TRENDS-in-MEDICINE

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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…

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NOTE: Subscribe to ***Trends-in-Medicine*** for coverage of the **Conference on Retroviruses and Opportunistic Infections** (CROI) in Atlanta and the **American College of Cardiology** (ACC) meeting in San Francisco.

SHORT TAKES

- **ACELRX PHARMACEUTICALS' Sufentanil NanoTab –** The company announced that this drug-device combination, a patient-controlled analgesia for post-operative pain, met the primary endpoint in a Phase IIIa trial in 178 abdominal surgery patients. At 48 hours, Sufentanil patients had a significantly greater reduction in pain vs. placebo.

- **ALLSCRIPTS** bought two privately held healthcare information technology (HIT) firms – **dbMotion**, which provides a strategic platform for combining information from many IT sources into a single patient record, and **Jardogs**, which develops programs such as a secure messaging system and a prescription-drug reordering function.

- **AMAG PHARMACEUTICALS' Feraheme (ferumoxytol) –** The company said the FDA accepted its supplemental new drug application (sNDA) for a broader indication to include patients with iron deficiency anemia who failed or can't take oral iron treatments. The PDUFA date is October 21, 2013.

- **CELGENE's apremilast –** The 844-patient Phase III ESTEEM-1 trial, presented at the American Academy of Dermatology meeting, found that this investigational phosphodiesterase-4 (PDE4) inhibitor improved psoriasis, particularly for naïve patients, with 33.1% of apremilast patients vs. 5.3% of placebo patients achieving PASI75 ($p \leq 0.0001$) at Week 16. In addition, 59% of apremilast patients vs. 17% of placebo patients had a 50% reduction in symptoms.

- **DEPOMED's Sefelsa (extended-release gabapentin) –** The FDA's Reproductive Health Drugs Advisory Committee voted 13-1 that it was not effective in treating non-hormonal hot flashes in menopausal women, with three trials failing to show a significant reduction in hot flashes over 12 weeks. The panel also voted 12-2 against recommending approval of this drug. The PDUFA date is May 31, 2013.

- **EDWARDS LIFESCIENCES' Sapien –** The FDA is considering the company's request to extend the patent on this transcatheter aortic valve by almost five years (1,757 days). The FDA is accepting public comments on the request through April 23, 2013.

- **Head and neck cancer –** Targeted therapies have failed to work in prostate cancer, and they aren't any more successful in head and neck cancer. A study published in the ***Journal of Clinical Oncology*** reported on trials of two targeted agents that failed in

head and neck cancer: **AstraZeneca's Iressa** (gefitinib) + docetaxel and **Roche/Genentech's Tarceva** (erlotinib) + cisplatin-based chemoradiation.

- **HIKMA PHARMACEUTICALS** is considering selling its injectable drug business.

- **HISAMITSU PHARMACEUTICAL/NOVEN PHARMACEUTICALS' Pexeva (paroxetine mesylate)** – The FDA's Reproductive Health Drugs Advisory Committee voted 10-4 against recommending approval of this low-dose SSRI antidepressant as a treatment for non-hormonal hot flashes in menopausal women. The panel said that it was not clear whether the drug was superior to placebo. The PDUFA date is June 28, 2013.

- **JOHNSON & JOHNSON and BAYER's Xarelto (rivaroxaban)** – For the second time, the FDA turned down an sNDA for this Factor Xa inhibitor to treat patients with acute coronary syndrome (ACS).

- **JOHNSON & JOHNSON/DEPUY's ASR hip implant** – The jury in the first trial over the safety of this recalled metal-on-metal hip implant found the company negligent by marketing a defective product and awarded the defendant $8.3 million in damages, less than the $100+ million sought. The jury found that the design of the implant was faulty but did not believe the company covered up the data. J&J plans to appeal the verdict.

- **LA JOLLA PHARMACEUTICAL's LJPC-501** – The FDA's Division of Cardiovascular and Renal Products told the company that there are enough data to support an investigational new drug (IND) application for this agent to treat patients with hepatorenal syndrome, a life-threatening form of kidney failure in patients with serious liver disease. LJPC-501 helps the kidneys balance fluids and electrolytes.

- **MEDICIS PHARMACEUTICAL/UCYCLYD PHARMA's Buphenyl (phenylbutyrate)** – A study published in ***Science Translational Medicine*** found that this orphan drug may be effective against lactic acidosis as well as the approved metabolic disorder, "maple syrup urine disease."

