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 FDA's new REMS for long-acting and extended-release opioids.

SHORT TAKES

- **AFFYMAX and TAKEDA's Omontys (peginesatide) –** **Fresenius** is buying enough Omontys for >100 of its dialysis centers and is considering broader use of this anemia drug.
- **ATHERSYS' MultiStem cell therapy**, used in the treatment of Hurler's Syndrome, was granted orphan drug status by the FDA.
- **BIOMIMETIC THERAPEUTICS' Augment –** The company submitted an amended filing with the FDA for approval of this bone graft product, with additional data, saying it is not inferior to an autograft. The company expects the FDA to make a final decision in 2013.
- **Breast cancer –** There was no clear winner in the head-to-head Study 301 trial of **Roche's Xeloda** (capecitabine) and **Eisai's Halaven** (eribulin) in metastatic breast cancer, with no statistically significant difference in either progression-free survival (PFS) or overall survival with either chemotherapy.
- **CUBIST PHARMACEUTICALS' CB-315 –** The company started a Phase III trial of this investigational treatment for *C. difficile*-associated diarrhea vs. oral vancomycin.
- **DIAMYD MEDICAL's** gene therapy for cancer pain was no more effective than placebo in a 33-patient Phase II trial. The therapy uses a modified herpes simplex virus to deliver a gene for the endogenous painkiller enkephalin to the dorsal root ganglion. The company is now re-evaluating plans for future research.
- **Drug-eluting stents (DES) –** A study of ~1.5 million U.S. stent patients from 2004-2010, published in the ***Archives of Internal Medicine***, found that cardiologists routinely overuse DES instead of bare metal stents for patients at low risk of another artery blockage. The researchers estimated that the healthcare system could save >$200 million/year if DES were used just half as often in low-risk patients.
- **GALENICA's PA-21 –** The company said this kidney drug, which is being developed in collaboration with **Fresenius Medical Care**, met the primary and secondary end-points in a Phase III trial. At 6 months, maintenance doses of PA-21 were superior in sustaining the phosphate-lowering effect in dialysis patients with chronic kidney disease (CKD) vs. an inactive low-dose PA-21. The company plans to submit the drug to the FDA in 4Q12.

- **GILEAD's Letairis (ambrisentan)** – According to Health Canada, **GlaxoSmithKline** *(yes, GSK)* recently warned doctors not to use this drug – which GSK sells outside the U.S. as Volibris – in patients with idiopathic pulmonary fibrosis (IPF) after an IPF trial showed higher rates of disease progression or deaths with Volibris vs. placebo.

- **HDL cholesterol** – Why haven't HDL-raising CETP inhibitors worked (at least so far)? Perhaps it is because it is the concentration of the ***particles*** that transport HDL, not the HDL cholesterol itself, that is important. In a study published in the ***Journal of the American College of Cardiology***, researchers reported on a cohort study which found that this was the case – that only HDL particles were inversely associated with carotid intima-media thickness.

- **HEMISPHERX BIOPHARMA's Ampligen (rintatolimod)** – In 2009, the FDA rejected this treatment for chronic fatigue syndrome, asking for at least one more clinical trial. However, Hemispherx said the FDA has now agreed to review new analyses of an earlier Phase III trial, and the company plans to submit a response to the FDA in 3Q12.

- **HORIZON DISCOVERY and BAYER** will collaborate to develop preclinical cell line models to support Bayer's oncology research and development programs, using Horizon's precision genome editing technology, Genesis.

- **INOVIO PHARMACEUTICALS' SynCon vaccine** – The company reported that the first patients have been treated in a Canadian trial evaluating immune responses in elderly adults receiving this vaccine alone as well as in combination with the 2012 seasonal flu vaccine.

- **IPSEN and INSPIRATION BIOPHARMACEUTICALS' IB-1001** – The FDA put two clinical trials of this hemophilia drug on hold due to a "potential safety concern." Inspiration noticed that patients being treated with IB-1001 were more likely to test positive for anti-CHO antibodies, the product's host cell protein.

- **JOHNSON & JOHNSON's Xarelto (rivaroxaban)** – The FDA granted priority status to J&J supplemental new drug applications (sNDAs) for the use of this anticlotting drug to treat – and prevent – both deep vein thrombosis and pulmonary embolism.

