, and swelling were completely resolved.

Among 560 participants whose acute otitis externa was confirmed to be caused by *P. aeruginosa* or *S. aureus*, 70% of those who received Xtoro achieved clinical cure compared with 37% of those who received vehicle. The most common side effects in Xtoro-treated subjects were pruritus of the ear and nausea.

Source: FDA, December 17, 2014

**Rapivab for Influenza**
The FDA has approved peramivir injection (Rapivab, BioCryst Pharmaceuticals), an intravenous neuraminidase inhibitor, to treat acute uncomplicated influenza in patients 18 years of age and older who have been symptomatic for no more than two days.

The approval was supported by positive data from more than 2,700 subjects treated with peramivir in 27 clinical trials. Peramivir was launched in Japan in January 2010 under the trade name Rapiacta; it is estimated that more than 1 million patients have received peramivir treatment to date.

The recommended regimen for Rapivab is a single 600-mg dose administered via intravenous infusion for 15 to 30 minutes in most patients 18 years of age or older with acute uncomplicated influenza.

Source: BioCryst Pharmaceuticals, December 22, 2014

**Generic Approvals**

**Valsartan Tablets**
Five more companies are selling generic versions of Novartis’ Diovan tablets, which had U.S. sales of approximately $2 billion for the 12 months ending September 30, 2014, according to IMS Health.

Aurobindo USA, Jubilant Life Sciences Ltd., Lupin Pharmaceuticals Inc., Mylan Inc., and Teva Pharmaceutical Industries Ltd. have launched valsartan tablets USP 40 mg, 80 mg, 160 mg, and 320 mg, indicated for the treatment of hypertension.

Diovan went off patent in 2012, but Ranbaxy Laboratories Ltd., which had 180 days of marketing exclusivity for the drug, was unable to start selling it because FDA inspectors found quality issues at most of its plants. Eventually, Ranbaxy subsidiary Ohm Laboratories received FDA approval to manufacture and market the drug; the 180-day exclusivity has now expired.

Sources: Mylan Inc., January 5, 2015; Pharma Major Lupin Ltd., Teva Pharmaceutical Industries Ltd., and Jubilant Life Sciences Ltd., January 6, 2015; and Aurobindo USA, January 7, 2015

**Estradiol Transdermal System**
Mylan Inc. has launched its estradiol transdermal system USP, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day (twice weekly)—the first generic version of Novartis’ Vivelle-DOT.

The product is indicated for the treatment of moderate-to-severe vasomotor symptoms and moderate-to-severe symptoms of vulvar and vaginal atrophy due to menopause; hypoestrogenism due to hypogonadism, castration or primary ovarian failure; and the prevention of postmenopausal osteoporosis. U.S. sales were approximately $262.5 million for the 12 months ending September 30, 2014, according to IMS Health.

Source: Mylan Inc., December 22, 2014
**Methocarbamol Injection**
The FDA has approval the application of Mylan Inc. to produce methocarbamol injection USP, 100 mg/mL, packaged in 1,000 mg/10 mL single-dose vials. This is the first generic version of Hikma Maple Limited’s Robaxin injectable. Methocarbamol injection, a carbamate derivative of guaifenesin, is a central nervous system depressant with sedative and musculoskeletal relaxant properties intended for intramuscular or intravenous administration.

Sources: FDA, December 5, 2014, and Robaxin prescribing information

**NEW INDICATIONS**

**Saxenda to Manage Weight**
The FDA has approved liraglutide (rDNA origin) injection (Saxenda, Novo Nordisk) for use in chronic weight management with a reduced-calorie diet and physical activity. The drug is indicated for adults who have a body mass index (BMI) of 30 or greater or who have a BMI of 27 or greater with at least one weight-related condition, such as hypertension, type-2 diabetes, or dyslipidemia.

Liraglutide, a glucagon-like peptide-1 receptor agonist, should not be combined with any other drug in this class, including the type-2 diabetes treatment Victoza (Novo Nordisk). Saxenda and Victoza provide the same active ingredient at different doses (3.0 mg and 1.8 mg, respectively), but Saxenda is not indicated for type-2 diabetes treatment.

The safety and effectiveness of liraglutide injection were evaluated in three clinical trials with approximately 4,800 obese and overweight patients with and without significant weight-related conditions. All received counseling on lifestyle modifications, including a reduced-calorie diet and regular physical activity.

In a clinical trial with nondiabetic patients, those treated with liraglutide injection had an average weight loss of 4.5% from baseline compared with placebo at one year; 62% of patients treated with liraglutide lost at least 5% of their weight, compared with 34% of patients given placebo. In a trial that enrolled patients with type-2 diabetes, patients had an average weight loss of 3.7% from baseline compared with placebo at one year; 49% of those treated with liraglutide lost at least 5% of their weight compared with 16% of patients given placebo.

A boxed warning says thyroid C-cell tumors have been observed in rodent studies with liraglutide, but it is not known whether the drug causes such tumors, including medullary thyroid carcinoma (MTC), in humans. Saxenda should not be used in patients with a personal or family history of MTC or in patients with multiple endocrine neoplasia syndrome type 2, which predisposes them to MTC.

