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…

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: Subscribe to ***Trends-in-Medicine*** for coverage of the **European Respiratory Society** meeting in Vienna, Austria.

SHORT TAKES

- **AMGEN's TVEC immunotherapy vaccine –** Reports have surfaced that this treatment showed "some effect" in a Phase III trial in regional melanoma when injected directly into a lesion or into a lymph node.
- **ASTRAZENECA** hired former Genentech CEO Pascal Soriot (and former COO of **Roche**'s pharmaceutical division) as its new chief executive officer, effective October 1, 2012. *Soriot has extensive experience in mergers and acquisitions, so watch for more AstraZeneca activity in that area.*
- **BAYER and ONYX's regorafenib (BAY-73-4506) –** Bayer submitted this investigational treatment for metastatic or unresectable gastrointestinal stromal tumors (GIST) in patients who failed other therapies to the FDA.
- **Electronic health records (EHRs) –** A study of 21,200 doctors, sponsored by ***Medscape***, found that EHR adoption is increasing, with 74% of doctors already using an EHR and 8% in the process of installation/implementation.
- **Gabapentin –** A small (62-patient), 10-week study in Australia, published in ***The Lancet***, found that this antiepileptic relieved coughing and other symptoms in patients with long-term, refractory, chronic cough.
- **GI DYNAMICS' EndoBarrier device –** The FDA gave the company the go-ahead to start a 12-month pivotal study of this investigational therapy for Type 2 diabetes and obesity without doing a pilot study first, and the company plans to get that trial started by the end of 2012.
- **HOSPIRA** bought a research and development facility in India from **Orchid Chemicals and Pharmaceuticals**.
- **Implantable cardiac defibrillators (ICDs) –** A number of hospitals received letters from the Department of Justice (DOJ) with instructions on how to resolve the government's investigation of their off-label use of ICDs. The letters outline the situations in which DOJ is likely to seek damages and those where they are unlikely to do that even though they may technically violate CMS' National Coverage Decision on the devices (e.g., less than 40 days post-MI where there is a medical justification for the device).

- **JOHNSON & JOHNSON's Zytiga (abiraterone)** – The FDA granted expedited review for a supplemental new drug application for this prostate cancer drug in combination with prednisone in patients with metastatic castration-resistant prostate cancer (mCRPC) who are mildly symptomatic or asymptomatic after unsuccessful hormone-deprivation therapy (prior to chemotherapy).

- **LILLY's pomaglumetad methionil** – The company said it is discontinuing development of this investigational schizophrenia drug after the independent data monitoring committee reported that the 600-patient Phase III trial would not meet the primary efficacy endpoint. Safety was not an issue.

- **MERCK's Victrelis (boceprevir) and VERTEX's Incivek (telaprevir)** – A study published in ***Hepatology*** found that treating naïve hepatitis C virus genotype 1 (HCV-1) patients with the TT genetic allele with either of these drugs is "highly cost-effective." The authors also concluded that using rapid virological response (RVR) and genetic testing strategies to guide therapy is likely to be cost-effective vs. universal treatment of all HCV-positive patients. They estimated the cost per quality-adjusted life year (QALY) was <€10,000.

- **MSD CONSUMER CARE's Oxytrol for Women** – The company is seeking FDA approval for over-the-counter sales of this transdermal oxybutynin product for women with overactive bladder. The FDA's Non-prescription Drugs Advisory Committee will consider the request on November 9, 2012.

- **NOVARTIS and SOSEI and VECTURA's QVA-149 (glycopyrronium + indacaterol)** – The company filed this combination of a long-acting muscarinic antagonist and a long-acting beta-2 agonist with European and Japanese regulators after a fifth Phase III trial was positive, reducing exacerbations, improving exercise capacity, and generally meeting safety and efficacy endpoints in chronic obstructive pulmonary disease (COPD).