- **LILLY's pomaglumetad methionil** – This mGlu2/3 failed in a Phase III monotherapy trial in schizophrenia, but data are expected soon from a recently completed Phase II trial in combination with other schizophrenia therapies.

- **Multiple sclerosis (MS)** – A German study, published in the ***New England Journal of Medicine***, found that 47% of MS patients had IgG antibodies to KIR4.1 vs. <1% of patients with other neurologic conditions and none of the 59 healthy patients. If these data hold, KIR4.1 (a potassium-channel autoantibody) would be the first autoantigen identified in MS.

- **OREXIGEN THERAPEUTICS' Contrave (naltrexon + bupropion)** – The company said patient enrollment in a large-scale cardiovascular outcomes trial – undertaken after the FDA rejected this weight-loss drug – will be completed faster than expected, showing that Orexigen is able to carry out a large-scale cardiovascular clinical trial.

- ***Pseudomonas aeruginosa*** – Writing in the ***American Journal of Respiratory and Critical Care Medicine***, researchers from Brigham and Women's Hospital reported that they have discovered a vaccine that may one day be able to prevent infections in hospitalized patients and in people with cystic fibrosis.

- **SANOFI's Mulsevo (semuloparin)** – The company voluntarily withdrew its marketing authorization requests for this drug to prevent blood clots in chemotherapy patients after an FDA advisory committee voted 14-1 against approval in June 2012.

- **WATSON PHARMACEUTICALS** – The Federal Trade Commission (FCC) asked for more information about Watson's proposed acquisition of **Actavis Group**.

- **WELLPOINT** is buying **Amerigroup**. The combined company will have >4.5 million Medicaid beneficiaries. The deal is expected to close in 1Q13.

NEWS IN BRIEF

ACTELION – restructuring plans

The company plans to focus on its core area of expertise – pulmonary arterial hypertension (PAH) – and is taking several cost-cutting and restructuring actions, including:

- Cutting 135 jobs in Switzerland in research and development (R&D) and administration.
- Refocusing its R&D activities toward orphan and specialty indications, which is expected to result in lower and more targeted R&D spending.
- Reviewing the portfolio and stopping or out-licensing projects not in alignment with the new strategy.

CELGENE's apremilast – positive results in PsA

The company announced that this oral PDE-4 inhibitor had positive results in psoriatic arthritis (PsA) in the 495-patient Phase III PALACE-1 trial, with ACR20 achieved by a statistically significant percentage of patients at both doses (20 mg and 30 mg), though the company didn't say what that percentage was. A significant number of patients also achieved ACR50 with both doses and ACR70 with 30 mg.

However, Celegene said that a pilot study of apremilast + methotrexate in rheumatoid arthritis (RA) missed the primary endpoint. The results of a study of apremilast monotherapy in RA are expected in 3Q12.

GLAXOSMITHKLINE

- **Albiglutide.** GSK said it plans to submit this once-weekly injected GLP-1 receptor agonist for Type 2 diabetes to regulators in early 2013. The company said top-line results from a trial showed a statistically significant reduction in HbA_{1c} with albiglutide vs. **Merck's Januvia** (sitagliptin).
- **Promacta/Revolade (eltrombopag).** A study published in the ***New England Journal of Medicine*** found that this oral thrombopoietin mimetic had promising results in a 25-patient trial in refractory aplastic anemia. At Week 12, 44% of patients refractory to standard immunosuppression had clinically significant response to Promacta, with platelet counts rising enough for nine of the patients to go off platelet transfusions.
- **Tykerb (lapatinib).** GSK withdrew its application to the FDA – but not from the European Medicines Agency (EMA) – for expanded use of this monoclonal antibody with **Roche's Herceptin** (trastuzumab) in metastatic breast cancer after discussions with the FDA "highlighted questions that could not be addressed with the data currently available." The advisory committee scheduled for July 24 obviously is canceled.

HUMAN GENOME SCIENCES

- **Benlysta (belimumab).** A post hoc analysis of two Benlysta trials, published in ***Arthritis & Rheumatism***, found that patients with systemic lupus erythematosus (SLE) had significant changes in immunologic biomarkers along with their clinical responses, with IgG levels falling by 15.3% with Benlysta vs. a drop of 2.5% with placebo.
- **Raxibacumab.** The FDA accepted the resubmission of this drug to treat inhalational anthrax. The PDUFA date is December 15, 2012.

