TRENDS-in-MEDICINE

March 18, 2012

by Lynne Peterson

Quick Takes

…Highlights from this week's news relating to drugs and devices in development that are not covered in other *Trends-in-Medicine* reports…

Trends-in-Medicine
Stephen Snyder, *Publisher*
2731 N.E. Pinecrest Lakes Blvd.
Jensen Beach, FL 34957
772-334-7409
Fax 772-334-0856
www.trends-in-medicine.com
TrendsInMedicine@aol.com

NOTE: For full coverage of the FDA's Arthritis Advisory Committee meeting March 12, 2012, on the **outlook for future development of anti-nerve growth factors for pain**, subscribe to *Trends-in-Medicine*.

Short Takes

- **Affectis Pharmaceuticals' cimicoxib –** In a 66-patient, double-blind, placebo-controlled study, adding this Cox-2 inhibitor, which was licensed from **Palau Pharma**, to **Pfizer's Zoloft** (sertraline) was more effective in treating major depressive disorder than Zoloft alone. The results were reported at the European Congress of Psychiatry.

- **Anthera Pharmaceuticals' varespladib –** The Phase III VISTA-16 trial of this PLA2 inhibitor, an anti-inflammatory for acute coronary syndrome, was halted because of futility. The data safety monitoring board (DSMB) recommended the trial be stopped after finding no evidence of efficacy when adding varespladib 500 mg QD to **Pfizer's Lipitor** (atorvastatin).

- **Anti-nerve growth factors (NGFs) –** The FDA's Arthritis Advisory Committee voted 21-0 that development of anti-NGFs should continue for treatment of pain in conditions even where there are approved alternatives, and the panel voted 20-1 that development also should continue for other pain conditions where there are not approved pain therapies, despite agreement that there is a signal linking the drugs to joint deterioration and a recommendation that they not be used with NSAIDs.

- **Apotex** sued the FDA for $520 million, claiming that its U.S. division was adversely affected by a nearly two-year FDA block on shipments into the U.S. from two of its Toronto plants. Apotex said the shipping ban violated the North American Free Trade Agreement (NAFTA).

- **Asahi Kasei** is buying **Zoll Medical**, which makes devices such as the **LifeVest**, a wearable defibrillator. The deal is expected to close in 2Q12, and Zoll will become a wholly owned subsidiary managed by the current Zoll management team and with all current business units and operations remaining intact.

- **AstraZeneca's Seroquel (quetiapine) –** The company sued the FDA in U.S. District Court in Washington DC, seeking to overturn the Agency's denial of its request for labeling on generic versions of this antipsychotic that warn about the risks of high glucose and suicidality.

- **Atypical antipsychotics –** Experts are worried about the increasing off-label use of atypical antipsychotics for conditions other than schizophrenia or bipolar disorder – e.g.,

for anxiety, attention-deficit disorder, sleep difficulties, behavioral problems in toddlers, and dementia.

- **BIODELIVERY SCIENCES INTERNATIONAL's Onsolis (buccal fentanyl)** – The FDA ordered the company to modify the formulation of this pain drug to prevent the color from fading during its shelf life. The company blamed the color issue on an excipient, which it said could be removed.

- **CELLTEX THERAPEUTICS** – Leigh Turner, PhD, an ethics professor from the University of Minnesota, wrote to the FDA, urging the Agency to investigate this company, which stores patients' stem cells for possible medical uses in the future. *Celltex stored the cells used in the experimental procedure performed on Texas Gov. Rick Perry to treat his back pain.*

- **CORNERSTONE THERAPEUTICS' CRTX-800** – The FDA accepted the company's submission of this drug to treat hyponatremia. The PDUFA date is October 29, 2012.

- **Diacetylmorphine**, the active ingredient in heroin, may be more effective than methadone for refractory opioid addiction. A mathematical model study published in the ***Canadian Medical Association Journal*** suggested that patients on diacetylmorphine would gain more quality-adjusted life years at a lower cost than with methadone.

- **KALA PHARMACEUTICALS** received two grants from separate divisions of the National Institutes of Health to support its research into cystic fibrosis (CF) and ocular disease. The National Heart, Lung, and Blood Institute (NHLBI) is funding the development of an inhaled treatment for infection related to CF, and the National Eye Institute (NEI) is funding development of new formulations for ocular drugs.