- **PAR PHARMACEUTICAL** will be operating under a corporate integrity agreement (CIA) with the Justice Department for the next five years. That's part of the punishment for charges it criminally misbranded and improperly marketed its weight-gain (anorexia and malnutrition) drug **Megace ES** (megestrol acetate). *A CIA is not easy.*

- **Prostate cancer** – A 254-patient study by U.K. researchers, published in ***The Lancet Oncology***, found that estrogen patches may be a cheaper and safer treatment for prostate cancer than an LHRH (luteinizing hormone-releasing hormone). The researchers found the estrogen patches were safe and avoided the menopause-like side effects of LHRH antagonists and seem to produce the same castration level of testosterone. A >600-patient trial is now underway to confirm these findings.

- **RXI PHARMACEUTICALS** is acquiring **OPKO Health**'s RNA interference (RNAi) assets, which include vascular endothelial growth factor (VEGF), hypoxia-inducible factor 1-alpha (HIF-1-alpha), intracellular adhesion molecule 1 (ICAM-1), angiopoietin 2 (Ang2), and complement component 3 (C3).

- **ROCHE** and **BIOLAMINA** are collaborating on research and development of novel cell culture systems for various applications, including stem cell research. Roche will provide R&D funding and scientific expertise to BioLamina.

- **Sickle cell disease** – In a study published in ***Nature Medicine***, University of Michigan researchers reported that a 50-year-old antidepressant, Parnate (tranylcypromine), may reduce the effects of sickle cell disease. A 15-patient Phase I safety trial is planned.

- **UCB's Vimpat (lacosamide)** – The company announced that a Phase III trial of the drug as monotherapy for epilepsy was positive, and it plans to submit the data in support of a supplemental indication. It is already approved as adjunctive therapy for partial-onset seizures in adults with epilepsy.

NEWS IN BRIEF

ALLERGAN

- **Aczone (dapsone).** A placebo-controlled study presented at the American Academy of Allergy, Asthma, & Immunology (AAAAI) meeting found that this antibiotic is beneficial for chronic idiopathic urticaria that is refractory to high-dose antihistamines, but larger studies are needed to confirm the findings and determine the optimal dose and duration of therapy.

- **Lap-Band.** It's official. Allergan has decided to sell its Obesity Intervention Division, which includes Lap-Band.

BIOGEN IDEC's Tysabri (natalizumab) – early PML diagnosis can make a difference

A 319-patient study to be presented at the American Academy of Neurology meeting later this month suggested that early detection of progressive multifocal leukoencephalopathy (PML), a devastating side effect of Tysabri, improves the survival and leads to less disability. Patients who were diagnosed

and treated before symptoms became evident appeared to do better. As of January 1, 2013, all of the 21 people (100%) with no symptoms at the time of PML diagnosis were living, vs. 77% of symptomatic patients.

Electronic health records – survey and HHS agenda

- **EHRs.** The results of a survey of 49 community practices in a large EHR pilot in Massachusetts – published in ***Health Affairs*** – found that the average doctor will lose $43,743 in the first five years after EHR implementation. The study also found that only 27% of practices would see a positive return on their EHR investments within five years. Another 14% could turn a profit if they met the meaningful use requirements. The study found that doctors who use EHRs to improve billing or see more patients were more likely to see a positive return.
- **HHS 2013 HIT agenda.** Centers for Medicare and Medicaid Services (CMS) Acting Administrator Marilyn Tavenner and National Coordinator for Health Information Technology Farzad Mostashari, MD, announced a plan to accelerate health information exchanges (HIEs). The Department of Health and Human Services (HHS) said that this year:
  - The goal is for 50% of physician offices to be using an EHR by the end of this year.
  - Another goal is to have 80% of eligible hospitals receiving meaningful use incentive payments by the end of 2013.
  - There will be an increased emphasis on interoperability.
  - Rules will be implemented defining what is required in Meaningful Use Stage 2.

European CVD reporting – standardization effort

The European Society of Cardiology is creating an inventory of cardiovascular disease (CVD) registries and a task force on data standardization so that data from different registries can be compared. The registry inventory is intended to serve as a single entry point for people looking for real-life data on cardiovascular diseases – and to avoid duplication of data collection in Europe.

