TRENDS-in-MEDICINE

July 5, 2020

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
772-285-0801
Fax 772-334-0856
www.trends-in-medicine.com
TrendsInMedicine@aol.com

NOTE: Remember that coronavirus news is being reported primarily in separate Coronavirus Update bulletins.

Be careful, be safe, and be well. We hope you enjoyed the Fourth of July weekend.

Top news of the week (*read details in other sections of* ***Quick Takes***)

- ✓ ASTELLAS/AUDENTES THERAPEUTICS' AT-132 – A pivotal trial of this gene therapy for X-linked myotubular myopathy was put on hold by the FDA over a safety issue.
- ✓ Covid-19 – A vaccine will need to be ≥50% better than placebo for FDA approval.
- ✓ HERON THERAPEUTICS' HTX-011 (extended-release bupivacaine + meloxicam) was rejected by the FDA for a second time as a treatment for postoperative pain.
- ✓ INTERCEPT PHARMACEUTICALS' Ocaliva (obeticholic acid) was rejected by the FDA as a treatment for NASH.
- ✓ **Positive drug trials:**
  - AKERO THERAPEUTICS' efruxifermin – in NASH.
  - CORFLOW THERAPEUTICS' CoFI System – in STEMI patients.
  - Hydroxychloroquine – cut mortality in half in hospitalized Covid-19 patients.
  - REGENERON PHARMACEUTICALS' Arcalyst (rilonacept) – in recurrent pericarditis.
- ✓ **Negative drug trials:**
  - ABBVIE's Kaletra (lopinavir + ritonavir) – in Covid-19 patients on oxygen.
  - MEI PHARMA and HELSINN's pracinostat – in AML.
  - ZYNERBA PHARMACEUTICALS' Zygel (cannabidiol gel) – in Fragile X syndrome.

SHORT TAKES

- ABBOTT is partnering with Tandem Diabetes Care to combine its FreeStyle Libre continuous glucose monitor with Tandem's t:slim X2 insulin pump.
- ABBVIE's Kaletra (lopinavir + ritonavir) – In an analysis of 4,972 patients in the RECOVERY trial by researchers at the University of Oxford, this HIV drug did *not* benefit Covid-19 patients on oxygen.
- ABIOMED's Impella 5.5 with SmartAssist – A 55-patient study, published in the ***American Society for Artificial Internal Organs Journal***, showed this percutaneous left ventricular assist device was beneficial in unloading cardiogenic shock patients, with improved survival.

- AKERO THERAPEUTICS' efruxifermin – Of the 40 non-alcoholic steatohepatitis (NASH) patients in a Phase II trial with biopsies, 48% had ≥1-stage improvement in fibrosis with no worsening of inflammation or other biological markers of disease. In addition, 48% of patients had NASH resolution without fibrosis worsening, and nearly a third had a 2-stage improvement in fibrosis without inflammation worsening. Patients on the high dose also had significant weight loss.

- ANCORA HEART's AccuCinch – The FDA granted an investigational device exemption (IDE) for this ventricular restoration system that reshapes the left ventricle of the heart, clearing the way for a trial in patients with heart failure and reduced ejection fraction (HFrEF).

- ASTELLAS/AUDENTES THERAPEUTICS' AT-132 – After two children with myotubular myopathy who got the high dose (300 trillion vector genomes/kg) of this AAV gene therapy in a pivotal trial died from liver failure and sepsis, the company halted dosing. Now, the FDA has put a clinical hold on new enrollments in the trial.

- ASTRAZENECA's Lynparza (olaparib) – A mouse study by Australian researchers, published in the ***Journal of Human Reproduction***, found that this PARP inhibitor damaged immature eggs in the ovaries of the mice, leading the authors to recommend that young women who are considering taking olaparib for their cancer should have fertility preservation counseling.

- BRAINLAB is buying **Level Ex**, which makes medical video games for surgeons.

- CORFLOW THERAPEUTICS' CoFI System – Interim clinical data from 10 patients in the first-in-human Phase II MOCA-1 trial in Switzerland, presented at the virtual PCR e-Course, showed that this device was safe and effective in ST-elevation myocardial infarction (STEMI) patients, with no device-related adverse events and no device-related deaths.