Serious adverse events reported with Saxenda include pancreatitis, gallbladder disease, renal impairment, and suicidal thoughts. Saxenda can increase the heart rate and should be discontinued in patients who experience a sustained increase in resting heart rate. The most common side effects have included nausea, diarrhea, constipation, vomiting, hypoglycemia, and decreased appetite.

The FDA is requiring postmarketing studies to evaluate dosing, safety, and efficacy in pediatric patients; assess potential effects on growth, sexual maturation, and central nervous system development and function in immature rats; evaluate the potential risk of breast cancer; and investigate cardiovascular safety. An MTC case registry must be maintained for at least 15 years. The FDA approved Saxenda with a risk evaluation and mitigation strategy.

**Kalydeco for More CF Patients**
The FDA has extended the use of ivacaftor (Kalydeco, Vertex Pharmaceuticals) to patients ages 6 years and older with cystic fibrosis (CF) who have the R117H mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Ivacaftor now has U.S. approval for use in subjects ages 6 years and older with CF who have one of these 10 mutations: R117H, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, or G1349D. The new approval is based on data from a phase 3 study that enrolled 69 subjects ages 6 years and older with CF and the R117H mutation.

CF is caused by a defective or missing CFTR protein resulting from mutations in the CFTR gene. In people with the R117H mutation, the CFTR protein reaches the cell surface but does not function properly. Approximately 500 people ages 6 years and older have this mutation in the U.S. With the new approval, ivacaftor is now indicated for the treatment of more than 3,100 people ages 6 years and older in North America, Europe, and Australia who have specific mutations in the CFTR gene.

Ivacaftor is the first medication to treat the underlying cause of CF in people with specific mutations in the CFTR gene. A CFTR potentiator, it is designed to keep CFTR proteins at the cell surface but does not function properly. Approximately 500 people ages 6 years and older have this mutation in the U.S. With the new approval, ivacaftor is now indicated for the treatment of more than 3,100 people ages 6 years and older in North America, Europe, and Australia who have specific mutations in the CFTR gene.

Ivacaftor can cause serious adverse reactions, including abdominal pain and high liver enzymes in the blood. The most common adverse effects associated with ivacaftor include headache; upper respiratory tract infection, including sore throat, nasal or sinus congestion, and runny nose; abdominal pain; diarrhea; rash; and dizziness.

Source: Vertex Pharmaceuticals, December 29, 2014
Somatuline Depot for GEP-NETs

The FDA has approved lanreotide injection (Somatuline Depot, Ipsen) to treat adults with unresectable, well-or-moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs).

Somatuline was previously approved in the U.S. for the long-term treatment of acromegalic patients who had shown an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy was not an option.

The new approval was based on the demonstration of improved progression-free survival (PFS) in the randomized, double-blind, placebo-controlled CLARINET trial, which enrolled 204 patients with unresectable, well-or-moderately differentiated, locally advanced or metastatic, nonfunctioning GEP-NETs. Patients were randomly assigned to receive either lanreotide 120 mg or placebo, administered via subcutaneous injection every 28 days.

PFS was significantly longer in the lanreotide arm compared with the placebo arm. The median PFS in the lanreotide arm had not been reached at the time of the final analysis and therefore is greater than 22 months. The median PFS in the placebo arm was 16.6 months. PFS was determined by an independent central radiology review.

The most commonly reported adverse reactions in lanreotide-treated patients included abdominal pain, musculoskeletal pain, vomiting, headache, injection-site reactions, hyperglycemia, hypertension, and cholelithiasis. Vomiting was the most common serious adverse reaction, affecting 4% of patients.

The recommended dosage of lanreotide for patients with GEP-NETs is 120 mg administered by deep subcutaneous injection every 28 days. Treatment should continue until disease progression or unacceptable toxicity occurs.

Lanreotide acetate is a somatostatin analogue that inhibits the secretion of several endocrine, exocrine, and paracrine functions. It has been shown to be effective at inhibiting the secretion of growth hormone and of some hormones in the digestive system.

Source: Ipsen, December 16, 2014

Bellafill for Acne Scarring

The FDA has approved the dermal filler Bellafill (Suneva Medical, Inc.) for the treatment of acne scars.

Bellafill is made primarily of bovine collagen. When injected, it lifts and smooths pitted scars to the level of the surrounding skin. It is designed to treat moderate-to-severe acne scars on the cheeks of patients over the age of 21 years.

The FDA’s decision was based on a double-blind, randomized, placebo-controlled pivotal study. At six months, response rates for the Bellafill group and a control group that received saline injections were 64% and 33%, respectively. A responder was defined as a subject who showed improvement in 50% or more of treated acne scars, as indicated by two or more points on a validated four-point Acne Scar Rating Scale. Bellafill continued to show effectiveness by an unblinded assessment at 12 months (71%).

Bellafill was initially approved in the U.S. in 2006 to smoothen “smile lines.”