GENOMINE – RCC biomarkers identified

Data published in ***Cancer Epidemiology, Biomarkers & Prevention***, a journal of the American Association for Cancer Research, found that an assay developed by this Korean company and South Korean researchers successfully used a trio of biomarkers to identify early-stage kidney cancer. The researchers measured the levels of three potential biomarkers: nicotinamide N-methyltransferase (NNMT), L-plastin (LCP1), and nonmetastatic cells 1 protein (NM23A) in 102 healthy controls and 87 RCC patients. All three biomarkers were highly elevated in patients with kidney cancer, and the assay was highly accurate in distinguishing between healthy controls and renal cell carcinoma (RCC) patients. The company is working toward FDA approval for the assay.

NOVARTIS' Miacalcin and UNIGENE LABORATORIES and UPSHER-SMITH LABORATORIES' Fortical (calcitonin salmon nasal sprays) – neither safe nor effective

FDA reviewers found an increased risk of prostate cancer in male patients receiving an oral form of calcitonin salmon, leading the FDA to convene a joint meeting of its Reproductive Health Drugs Advisory Committee and its Drug Safety and Risk Management Advisory Committee. The panel recommended use of these osteoporosis treatments be stopped because they don't work and may increase the risk of cancer. The panel voted 12-9 that the risks outweigh the benefits.

Last summer the European Medicines Agency (EMA) recommended against using these products long term after a study found a slightly higher increased risk of cancer in patients on long-term therapy. Health Canada also warned about the possible risk of cancer with long-term use.

The panel also voted 20-1 that biotech versions of new calcitonin salmon products must be studied in clinical trials to demonstrate that they reduce the risk of fracture.

QUESTCOR PHARMACEUTICALS' Acthar (adrenocorticotropic hormone, ACTH) – small trial shows efficacy with monthly pulse dosing

A 23-patient study to be presented at the American Academy of Neurology meeting later this month found that ACTH may be helpful for people whose multiple sclerosis (MS) is not well-controlled with the current treatment. In patients already on beta-interferon who have "breakthrough MS" – a relapse or brain scan showing new disease activity – monthly pulse ACTH for 12 months was more effective than monthly pulse methylprednisolone.

Over 15 months, ACTH patients had 0.08 relapses per patient vs. 0.8 relapses per patient with methylprednisolone. Psychiatric side effects were also much lower with ACTH (0 vs. 0.55 episodes per patient).

Restless legs syndrome – what's the best therapy?

Meta-analyses by University of Minnesota researchers – sponsored by the Agency for Healthcare Research and Quality (AHRQ) and published in ***JAMA Internal Medicine*** – compared the efficacy of different therapies for restless legs syndrome. This was not a head-to-head comparison, but the results were informative:

- Both classes of drugs were effective.
- The most effective dopamine agonist was rotigotine, but it also had the highest withdrawal rate for adverse events.
- The most effective calcium channel alpha-2-delta ligand was **GlaxoSmithKline** and **XenoPort's Horizant** (gabapentin enacarbil). **Pfizer's Lyrica** (pregabalin) was not significantly better than placebo.

Meta-Analyses of Restless Legs Syndrome Therapies

Measurement	Calcium channel alpha-2-delta ligands	Dopamine agonists
Number of trials in analysis	7	18
Responders (≥50% reduction in symptoms) vs. placebo	61% vs. 37% NNT 4.1	61% vs. 41% NNT 4.9
Very much or much improved vs. placebo	74% vs. 44% NNT 3.2	68% vs. 46% NNT 4.4
Adverse events	Somnolence, dizziness, and dry mouth	Discontinuation for adverse events: 10% vs. 6%, mostly nausea, vomiting, sleepiness

ROCHE/GENENTECH

- **Erivedge (vismodegib, GDC-0449).** A study presented at the American Academy of Dermatology meeting found that surgical removal of basal cell carcinoma lesions caused less scarring in patients who received neoadjuvant treatment with this hedgehog inhibitor, made in partnership with **Curis**. The lesion defect decreased by ~50% and the surgical defect by ~40%.
- **Rituxan (rituximab).** A study by French researchers, published in ***Science Translational Medicine***, found that Rituxan effectively cured most cases of pemphigus, a rare and deadly skin disease, suggesting that Rituxan could ultimately become the standard therapy in place of steroids. A larger trial of front-line therapy vs. steroids is underway.

REGULATORY NEWS

FDA forms Office of Computational Science

The Office of Computational Science (OCS) was formed to oversee the Center for Drug Evaluation and Research's (CDER's) scientific computing operations. CDER's Computational Science Center (CSC), which aims to make study analysis and evaluation more efficient, will be managed by OCS. Janet Woodcock, MD, director of CDER said, "OCS will enhance the accessibility of data, strive to reduce data integrity issues, and support robust data governance. It will help to improve coordination and prioritization of CDER's scientific computing plans and activities. Through OCS, we are emphasizing the importance of coupling data, tools, and technology with reviewer-focused training."

