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 Alzheimer's Association International Conference and FDA approval of **Gilead's Truvada** for HIV prevention.

SHORT TAKES

- **ACADIA PHARMACEUTICALS' pimavanserin –** The company said it has redesigned its Phase III trial of this drug to treat psychosis in Parkinson's disease patients. The study will now have only North American patients and will not include mildly psychotic patients. *Will there be a statistical penalty for the changes?*

- **ALNYLAM PHARMACEUTICALS' ALN-TTR02 –** A study in 17 healthy volunteers found that this investigational drug for TTR-mediated amyloidosis reduced levels of the protein that causes the disease by as much as 94% in a dose-dependent manner, with responses starting with a single dose and leading to durable effects. A Phase II trial has begun.

- **BRISTOL-MYERS SQUIBB's brivanib alaninate (BMS-540215)**, a VEGFR-2 inhibitor, missed the primary endpoint in a Phase III trial in advanced hepatocellular carcinoma, failing to show any significant improvement in survival vs. **Bayer's Nexavar** (sorafenib). In December 2011, brivanib failed to show a survival benefit in hepatocellular cancer patients who were intolerant to or had failed Nexavar. Earlier this year, brivanib also failed to improve survival in a trial in metastatic, chemotherapy-refractory colorectal cancer. *Will BMS give up on brivanib?*

- **GLAXOSMITHKLINE** is buying **Human Genome Sciences**, which finally agreed to the deal.

- **GSK and THERAVANCE's Breo (fluticasone furoate/vilanterol)** was submitted to the FDA for approval as a once-daily treatment for asthma and chronic obstructive pulmonary disease (COPD). The long-acting beta agonist, which will be called **Relvar** in Europe, was also submitted to the European Medicines Agency (EMA). It is a replacement for GSK's **Advair** (fluticasone + salmeterol). Breo/Relvar will use a new inhaler called Elliptra.

- **HEMOFARM** said it fixed the contamination issues discovered by the FDA in its aseptic production line, which had halted exports to the U.S.

- **IDO inhibitors and cancer –** Preclinical data published in ***Cancer Discovery*** provide support and a clear genetic rationale for the ongoing clinical trials of inhibitors of indoleamine 2,3-dioxygenase (IDO) to treat recurrent or refractory solid tumors, particularly primary and metastatic lung tumors.

- **Melanoma –** An uncommon mutation of the BRAF gene in melanoma patients responds to MEK inhibitor drugs, according to a Vanderbilt-Ingram Cancer Center

study published in ***Cancer Discovery***. Researchers said the findings provide a rationale for routine screening and therapy in melanoma patients with the BRAF L597 mutation.

- **NESTLÉ** has invested in **Accera**, which the Nestlé Health Science president/CEO said was "our first step in developing our brain health portfolio." Accera makes **Axona**, a shake marketed as a medical food that is supposed to help the brain and has been prescribed to ~30,000 Alzheimer's patients.

- **NOVARTIS/SANDOZ** – The Federal Trade Commission (FTC) ordered Novartis to give up marketing rights to four skin care products as part of its purchase of **Fougera Pharmaceuticals**: calcipotriene for psoriasis; lidocaine-prilocaine cream, a local anesthetic; metronidazole gel for rosacea; and diclofenac sodium for actinic keratosis.

- **OMEROS' OMS-824** – The company notified the FDA it plans to submit an investigational new drug (IND) application in 3Q12 for this investigational phosphodiesterase-10 (PDE10) inhibitor to treat schizophrenia.

- **ONYX PHARMACEUTICALS' Kyprolis (carfilzomib)** received accelerated approval to treat patients with multiple myeloma who have received at least two prior therapies, including treatment with **Takeda's Velcade** (bortezomib) and an immunomodulatory therapy.

- **PAR PHARMACEUTICAL** is being acquired by **TPG**, a private-equity firm – unless Par gets a better offer before August 24, 2012.

- **PSIVIDA's Iluvien (fluocinolone acetate intravitreal insert)** – The company said the FDA gave permission for them to go directly to Phase III with this back-of-the-eye sustained-release eye insert (licensed to **Alimera Sciences**) for treating uveitis, skipping earlier stage trials. However, the the FDA is requiring that the primary endpoint be uveitis recurrence at one year.