Sources: Suneva Medical, Inc., and Reuters, January 6, 2015

Gadavist MRI Use Expanded

The FDA has approved gadobutrol injection (Gadavist, Bayer HealthCare) for use with magnetic resonance imaging (MRI) in pediatric patients younger than 2 years of age, including term neonates, to detect and visualize areas with a disrupted blood–brain barrier and/or abnormal vascularity of the central nervous system.

The FDA’s priority review was based on a study showing that the pharmacokinetic and safety profiles of gadobutrol in this age group were similar to those of older children and adults at the standard dose (0.1 mmol/kg). Gadobutrol injection received FDA approval for the same purpose in adults and children 2 years of age and older in March 2011.

Gadavist is an aqueous 1.0-M solution of gadobutrol, a gadolinium-based extracellular contrast agent for MRI with a macrocyclic structure.

Source: Bayer HealthCare, January 5, 2015

NEW FORMULATIONS

Duopa Enteral Suspension

An enteral suspension of carbidopa and levodopa (Duopa, AbbVie) has secured FDA approval for the treatment of motor fluctuations in patients with advanced Parkinson’s disease (PD). The treatment is administered using a small, portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally placed tube.

In advanced PD, patients may begin to experience “off” time, or periods of poor mobility, slowness, and stiffness. In addition, in PD patients, the spontaneous emptying of the stomach becomes delayed and unpredictable, which can affect the timing of when orally administered medications leave the stomach and are absorbed in the small intestine.

Duopa provides the same active ingredients as oral carbidopa and levodopa immediate release (IR), but it is delivered in a suspension that goes directly into the small intestine via a tube placed by a percutaneous endoscopic gastrostomy procedure with jejunal extension.

Duopa received orphan drug status. The FDA’s approval was based on a phase 3, 12-week, double-blind, double-placebo, active-control, parallel-group trial that compared the efficacy and safety of Duopa with that of oral, IR carbidopa/levodopa.
Duopa significantly reduced daily (per 16 waking hours) mean “off” time by four hours at 12 weeks, resulting in an average of 1.9 fewer hours of “off” time compared with carbidopa/levodopa IR tablets.

The most common adverse events included complications of device insertion, nausea, constipation, incision-site erythema, dyskinesia, depression, post-procedural discharge, peripheral edema, hypertension, upper respiratory tract infection, oropharyngeal pain, atelectasis, confusion, anxiety, dizziness, and hiatal hernia.

Duopa was approved as a combination product administered with the CADD Legacy 1400 pump.

Sources: AbbVie, January 12, 2015, and Duopa prescribing information

### Rytary for Parkinson’s Disease

The FDA has approved an extended-release oral capsule formulation of carbidopa and levodopa (Rytary, Impax Laboratories) for the treatment of Parkinson’s disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow intoxication with carbon monoxide and/or manganese. The product is not meant for patients receiving nonselective monoamine oxidase inhibitors.

Rytary contains extended-release (ER) and immediate-release (IR) beads with carbidopa and levodopa and provides both initial and extended levodopa plasma concentrations after a single dose. For patients who have trouble swallowing, the capsule may be opened so the beads can be sprinkled on applesauce and consumed immediately. Rytary will be available in four carbidopa/levodopa strengths—23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg.

In the APEX-PD trial, with 381 levodopa-naïve patients, Rytary met its primary efficacy endpoint of a mean change from baseline in the sum of scores on two parts of the Unified Parkinson’s Disease Rating Scale—Part II (activities of daily living) and Part III (motor skills)—compared with placebo at week 30 or early termination.

The ADVANCE-PD trial enrolled 393 patients with advanced PD having “off time.” Rytary reduced the percentage of “off” time (from 36.9% to 23.8%) from baseline compared with IR carbidopa/levodopa (from 36.0% to 29.8%) during waking hours to the end of the study. Rytary increased “on” time without troublesome dyskinesia during waking hours compared with baseline to the end of the study by 1.8 hours.

The most common adverse events (AEs) associated with Rytary in the APEX-PD trial included nausea, dizziness, headache, insomnia, abnormal dreams, dry mouth, dyskinesia, anxiety, constipation, vomiting, and orthostatic hypotension. In the ADVANCE-PD trial, the most common AEs were nausea and headache.

Source: Impax Laboratories, January 8, 2015

### Dyloject Injection for Pain

Diclofenac sodium injection (Dyloject, Hospira, Inc.), a nonsteroidal anti-inflammatory drug (NSAID), has received FDA approval to manage adults’ mild-to-moderate pain and moderate-to-severe pain alone or with opioid analgesics.

The drug can be administered in a small-volume intravenous (IV) bolus over 15 seconds as opposed to other injectable nonopioid analgesics, which are formulated in large volumes or require dilution before administration and typically require an infusion of 15 to 30 minutes for the full dose.

The product’s approval was based on two double-blind, placebo- and active-controlled, multiple-dose clinical studies. In both, IV morphine was permitted as a rescue medication for pain management. In the studies, 522 adults with post-operative pain were treated with Dyloject, a positive NSAID control (ketorolac tromethamine), or placebo administered every six hours for up to five days, starting within six hours after surgery. Fewer patients in the two Dyloject groups (approximately 63% and 74%) took rescue medication within the first 48 hours of treatment compared with patients in the two placebo groups (92% and 92%).