- **Pharma sales reps** – According to a survey by the marketing firm ZS Associates, pharma sales reps have the toughest time getting to see oncologists of the 20 medical specialties reviewed. The survey found that 61% of oncologists, 47% of cardiologists, and 38% of primary care doctors placed moderate-to-severe restrictions on visits from the sales reps.

- **PROACTA's PR-610** – The FDA has given the company the green light to begin a clinical trial of this hypoxia-activated irreversible multikinase inhibitor in non-small cell lung cancer (NSCLC) patients who don't respond to reversible tyrosine kinase inhibitors.

- **ST. JUDE MEDICAL** is cutting 300 jobs as part of a restructuring plan that will consolidate its four business units into two larger groups: implantable electronic systems and cardiovascular and ablation technologies. The company also is centralizing several support functions, including information technology, human resources, legal, business development, and some marketing activities.

- **SAREPTA THERAPEUTICS' eteplirsen (AVI-4658)** – According to a media report, a 12-year-old boy, getting a 50 mg/kg dose of this experimental treatment in a 12-patient Phase II trial in Duchenne muscular dystrophy, had a positive response. Sarepta Therapeutics is the new name of **AVI BioPharma**.

- **Statins** – A study published in the journal ***Optometry and Vision Science*** suggested that statins may increase the risk for age-related cataracts to a level comparable to that of people with Type 2 diabetes.

- **SUN PHARMACEUTICAL INDUSTRIES/CARACO** was given permission by the FDA to resume production and packaging at two Michigan sites, but only of two generic drugs – the antibiotic paromomycin and the beta blocker carvedilol.

- **Tamoxifen** – A study published in ***BMC Medicine*** found that this breast cancer drug may reduce some of the side effects from hormone therapy for prostate cancer (breast enlargement and breast pain).

- **TEVA's laquinimod** – The company said it has begun testing a higher dose of this oral multiple sclerosis drug in a new trial of ~1,800 patients to see if that would delay disability progression.

- **VERTEX's Kalydeco (ivacaftor)** – The FDA warned that a rat study suggests that children taking this cystic fibrosis drug may be at risk of developing cataracts. The Agency asked Vertex to do a clinical trial in children age <11 who are already on the drug and added the risk to the drug's label.

NEWS IN BRIEF

ABBOTT's Humira (adalimumab) – panel backs ulcerative colitis treatment

The FDA's Gastrointestinal Drugs Advisory Committee recommended that the FDA expand Humira's approval to include ulcerative colitis. The FDA previously turned down an

indication in ulcerative colitis; but for ulcerative colitis the panel may change the Agency's mind, voting:

- 15-2 that the benefits of this arthritis drug outweigh its risks.
- 15-1 (with 1 abstention) that the statistically significant treatment difference in clinical remission at Week 8 (8.5%-18.5% vs. 4.1%-9.3% for placebo) was a clinically meaningful benefit.
- 10-6 (with 1 abstention) that the difference in clinical remission at both Week 8 and Week 52 was clinically meaningful.
- 14-3 that the optimal dose for moderate-to-severe disease had not been adequately established.
- 14-2 (with 1 abstention) that additional pre-approval studies are not needed.

ARQULE's tivantinib – safety issue in Japanese trial

The company said its Japanese partner, **Kyowa Hakko Kirin**, temporarily suspended patient enrollment in a Phase III trial in non-squamous non-small cell lung cancer in combination with **Roche's Tarceva** (erlotinib) vs. Tarceva alone. ArQule said Kyowa's independent safety monitoring board recommended the action after some possible cases of interstitial lung disease were observed in trial patients. No new patients are being enrolled, but existing patients will continue treatment while the safety panel reviews additional information on the suspected cases.

BG MEDICINE's Architect Galectin-3 test – beneficial test in NIH study

A study by researchers at the National Heart, Lung, and Blood Institute, published in the ***Journal of the American College of Cardiology***, found that patients with an elevated level of galectin-3 (a marker of cardiac fibrosis) had a significantly increased risk of developing heart failure or dying. Having high levels of galectin-3 doubled the odds of having elevated left ventricular mass. For people with the highest quartile of galectin-3 levels, the annual heart failure rate was 12 per 1,000 person-years (PY) vs. 3 per 1,000 PY for the lowest quartile.