- **REPROS THERAPEUTICS' Proellex (telapristone)** – The company said it plans to seek FDA permission soon to start a Phase II trial of this investigational oral therapy for uterine fibroids and endometriosis, testing two doses – 6 mg and 12 mg. In 2009, the FDA stopped a trial because of liver toxicity linked to higher doses, and the company hopes the Agency will at least partially lift that hold.

- **ROCHE/GENENTECH's Avastin (bevacizumab)** – A study published in the ***Canadian Journal of Ophthalmology*** found that patients with inflammatory ocular neovascularization had significant visual improvement and foveal flattening with three years of Avastin. The researchers followed 81 consecutive patients, reporting that best corrected visual acuity was 0.70 with Avastin and 0.43 with placebo ($p<0.001$).

- **ST. JUDE MEDICAL's Riata** – The company announced top-line results from the prospective, 775-patient Riata Lead Evaluation Study conducted in the U.S., Canada, and Japan, saying it found the inside-out erosion seen with these implantable cardioverter defibrillator (ICD) leads occurred most frequently in larger-diameter leads. The rate with 7 Fr leads was 9.3% vs. 24% with 8 Fr leads. The next phase of the study will collect longer-term (2-year) data.

- **SANOFI** signed a research agreement with Brigham and Women's Hospital to study the immunology of Type 1 diabetes, focusing on a target that has shown promise in animal studies.

- **TARO PHARMACEUTICAL INDUSTRIES** rejected a buyout offer from competitor **Sun Pharmaceutical Industries**, saying the bid was too low. Sun already owns two-thirds of Taro.

- **TEVA/CEPHALON's Provigil (modafinil)** – An ***ABC News*** report said that this narcolepsy and sleep apnea drug is being used off-label to boost energy and focus, calling the users a "kind of secret society" and describing the drug as "a hidden edge discovered by some very successful Americans." However, the wife of one of the reporters is a doctor, and he said she told him not to take Provigil off-label. *It is surprising that ABC would report this without any attribution.*

- **VIIV HEALTHCARE's Selzentry (maraviroc)** – The National Institutes of Health announced that it will fund a new, 400-patient, 48-week study – testing three regimens of Selzentry and one regimen of **Gilead's Truvada** (emtricitabine + tenofovir) – to prevent HIV infection.

- **WALGREENS** and **Express Scripts** have settled their dispute and will renew their relationship starting September 15, 2012.

- **ZOGENIX's Zohydro (extended-release hydrocodone)** – The company said the FDA accepted this investigational chronic pain drug for review. The PDUFA date is March 1, 2013.

NEWS IN BRIEF

AMAG PHARMACEUTICALS and TAKEDA's Feraheme (ferumoxytol) – seeking broader label

AMAG reported that a Phase III trial found this IV iron was better at 5 weeks than placebo at increasing hemoglobin levels in patients with all-cause anemia. Feraheme also beat intravenous sucrose in another trial. Based on these results, AMAG plans to submit a supplemental new drug application (sNDA) for a broader indication – to treat iron deficiency anemia *regardless of the underlying cause* – by the end of this year and to make a European submission in 2013. It currently is approved to treat iron deficiency anemia in patients with chronic kidney disease.

ASTRAZENECA's Brilinta (ticagrelor)

- The company is expanding studies of this blood thinner to include patients with peripheral artery disease (PAD). The 11,500-patient EUCLID trial will compare Brilinta 90 mg BID to clopidogrel 75 mg QD in people age ≥50.
- Updated ACCF/AHA guidelines for unstable angina now put this blood thinner on a par with clopidogrel and **Lilly's Effient** (prasugrel) for treating patients with a myocardial infarction (MI) or angina, though aspirin remains the first-line therapy for patients with non-STEMI and unstable angina immediately after hospitalization.

CPAP – effective in milder OSA/daytime sleepiness

A 239-patient, 16-week study published in the ***American Journal of Respiratory and Critical Care Medicine*** found continuous positive airway pressure (CPAP) significantly more effective than sham in patients with mild to moderately severe obstructive sleep apnea (OSA) and daytime sleepiness.