The most common adverse reactions in clinical trials included nausea, constipation, headache, infusion-site pain, dizziness, flatulence, vomiting, and insomnia. The labeling includes a boxed warning regarding the potential for serious cardiovascular and gastrointestinal adverse events. Dyloject is contraindicated for the treatment of perioperative pain in coronary artery bypass graft surgery.

Source: Hospira, Inc., December 30, 2014

### Long-Acting-Release Signifor

The FDA has approved long-acting-release pasireotide for injectable suspension for intramuscular use (Signifor LAR, Novartis) to treat patients with acromegaly who have had an inadequate response to surgery or for whom surgery is not an option.

Acromegaly is a rare endocrine disorder caused by the excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). Signifor LAR is a next-generation somatostatin analog (SSA).

This FDA approval was based on two multicenter phase 3 studies; one examined medically naïve patients who have had prior surgery or for whom surgery was not an option, and the other included patients with acromegaly inadequately controlled on first-generation SSAs. In both studies, higher rates of full biochemical control (defined as mean GH level less than 2.5 mcg/L and normal IGF-1 levels) were achieved with Signifor LAR compared with a first-generation SSA.

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Signifor LAR is administered intramuscularly once a month and exerts its pharmacological activity by binding to somatostatin receptors. It has an orphan drug designation for acromegaly. The most common adverse events in both clinical trials with Signifor LAR included hyperglycemia and diabetes mellitus.

Source: Novartis, December 16, 2014

**DRUG NEWS**

**Fast-Track Designations**

**Cenicriviroc for NASH**

The FDA has granted a fast-track designation to cenicriviroc (Tobira Therapeutics, Inc.) for the treatment of nonalcoholic steatohepatitis (NASH) in patients with liver fibrosis. Tobira is enrolling patients in a phase 2b, randomized, double-blind proof-of-concept study designed to compare cenicriviroc to placebo in approximately 250 patients.

Cenicriviroc is a first-in-class immunomodulator and dual inhibitor of CCR2 and CCR5. Its safety and tolerability have been evaluated in approximately 580 subjects in phase 1 and phase 2 trials.

Source: Tobira Therapeutics, Inc., January 6, 2015

**SGX301 for T-Cell Lymphoma**

Synthetic hypericin (SGX301, Soligenix, Inc.) has received FDA fast-track status for the first-line treatment of cutaneous T-cell lymphoma (CTCL), a class of non-Hodgkin’s lymphoma.

SGX301 is a first-in-class photodynamic therapy. Synthetic hypericin, a potent photosensitizer, is topically applied to skin lesions and activated by fluorescent light 16 to 24 hours later. In a phase 2 clinical study, CTCL patients experienced a statistically significant improvement with topical hypericin treatment (58.3%) compared with placebo (8.3%). SGX301 previously received an orphan drug designation.

Source: Soligenix, Inc., January 7, 2015

**Anti-infectious Agent Debio 1450**

Debiopharm Group’s anti-infectious agent Debio 1450, which exhibits unique selectivity for staphylococcal species, has received an FDA fast-track designation. Debio 1450 is expected to prevent development of multiple drug-resistant organisms such as vancomycin-resistant enterococci and to reduce antibiotic-associated side effects. It was designated a qualified infectious disease product in September 2014.

Source: Debiopharm Group, January 8, 2015

**Orphan Drug Designations**

**NiCord for ALL and Other Diseases**

Investigational NiCord (Gamida Cell) has received an FDA orphan drug designation for the treatment of acute lymphoblastic leukemia, acute myeloid leukemia, Hodgkin’s lymphoma, and myelodysplastic syndrome. NiCord is derived from a single cord blood unit that has been expanded in culture and enriched with stem cells using Gamida Cell’s proprietary technology. It is being tested in a phase 1/2 study as an investigational treatment for hematological malignancies.

Source: Gamida Cell, January 6, 2015

**Translarna for Mucopolysaccharidosis I**

Ataluren (Translarna, PTC Therapeutics, Inc.) has received the FDA’s orphan drug designation for the treatment of patients with mucopolysaccharidosis I (MPS I), an inherited genetic disorder caused by a deficiency in an essential enzyme that is responsible for the breakdown of by-products in the body’s cells.

Translarna is designed to enable the formation of a functioning protein in patients with genetic disorders caused by a nonsense mutation, and also has an orphan drug designation for Duchenne muscular dystrophy and cystic fibrosis.

Source: PTC Therapeutics, Inc., December 19, 2014

**Lonafarnib for Hepatitis D**

Lonafarnib (Eiger BioPharmaceuticals, Inc.), a first-in-class investigational treatment for patients infected with hepatitis D virus (HDV), has been granted an orphan drug designation by the FDA. In a phase 2a proof-of-concept study evaluating two doses of lonafarnib, HDV RNA viral levels decreased significantly compared with placebo in patients with chronic HDV infection after treatment for 28 days. Lonafarnib was generally well tolerated.