- **LEO PHARMA and WARNER CHILCOTT's Picato (ingenol mebutate)** – A study published in the ***New England Journal of Medicine*** found that this FDA-approved topical gel for actinic keratosis may work "in a matter of days," with a clearance rate of 42.2% vs. 3.7% for placebo, which means shorter exposure and probably better compliance.

- **Mylan** – ***Reuters*** reported that sources said Mylan has broken off talks to purchase **Rottapharm.**

- **Prazosin** – A study presented at the European Congress of Psychiatry suggested that this generic blood pressure drug, an alpha-adrenergic blocker, helps relieve nightmares related to post-traumatic stress disorder (PTSD).

- **ROCHE** was asked by the Federal Trade Commission (FTC) for more information on its proposed acquisition of **Illumina**, which extends the waiting period until 10 days after Roche has substantially complied with this request.

- **SHIRE's Replagal (agalsidase alfa)** – The company is giving up again – for the second time – on this Fabry therapy. Shire pulled its FDA application just two weeks before an FDA advisory committee was scheduled to review it. The issue does not appear to be safety but the likelihood that the FDA will demand additional studies.

- **Statins** – A 2,072-patient study published in ***Diabetes and Metabolism Research and Reviews*** found that patients who start taking a statin after initiating oral anti-diabetic therapy have a higher discontinuation rate than patients who start a statin first (62.8% s. 48.2%).

- **TRANS1's AxiaLIF**, a pre-sacral lumbar interbody fusion implant, has been granted its own CPT code, 225XX1, for use in L5-S1 spinal fusions, effective January 1, 2013. Other CPT codes for the device were clarified.

- **WALGREENS** will use **Surescripts**' Clinical Interoperability e-prescribing network to share immunization records between the company's Walgreens pharmacies, **Duane Reade** pharmacies, 350 **Take Care Clinics**, the patients' primary care providers, and state and local public health agencies.

NEWS IN BRIEF

ASPENBIO PHARMA's AppyScore – blood test for appendicitis

A 503-patient study presented at the Western Region meeting of the Society for Academic Emergency Medicine found that this test had 97% negative predictive value and 96% sensitivity for the absence of acute appendicitis in children and adolescents presenting with abdominal pain. The test uses an MRP 8/14 biomarker, C-reactive protein (CRP), and a white blood cell count to identify young patients at low risk of acute appendicitis and potentially avoid a CT scan. The company is hoping for a CE Mark by the end of 2012 and plans to start an FDA registration trial this year.

BMP – one Blue trying to limit off-label use

According to an article in ***Orthopedics This Week***, Blue Cross Blue Shield (BCBS) of Minnesota is threatening to deny payment for surgeries in which bone morphogenic protein (BMP) is used off-label. The insurer isn't proposing to deny payment just for the BMP but for the entire procedure if BMP is used. BCBS said the new coverage decision, which went into effect in November 2011, says: "When BMP is used for

indications that are considered investigative or not medically necessary, any procedures performed in conjunction with BMP will not be covered. This includes, but is not limited to, professional, facility, and anesthesia services as well as supplies."

After numerous complaints, BCBS of Minnesota is reviewing its new policy, *but if it isn't withdrawn or modified, it could put quite a chill on BMP use, particularly if other insurers adopt the same or similar coverage rules.*

Breast cancer – is cadmium a culprit?

A study published in ***Cancer Research***, a journal of the American Association for Cancer Research, found that dietary cadmium, a toxic metal found in many fertilizers, may be linked to an increased risk of breast cancer. Cadmium is found in bread, cereal, potatoes, root crops, and vegetables. In the study, Swedish researchers observed 55,987 women for >12 years. They found high exposure to cadmium was associated with a 1% increase in breast cancer, and lean/normal weight women with high exposure had a 27% increased risk. It appeared that cadmium consumed in grains and vegetables was less dangerous than other dietary sources.

Helicobacter pylori (H. pylori) – responsible for Type 2 diabetes and stomach ulcers?

A cross-sectional analysis of two cohorts of NHANES with >13,000 patients, published in the ***Journal of Infectious Diseases***, found that *H. pylori* was positively associated with levels of HbA_{1c} and the combination of *H. pylori* and elevated body mass index (BMI) was associated with higher HbA_{1c} levels than either factor alone.