At Week 8, mean change in the Functional Outcomes of Sleep Questionnaire (FOSQ) was 0.89 for actively treated patients and -0.06 for sham-treated patients ($p=0.006$). At Week 16, the mean improvement in FOSQ was 1.73 ($p<0.00001$). Significant improvements with CPAP were also seen in other scores.

Principal investigator Terri Weaver, PhD, RN, from the University of Illinois at Chicago College of Nursing, said, "The improvements we saw were highly significant and clinically relevant."

Electronic health records (EHRs) – more than half the nation's doctors are using them

A survey by the U.S. Centers for Disease Control and Prevention's National Center for Health Statistics found that 55% of U.S. doctors use electronic health records as part of their routine practice. Among the other findings:

- ~75% of doctors said that EHRs play a "meaningful" role in their practice.
- 47% of doctors using an EHR system are "somewhat" satisfied with it.
- 38% of doctors using an EHR system are "very" satisfied with it.
- Nearly half of doctors without an EHR system plan to do so in the coming year.
- >70% said they would buy the same EHR system again.
- 5% of EHR adopters are dissatisfied, and 10% are somewhat dissatisfied.
- The EHR adoption rate is 29% for solo practitioners, 60% for two-physician practices, 62% for 3-10 physician practices, and 86% for groups of 11 doctors or more.

FOREST LABORATORIES' Namenda (memantine) – may improve memory in Down syndrome

A 16-week, 38-patient University of Colorado study found this Alzheimer's drug can boost memory function in Down syndrome patients. Researchers said Namenda improved "verbal episodic memory," such as retaining long lists of vocabulary words, better than placebo. However, there was no improvement in adaptive thinking or most areas of cognitive ability with Namenda. Although researchers called this a major milestone, they said the results need to be confirmed in a larger study.

Gastric bypass – not cost-effective in older veterans

A retrospective Veterans Administration study published in the ***Archives of Surgery*** found that bariatric surgery was not associated with lower healthcare expenditures in the 3 years after the operation in older obese patients. Outpatient, inpatient, and total healthcare spending all spiked around the time of the operation and then fell to levels comparable to the non-surgical group. The researchers compared 847 veterans who underwent bariatric surgery to 847 veterans who didn't. These findings are very different from previous observational analyses conducted in younger, predominantly female cohorts that showed lower healthcare expenditures in the 2-5 years post-surgery.

JOHNSON & JOHNSON

- Purchased privately held **Calibra Medical**, which is developing a wearable three-day insulin patch designed to offer a mealtime insulin dosing option for people with diabetes who take multiple daily injections of insulin.
- **Simponi (golimumab).** The company asked both the FDA and the EMA to expand the indication for this once-monthly subcutaneous rheumatoid arthritis therapy to include patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

LILLY

- **Strattera (atomoxetine).** The FDA added a new warning to the label of this attention-deficit/hyperactivity disorder (ADHD) drug that people with severe heart conditions should avoid use after reviewing clinical trials that found that 5%-10% of users have blood pressure and heart rate increases.
- **Xigris (drotrecogin alfa).** It's too late for this sepsis drug, which **Lilly** pulled from the market in October 2011. However, a meta-analysis of 10 years of real-life usage found the safety and efficacy were comparable to that reported in the clinical trials that led to its approval. The meta-analysis reviewed 9 controlled trials and 16 single-group studies with a total of 47,223 patients as well as 20 safety analyses with another 8,245 patients. The findings contradict the randomized trial that led to the drug's withdrawal.

Multiple sclerosis – interferon beta doesn't delay disability

A long-term, open-label, 2,656-patient, prospective, Canadian registry study published in the ***Journal of the American Medical Association*** found that interferon beta – **Bayer's Betaseron** (interferon beta-1b), **Biogen Idec's Avonex** (interferon beta-1a), **Merck Serono's Rebif** (interferon beta-1a) – has little effect on a multiple sclerosis (MS) patient's disability progression in real-world practice.