- GLAXOSMITHKLINE's Ventolin (salbutamol) – A study by U.K. researchers, published in ***ACS Chemical Neuroscience***, suggests that this now generic asthma drug may be able to be repurposed to treat Alzheimer's disease by reducing insoluble tau fibers in the brain.

- GLENMARK PHARMACEUTICALS was charged by the U.S. Department of Justice with price fixing on generic drugs, saying Glenmark conspired with Apotex and other drug companies to inflate the price of pravastatin, a cholesterol-lowering drug.

- HERON THERAPEUTICS' HTX-011 (extended-release bupivacaine + meloxicam) was rejected by the FDA for a second time as a treatment for postoperative pain. The FDA issued a complete response letter that requested more information on four issues – three related to excipients and another requesting a change in a manufacturing specification – but no new trials were requested.

- Hydroxychloroquine – A reputable study of 2,541 Covid-19-positive patients at Henry Ford Health System in Michigan, published in the ***International Journal of Infectious Diseases***, found that this lupus drug cut mortality in half, from 26% to 13%. Cardiac side effects were not an issue because the drug wasn't given to patients with a history of relevant cardiac issues. That's more than the mortality benefit with dexamethasone, and Gilead Sciences' remdesivir hasn't shown any survival benefit.

- Influenza – Researchers in China reported a new strain of swine flu with similarities to H1N1 (which caused the 2009 swine flu pandemic). The virus isn't an immediate threat but has the potential to become a pandemic.

- INTERCEPT PHARMACEUTICALS' Ocaliva (obeticholic acid) – The FDA rejected expanded approval to treat fibrosis due to NASH, issuing a complete response letter that said the benefit is based on a surrogate endpoint and therefore uncertain and doesn't sufficiently outweigh the potential risks. The FDA said Intercept will need additional trial data and could submit additional data from the ongoing REGENERATE study to support the application for accelerated approval but wants that trial to continue to collect long-term outcomes data. The company's CEO accused the FDA of conducting "an apparently incomplete review."

- MEDTRONIC's Arctic Front Advance and Freezor MAX – The STOP Persistent AF trial, published in the journal ***Heart Rhythm*** – and led by Wilber Su, MD, chief of cardiac electrophysiology at Banner/University Medicine Heart Institute Phoenix – found that using these cryoballoons to ablate pulmonary veins was safe and effective in treating persistent atrial fibrillation.

- MEI PHARMA and HELSINN's pracinostat – An interim analysis of an ongoing Phase III trial of this HDAC inhibitor + azacitidine in acute myeloid leukemia (AML) patients unfit for standard intensive chemotherapy determined that the study was unlikely to meet the primary endpoint of overall survival, and the study was discontinued.

- NORDIC NANOVECTOR's Betalutin (^{177}Lu lilotomab satetraxetan), a next-generation radioimmunoconjugate, was granted fast track status by the FDA as a treatment for relapsed/refractory marginal zone lymphoma patients who have undergone ≥2 systemic therapies.

- OSMOTICA PHARMACEUTICALS' Ontinua (arbaclofen extended-release) – The company submitted an amended new drug application (NDA) to the FDA, seeking approval to treat spasticity in multiple sclerosis (MS) patients. The FDA rejected the drug in 2016, saying an additional Phase III trial was needed, and the resubmission included both a new Phase III trial and data from a long-term open-label trial.

- PFIZER's Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) – Pfizer sued the Department of Health and Human Services (HHS), accusing the agency of blocking it from providing financial aid to Medicare beneficiaries for these two cardiac drugs (which cost $225,000/year). HHS considers the subsidized copays illegal kickbacks, requiring that any copay assistance be done through donations to non-profits that dispense the aid. Pfizer claims this approach violates its constitutional rights to free speech and due process. *It will be interesting to see how the courts rule. This case could have broad implications.*

- REGENERON PHARMACEUTICALS' Arcalyst (rilonacept), an anti-IL-1α/β met the primary endpoint in a Phase III trial, with a 96% reduction in recurrent pericarditis vs. placebo. At Week 16 of the randomized withdrawal period 81% of Arcalyst patients vs. 20% of placebo patients maintained a clinical response, and 81% of Arcalyst patients had no/minimal pericarditis symptoms vs. 25% of placebo patients.