This is the first time that galectin-3 has been confirmed to be a predictor of future heart failure in apparently healthy people, and it may support use of the Architect test, which is currently under review by the FDA.

GILEAD SCIENCES

- **GS-7977.** A Phase III trial is under way, and the company plans to file for regulatory approval in mid-2013, seeking an indication for 12-16 weeks in combination with ribavirin in HCV-2/3 and for 12 weeks in HCV-1/4/5/6 in combination with pegylated interferon + ribavirin.
- **GS-7977 + GS-5885 (an NS5A inhibitor).** The company said it plans to start an 800-patient, Phase III trial of a one-pill combination of these two drugs in 4Q12 to treat people infected with HCV.

Greece – drug access getting more difficult

Reuters reported that the Pan-Hellenic Pharmaceutical Association, which represents Greece's ~12,000 pharmacies, said its members will no longer supply drugs prescribed by the country's National Organization for Health Care Provision without immediate payment in cash, effective September 1, 2012. The pharmacists urged:

- Eopyy, the country's largest state-run healthcare provider, to pay outstanding debts of >85 days.
- The government to start financing Eopyy with 0.6% of GDP and to guarantee bank loans taken by pharmacists.

IDENIX PHARMACEUTICALS

- **IDX-19368.** The FDA put a clinical hold on this investigational NS5B nucleotide polymerase inhibitor for HCV, which has not been tested in humans. An investigational new drug (IND) application is pending at the FDA.
- **IDX-184.** The FDA asked the company for additional cardiac testing on patients in the ongoing Phase IIb trial of this NS5B nucleotide polymerase inhibitor for HCV, which already was on partial hold after the heart failure death of a patient in a trial of a **Bristol-Myers Squibb** drug in the same class.

MERCK

- **Tredaptive (extended-release niacin + laropiprant).** The company said it plans to submit this investigational cholesterol-lowering drug to the FDA and the European Medicines Agency (EMA) in 2013.
- **Vorapaxar.** The company said it plans to submit this investigational anticoagulant to the FDA and the EMA in 2013 for the prevention of cardiovascular events in patients with a history of heart attack but without a history of stroke or transient ischemic attack.

ROCHE/GENENTECH

- **Herceptin (trastuzumab).** This breast cancer drug was found to increase the risk for heart failure and cardiomyopathy in an observational study published in the ***Journal of the National Cancer Institute***. Women who took Herceptin were 4.12 times more likely to develop heart failure, and the risk was greatest if the women also took an anthracycline.
- **Trastuzumab emtansine (T-DM1).** The company announced that the randomized, open-label, Phase III EMILIA trial found that T-DM1 extended overall survival in women with HER2-positive breast cancer who had previously received **Herceptin** (trastuzumab) vs. standard therapy with **GlaxoSmithKline's Tykerb** (lapatinib) + **Roche's Xeloda** (capecitabine). Thus, T-DM1 now has met both primary endpoints in EMILIA (overall survival and progression-free survival). Roche said it has submitted T-DM1 to the FDA and soon will submit it to the EMA.

ROCHE/GENENTECH and CURIS' Erivedge (vismodegib, GDC-0449) – may work in breast cancer

This hedgehog inhibitor, which is approved to treat large basal cell carcinoma, may also be able to treat breast cancer in patients who become resistant to tamoxifen. In a study published in the journal ***Cancer Research***, researchers at the Ohio State University Comprehensive Cancer Center found that tamoxifen resistance can develop through the hedgehog pathway, and they showed in an animal model that Erivedge inhibits growth of tamoxifen-resistant human breast tumors.

The researchers also found a link between hedgehog signaling and the PI3K/AKT pathway, suggesting that combining a hedgehog inhibitor with a PI3K inhibitor could lead to a novel treatment for endocrine-resistant tumors without a need for chemotherapy. They hope to get a clinical trial of Erivedge under way in tamoxifen-resistant breast cancer.