MERCK

- **Odanacatib.** The company ended a Phase III trial of this osteoporosis drug at the recommendation of the data safety monitoring committee, which determined that there was clear evidence the drug reduces the risk of bone fractures in post-menopausal women with osteoporosis vs. placebo.
- **Propecia (finasteride).** The FDA warned that the sexual dysfunction side effects of this approved therapy for male pattern baldness may be long-lasting or even permanent after a 54-patient study by George Washington University researchers found 96 percent of the men had sexual dysfunction – low libido, erectile dysfunction, trouble having an orgasm, and shrinking/painful genitals – months after stopping the drug.

PURDUE PHARMA's OxyContin (oxycodone) – illegal use declines after reformulation

Ever since Purdue switched out the original OxyContin for its reformulated version, which is less abusable – though Purdue is not allowed to make that claim – illegal use of OxyContin has been declining. Unfortunately, that doesn't mean fewer drug abusers, just that they are switching to other options, particularly to heroin and to **Endo Pharmaceuticals' Opana** (oxymorphone). However, a new version of Opana is in the works, and that may further push addicts to heroin.

A study published in the ***New England Journal of Medicine*** reported on a survey of opioid-dependent patients entering a treatment program; it found that the major opioid of abuse was OxyContin for 35.6% surveyed before the new OxyContin formulation, but for only 12.8% of patients by the beginning of 2012. At the same time, use of fentanyl, hydromorphone, oxymorphone, and heroin rose from 20.1% to 32.3%.

The researchers commented, "Abuse-deterrent formulations may not be the 'magic bullets' that many hoped they would be in solving the growing problem of opioid abuse."

ROCHE/GENENTECH's Avastin (bevacizumab) – only modest benefit in breast cancer

A Cochrane review of four Avastin trials with a total of 2,886 patients, published in the ***Cochrane Database of Systematic Reviews***, found only a modest benefit for this VEGF inhibitor in improving PFS in metastatic breast cancer and no effect on overall survival but added significant toxicity. The researchers concluded, "The overall patient benefit from adding bevacizumab to first- and second-line chemotherapy in metastatic breast cancer can at best be considered as modest…

Bevacizumab has no significant impact on the patient-related secondary outcomes of overall survival or quality of life, which indicate a direct patient benefit…For this reason, the clinical value of bevacizumab for metastatic breast cancer remains controversial."

VERASTEM

- **VS-6063.** This focal adhesion kinase (FAK) inhibitor (formerly PF-04554878) was in-licensed from **Pfizer** after a 36-patient Phase I trial showed positive results in advanced solid tumors.
- **VS-507 (salinomycin).** Verastem is collaborating with **Eisai** on next-generation small-molecule Wnt inhibitors, including this one, which is a proprietary formulation of salinomycin and the "starting point" for development of proprietary analogs.

ViiV (a collaboration of GSK and Pfizer)

- **Dolutegravir – beats Atripla.** This investigational once-daily integrase inhibitor – on which Shionogi also is collaborating – beat **Gilead's Atripla** (efavirenz + emtricitabine + tenofovir) in a head-to-head study in HIV. At Week 48, virus was undetectable in 88% of patients getting dolutegravir + 2 other drugs vs. 81% of Atripla patients. In the study, 10% of Atripla patients dropped out due to adverse events vs. 2% of dolutegravir patients. *Remember that Gilead's Quad was comparable to Atripla, but not better.*

  In an earlier Phase III trial, dolutegravir showed positive results vs. **Merck's Isentress** (raltegravir), and the results of two more Phase III trials are expected to be available later this year.

- **Selzentry (miraviroc).** Stem cell transplant patients, who are at high risk for graft-vs.-host disease (GVHD), appear to benefit when this HIV drug (a CCR5 antagonist) is added to their standard prophylactic regimen. In a 38-patient Phase I/II study published in the ***New England Journal of Medicine***, at Day 100 Selzentry-treated patients had no cases of hepatic or gut GVHD, total Grade 2 GVHD was 14.7%, and Grade 3/4 was 2.9% vs. a historical rate of 30%-50%.

REGULATORY NEWS

FDA releases final guidance on CAD

Almost three years after issuing draft guidance, the FDA at last issued its final guidance, in two parts, on regulating computer-assisted detection (CAD) technology – computer-assisted detection (CADe) technology but not computer-assisted diagnosis (CADx).