Lonafarnib is a well-characterized, late-stage, orally active inhibitor of farnesyl transferase, an enzyme involved in modification of proteins through prenylation. HDV uses this host-cell process inside liver cells for a key step in its life cycle.


**Ebola Vaccine Front-Runners**

Three promising experimental vaccines against the Ebola virus are being tested in humans, according to the website Live Science.

Johnson & Johnson’s vaccine candidate contains modified versions of a human cold virus, the smallpox virus, and bits of Ebola’s genetic material. In a phase 1 study in the United Kingdom, 72 healthy volunteers are receiving the vaccine or a placebo. The vaccine involves two shots: The first dose “primes” the immune system, while the second (given a month or two later) boosts the body’s immune response. Earlier experiments found that the vaccine protected monkeys against the Zaire strain of the Ebola virus, which is causing the current outbreak. Janssen Pharmaceuticals, a J&J subsidiary, is developing the vaccine with Bavarian Nordic.

A phase 1 trial of GlaxoSmithKline’s cAd3-EBO vaccine found that it was well tolerated and appeared effective. Twenty healthy U.S. adults who received the vaccine produced antibodies against the Ebola virus. The company is preparing to
test the vaccine in a larger cohort. The vaccine, developed with the National Institutes of Health, is made of a harmless cold virus that affects chimpanzees, but it is coated with proteins from the Zaire and Sudan strains of the Ebola virus.

Researchers stopped a phase 1 trial in Switzerland of a Merck vaccine, VSV-ZEBOV, when some volunteers reported joint pain. These symptoms resolved without treatment, however, and researchers resumed the trial using a lower dose. VSV-ZEBOV consists of the vesicular stomatitis virus (VSV), which mainly infects animals. In the vaccine, one gene of VSV has been replaced with the gene that codes for the outer protein of the Zaire strain of Ebola. The vaccine was developed at the Public Health Agency of Canada’s National Microbiology Laboratory; it has been licensed to NewLink Genetics Corp. and to Merck.

The Ebola virus has infected more than 20,000 people in West Africa and has killed at least 8,200, according to the World Health Organization.

Source: Live Science, January 8, 2015

**IV Erwinaze for ALL**

Asparaginase *Erwinia chrysanthemi* (Erwinaze, Jazz Pharmaceuticals) can now be given intravenously as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to *Escherichia coli*-derived asparaginase.

Prior to FDA approval of new labeling, the only approved route of administration for Erwinaze was intramuscular injection. With the expanded label, the formulation of Erwinaze already on the market may be administered by either intravenous infusion or intramuscular injection. Since Erwinaze is derived from the bacterium *E. chrysanthemi*, it is immunologically distinct from *E. coli*-derived asparaginase and is suitable for patients with hypersensitivity to *E. coli*-derived treatments.

Source: Jazz Pharmaceuticals, December 19, 2014

**Medication Recalls Wallcur IV Training Products**

Wallcur, LLC, is recalling intravenous (IV) bags of sodium chloride intended solely for training and simulation purposes after the products were administered to more than 40 patients. The products are not sterile and are not intended for human or animal administration.

The FDA says many adverse events have been reported, including fever, chills, tremors, and headache. Some patients were hospitalized. One death is associated with the products, the FDA adds; “it is not known if this death is directly related to the use of the product.”

The recall involves Practi-0.9% sodium chloride IV bags supplied in 50-mL, 250-mL, 500-mL, and 1,000-mL sizes and the Practi-0.9% sodium chloride 100-mL IV solution bag with sterile distilled water. Wallcur intends to enhance its labels prior to future distribution to emphasize that the product is for training purposes only and is not for human or animal injection.

Customers with questions may call Wallcur at 619-702-4333 and can notify the FDA of adverse events at 1-800-332-1088.

Sources: Wallcur, January 7, 2015, and FDA, January 14, 2015

**Hospira Mitoxantrone**

Hospira, Inc., recalled 10 lots of mitoxantrone (human and veterinary) due to confirmed subpotency and elevated impurity levels. The lots were distributed from February 2013 through November 2014. More information (including lot numbers), is available at http://tinyurl.com/HospiraMitoxantrone. For assistance, call Stericycle at 1-844-265-7407, Monday through Friday, 8 a.m. to 5 p.m. Eastern time.

Source: Hospira, Inc., December 23, 2014

**RESEARCH BRIEFS**

**A Resistance-Free Antibiotic?**

A newly discovered antibiotic eliminates pathogens without encountering detectable resistance, Northeastern University researchers report in *Nature*. Their finding holds promise for treating chronic infections caused by bacteria such as *Mycobacterium tuberculosis* and methicillin-resistant *Staphylococcus aureus*.

Professor Kim Lewis and colleagues discovered the antibiotic teixobactin while developing a novel method for growing uncultured bacteria. Lewis said this marks the first discovery of an antibiotic to which resistance by mutations of pathogens has not been identified.