SANOFI

- **Eloxatin (oxaliplatin).** A subgroup analysis of the MOSAIC trial, published in the ***Journal of Clinical Oncology***, suggested that oxaliplatin may not improve overall survival in Stage II colorectal cancer (CRC) patients.
- **Lemtrada (alemtuzumab).** The FDA rejected Sanofi/Genzyme's submission of a supplemental Biologics License Application (sBLA) for this investigational multiple sclerosis drug, issuing a Refusal to File letter saying the data needed "reorganization." No new clinical data were requested.

TAIHO PHARMACEUTICAL's TAS-102 – positive Phase II results in CRC

A Phase II Japanese study published in ***Lancet Oncology*** found that this nucleoside boosted survival in refractory metastatic CRC in patients unresponsive to or intolerant of standard chemotherapy. Median overall survival was 9 months vs. 6.6 months with control, median progression-free survival (PFS) was 2 months vs. 1 month, and stable disease occurred in 43% of patients vs. 11% of control. The main toxicity was neutropenia, and 20% of patients needed a dose reduction at some point, usually due to neutropenia or thrombocytopenia, and 31% had temporary treatment interruptions. The international Phase III RECOURSE trial is ongoing in refractory metastatic CRC.

REGULATORY NEWS

Five groups approved as EHR certifiers

The Department of Health and Human Services' Office of the National Coordinator for Health Information Technology approved five groups to issue certifications that EHR software meets federal criteria under the incentive payment program:

- Certification Commission for Health Information Technology
- Drummond Group
- ICSA Labs
- InfoGard Laboratories
- Orion Register

FDA approvals/clearances

- **COVIDIEN's iDrive Ultra**, an endoscopic surgical stapler, was cleared for use.
- **CROSPON's EndoFLIP**, an imaging system, was cleared for use in measuring esophageal pressure and dimensions and as an adjunct to other gastroenterology techniques used to evaluate esophageal sensory hypersensitivity symptoms.
- **FOREST LABORATORIES and IRONWOOD PHARMACEUTICALS' Linzess (linaclotide)** was approved to treat chronic idiopathic constipation and irritable bowel syndrome with constipation (IBS-C). A boxed warning says the drug should not be taken by patients age ≤16.
- **GILEAD SCIENCE's Stribild (formerly Quad: elvitegravir + cobicistat + emtricitabine + tenofovir disoproxil fumarate)**, an oral, QD drug to treat naïve HIV patients was approved. Stribild's label includes a boxed warning that (1) it can cause a buildup of lactic acid in the

blood and severe liver problems, both of which can be fatal, and (2) it is not approved to treat chronic hepatitis B virus (HBV) infection. The FDA is requiring additional post-marketing safety studies in women and children, on development of resistance and on drug-drug interactions. Gilead priced Stribild at ~$28,500/year, which AIDS Healthcare Foundation President Michael Weinstein called "shockingly irresponsible."

- **HOLLYWOG's WiTouch and WiTouch Pro**, two wireless, remote-controlled devices for treating back pain, received 510(k) clearance. The WiTouch was cleared for non-prescription use, and the WiTouch Pro for prescription use.
- **JOHNSON & JOHNSON's Nucynta ER (tapentadol extended-release)** is the first opioid to be approved to treat neuropathic pain associated with diabetic peripheral neuropathy. Tapentadol was already approved to treat moderate-to-severe acute pain and moderate-to-severe chronic pain.
- **MEDIVATION and ASTELLAS' Xtandi (enzalutamide, MDV-3100)** was approved to treat metastatic castration-resistant prostate cancer patients post-docetaxel.
- **NOVARTIS' Afinitor Disperz (everolimus tablets for oral suspension)**, the first drug formulated specifically for children with subependymal giant cell astrocytoma (SEGA), a rare brain cancer, received accelerated approval and is an orphan drug. Long-term safety and effectiveness studies are already under way.
- **SYMMETRY MEDICAL's Evolution**, a stainless steel valve for the company's FLASH PAK sterilization product, received 510(k) clearance.
- **TEVA/SICOR BIOTECH's tbo-filgrastim**, a treatment for cancer-induced neutropenia, was approved and will compete with **Amgen's Neupogen** (filgrastim).
- **TOSHIBA AMERICA MEDICAL SYSTEMS' Aquilion RXL**, a 16-detector-row CT scanner, was cleared for use.
- **WELKINS' EMT/ICU** device, which is used to help manage patient temperature, was cleared for use.