- In NHANES 1990-2000, the 2,403 participants who were *H. pylori*-positive had a mean HbA_{1c} level of 5.49% vs. 5.40% for the participants without *H. pylori* ($p=0.02$).
- In NHANES III (1988-1994), the overall difference in HbA_{1c} levels was non-significant but became significant ($p<0.01$) when diabetics and insulin users were excluded.
- In both cohorts, participants with a BMI ≥25 and *H. pylori* had a higher HbA_{1c} than either factor alone.

The researchers cautioned that the study doesn't prove causality, but they said the findings "could have important clinical and public health implications." An accompanying editorial suggested that people with *H. pylori* and a high BMI – even if asymptomatic – may need treatment to prevent or control diabetes.

If these findings are confirmed, they could have dramatic implications for Type 2 diabetes medications. The idea of H. pylori being responsible for a significant part of Type 2 diabetes might seem off-the-wall, but that's what gastroenterologists thought when the link to ulcers was first suggested.

PFIZER

- The company terminated a deal to market insulin products manufactured by **Biocon**, an Indian company.
- **Prevnar 13.** A study found that this pneumococcal vaccine appears to be effective in children aged 5-17.

REGULATORY NEWS

CMS might be forced to cover virtual colonoscopies

A bipartisan bill (HR4165) was introduced in the House of Representatives by Rep. Danny Davis (D-IL) and Ralph Hall (R-TX) that would require Centers for Medicare and Medicaid Services (CMS) to cover virtual colonoscopies – 3D reconstructions of the colon using abdominal CT scans. This would make CMS reverse its 2009 decision not to cover the tests.

CMS to expand access to emergency psychiatric care

A new demonstration program in 11 states and Washington DC – part of the Affordable Care Act – will test whether Medicaid beneficiaries who experience a psychiatric emergency get more immediate, appropriate care when institutions for mental diseases receive Medicaid reimbursement.

The program will provide ≤$75 million in federal Medicaid matching funds over three years to Alabama, California, Connecticut, Illinois, Maine, Maryland, Missouri, North Carolina, Rhode Island, Washington, and West Virginia, plus DC, to enable private psychiatric hospitals to receive Medicaid reimbursement for emergency care provided to Medicaid enrollees aged 21 to 64 who have an acute need for treatment.

CMS panel says patients should pay more for imaging

The Medicare Payment Advisory Commission (MedPAC) wants Congress to mandate that the Department of Health and Human Services (HHS) develop a fee-for-service program that would raise patient copayments for advanced imaging tests. The idea is that higher copayments would limit the use of unnecessary tests.

CMS to stop covering TENS for chronic low back pain

The Centers for Medicare and Medicaid Services currently covers the cost of transcutaneous electrical nerve stimulation (TENS) devices prescribed by a doctor for chronic low back pain, but CMS has proposed changing that to cover only devices for patients who are participating in a randomized clinical trial of the technology's effectiveness. The policy change comes after a 2010 report by an American Academy of Neurology panel reviewed published TENS studies and found the treatment was ***ineffective***.

To have the device covered, patients in a trial must have been suffering for ≥3 months from low back pain not caused by inflammatory autoimmune disease or metastatic spinal tumors, the trial must be designed and powered to provide a definitive answer about efficacy, and the trial must be listed on **www.clinicaltrials.gov**.

CMS will continue to reimburse for TENS when it is prescribed for other chronic, treatment-refractory pain, such as severe postoperative pain. Public comments on the proposed decision will be accepted through April 12, 2012.

FDA proposes lower risk class for TB tests

The FDA issued a proposed rule that would lower the current risk classification for nucleic acid-based tests used to detect tuberculosis (TB). This rule would allow manufacturers to utilize a faster, more streamlined clearance pathway for medical devices. Currently, these tests are Class III (high-risk) devices that require PMA approval. The FDA is proposing to make them Class II (moderate-risk). The FDA is accepting public comments on the draft guidance for 90 days.

FDA trying to prevent device shortages

The FDA wants to collect information on medical devices for the Agency's Emergency Shortages Data Collection System (ESDCS). The Agency plans to communicate with manufacturers who produce "key medical devices" – devices for which there would probably be high demand during a specified emergency or disease or for which there are so few manufacturers that the loss of one or more of them would create a shortage.