The screening of soil microorganisms has produced most antibiotics, but only 1% of them will grow in the lab, and this limited resource was overmined in the 1960s, Lewis explained. He and his colleagues spent years trying to address this problem by tapping into a new source of antibiotics beyond those created by synthetic means: uncultured bacteria, which make up 99% of all species in external environments.

The researchers developed a novel method for growing uncultured bacteria in their natural environment. Their approach involves the iChip, a miniature device that can isolate and help grow single cells in their natural setting, providing researchers with improved access to uncultured bacteria. The investigators have assembled about 50,000 strains of uncultured bacteria and have discovered 25 new antibiotics; teixobactin is the latest and most interesting, Lewis said.

Teixobactin was discovered during a routine screening for antimicrobial material. Lewis tested the compound for the development of resistance and did not find mutant MSRA or *Mycobacterium tuberculosis* (which causes tuberculosis) resistant to teixobactin, which blocks several targets in the cell-wall synthesis pathway.

**Sources:**
- Hospira, LLC, is recalling intravenous (IV) bags of sodium chloride intended solely for training and simulation purposes after the products were administered to more than 40 patients. The products are not sterile and are not intended for human or animal administration.
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Lewis and his colleagues hope to develop teixobactin into a drug.

Source: Northeastern University, January 7, 2015

Endocrine Therapy Adherence

Endocrine therapy reduces the risk of recurrent breast cancer, but nonadherence is high. To learn why, researchers from Utrecht University, Leiden University, and Diaconessenhuis Hospital (Leiden) developed the Tailored Medicine Inventory.

Researchers asked the 241 respondents questions about their perceptions of the efficacy of endocrine therapy, worries about side effects, and practical problems, such as packaging and refills. The study also employed the Understanding and Use Self-Efficacy Scale, the Medication Adherence Rating Scale-5, and the Morisky Medication Adherence Scale.

The researchers found that many women were not convinced of endocrine therapy’s efficacy. Nearly 20% didn’t know how endocrine therapy works, lacked information about it, and didn’t know how much it reduced the chances of recurrence.

Nearly half of the women had experienced practical problems, often related to information, intake of tablets, and packaging. Practical problems were more common, some well known (hot flushes, reduced libido, cramps, and joint ache and stiffness) and others less so (memory and concentration problems).

Source: Clinical Breast Cancer, December 2014

Dabigatran Versus Warfarin

To compare dabigatran to warfarin in real-world treatment, researchers from the Iowa City Veterans Affairs (VA) Medical Center, University of Iowa, and University of Toronto studied VA data from 2010 to 2012.

In 2010, dabigatran became the first FDA-approved alternative to warfarin for stroke prevention in atrial fibrillation (AF). The advantages: a more predictable anticoagulation response, fewer diet restrictions, and less frequent monitoring. Clinical trials showed similar rates of major bleeding for the two drugs, but higher rates of gastrointestinal (GI) bleeding for dabigatran. However, those data were based on carefully selected patients, say the researchers, whose study included 85,344 VA patients with AF who had been taking warfarin for at least six months before June 2011. Of those, 1,394 switched to dabigatran during the next 15 months.

Overall, 10,734 patients experienced bleeding events, including 131 events after starting dabigatran. The risk-adjusted rate of bleeding was higher with dabigatran, mainly because of a 54% higher risk of GI bleeding. This finding persisted in sensitivity analyses.

However, dabigatran initiation was not associated with significant rates of intracranial or other bleeding. Nor did the researchers find an association between dabigatran and death, after controlling for differences in the characteristics of patients who did and did not change to dabigatran. Patients who switched to dabigatran were more likely to have a history of labile international normalized ratios (INRs) while taking warfarin, were somewhat younger, and appeared to have more advanced heart disease.

The researchers note that their observational study had low power because of the relatively few patients who switched to dabigatran during the observation period. Moreover, most VA patients are men with more chronic conditions than the general population, including conditions associated with poor time in therapeutic INR range.

The high risk of GI bleeding can be offset, the researchers say, by careful evaluation of patients and education about the drug, the importance of adhering to the dosing regimen, and the early signs of potential hemorrhage.

Source: American Journal of Medicine, December 2014

Gauging Pneumocystosis Risks

Pneumocystis jiroveci pneumonia can be deadly in immunocompromised HIV-negative patients, with in-hospital mortality rates of 50% to 86%. Trimethoprim-sulfamethoxazole (TMP-SMX) is an effective prophylaxis, but the range of immunosuppressive conditions predisposing patients to pneumocystosis and the limited data on its incidence in HIV-free patients have confounded an evidence-based guideline.

Researchers from Hôpital Pontchaillou, Hôpital Sud, and Université Rennes I in France retrospectively analyzed all documented pneumocystosis in HIV-negative patients admitted to Rennes University Hospital between 1990 and 2010. Of 293 cases of pneumocystosis, 154 (53%) tested negative for HIV. The study found pneumocystosis remains a significant problem in immunocompromised patients with and without HIV. Pneumocystosis is more severe in HIV-negative patients, with much higher rates of intensive care unit (ICU) admission and mortality.