The researchers found that patients taking one of these interferons were no less likely to suffer long-term disability than those who took none of those drugs, "We did not find evidence that administration of interferon beta was associated with a reduction in disability progression in patients with relapsing-remitting MS…Our findings bring into question the routine use of interferon beta drugs to achieve this goal in MS."

In an accompanying editorial, two Swiss neurologists cautioned that doctors and patients shouldn't abandon interferon beta because of these results. However, they agreed that the assumption that interferon beta has a long-term benefit remains unproven.

NOVO NORDISK

- **Victoza (liraglutide) –** A study, presented at the International Congress on Abdominal Obesity (ICAO), of 19 Type 2 diabetics with HbA_{1c} >7%, a body mass index (BMI) >30 kg/m^2, and central obesity found that QD injections of Victoza (0.6 mg to start, increased to 1.2 mg after 2 weeks) added to oral metformin decreased BMI and waist circumference.
- **Tresiba (degludec) and Ryzodeg (degludecPlus) –** The FDA postponed its decision on these drugs for Type 2 diabetes for a second time. The initial PDUFA date was July 29, 2012, and that was extended to October 29, 2012. No new PDUFA date has been set, but a meeting of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee is scheduled for November 8, 2012, to discuss these drugs.

Polypill – reduces blood pressure, cholesterol

A study by U.K. researchers, published in ***PLoS ONE***, found the tri-layered Polypill, containing three blood pressure medications and a statin, reduced blood pressure by 12% and LDL cholesterol by 39% in people without cardiovascular disease age ≥50.

- The principal investigator, David Wald, MD, an interventional cardiologist from the Wolfson Institute of Preventive Medicine at Queen Mary, University of London, said, "If people took the Polypill from age 50, an estimated 28% would benefit by avoiding or delaying a heart attack or stroke during their lifetime. On average, those who benefit would gain 11 years of life without a heart attack or stroke."
- Another investigator, David Taylor, MD, from University College London said, "The Polypill concept is a major public health advance. This study shows that it works. The Polypill should be made generally available as a matter of urgency. I welcome the opportunity to substantially cut my risk of having a stroke or heart attack without the disempowering fuss and bother usually required to obtain preventive medicines."
- The pill's inventor, Professor Sir Nicholas Wald, director of the Wolfson Institute, said, "We now need public, professional, and regulatory support to make the Polypill available without delay. The net benefits are too large to ignore. Even if only 50% of people aged ≥50 took the Polypill, ~94,000 heart attacks and stroke would be prevented each year in the U.K."

VIVUS' Qsymia (phentermine + topiramate extended-release), formerly Qnexa – gets FDA approval

Qsymia became the second weight-loss drug to get FDA approval in a month. Two doses were approved: a standard 7.5 mg phentermine + 46 mg topiramate extended-release dose and a double dose (15/92) for "select patients."

The approval is for chronic weight management in adults with a body mass index (BMI) ≥30 (obese) or a BMI ≥27 (overweight) who have at least one weight-related condition such as hypertension, Type 2 diabetes, or dyslipidemia. This is the same indication that **Arena Pharmaceuticals** and **Eisai** got for their **Belviq** (lorcaserin).

However, there are differences in the approvals for the two drugs:

- Qsymia will be dispensed only through specially certified pharmacies. Distribution of Belviq is not restricted this way.
- Two doses of Qsymia were approved; one dose of Belviq was approved.
- Qsymia is contraindicated in pregnant women, though not in all women of child-bearing age. The FDA also said Belviq should not be used in pregnant women, but the warning was not as strong.
- Qsymia is contraindicated in patients with glaucoma, hyperthyroidism, stroke, unstable or recent heart disease. And regular monitoring of heart rate was recommended for all patients taking the drug, especially when starting the drug or increasing the dose. The Belviq warning was to take extra care giving it to patients with congestive heart failure.

Arena and Vivus are both required to meet several post-marketing requirements, including a long-term cardiovascular outcomes trial, but Arena has to do 6 trials while Vivus has 10 requirements.

Let the marketing wars begin.