FDA issues new rules on pulse oximeter submissions

The FDA updated its guidelines for premarket notification applications for pulse oximeters, outlining how manufacturers need to identify, test, and verify the safety of their devices when preparing 510(k) submissions.

FDA looking for HIT volunteers

In an FDA blog, **Bakul Patel, MS, MBA**, a policy advisor in the FDA's Office of the Center Director, Center for Devices and Radiological Health (CDRH), said the FDA put out a last-minute call for volunteers to serve on a working group to help develop the congressionally man-dated report on a risk-based regulatory framework for healthcare information technology (HIT). The deadline for nominations was March 8, 2013.

Among the issues the working group will be addressing are:

- How to protect patient privacy.
- How to make sure the information is accurate.
- How to foster efficiency and curtail costs in the way information such as a radiological image is sent to an iPad in a pediatrician's office outside the U.S.

FDA reorganizes its oversight of drug advertising

Instead of separate divisions for consumer advertising (the Division of Consumer Drug Promotion) and healthcare promotional labeling and advertising (the Division of Professional Drug Promotion), the FDA is reorganizing its Office of Prescription Drug Promotion (OPDP), combining consumer and professional advertising/promotional oversight. There will still be two divisions – the Division of Advertising and

Promotion Review I and the Division of Advertising and Promotion Review II – but now the divisions will each have oversight of different therapeutic classes of drugs.

FDA urged to be more transparent

A coalition called OpenTheGoverment.org is asking the FDA to overturn a policy that it uses to withhold details about drugs and medical devices from the public by blacking out sections of federal documents before releasing them under Freedom of Information Act (FOIA) requests. The FDA reportedly is reviewing a formal request to overturn the policy.

OIG urges CMS to boost oversight of formulary committees and sponsors

The Office of the Inspector General (OIG) released a report recommending that CMS:

- Take steps to improve its oversight of pharmacy and therapeutics (P&T) committees.
- Set standards for the oversight of conflicts of interest involving P&T committees and sponsors (the private insurers that contract with the CMS to administer drug coverage under Part D).

The OIG found that 53% of P&T committees said their conflict-of-interest definitions did not include financial interests with sponsors or drug manufacturers; 33% said they did not define financial interests in pharmacy benefit managers (PBMs) as conflicts; and 59% of sponsors' P&T committees allowed members to determine their own conflicts and recusals.

Physician payments – do away with fee-for-service?

The 14-member National Commission on Physician Payment Reform recommended changing the way physicians are paid and discouraging incentives that can lead to higher costs and higher volumes of care. The biggest change: Do away with fee-for-service payments to doctors by 2020.

Among their other recommendations:

- Annual payment updates should include evaluation and management diagnostic codes, which the panel said are undervalued.
- Eliminate higher payments for facility-based services that can be performed in a lower-cost setting.
- Make fixed payments where there is significant potential for cost savings – e.g., people with multiple chronic conditions and in-hospital procedures and their follow-up.
- Include quality metrics in negotiated reimbursement rates in fee-for-service contracts.
- Eliminate the sustainable growth rate (SGR) formula.
- Have more transparency in decision making by Medicare's Relative Value Scale Update Committee (RUC) and make CMS less dependent on the RUC.

Steven Schroeder, MD, commission chair and professor of internal medicine at the University of California San Francisco, told ***MedPage Today***, "Evaluation and management (E&M) services are relatively undercompensated, and the technological services are relatively overcompensated."

FDA approvals/clearances

- **JOHNSON & JOHNSON/LIFESCAN's OneTouch VerioSync system**, which wirelessly monitors blood glucose in diabetics, was cleared for use.
- **ROCHE's COBAS AmpliPrep/COBAS TaqMan HCV Test**, v2.0, a next-generation *in vitro* nucleic acid amplification test for evaluating response to HCV therapy, was approved.
- **SIEMENS HEALTHCARE's Artis Q and Artis Q.zen angiography devices** were cleared for use.
- **TOSHIBA MEDICAL SYSTEMS/VITAL IMAGES' CT TAVR planning application** received 510(k) clearance. The app allows doctors to image and measure the vascular anatomies in patients undergoing transcatheter aortic valve replacement (TAVR).