The risk of pneumocystosis was par-
ticularly high (more than 45 cases per 100,000 patient-years) in patients with inflammatory diseases/vasculitis (polyarteritis nodosa, granulomatosis with polyangiitis, and polymyositis/dermatomyositis) and in three hematological malignancies (acute leukemia, chronic lymphocytic leukemia, and non-Hodgkin’s lymphoma). The risk was intermediate (25–45 cases per 100,000 patient-years) for Waldenström macroglobulinemia, multiple myeloma, and central nervous system cancer. Most patients with solid tumors and inflammatory diseases were at low risk (less than 25 cases per 100,000 patient-years).

The findings can help guide more systematic use of TMP-SMX prophylaxis, the researchers say. For high-risk patients, they suggest TMP-SMX prophylaxis may be beneficial given the high morbiditity and mortality. For intermediate-risk patients, the researchers recommend a low threshold for prophylaxis: Any additional risk factor, such as prolonged corticosteroid use, should prompt initiation of TMP-SMX. But for low-risk patients, they advise avoiding routine pneumocystosis prophylaxis.

Source: American Journal of Medicine, December 2014

Assessing Cancer Symptoms

Repeatedly assessing cancer patients’ symptoms could help improve care and predict risk of death more precisely, according to researchers from the University of Toronto.

Assessments of cancer patients’ symptoms often focus on a single time point, such as the baseline interview at diagnosis or hospice admission—even though symptom severity changes rapidly in such patients, especially as death nears. The researchers designed a longitudinal study of 66,112 outpatients with more than 310,000 assessments of symptoms.

Using patient symptom reports from the Edmonton Symptom Assessment System (used in all Ontario cancer centers since 2007), they compared a model using a time-varying covariate for each symptom with one that used a time-fixed (baseline) covariate for each symptom. The median follow-up was 19 months, with a median of three assessments per patient and a median of 1.16 months between assessments. Each assessment covered nine symptom scores: fatigue, appetite, well-being, drowsiness, pain, shortness of breath, anxiety, depression, and nausea.

The repeated assessments improved predictions for risk of death, with increased pain, fatigue, and reduced appetite the strongest predictors. As symptoms became more severe, the hazard of death increased significantly. For example, at any given time, a patient with a severe pain score had double the risk of death compared with a patient with no pain. Similarly, among breast cancer patients, a woman with the worst appetite score had more than three times the risk of death compared with a woman with the best appetite score. The researchers found no significant associations between depression and death.

The researchers encourage recording measurements of symptom scores over time, at each visit, using paper-based visual scales or electronic surveys. Information about changing symptoms could prompt interventions such as exercise for fatigue and nutritional support for anorexia. On the other hand, worsening pain, fatigue, and appetite may be unavoidable, the researchers say, and a “flag for impending death”—in which case a more timely assessment might sooner identify patients in need of palliative care.

Source: Journal of Pain and Symptom Management, December 2014

DEVICE NEWS

FDA Clears Test to Help Predict Risk of Heart Events

The FDA has cleared the PLAC Test for Lp-PLA2 Activity (diaDexus, Inc.)—a screening test that predicts a patient’s risk of future coronary heart disease (CHD) events, such as heart attacks.

The test is approved for use in all adults with no history of heart disease, but studies submitted by the manufacturer showed that the test is better at discerning this risk in women, particularly African-American women.

The test measures the activity of lipoprotein-associated phospholipase A2 (Lp-PLA2) in blood. Lp-PLA2 is a biological marker for vascular inflammation, a condition associated with the buildup of plaque in the arteries that supply blood to the heart. Over time, this buildup can result in narrowing of the arteries and can lead to CHD. Patients with test results that show Lp-PLA2 levels greater than 225 nmol/min/mL are at increased risk for a CHD event compared with patients with test results below this level.

Heart disease is the leading U.S. cause of death for most racial and ethnic groups. CHD kills more than 385,000 people annually. Almost two-thirds of women and half of men who die suddenly of CHD have no previous symptoms.

The FDA’s review included results from the PLAC Test for Lp-PLA2 Activity validation study. Researchers performed the test on 4,598 participants ranging in age from 45 to 92 years with no history of CHD (58.3% women, 41.7% men; 58.5% white, 41.5% African-American).

The investigators recorded CHD-related events during a median follow-up period of 5.3 years. Participants with test results higher than 225 nmol/min/mL had a CHD event rate of 7.0%, while patients with test results below that level had a CHD event rate of 3.3%.

Source: FDA, December 15, 2014
**NEW DRUGS**

**Intercept Blood System to Cut Infections in Transfusions**

The FDA has approved the Intercept Blood System (Cerus Corporation), a pathogen-reduction system for use in the preparation of plasma to lower the risk of transfusion-transmitted infections.

The system inactivates a broad spectrum of enveloped and nonenveloped viruses in plasma, as well as gram-positive and gram-negative bacteria, spirochetes, and parasites. Its photochemical process involves controlled exposure to ultraviolet light and amotosalen, a chemical that facilitates the inactivation process. The plasma is then purified to remove the chemical and its by-products.

The process can inactivate susceptible pathogens whether or not they have been identified as specific blood-supply risks.

The Intercept system has been used in Europe for more than a decade.