- **Part 1** provides recommendations on documentation and performance testing for a 510(k) submission for Class II CADe devices applied to radiology images and radiology device data.
- **Part 2** offers recommendations on clinical performance studies for both 510(k) and premarket approval (PMA) applications.

FDA to provide early feedback on medical device applications

The FDA announced a proposed new program, Pre-Submission (Pre-Sub), which will provide feedback to medical device manufacturers *before* they submit applications for approval. An FDA official said, "Early feedback on studies can facilitate the development of a quality premarket submission and help industry avoid regulatory hurdles during the review process." Pre-Sub is the device version of the Special Protocol Assessment (SPA) program for drugs.

Pre-Sub replaces and updates the pre-Investigational Device Exemption (pre-IDE) program and includes Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, and Premarket Notification 510(k) submissions, as well as IDEs. Pre-Sub also includes devices regulated by the Center for Biologics Evaluation and Research (CBER).

A Pre-Sub is a formal written request from a company for formal, written feedback from (or a meeting or teleconference with) the FDA. Companies are not required to make a Pre-Sub; it is completely voluntary, but the FDA said Pre-Subs "are strongly encouraged" before submission of an IDE or PMA.

The FDA is accepting comment on the Pre-Sub draft guidance for 90 days.

FDA names new head of generic drugs

Gregory Geba, MD, MPH, was named director of the Office of Generic Drugs, effective July 15, 2012. Dr. Geba has served in senior-level clinical/managerial positions in the pharmaceutical industry for the past 15 years. Most recently, he was deputy chief medical officer at **Sanofi US**. He is also experienced at making presentations to FDA advisory committees.

Collaboration on food pathogen genome database

The FDA, the University of California at Davis, **Agilent Technologies**, and the Centers for Disease Control and Prevention (CDC) are collaborating on the creation of a public database of foodborne pathogen genomes to help speed identification of bacteria responsible for foodborne illness outbreaks. The 100K Genome Project is a 5-year effort to sequence the genetic code of ~100,000 foodborne pathogens (including *E. coli*, *Listeria*, and *Salmonella*) and then make the information available in a free, public database – the National Institutes of Health's National Center for Biotechnology Information database.

The project will provide a roadmap for development of tests to identify pathogens and will provide information where the pathogen originated within days or hours, which is significantly faster than the ~1 week it now takes.

- The FDA will contribute scientific and technical expertise necessary to create and maintain the database as well as whole genomes that have already been sequenced.
- Agilent will provide scientific expertise, instrumentation, and funding to support a portion of UC Davis activities.
- The CDC will provide its foodborne disease expertise, strains to be sequenced, and other information for use in the project. CDC experts also will serve on the project's steering committee.
- The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) also will collaborate on the project, submitting bacterial strains from its regulatory testing program for sequencing at UC Davis.
- UC Davis will coordinate the genomic sequencing and provide access to its collection of bacteria samples.

FDA approvals/clearances

- **ASTHMAPOLIS' asthma inhaler sensor**, which captures the time and date of an asthma attack and transmits it to a user's smartphone and then uses satellite positioning to relay location information to the company's servers – providing data that can then be used by individuals to keep track of day-to-day symptoms and patterns that trigger attacks – was granted 510(k) clearance. It will be available only by prescription.
- **BECTON DICKINSON/BD DIAGNOSTICS' BD MAX MRSA molecular test**, an assay that runs on the BD MAX system and detects patients infected with MRSA, was cleared for use.
- **COOK MEDICAL's Evolution Colonic Controlled-Release Stent** received 510(k) clearance for use in treating uncomfortable or painful colonic obstructions in patients slated for colectomy procedures.
- **FLEXIBLE STENTING SOLUTIONS' FlexStent**, a self-expanding biliary stent, received expanded 510(k) approval for new diameters and lengths.
- **MEDTRONIC's Pillar Palatal Implant** was granted expanded approval to treat snoring disorders.
- **ST. JUDE MEDICAL's ViewFlex Xtra intracardiac echocardiography catheter**, which aids in viewing the heart's anatomy during interventional or electrophysiology procedures, was given 510(k) clearance for use with the ViewMate Z intracardiac ultrasound console, which St. Jude co-developed with **Zonare Medical Systems**.