REGULATORY NEWS

Bill proposed to mandate opioids be tamper-resistant

Four House members introduced a bill that would require most opioids to include some form of abuse deterrence (e.g., crush-resistance). The legislation, which would require the FDA to establish requirements, includes incentives for pharmas to pursue tamper-resistant technology.

FDA approvals/clearances

- **CRUX BIOMEDICAL's VCF**, a vena cava filter with bidirectional retrieval through either the femoral or jugular veins, was approved.
- **FERRING PHARMACEUTICALS' Prepopik (sodium picosulfate + magnesium oxide + citric acid)** was approved to help cleanse the colon in adults preparing for colonoscopy. The company is required to do a post-marketing pediatric study.
- **GE HEALTHCARE's Discovery CT750 HD Freedom Edition** cardiac CT imaging system was cleared for use.
- **MAZOR ROBOTICS' Renaissance**, a surgical robot designed to replace the company's **SpineAssist System**, was granted expanded approval.
- **MYOSCIENCE's PCP 1.0 system**, a hand-held pain management device for use in a physician's office – which administers cold energy to targeted nerves – was cleared.
- **NOVARTIS' Afinitor (everolimus)**, an mTOR inhibitor, was approved for use in combination with its **Aromasin** (exemestane) to treat certain postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer who have recurred or progressed after treatment with another aromatase inhibitor.
- **ROCHE's Accu-Chek Combo** system for insulin pump therapy was cleared for use. It seamlessly combines a blood glucose meter with an insulin pump, which are able to exchange data in both directions via Bluetooth wireless technology.

FDA recalls/warnings

HOSPIRA recalled several lots of four cancer drugs – carboplatin, cytarabine, paclitaxel, and methotrexate – due to particulate in the vials.

European regulatory actions

- **EMA decisions to become more transparent.** The EMA – which has long been accused of acting in secrecy – plans to make more of its data available to independent researchers. The EMA plans to hold a conference in November 2012 to consider ways to make large data sets available rapidly and routinely to outside investigators. A senior EMA official called it "a sea-change in attitude." Previously, the EMA claimed that clinical trial data paid for by industry were commercially confidential, but the European ombudsman ruled that such confidentiality is not in the public interest.

- **ASCENDX SPINE's Acu-Cut Vertebral Augmentation System** and **Ascendx VCF Repair System** were both granted a CE Mark.
- **EMMAUS MEDICAL's levoglutamide (L-glutamine)** received orphan medicinal product designation from the European Commission to treat sickle cell disease. A Phase III trial is underway.
- **SPHERE MEDICAL's Pelorus 1500**, a point-of-care *in vitro* diagnostic tool for use by anesthetists to rapidly measure the concentration of propofol in blood samples, was granted a CE Mark.