Platelets, plasma, and red blood cells do not need functional DNA or RNA for therapeutic efficacy. However, bacteria, viruses, parasites, and white blood cells require these nucleic acids to replicate. The Intercept system targets this basic biological difference, using a proprietary molecule that, when activated, binds to and blocks the replication of DNA and RNA, rendering the pathogen inactive.

The safety and efficacy of plasma prepared with the Intercept system have been evaluated in six clinical studies involving more than 500 patients. In addition, routine use of Intercept-processed plasma was monitored in about 10,000 patients in a hemovigilance study in Europe.

Sources: FDA and Cerus Corporation, December 16, 2014

**Blood Test for HIV, HCV, HBV**

The FDA has approved the cobas TaqScreen MPX test, v2.0, to detect and identify human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV) in donations of human whole blood and blood components, including source plasma.

This version of the cobas TaqScreen MPX test provides increased sensitivity and simultaneously detects and identifies the most critical viral targets in one assay. The automated system eliminates the need for consecutive rounds of testing and facilitates earlier donor counseling in the event of a positive result. The test uses real-time, multi-dye polymerase chain reaction technology, reducing the required sample volume and turn-around time.

The cobas TaqScreen MPX test, v2.0, is a qualitative *in vitro* test for the direct detection of HIV type 1 (HIV-1) group M RNA; HIV-1 group O RNA; HIV type 2 (HIV-2) RNA; HCV RNA; and HBV DNA in human plasma. The test runs on the automated cobas s 201 system, which is designed to increase processing efficiency in a new modular design with ready-to-use reagents.

Source: Roche, January 9, 2015

**Device Recalls**

**INRatio Problem Now a Recall**

Problems with the INRatio and INRatio2 PT/INR Monitor system (Alere Inc.), disclosed in an “urgent correction letter” in December 2014, have been labeled a class I recall after 18,924 reports of malfunctions; most patients required reinsertion of endotracheal tubes. For information about this class I recall (including a list of recalled products and lot numbers), see http://tinyurl.com/KimVentRecall.

Source: FDA, December 31, 2014

**KimVent® Microcuff® Endotracheal Tubes**

Halyard Health has recalled KimVent® Microcuff® Subglottic Suctioning Endotracheal Tubes because the cuff inflation line may detach during use if pulled or tugged. The cuff will then gradually deflate, which may lead to an air leak between the cuff and the tracheal wall and reduce the air reaching the lungs.

The affected devices were distributed from December 20, 2013, to October 30, 2014. The firm has received 19 reports of malfunctions; most patients required reinsertion of endotracheal tubes. For information about this class I recall (including a list of recalled products and lot numbers), see http://tinyurl.com/KimVentRecall.

Source: FDA, December 31, 2014

**DEVICE SPOTLIGHT**

**Kunj Gohil, PharmD, RPh**

**Name:** IN.PACT Admiral drug-coated balloon (DCB)

**Manufacturer:** Medtronic, Minneapolis, Minnesota

**Approval Date:** January 5, 2015

**Purpose:** The IN.PACT Admiral DCB is designed to reopen arteries in the upper leg, specifically the superficial femoral and popliteal arteries, when they have been blocked or narrowed by plaque.

**Description:** The drug-coated balloon is inserted into the blocked artery, much like conventional methods. Uniquely, once the drug reaches the narrowed or blocked artery, the balloon delivers a dose of paclitaxel, an antirestenotic drug, to prevent scarring and renarrowing of the artery.

**Benefit:** The IN.PACT Admiral DCB has the potential to revolutionize the way peripheral artery disease is treated. Although revascularization with balloon procedures is common today, it is often associated with the need for repeat procedures. The addition of localized admin-

*continued on page 118*
istration of paclitaxel has shown superior efficacy compared with traditional methods. Data from the IN.PACT SFA Trial showed that only 2.4% of patients required a repeat procedure at one year when treated with the IN.PACT DCB, compared to 20.6% of patients who underwent percutaneous transluminal angioplasty.

Sources: www.fiercemedicaldevices.com, www.medtronic.com

Name: Laboratory-in-a-tube (Liat) technology
Manufacturer: Roche, Basel, Switzerland
Launch Date: December 16, 2014
Purpose: The cobas Liat system is a molecular diagnostic platform that offers real-time polymerase chain reaction results in 20 minutes or less.
Description: Liat is a compact system, compared with traditional methods, designed to provide immediate testing at both the point of care and the laboratory. A patient sample is added to an assay tube, a barcode is scanned, and the sample is analyzed. Pathogens supported by this system are influenza A, influenza B, and streptococcus A.
Benefit: Evaluating patients for specific pathogens can be very time-consuming, but time is of the utmost importance. A system that can effectively identify particular pathogens, such as the Liat system, can facilitate time-sensitive diagnoses and treatment decisions. This innovative system cannot only provide timely results, but can also be used with a few simple steps at the point of care. The Liat system eliminates time-consuming steps and can help physicians make critical patient decisions.
Sources: www.fiercemedicaldevices.com, https://usdiagnostics.roche.com