FDA recalls/warnings

- **BRISTOL-MYERS SQUIBB's BiCNU (injectable carmustine)** – Ten lots of this chemotherapy drug were recalled after one vial was found to be overfilled, putting patients at risk of an overdose that could cause kidney toxicity or death, though no adverse events have been reported so far.
- **HOSPIRA** – The company received a warning letter from the FDA about quality and compliance violations at its plant in Costa Rica, which primarily manufactures infusion pumps.
- **I-FLOW's ON-Q Pump with ONDEMAND Bolus Button** – The FDA announced a Class I recall because the bolus button may not lock in the down position when depressed and/or the bolus refill indicator may stay in the lowest position, either of which can cause the patient to receive the drug at a faster rate than expected, which can cause serious adverse events or death.
- **PFIZER's Revatio (sildenafil)** – The FDA notified health-care professionals and medical societies that this phospho-diesterase-5 (PDE-5) inhibitor approved to treat pulmonary arterial hypertension should not be used off-label in children after a long-term pediatric trial found (a) a higher risk of death in children taking a high dose and (b) the low dose was ineffective in improving exercise ability in children. The label also was changed to reflect these findings.
- **PHILIPS HEALTHCARE/RESPIRONICS' V60 Ventilators** – A limited number (116) of these devices were voluntarily recalled in the U.S. due to a "manufacturing issue."
- **SANOFI/GENZYME's thymoglobulin** – Nine lots of this anti-rejection drug for kidney transplant patients were recalled after one lot failed a stability test.

European Union (EU) regulatory actions

- **ADVANCIS SURGICAL's HemoSep** autotransfusion system, which was licensed from the University of Strathclyde in Scotland, received a CE Mark.
- **ARIAD PHARMACEUTICALS' ponatinib** – The company said the EMA granted accelerated assessment of this investigational therapy for chronic myeloid leukemia (CML). The drug also is under review by the FDA.
- **ASTRAZENECA's Zinforo (IV ceftaroline)**, an antibiotic, was approved by the European Commission to treat patients with complicated skin and soft-tissue infections and community-acquired pneumonia. In the U.S. this is FDA approved and sold by Forest Laboratories as Teflaro.
- **BOSTON SCIENTIFIC**
  - **Precision Plus Spinal Cord Stimulator System**, a rechargeable spinal cord stimulator for recurrent, intractable trunk pain, received a CE Mark.
  - **Watchman Left Atrial Appendage** closure device was granted expanded approval for use in atrial fibrillation patients unable to take warfarin or other oral blood thinners.

- **GE HEALTHCARE's Discovery IGS 730**, a laser-guided interventional imaging device that combines a robotic C-arm and a fixed x-ray, received a CE Mark.
- **NOVARTIS' Jakavi (ruxolitinib)** – The European Commission approved this JAK inhibitor to treat myelofibrosis. Novartis licensed the European rights from Incyte, which sells it as Jakafi in the U.S.
- **PACIRA PHARMACEUTICALS' DepoCyte (cytarabine)** – The EMA recommended the recall of this cancer drug after a joint U.K./French inspection of a U.S. plant found inadequate sterility and possibly microbial contamination.

Regulatory news from other countries

Canada: **H. LUNDBECK's Treanda (bendamustine)** was approved by Health Canada to treat chronic lymphocytic leukemia (CLL). Lundbeck licensed the Canadian rights from Teva/Cephalon.