During an initial call, the FDA will make specific data requests and then follow up with additional calls and letters to confirm information or request additional details.

It sounds like the FDA wants to avoid the type of shortage problem with devices that has occurred with drugs.

FDA may meet with device companies before ordering postmarket studies

According to a report in ***The Gray Sheet***, the FDA's Center for Devices and Radiological Health (CDRH) appears open to an industry suggestion for "pre-522" meetings as a way to make postmarket study mandates quicker and more efficient. The FDA has the authority to require Section 522 studies, the technical name for postmarketing studies for Class II or III devices. The affected devices are life-sustaining or life-supporting, implanted in the body for ≥1 year, and have significant pediatric uses, or ones where failure is likely to lead to serious health consequences.

FDA approvals/clearances

- **BAYER HEALTHCARE PHARMACEUTICALS' Natazia** (dienogest and estradiol), an oral contraceptive, was granted a new indication – treating heavy menstrual bleeding in women not diagnosed with any medical condition affecting the uterus.
- **EFFRX PHARMACEUTICALS' Binosto** (alendronate sodium), an effervescent formulation, was approved to treat osteoporosis in postmenopausal women and to increase bone mass in men.
- **K2M's Santorini Corpectomy Cage System** was granted 510(k) clearance to replace collapsed, damaged, or unstable vertebral bodies.
- **MAINE STANDARDS' Validate Vit D calibration test kit**, which helps laboratories perform calibration verification and linearity tests on vitamin D tests being marketed, received 510(k) clearance.
- **ORGANOGENESIS' Gintuit**, a cell-based product (that combines donated skin cells in a bovine collagen) designed to replace receding gum tissue during dental gum surgeries, was approved.
- **SIENTRA's Silimed silicone breast implants** – including shaped as well as round implants – were approved, but the company must conduct postmarketing studies on long-term safety and effectiveness.
- **SURGITOOLS' Singh Colpotomizer System**, which provides visualization for surgeons during total laparoscopic hysterectomies, received 510(k) clearance.

FDA recalls/warnings

- **Brilliant Blue G compounded at FRANCK'S LAB** – The FDA issued an urgent recall because of suspected contamination after reports of patients developing fungal infections in the eye.

- **I.E.M. GMBH** received a warning letter from the FDA that its Germany plant, which manufactures blood pressure monitors, does not have adequate adverse event reporting procedures.
- **JOHNSON & JOHNSON/ETHICON/ACCLARENT's Inspira AIR Balloon Dilation System** was recalled (a Class I recall) because it may fail to deflate or may deflate slowly. There have been reports of at least one patient injury.
- **WARNER CHILCOTT:**
  - **Ovcon 50** (norethindrone and ethinyl estradiol tablets). The FDA sent a warning letter saying that the company did not fully investigate the reason some batches of this oral contraceptive failed in stability tests and asked the company to submit a plan for ensuring that its products will meet shelf-life expectations.
  - **Puerto Rican plant.** The FDA said the company's manufacturing plant in Puerto Rico is not in compliance with cGMP, and the company's corrective actions have been insufficient.

European regulatory actions

- **IMTHERA MEDICAL's aura6000**, a system for treating obstructive sleep apnea (OSA) by focused neurostimulation on certain muscles of the tongue during sleep, received a CE Mark. The company plans to start selling it later this year.
- **QUIDEL's Quidel Molecular RSV + hMPV assay** for diagnosing human metapneumovirus and respiratory syncytial virus (RSV) received a CE Mark.

U.K.'s National Institute for Health and Clinical Excellence (NICE) News

- **BAYER and JOHNSON & JOHNSON's Xarelto (rivaroxaban)** – NICE asked for more information on the clinical efficacy and cost-effectiveness of this anticoagulant for the treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT. Previously, NICE asked for additional information on Xarelto for stroke prevention in atrial fibrillation.
- **BOEHRINGER INGELHEIM's Pradaxa (dabigatran)** – NICE recommended reimbursement for this anticoagulant to prevent stroke and systemic embolism in atrial fibrillation patients as a "useful alternative option" to warfarin, but NICE said patients should be informed about the drug's risks and benefits vs. warfarin before starting therapy.
- **JOHNSON & JOHNSON's Zytiga (abiraterone)** – NICE did not approve this prostate cancer drug for use by the National Health Service in England, but regulators in Wales approved it there.
- **NOVARTIS' Gilenya (fingolimod)** – NICE changed its mind and decided that this oral multiple sclerosis (MS) therapy should be reimbursed for patients with highly active relapsing-remitting disease.