- RUBIUS THERAPEUTICS' RTX-240 – The company said there have been no adverse events so far in the Phase I/II trial of this allogeneic cellular therapy for treating relapsed/refractory or locally advanced solid tumors.

- SAREPTA THERAPEUTICS bought the exclusive worldwide license to **Hansa Biopharma's imlifidase** as a pre-treatment for gene therapy in Duchenne and Limb-girdle muscular dystrophy patients with pre-existing antibodies to AAV.

- SUMITOMO DAINIPPON PHARMA merged two divisions – Tolero Pharmaceuticals and Boston Biomedical – into Sumitomo Dainippon Pharma Oncology.

- TAKEDA is collaborating with **Carmine Therapeutics** on discovery, development, and commercialization of two non-viral gene therapies – that use red blood cell extracellular vesicles instead of AAV vectors – for rare diseases.

- VERVE THERAPEUTICS – A monkey study, presented at the International Society for Stem Cell Research virtual meeting, showed that LDL cholesterol and triglyceride levels could be permanently reduced by turning off two genes using adenine base editing.

- ZYNERBA PHARMACEUTICALS' Zygel (cannabidiol gel) missed the primary endpoint in the Phase III 14-week CONNECT-FX trial in Fragile X syndrome, failing to significantly improve the Social Avoidance subscale of the Aberrant Behavior Checklist-Community FXS (ABC-C_{FXS}). Zygel also missed the secondary endpoints of irritability, unresponsive/lethargic subscale score, and clinical global impression (CGI). However, the company said Zygel did have positive results on the primary endpoint at Week 12, so it isn't quite ready to give up on the drug.

NEWS IN BRIEF

GILEAD SCIENCES

- **Biktarvy (bictegravir + emtricitabine + tenofovir alafenamide).** New data on this once-daily treatment for HIV will be presented at the virtual AIDS 2020 meeting showing:
  - **Age.** A pooled analysis of 4 international trials showed that at 48 weeks 92% of patients age ≥65 who switched to Biktarvy maintained virologic suppression, with HIV RNA<50 copies/mL, without significant impact on lipid levels, weight, or interactions with other drugs taken for comorbidities (e.g., diabetes).
  - **Resistance.** A new analysis from multiple studies of drug resistance found that HIV patients with a history of treatment failure or pre-existing NRTI resistance could safely be switched to Biktarvy without increasing "blips" in treatment.

- **Veklury (remdesivir)** was priced at $390/vial (or $2,340 for a typical 5-day treatment) for the Department of Defense and Veterans Affairs hospitals, but the cost will be $520/vial or $3,120 per course for insurance companies. For developing countries (where generics are allowed) the price is $600 for a series of six treatments.

REGULATORY NEWS

Regulatory tidbits

- **Covid-19.** HHS plans to renew the public health emergency declared over Covid-19 before it expires on July 25, extending it for another 90 days.

- **FDA**
  - **Covid-19 tests.** The FDA issued its first SARS-CoV-2 reference panel materials to help in validation of Covid-19 diagnostic tests.

- **Covid-19 vaccines.** The FDA issued guidance on requirements for approval of a vaccine, suggesting that a vaccine – even for an emergency use authorization (EUA) – will have to have 6-month safety data, clinical efficacy (defined as preventing or decreasing severity by ≥50%), and a study with thousands of patients. However, once one vaccine is approved, it may be easier for follow-on vaccines using the same approach to get approved.
- **UDIs.** The FDA extended the date for compliance with unique device identifier requirements for Class I devices, unclassified medical devices, and certain other devices to September 24, 2022.

■ Pay-for-delay. Under a California Supreme Court ruling, county district attorneys can seek civil penalties and restitution from drug companies that engage in patent settlements that violate a statute prohibiting unfair or fraudulent business practices.