FDA recalls/warnings

- **AD-TECH MEDICAL INSTRUMENT's Macro Micro Subdural Electrodes** – A Class I recall was initiated due to concerns that the microelectrodes, which are used on epilepsy patients for the recording, monitoring, and stimulation of electrical signals on the surface level of the brain, are defective and could cause injury to the brain. The FDA said there has been at least one possibly related serious injury.
- **CRYOLIFE** received a warning letter that its manufacturing plant was not in compliance with current Good Manufacturing Practice (cGMP) requirements. In particular, FDA inspectors were concerned with disinfection practices, sterility, and contamination. And the Agency was not happy with most of the company's responses to its complaints.
- **HOSPIRA** received a warning letter that listed 20 production and quality issues at its Rocky Mount NC plant, a few of which were the same as inspectors found three years ago.

Hospira claims none of the issues is safety-related. However, two other Hospira plants (Clayton NC and Costa Rica) were cited for similar violations of cGMP that ultimately led to production shutdowns, contributing to the drug shortage problem.

- **IMPAX LABORATORIES** – FDA inspectors completed a reinspection and identified 12 different problems at the company's Hayward CA plant.
- **LASER ENERGETICS' Dazer Laser Defender model family and Dazer Laser Guardian model family** – The company received a warning letter from the FDA that it is not in compliance with FDA regulations and has not provided product reports or annual reports, has uncorrected defects in its products, and is not in compliance with limits on the device class – and may not ship any lasers until it is in compliance. The FDA also wrote, "Your internet website states that your products have military applications. It is the CDRH's position that CDRH will not grant variances for products that allow the products to also be sold to the Department of Defense (DoD)…[You] must seek prior authorization from a DoD contracting officer."

European regulatory news

- **GLAXOSMITHKLINE's Eperzan (albiglutide)**, a once-weekly GLP-1 agonist, was submitted to the EMA for approval to treat Type 2 diabetes.
- **MEDTRONIC's Attain Performa quadripolar leads**, which are used with the company's Viva/Brava cardiac resynchronization therapy defibrillators (CRT-Ds), received a CE Mark.
- **MERCATOR MEDSYSTEMS' Cricket and Bullfrog micro-infusion catheters**, which are used to deliver drugs straight to deep tissue through blood vessel walls, received CE Marks.
- **ONCOASSIST's ONCOassist app**, a smartphone application designed to give oncologists mobile access to point-of-care clinical decision support tools, received a CE Mark. Right now, the app is only for the iPad and the iPhone, but the company plans to have an Android version in 6-12 months.
- **ROCHE's Perjeta (pertuzumab)** – The EMA approved this antibody to treat previously untreated HER2+ metastatic breast cancer in combination with Roche's Herceptin (trastuzumab) and docetaxel.
- **SILENCE THERAPEUTICS' ATU-027** – Germany's Federal Institute for Drugs and Medical Devices gave the company the go-ahead to conduct a trial of this investigational treatment in pancreatic cancer in combination with **Lilly's Gemzar** (gemcitabine).
- **WERFEN LIFE GROUP/BOLTON MEDICAL's Treovance system**, a stent graft used to treat abdominal aortic aneurysms, received a CE Mark.

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

NOVARTIS' Xolair (omalizumab) – NICE announced that it is changing its mind and plans to recommend approval of this asthma drug to treat severe allergic asthma attacks, after recommending against it in November 2012. An additional analysis on the safety in children and adolescents combined with the company's patient-access scheme (PAS) and a price discount apparently convinced NICE.

Regulatory news from other countries

- ***Canada:*** **VERTEX PHARMACEUTICALS' Incivek (telaprevir)** – Health Canada issued a warning about the possibility of serious skin reactions with this hepatitis C virus (HCV) drug.
- ***China:*** The government is likely to form a combined food and drug regulatory agency as part of an ongoing restructuring effort. Currently, oversight is handled by up to 13 different agencies, including the State Food and Drug Administration.
- ***Greece:*** More than 50 pharmas stopped shipping drugs to Greece, which is creating drug shortages there. The president of the National Organization for Medicines in Greece said the pharma action is due to (1) Greece not being a profitable market for them, (2) concern that the drugs will be exported to other, richer countries, and (3) the country's pricing system is problematic.
- ***Japan:*** **JOHNSON & JOHNSON and MEDIVIR's simeprevir (TMC-435)** – This NS3/4A protease inhibitor was submitted to the Japanese Ministry of Health, Labour, and Welfare to treat patients with genotype 1 HCV – who are treatment-naïve prior non-responders/relapsers – with simeprevir (a once-daily oral pill) in combination with pegylated interferon and ribavirin.