Upcoming FDA Advisory Committees and Other Regulatory Meetings of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
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 10	**Postmarket monitoring** of medical devices	FDA public workshop
September 10	**Navidea Biopharmaceuticals' Lymphoseek** (tilmanocept), a radioactive agent for tracing lymph nodes in cancer patients	PDUFA date (extended from June 10)
September 13	**Cornerstone Therapeutics/Cardiokine Biopharma's lixivaptan** for treatment of symptomatic hypervolemic and euvolemic hyponatremia associated with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH) and **WestWard Pharmaceutical's phenylephrine hydrochloride injection** to increase blood pressure in acute hypotensive states	FDA's Cardiovascular and Renal Drugs Advisory Committee
September 21	Classification of posterior **cervical screws**, including pedicle 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 15	Need for and design of **clinical development programs** for approval of **parenteral lipid emulsion products** as nutritional support	FDA's Gastrointestinal Drugs Advisory Committee
October 16	**NPS Pharmaceuticals' Gattex** (teduglutide) for short bowel syndrome	FDA's Gastrointestinal Drugs Advisory Committee
October 17	**Aegerion Pharmaceuticals' lomitapide** to treat homozygous familial hypercholesterolemia	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
October 17	**ThromboGenics' ocriplasmin** to treat vitreomacular adhesions	PDUFA date
October 18	**Sanofi/Genzyme** and **Isis Pharmaceuticals' Kynamro** (mipomersen) to reduce cholesterol in patients with homozygous familial hypercholesterolemia	FDA's Endocrinologic and Metabolic Drugs Advisory Committee
October 21	**Impax Laboratories' IPX-066** for Parkinson's disease	PDUFA date
October 24	**Hologic's Selenia Dimensions 3D System –** expanded indication to combine digital breast tomosynthesis with synthetic 2D images for cancer screening	FDA's Radiological Devices Advisory Committee
October 29	**Cornerstone Therapeutics' CRTX-080** to treat hyponatremia	PDUFA date
October 29-30	Discussion of benefits, risks, and abuse of drugs containing **hydrocodone**	FDA's Drug Safety and Risk Management Advisory Committee
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
November 8-9	**Exelixis' cabozantinib** for progressive, unresectable, locally advanced or metastatic medullary thyroid cancer	FDA's Oncologic Drugs Advisory Committee (ODAC) – ***canceled***
November 9	**MSD Consumer Care's "Oxytrol for Women,"** an over-the-counter transdermal oxybutynin to treat overactive bladder in women	FDA's Non-prescription Drugs Advisory Committee
November 14	Optimization of outcomes with **ventricular assist devices** (VADs) for patients with heart failure	CMS' MEDCAC
November 22	**Medivation** and **Astellas' enzalutamide** (MDV-3100) for castration-resistant prostate cancer	PDUFA date
November 21	**Pfizer's tofacitinib**, an oral JAK inhibitor for rheumatoid arthritis	PDUFA date (extended from August 21)
November 28	Discussion of the use of **absorbable material** in a variety of medical devices	FDA Workshop on Absorbable Medical Devices: Lessons Learned From Correlations of Bench Testing and Clinical Performance
November 29	**Exelixis' cabozantinib** to treat medullary thyroid cancer	PDUFA date
December 15	**Human Genome Sciences' raxibacumab** to treat anthrax	PDUFA date
December 21	**Alexza 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
December 29	**Aegerion Pharmaceuticals' lomitapide** to treat homozygous familial hypercholesterolemia	PDUFA date
December 30	**NPS Pharmaceuticals' Gattex** (teduglutide) for short bowel disease	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 16	**Santarus' Uceris** (budesonide) for ulcerative colitis	PDUFA date (extended from October 16, 2012)
January 17	**NuPathe's Zelrix** (transdermal sumatriptan), a migraine patch	PDUFA date
January 29	**Sanofi/Genzyme** and **Isis Pharmaceuticals' Kynamro** (mipomersen) 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 – ***delayed*** because FDA rejected the filing