FDA approvals

■ ACACIA PHARMA's Byfavo (remimazolam) was approved for the induction and maintenance of procedural sedation in procedures lasting ≤30 minutes.

■ AXONICS MODULATION TECHNOLOGIES' Axonics r-SNM System was granted MRI-conditional labeling for use in a 3T full-body MRI.

■ BOSTON SCIENTIFIC's LUX-Dx, an insertable cardiac monitor for detecting arrhythmias related to conditions such as cryptogenic stroke, syncope, and atrial fibrillation, was granted 510(k) clearance.

■ CORELINK's F3D-C2, a 3D-printed implant for use during spine surgery to remove a degenerative or herniated cervical disk, was granted 510(k) clearance.

■ ENDO GI MEDICAL's stent placement system for simultaneously placing two stents in the bile ducts connected to the pancreas was approved for use.

■ MASIMO's Bridge, a wearable neuromodulation-based device for reducing heightened neuron activity in people experiencing opioid withdrawal, was granted de novo clearance.

■ MEDTRONIC's Arctic Front Advance, a cryoballoon, was approved to ablate pulmonary veins in patients with *persistent* atrial fibrillation.

■ MERCK MSD's Keytruda (pembrolizumab) was approved as a first-line treatment for unresectable/metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (without chemotherapy).

■ ORTHOFIX's Firebird SI 3D-printed titanium bone screws were granted 510(k) clearance for use in treating sacroiliac joint dysfunction.

■ PFIZER and MERCK KGAA's Bavencio (avelumab) was granted expanded approval for first-line maintenance of bladder cancer.

■ ROCHE's Phesgo (fixed-dose combination of pertuzumab, trastuzumab, and hyaluronidase-zzxf) was approved for subcutaneous injection for use (1) in combination with chemotherapy as a neoadjuvant treatment for HER2+ locally advanced, inflammatory, or early-stage breast cancer or as an adjuvant treatment in HER2+ early breast cancer patients at high risk of recurrence and (2) in combination with docetaxel to treat HER2+ metastatic breast cancer patients who have not had prior anti-HER2 therapy or chemotherapy for metastatic disease.

■ ULTRAGENYX PHARMACEUTICAL's Dojolvi (triheptanoin, UX-007) was approved for a new indication – treating pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

■ VIIV HEALTHCARE's Rukobia (fostemsavir), an antiretroviral, was approved to treat adults whose HIV infection could not be successfully treated with other therapies because of resistance, intolerance, or safety considerations.

FDA recalls/warnings

■ ARROW INTERNATIONAL's Arrow AutoCAT2 and AC3 Optimus Intra-Aortic Balloon Pump (IABP) Series were recalled (Class I) due to the possibility of a motor connector wire breaking.

■ Covid-19

- **Unapproved products.** The FDA and the Federal Trade Commission (FTC) jointly sent a warning letter to:
  - ✓ Two Hong Kong companies – SuperHealthGuard and Loyal Great International – to order them to stop selling unapproved products online to customers in the U.S. that claim to mitigate, prevent, treat, diagnose, or cure Covid-19.
  - ✓ The Center for Wellness and Integrative Medicine for selling unapproved/unauthorized products to mitigate, prevent, treat, diagnose, or cure Covid-19.
- **Hand sanitizer**
  - ✓ ESKBIOCHEM – The FDA warned consumers not to use hand sanitizer products manufactured in Mexico by this company due to potential contamination with methanol (wood alcohol), which can be toxic when ingested or absorbed through the skin.

✓ TRANSLIQUID TECHNOLOGIES' Mystic Shield, a hand sanitizer, was recalled because it contains methanol.

European Regulatory News

- BRISTOL-MYERS SQUIBB/CELGENE and ACCELERON PHARMA's Reblozyl (luspatercept), an erythroid maturation agent, was approved by the European Medicines Agency (EMA) to treat anemia in adults with low- or intermediate-risk myelodysplastic syndrome (MDS) who have ring sideroblasts.
- GILEAD SCIENCES' Veklury (remdesivir) – The European Commission granted conditional marketing authorization to this antiviral to treat Covid-19 patients age ≥12 with pneumonia who need additional oxygen support.
- JOHNSON & JOHNSON's Zabdeno (Ad26.ZEBOV) and Mvabea (MVA-BN-Filo) – a two-dose Ebola vaccine – was approved by the European Commission.
- KDX DIAGNOSTICS' URO17 Bladder Cancer Recurrence test was granted a CE Mark.