FDA recalls/warnings

- **ALERE's Triage CardioProfiler Panel, Cardiac Panel, Profiler SOB Panel, BNP, and D-dimer tests** – A Class I recall was issued for several lots of these cardiovascular diagnostic tests because of potentially fatal sensitivity errors that could increase the rate of false-positive or false-negative results. The false results are unpredictable within lots and cannot be distinguished through quality-control sampling.
- **GE HEALTHCARE's Aestiva/5 7900 Ventilator** – A Class I recall was initiated because of the potential for two vaporizers to deliver each agent at the same time, which could result in over-delivery of a single agent if both vaporizers contain the same agent, or in delivery of more than one agent.
- **SIEMENS HEALTHCARE DIAGNOSTICS** – An inspection of the company's Newark DE plant, which manufactures *in vitro* diagnostic products, found problems with quality control, and the company's steps to address the FDA

concerns were found to be so inadequate that the FDA warned Siemens that PMA approvals for Class III devices "to which the Quality System regulation violations are reasonably related" will not be approved until the violations have been corrected and Requests for Certificates to Foreign Governments will not be granted until the violations have been corrected.

- **STRYKER's Rejuvenate and ABG II modular-neck stems –** The company initiated a voluntary recall of these products used in hip replacements because of potential risks associated with fretting and corrosion at the modular-neck junction. So far, at least 45 adverse events have been reported to the FDA about the devices causing pain and/or tissue swelling. Stryker is halting production and ceasing global distribution.

European regulatory news

- **Clinical trials –** The European Union (EU) plans to create new rules that make it easier for pharmas and researchers to do cross-border clinical trials. The number of clinical trials completed in the EU dropped by >15% in recent years, and the European Commission hopes that cutting cost and red tape will reverse this downward trend. One of the planned changes is a centralized submission instead of separate applications in each country participating in a trial. Once published, the Commission's proposal must be jointly agreed to by EU governments and the European Parliament, which could take up to two years.
- **DERMA SCIENCES' Medihoney HCS –** The entire portfolio of honey-based wound dressings received a CE Mark.
- **EISAI's Zonegran (zonisamide) –** The EMA broadened approval of this once-daily antiepileptic to include monotherapy for partial seizures in adults newly diagnosed with epilepsy.
- ***In vitro* diagnostics –** The U.K.'s Medicines and Healthcare products Regulatory Agency issued new guidance on how notified bodies should review the labeling and design of *in vitro* diagnostics designed for self-testing.

Regulatory news from other countries

Canada:

- **AUXILIUM PHARMACEUTICALS and ACTELION PHARMACEUTICALS CANADA's Xiaflex (collagenase clostridium histolyticum)** was approved to treat Dupuytren's contracture.
- **OPTIMER PHARMACEUTICALS' Dificid (fidaxomicin) –** This BID antibiotic for *C. difficile* was approved by Health Canada.

China:

- **MAXX MEDICAL's Freedom Total Knee System** was approved.
- **OCULUS INNOVATIVE SCIENCES' Microcyn Hydrogel**, an anti-infective for wound treatment, was approved by the Chinese State Food and Drug Administration to treat chronic and acute wounds.

Scotland: A national screening program for abdominal aortic aneurysms (AAAs) was approved. The rollout is expected to be completed by the end of 2013. The goal of the program is to reduce the number of emergency procedures related to AAAs, making the effort "cost-neutral."

Switzerland: **ARENA PHARMACEUTICALS' Belviq (lorcaserin)**, an obesity drug, was submitted to Swiss health officials for approval.

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 17	**Vivus' Qnexa** (phentermine + topiramate) for weight loss	PDUFA date (extended from April 17)
July 24	**GlaxoSmithKline's Tykerb** (lapatinib) **+ Roche's Herceptin** (trastuzumab), supplemental indication for HER2+ metastatic breast cancer	FDA's Oncologic Drugs Advisory Committee (ODAC) – **Canceled because GSK withdrew its application**
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 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 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 14	**Gilead Sciences' Truvada PrEP** HIV therapy to help prevent the transmission of HIV to healthy people	PDUFA date (extended from June 15)
September 23	**Regeneron's Eylea** (aflibercept) for central retinal vein occlusion (CRVO)	PDUFA date
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 Degludec and DegludecPlus** (human recombinant basal insulin)	PDUFA date (extended from July 29)
October 29-31	**Bayer's regorafenib** for metastatic CRC	PDUFA date
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
	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
April 11	**Sanofi/Genzyme and Bayer's Lemtrada** (alemtuzumab) for MS	PDUFA date