Regulatory actions in other countries

- ***Australia:*** **MERCK's Gardasil** – Australia became the first country to cover this human papillomavirus (HPV) vaccine for 12- and 13-year-old boys.
- ***Canada:*** Health Canada plans to increase its transparency by broadening its Summary Basis of Decisions and releasing public reports on regulatory decisions regarding certain medical devices and drugs. The transparency effort is being expanded to include data on decisions in the postmarketing stage and biosimilars as well as Class IV and III medical devices with novel technologies.
- ***France:*** **PSIVIDA's Iluvien (fluocinolone acetate intravitreal insert)** – The company announced the National Security Agency of Medicine and Health Products granted marketing authorization for this back-of-the-eye treatment for refractory diabetic macular edema.
- ***Korea:*** **PAREXEL INTERNATIONAL**, a contract research organization (CRO), said it was chosen by the Korea Drug Development Fund to help Korean biopharmaceutical companies develop and commercialize healthcare products for the global market.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
	July 2012	
July 24	Discussion of the use of **progression-free survival** as the primary endpoint in non-hematologic malignancies	FDA's Oncologic Drugs Advisory Committee (ODAC)
July 25	Discussion of presurgical identification of clear-cell carcinoma of the kidney using an imaging test	FDA's Oncologic Drugs Advisory Committee (ODAC)
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 26	**Roche/Genentech's Lucentis** (ranibizumab) for diabetic macular edema and **ThromboGenics' Jetrea** (ocriplasmin) for symptomatic vitreomacular adhesions, including macular holes	FDA's Dermatologic and Ophthalmic Drugs Advisory Committee
July 27	**Onyx Pharmaceuticals' Kyprolis** (carfilzomib) for multiple myeloma	PDUFA date
July 27	**Salix Pharmaceuticals and Progenics Pharmaceuticals' Relistor** (subcutaneous methylnaltrexone bromide) for chronic non-cancer pain	PDUFA date
July 30	**Regeneron's Arcalyst** (rilonacept) for gout	PDUFA date
July 30	**Almirall and Forest Laboratories' aclidinium** inhaled therapy for chronic obstructive pulmonary disease (COPD)	PDUFA date
	August 2012	
August 4	**Regeneron Pharmaceuticals** and **Sanofi's Zaltrap** (aflibercept) for colon cancer	PDUFA date
August 9	Draft guidance on **tablet scoring** and CDER's **nanotechnology** risk management working group activities	FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee
August 12	**Talon Therapeutics' Marqibo** (vincristine sulfate liposomes injection) for Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL)	PDUFA date (extended from May 13)
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
	Other 2012	
September tba	**Vivus' Qnexa** (topiramate + phentermine) for obesity	EMA oral hearing
September 5	**Salix Pharmaceuticals' Provir** (crofelemer) for HIV-related diarrhea	PDUFA date (extended from June 5)
September 5	**Novartis' tobramycin inhalation powder** for management of cystic fibrosis patients infected with *Pseudomonas aeruginosa*	FDA's Anti-Infective Drugs Advisory Committee
September 8	**Ironwood Pharmaceuticals and Forest Laboratories' linaclotide** for irritable bowel syndrome	PDUFA date
September 10	**Navidea Biopharmaceuticals' Lymphoseek** (tilmanocept), a radioactive agent for tracing lymph nodes in cancer patients	PDUFA date (extended from June 10)
September 21	Classification of posterior **cervical screws**, including pedicle and lateral mass screws	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee
September 23	**Regeneron's Eylea** (aflibercept) for central retinal vein occlusion (CRVO)	PDUFA date
September 27-28	Regulatory science considerations for performance validation of **radiation biodosimetry** devices	FDA public meeting
September 28	**Second Sight's Argus II Retinal Prosthesis System** for severe to profound retinitis pigmentosa	FDA's Ophthalmic Devices Advisory Committee
October 12	**Celgene's Abraxane** (nab-paclitaxel) to treat NSCLC	PDUFA date
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 29	**Cornerstone Therapeutics' CRTX-080** to treat hyponatremia	PDUFA date
October 29	**Novo Nordisk's Tresiba** (degludec) **and Ryzodeg** (degludecPlus), two basal insulins	PDUFA date **now postponed indefinitely** (after initial extension from July 29)
October 29-31	**Bayer's regorafenib** for metastatic CRC	PDUFA date
November 8	**Novo Nordisk's Tresiba** (degludec) **and Ryzodeg** (degludecPlus)	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
December 15	**Human Genome Sciences' raxibacumab** to treat anthrax	PDUFA date
December 21	**Alexa Pharmaceuticals' Adasuve** (loxapine) for agitation associated with schizophrenia or bipolar disorder	PDUFA date
December 28	**Biogen Idec's BG-12** for multiple sclerosis	PDUFA date

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
2013		
January 29	**Sanofi/Genzyme and Isis Pharmaceuticals' Kynamro** (mipromersen) for homozygous familial hypercholesterolemia	PDUFA date
January 30	**Raptor Pharmaceutical's cysteamine bitartrate** delayed-release (RP-103) to treat nephropathic cystinosis	PDUFA date
February 10	**Celgene's pomalidomide** for relapsed/refractory multiple myeloma	PDUFA date
February 24	**Dynavax's Heplisav** hepatitis B vaccine	PDUFA date
March 1	**Zogenix's Zohydro** (extended-release hydrocodone) for chronic pain	PDUFA date
April 11	**Sanofi/Genzyme and Bayer's Lemtrada** (alemtuzumab) for multiple sclerosis	PDUFA date