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

- VERTEX PHARMACEUTICALS' Kaftrio (tezacaftor + ivacaftor + elexacaftor) – NICE finally approved this treatment for cystic fibrosis if and when the EMA approves it.

Regulatory news from other countries

- *Australia.* MEDTRONIC's Infuse – The company pulled this bone morphogenetic protein from the market in Australia due to reports that spine surgeons were using it off-label. It will still be available through a special access program.
- *Japan.*
  - AKEBIA THERAPEUTICS and MITSUBISHI TANABE PHARMA's Vafseo (vadadustat) was approved by the Ministry of Health, Labour, and Welfare (MHLW) to treat anemia due to chronic kidney disease in dialysis-dependent and non-dialysis dependent adults.
  - GLAXOSMITHKLINE and KYOWA KIRIN's Duvroq (daprodustat) was approved by the MHLW to treat anemia caused by chronic kidney disease.
  - ROCHE's Enspryng (satralizumab), an anti-IL-6, was approved by the MHLW to treat adults and children with neuromyelitis optica spectrum disorder (NMOSD).

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
July 6	**BioSpecifics Technologies and Endo International's collagenase clostridium histolyticum** (CCH) for treating/removing cellulite from women's buttocks	PDUFA date
July 8	**Eagle Pharmaceuticals' Ryanodex** (dantrolene sodium) to treat heat stroke (resubmission)	PDUFA date
July 13	**Averitas Pharma's Qutenza** (capsaicin patch) – expanded approval to treat neuropathic pain from diabetic peripheral neuropathy	PDUFA date
July 13-14	Establishing a high-quality **real-world data** ecosystem	FDA and Duke-Margolis virtual public meeting
July 14	**GlaxoSmithKline's belantamab mafodotin** for relapsed/refractory multiple myeloma	FDA's Oncologic Drugs Advisory Committee *virtual* meeting
July 16	**Osmotica Pharmaceuticals/Vertical Pharmaceuticals' RVL-1201** (oxymetazoline hydrochloride ophthalmic solution) for acquired blepharoptosis	PDUFA date
July 17	2020 Clinical Outcome Assessments in **Cancer Clinical Trials**	FDA-ASCO virtual public workshop
July 21	**Jazz Pharmaceuticals' JZP-258** for cataplexy and excessive daytime sleepiness associated with narcolepsy	PDUFA date
July 21	Reauthorization of the **generic drug user fee amendment** (GDUFA)	FDA virtual public meeting
July 21 (est.)	**Seattle Genetics and GlaxoSmithKline's belantamab mafodotin**, an anti-BCMA for relapsed/refractory multiple myeloma	PDUFA date
July 23	**Reauthorization of the Prescription Drug User Fee Act (PDUFA)** for 2023-2027	FDA virtual public meeting
July 31	**GW Pharmaceuticals/Greenwich Biosciences' Epidiolex** (canabidiol) – expanded approval for use in treating seizures associated with tuberous sclerosis complex	PDUFA date
August 2 (est.)	**Theravance Biopharma and GlaxoSmithKline's Trelegy Ellipta** (fluticasone furoate + umeclidinium + vilanterol) – expanded approval for improving lung function, quality of life, and symptom control in asthma	PDUFA date
August 4	Development of **antifungal drugs** to treat unmet medical need	FDA public workshop *Rescheduled from May 7*
August 5	Development of **antifungal drugs to treat Valley Fever** (coccidioidomycosis)	FDA public workshop *Rescheduled from May 8*
August 5	**DBV Technologies' Viaskin Peanut** for treating children with peanut allergy	FDA target action date
August 7	**Trevena's Olinvo** (oliceridine) for moderate-to-severe pain in hospitalized patients	PDUFA date
August 10	**Gilead Sciences/Kite Pharma's KTE-X19** for relapsed/refractory mantle cell lymphoma	PDUFA date
August 10 (est.)	**Bausch Health/Eton Pharmaceuticals' EM-100**, an eyedrop for treating ocular itchiness (resubmission)	PDUFA date
August 11	Independent third-party assessment of IND FDA-Sponsor Communication practices in **PDUFA VI**	FDA virtual public meeting
August 13	**Spinal device premarket review**	FDA virtual public workshop
August 16	**Jazz Pharmaceuticals and PharmaMar's lurbinectedin** for second-line relapsed small cell lung cancer	PDUFA date
August 17	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date *Postponed to November 16, 2020*
August 18-19	**Annual meeting**	Science Advisory Board to the National Center for Toxicological Research
August 20	**Seattle Genetics' tucatinib** – in combination with Roche's Herceptin + Xeloda – to treat breast cancer	PDUFA date
August 21	**BioMarin Pharmaceutical's valoctocogene roxaparvovec**, a gene therapy for hemophilia A	PDUFA date
August 21	Development considerations of antimicrobial drugs to treat **gonorrhea**	FDA public workshop – virtual
August 24	**Roche's risdiplam** (RG-7916) to treat spinal muscular atrophy	PDUFA date *Extended from May 24*
August 27	**Cassiopea's Winlevi** (clascoterone cream 1%), a topical androgen receptor inhibitor for acne	PDUFA date
August 28	**Lipocine's Tlando** (oral testosterone) for hypogonadism (resubmission)	PDUFA date
August 28	**CDER standard core sets** clinical outcome assessements and endpoints grant program	FDA public meeting *and* webcast
August 30	**MorphoSys and Incyte's tafasitamab** for use in combination with lenalidomide to treat relapsed/refractory diffuse large B-cell lymphoma	PDUFA date