Regulatory news from other countries

- **Canada:** Canada hopes that approving critical medications faster than usual will help alleviate drug shortages. Health Minister Leona Aglukkaq said, "We are fast tracking approvals for products, including those produced abroad and approved by trusted counterparts. We are working with our international partners to share safety data to help speed up our review."
- **Canada: MEDTRONIC's Deep Brain Stimulation device**, which is used to treat epilepsy, was approved by Health Canada. It has a CE Mark but is not yet FDA-approved.
- **India: BAYER's Nexavar (sorafenib)** – Bayer was ordered to license a generic version of Nexavar to Natco Pharma because the brand price (~$5,600/month) was "unaffordable." The Natco generic is expected to cost ~$175/month. This is reportedly the first compulsory license in India of a patented drug. *The concern is this could lead to other compulsory licenses in India and elsewhere.*
- **Japan:** Regulators may allow seriously ill patients access to medical treatments approved in other countries (e.g., U.S. and Europe) but not in Japan under a compassionate use system if they haven't responded to standard therapy. In addition, the government may allow insurance companies to pay for some of the compassionate use therapies. The proposal will require new legislation, so it won't be implemented quickly.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	March 2012	
March 20	**GlaxoSmithKline's Votrient** (pazopanib) for advanced soft-tissue sarcoma (in the morning), and **Merck/Ariad's Taltorvic** (ridaforolimus) for maintenance therapy of metastatic soft-tissue sarcoma or bone sarcoma (in the afternoon)	FDA's Oncologic Drugs Advisory Committee (ODAC)
March 21	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	FDA's Oncologic Drugs Advisory Committee (ODAC)
March 22-23	Consideration of **broadening the eligibility for changing prescription drugs to over-the-counter medications**	FDA public meeting
March 23	Risk:benefit of **Stryker's Wingspan**, a self-expanding nitinol stent already in use under an HDE for treatment of intracranial arterial stenosis	FDA's Neurological Devices Advisory Committee
March 26	**MAP Pharmaceuticals' Levadex** (dihydroergotamine inhalation) for migraine	PDUFA date
March 26-27-28	Oral arguments on the **legality of Obamacare**	U.S. Supreme Court
March 27	**Affymax and Takeda's peginesatide** for anemia	PDUFA date
March 27	**Shire's Replagal** (agalsidase alfa) to treat Fabry disease	**Canceled** FDA's Cardiovascular and Renal Drugs Advisory Committee
March 28	**Chelsea Therapeutics' Northera** (droxidopa) for symptomatic neurogenic orthostatic hypotension with primary autonomic failure	PDUFA date
March 28	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS expected to publish National Coverage Decision (NCD) memo
March 28-29	Two-day discussion of pre-and post-approval assessment of **cardiovascular safety for diet drugs and biologics**	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
	April 2012	
April 2	Types of consumer studies needed to assess proper use of a **MedKit containing doxycycline** in the event of **anthrax exposure**	FDA's Anti-Infective Drugs Advisory Committee meeting jointly with the Non-Prescription Drugs Advisory Committee
April 3-4	**Pneumonic plague** discussion: animal models, ciprofloxacin efficacy and safety, **Johnson & Johnson's Leaquin** (levofloxacin) safety and efficacy	FDA's Anti-Infective Drugs Advisory Committee
April 5	**Astellas' Betanis** (mirabegron), a beta-3-adrenoceptor agonist to treat overactive bladder (OAB)	FDA's Reproductive Health Drugs Advisory Committee
April 11	**U-Systems' Automated Breast Ultrasound (ABUS) scanning device** for breast cancer detection in asymptomatic dense-breasted women	FDA's Radiological Devices Advisory Committee
April 12	Possible reclassification of **breast transilluminators**, which are currently pre-amendment Class III devices, and **blood irradiators**	FDA's Radiological Devices Advisory Committee
April 17	**Vivus' Qnexa** (phentermine + topiramate) for weight loss	PDUFA date for resubmission
April 18	Use of minimal residual disease as a biomarker for evaluating new drugs to treat **acute lymphoblastic leukemia (ALL)**	FDA public workshop in conjunction with the American Society of Clinical Oncology (ASCO)
April 25	**Takeda's alogliptin**, a DPP-4 for Type 2 diabetes	PDUFA date
April 25	**HeartWare's HVAD** left ventricular assist device	FDA's Circulatory System Devices Advisory Committee
April 26	**Amgen's Xgeva** (denosumab) for prevention/delay of bone metastases in castration-resistant prostate cancer	PDUFA date
April 26	Topic **TBA**	FDA's Circulatory System Devices Advisory Committee
April 27	**Salix Pharmaceuticals and Progenics Pharmaceuticals' Relistor** (methylnaltrexone injection) for opioid-induced constipation	PDUFA date
April 29	**Vivus' avanafil** for erectile dysfunction	PDUFA date
April 30	**Baxter and Halozyme's HyQ** for immunodeficiency	PDUFA date