2013 FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
March 14	Discussion of the FDA's **draft risk assessment model** for potential exposure to the variant **Creutzfeldt-Jakob disease (vCJD) agent in red blood cells for transfusion** in the U.S.	FDA's Transmissible Spongiform Encephalopathies Advisory Committee
March 17	**Bristol-Myers Squibb** and **Pfizer's Eliquis** (apixaban,) an oral anticoagulant to prevent stroke in atrial fibrillation patients	PDUFA date
March 18	**Pharmaxis' Bronchitol** (mannitol) for cystic fibrosis	PDUFA date
March 20	**Abbott's MitraClip** for mitral valve repair	FDA's Circulatory System Devices Advisory Committee
March 21	**Titan Pharmaceuticals' Probuphine** (buprenorphine subdermal implant) to treat opioid dependence	FDA's Psychopharmacologic Drugs Advisory Committee
March 22	**Cangene's BAT** (botulinum antitoxin), an anti-bioterrorism agent	PDUFA date
March 28	**Biogen Idec's BG-12** (dimethyl fumarate) for multiple sclerosis	PDUFA date (extended from December 28, 2012)
March 31	**Johnson & Johnson's Invokana** (canagliflozin), a SGLT2 inhibitor to treat Type 2 diabetes	PDUFA date
April 8	**Bausch & Lomb's Trulign Toric** implantable intraocular lens for post-cataract surgery patients	FDA's Ophthalmic Devices Advisory Committee
April 11	Potential effects of extreme weather and natural disasters on **medical device safety and quality**	FDA's Device Good Manufacturing Practice Advisory Committee
April 15	**MAP Pharmaceuticals' Levadex** (dihydroergotamine), inhaled migraine drug	PDUFA date
April 25	Reclassification of **methotrexate enzyme immunoassays, phencyclidine (PCP) enzyme immunoassays, and PCP radioimmunoassays**	FDA's Clinical Chemistry and Clinical Toxicology Devices Advisory Committee
April 26	Reclassification of **isoniazid test strips**	FDA's Clinical Chemistry and Clinical Toxicology Devices Advisory Committee
April 29	**Shire's Vyvanse** (lisdexamfetamine dimesylate), sNDA for ADHD treatment in children	PDUFA date
April 29-30	Discussion of **medical device labeling standardization**, including an online labeling repository for in-home medical devices	FDA public workshop
April 30	**Raptor Pharmaceutical's Procysbi** (cysteamine bitartrate delayed-release, RP-103) to treat nephropathic cystinosis	PDUFA date (extended from January 30, 2013)
May 2	**Aveo and Astellas' Tivopath** (tivozanib) for advanced renal cell carcinoma	FDA's Oncologic Drugs Advisory Committee
May 12	**GlaxoSmithKline** and **Theravance's Breo/Relvar** (fluticasone furoate + vilanterol) to treat chronic obstructive pulmonary disease (COPD)	PDUFA date
May 31	**Depomed's Sefelsa** (gabapentin extended-release), a hot-flash treatment (formerly known as Serada)	PDUFA date
June 20	**Dainippon Sumitomo Pharma/Sunovion Pharmaceuticals' Latuda** (lurasidone), a schizophrenia drug for use in treating bipolar disorder	PDUFA date
June 28	**Hisamitsu Pharmaceutical/Noven Pharmaceuticals' Pexeva** (paroxetine mesylate), a low-dose SSRI antidepressant to treat non-hormonal hot flashes in menopausal women	PDUFA date
July tba	**PET imaging** of brain beta-amyloid	CMS coverage decision expected
July 28	**Aveo Oncology** and **Astellas Pharma's Tivopath** (tivozanib) to treat advanced renal cell carcinoma	PDUFA date
August 17	**ViiV Healthcare's dolutegravir** for HIV	PDUFA date
October 2	**Lundbeck** and **Takeda's Brintellix** (vortioxetine), an antidepressant for major depressive disorder	PDUFA date
October 3	**Pfizer** and **Ligand Pharmaceuticals' Aprela** (bazedoxifene/conjugated estrogens) to treat menopausal symptoms and osteoporosis prevention	PDUFA date
October 19	**Actelion's Opsumit** (macitentan), a dual endothelin receptor antagonist to treat pulmonary arterial hypertension	PDUFA date
October 21	**AMAG Pharmaceuticals' Feraheme** (ferumoxytol) expanded indication	PDUFA date
December 18	**GlaxoSmithKline** and **Theravance's Anoro** (umeclidinium bromide + vilanterol) for COPD	PDUFA date