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
September tba	**Novartis' ofatumumab** for relapsing multiple sclerosis	PDUFA date *Extended from June 2020*
September 3	**Bristol-Myers Squibb's CC-486** (oral azacitidine) for acute myeloid leukemia	PDUFA date
September 27	**Aquestive Therapeutics' Libervant** (diazepam buccal film) for seizure clusters in epileptics	PDUFA date
Sept. 28-30	Global summit on regulatory science: **Emerging Technologies**	FDA summit **https://aralliance.org/gsrs/**
September 30	**Patient-reported outcomes** (PROs) and medical device investigations	FDA virtual public meeting
October 18	**Roche's Herceptin** (trastuzumab) **+ Perjeta** (pertuzumab) – a fixed dose combination to treat HER2+ breast cancer	PDUFA date
October 24	**Spectrum Pharmaceuticals' Rolontis** (eflapegrastim) for treating chemotherapy-induced neutropenia	PDUFA date
October 25	**Regeneron Pharmaceuticals' REGN-EB3** for Ebola	PDUFA date
November 15	**Alkermes' ALKS-3831** (olanzapine + samidorphan) for bipolar I disorder and schizophrenia	PDUFA date
November 16	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date *Postponed from August 17*
November 20	**Eiger BioPharmaceuticals' Zokinvy** (lonafarnib) for progeria and progeroid laminopathies	PDUFA date
November 25	**Revance Therapeutics' daxibotulinumtoxinA** for moderate-to-severe glabellar lines	PDUFA date
November 27	**Rhythm Pharmaceuticals' setmelanotide** for pro-opiomelanocortin deficiency obesity and leptin receptor deficiency obesity	PDUFA date
December tba	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	PDUFA date
December 3	**BioCryst Pharmaceuticals' berotralstat** (BCX-7353) for hereditary angioedema attacks	PDUFA date
December 20	**FibroGen and AstraZeneca's roxadustat** for anemia of chronic kidney disease	PDUFA date
December 20	**Myovant Sciences' Relumina** (relugolix) for advanced prostate cancer	PDUFA date
December 26	**Sumitomo Dainippon Pharma/Urovant Sciences' vibegron** for overactive bladder	PDUFA date
December 30	**Almirall and Athenex's tirbanibulin** (KX2-391, KX-01) for actinic keratosis	PDUFA date