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	Other 2012	
2Q12	**Arena Pharmaceutical and Eisai's Lorqess** (lorcaserin) for weight loss	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
May 1	**Protalix Biotherapeutics' taliglucerase alfa**, an investigational Gaucher disease drug	PDUFA date
May 4	**Alexza Pharmaceuticals' Adasuve** (loxapine inhalation powder) for the acute treatment of agitation associated with schizophrenia/bipolar I disorder	PDUFA date
May 8	**Regeneron Pharmaceuticals' Arcalyst** (rilonacept), an interleukin-1 inhibitor to prevent gout flares during initiaton of uric acid-lowering therapy	FDA's Arthritis Advisory Committee
May 9	**Pfizer's tofacitinib**, an oral JAK inhibitor, to treat rheumatoid arthritis	FDA's Arthritis Advisory Committee
May 10	**Gilead Sciences' Truvada** (emtricitabine + tenofovir) for HIV prevention	FDA's Antiviral Drugs Advisory Committee
May 13	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	PDUFA date
May 16-17	**Natural history studies of rare diseases:** meeting the needs of drug development and research	FDA workshop
May 22-23 (?)	**Bristol-Myers Squibb's Eliquis** (apixaban), an anticoagulant for prevention of stroke in AFib, and **Johnson & Johnson's Xarelto** (rivaroxaban), an anticoagulant for a supplemental indication in acute coronary syndrome (ACS)	FDA's Cardiovascular and Renal Drugs Advisory Committee (*Neither of these are official yet and which one is which day is uncertain but both are expected.*)
May 30-31	Discussion of **analgesic treatment of chronic pain** – mechanisms, epidemiology, new data on opioid efficacy, etc.	FDA Public Workshop
June	**Forest Laboratories and Ironwood Pharmaceuticals' linaclotide** for IBS-C	PDUFA date
June 5	**Salix Pharmaceuticals' crofelemer** for HIV-related diarrhea	PDUFA date
June 8	**Roche/Genentech's pertuzumab** in HER2+ advanced breast cancer	PDUFA date
June 15	**Gilead Sciences' Truvada** (emtricitabine + tenofovir) for HIV prevention	PDUFA date
June 25	**QRxPharma's MoxDuo** (morphine + oxycodone)	PDUFA date
June 26	**Edwards Lifesciences' Sapien** transcatheter aortic valve	CMS final NCD expected
June 28	**Bristol-Myers Squibb's Eliquis** (apixaban), an anticoagulant for the prevention of stroke in AFib	PDUFA date
June 29	**Astellas Pharma's mirabegron** for treatment of overactive bladder	PDUFA date
July 26	**Amarin's AMR-101** (omega-3 fish oil EPA) to treat hypertriglyceridemia	PDUFA date
July 26	**Horizon Pharma's Lodotra** (low-dose prednisone) for rheumatoid arthritis	PDUFA date
July 27	**Onyx Pharmaceuticals' carfilzomib** for multiple myeloma	PDUFA date
July 30	**Regeneron's Arcalyst** (rilonacept) for gout	PDUFA date
August 21	**Pfizer's tofacitinib**, an oral JAK2 inhibitor for rheumatoid arthritis	PDUFA date
August 27	**Gilead Sciences' Quad** (emtricitabine + tenofovir + elvitegravir + cobicistat) for HIV	PDUFA date
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 29	**Cornerstone Therapeutics' CRTX-800** to treat hyponatremia	PDUFA date