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

Remember, virtually all of the items in *Quick Takes* have a link somewhere in the item, except the calendar.

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

- ✓ ATRICURE is buying SentreHEART.
- ✓ BECTON DICKINSON/C.R. BARD's Lutonix – The FDA rejected expanded use of this paclitaxel-eluting balloon for treating peripheral artery disease below the knee.
- ✓ CONCEPT MEDICAL's MagicTouch, a sirolimus-eluting balloon for treating PAD below the knee, was granted breakthrough device designation by the FDA.
- ✓ DECIPHERA PHARMACEUTICALS' ripretinib met the primary endpoint in a Phase III trial in GIST.
- ✓ DMD – ICER's final report determined that both **PTC Therapeutics' Emflaza (deflazacort)** and **Sarepta Therapeutics' Exondys 51 (eteplirsen)** are not cost-effective.
- ✓ REGENERON PHARMACEUTICALS' evinacumab met the primary endpoint in a Phase III trial in homozygous familial hypercholesterolemia (HoFH).

SHORT TAKES

- ABIOMED's Impella – The Centers for Medicare and Medicaid Services (CMS) postponed for one year a proposed 27% decrease in Medicare reimbursement to hospitals for this percutaneous ventricular support device.
- AC IMMUNE is collaborating with the University of Pennsylvania's Center for Neurodegenerative Disease Research to determine the role of TDP-43 in frontotemporal lobar degeneration (FTLD) and amyotrophic lateral sclerosis (ALS).
- AKARI THERAPEUTICS' Coversin (nomacopan), an investigational treatment for hematopoietic stem cell transplant-associated thrombotic microangiopathy in pediatric patients, was granted fast track status by the FDA.
- ALLSCRIPTS HEALTHCARE SOLUTIONS/2BPRECISE is partnering with Q-State Biosciences to build clinical genomic datasets to help pharmas develop precision medicines.
- ASCYRUS MEDICAL's AMDS, a stent graft for treating acute Type A abdominal aortic dissections, was granted breakthrough device status by the FDA.
- ASKBIO bought Synpromics, which has customized synthetic promoters for use in gene therapy development.

- ATRICURE is buying **SentreHEART**, which will give it the Lariat for left atrial appendage (LAA) closure in atrial fibrillation patients.

- AUTOLUS is delaying several CAR T cell immunotherapy programs – AUTO3 for diffuse large B-cell lymphoma (DLBCL), and AUTO4 and AUTO5 for T-cell lymphoma – by five months because of delays in completing its new manufacturing facility at the U.K. Cell and Gene Therapy Catapult center. It also is terminating AUTO2 for multiple myeloma.

- BECTON DICKINSON/C.R. BARD's Lutonix – The FDA rejected expanded premarket approval for this paclitaxel-eluting balloon for treating peripheral artery disease below the knee (BTK), issuing a complete response letter that said the device is "not approvable in its current form."

- BOEHRINGER INGELHEIM is collaborating with the University of Texas MD Anderson Cancer Center on researching therapies for gastrointestinal and lung cancer, starting with KRAS pathway inhibitors and a Boehringer TRAILR2 antibody (maybe BI-905711), through MD Anderson's Therapeutics Discovery division.

- Chlamydia – The results of a 35-patient Phase I trial, published in ***Lancet Infectious Diseases***, showed that CTH-522, an investigational vaccine (administered by intramuscular injection), was safe and caused the women to produce an immune response. Two formulations were tested – one with liposomes added and one with aluminium hydroxide – and the liposomal formulation was the most effective. **Statens Serum Institut**, a Danish not-for-profit institute, has the rights to the vaccine.

- CONCEPT MEDICAL's MagicTouch, a sirolimus-eluting balloon for treating peripheral artery disease (PAD) below the knee, was granted breakthrough device designation by the FDA. *Remember, all approved DCBs elute paclitaxel.*

- CUREVAC is collaborating with Yale University on development of mRNA-based lung therapies.

- DECIPHERA PHARMACEUTICALS' ripretinib met the primary endpoint in the 129-patient Phase III INVICTUS trial in ≥4-line advanced gastrointestinal stromal tumors (GIST), significantly improving progression-free survival (PFS) vs. placebo (6.3 months vs. 1 month).

- DR. REDDY'S LABORATORIES – The FDA issued two complete response letters, rejecting: **gNuvaRing**, a generic version of Merck MSD's NuvaRing, a vaginal ring contraceptive; and **glatiramer acetate**, a generic version of Teva's Copaxone, a treatment for multiple sclerosis.

- DYNACURE's DYN-101, an investigational antisense drug for treating centronuclear myopathies, was granted orphan drug status by the FDA.

- Ebola update – A trial of four experimental therapies in the Democratic Republic of the Congo was halted early based on an interim analysis of 499 patients because **Regeneron's REGN-EB3** and **Ridgeback Biotherapeutics' mAb114** were found to have a better efficacy (a lower mortality rate) than Gilead Sciences' remdesivir and Mapp Biopharmaceutical's ZMapp.

- GE HEALTHCARE is collaborating with **Fujitsu** to support Australian research into use of artificial intelligence (AI) to detect brain aneurysms.

- GENECENTRIC THERAPEUTICS bought **Select Immuno-Genomics**, a data analysis, biomarker development, and immunogenomic services provider.

- GENETX BIOTHERAPEUTICS' GTX-102 – **Ultragenyx Pharmaceutical** agreed to partner on development of this treatment for Angelman syndrome.

- JAZZ PHARMACEUTICALS bought **Cavion**, a biotechnology company focused on rare, chronic neurological diseases, which has CX-8998, a T-type calcium channel modulator, in development to treat essential tremor.

- LILLY's Taltz (ixekizumab), an IL-17A inhibitor, demonstrated superiority to **Johnson & Johnson's Tremfya** (guselkumab), an IL-23 inhibitor, in the 1,027-patient head-to-head Phase IV IXORA-R trial in moderate-to-severe psoriasis. Taltz met the primary endpoint (PASI100) and all major secondary endpoints at Week 12

- MALLINCKRODT's StrataGraft – The results of a Phase Ib trial, published in ***Burns***, the journal of the International Society for Burn Injuries, showed that a single application of this regenerative tissue led to wound closure in 27 of 29 patients, and none of those 27 patients required an autograft by Day 28. At 12 months, the characteristics of the wounds treated with StrataGraft were comparable to patients treated with autograft.

- MERCK MSD's Keytruda (pembrolizumab) – Merck is collaborating with **Oncologie** to test this PD-1 inhibitor with Oncologie's bavituximab, a phosphatidylserine inhibitor, in a single-arm, open-label Phase II trial in patients with advanced gastric or gastroesophageal cancer. *Keytruda didn't work alone in these patients, and the hope is that dual therapy will work better.*

- NANJING XINBAI/DENDREON's Provenge (sipuleucel-T) – A review conducted by the FDA of the FDA Adverse Event Reporting System (FAERS), published in ***JAMA Network Open***, found that this vaccine for metastatic castration-resistant prostate cancer (mCRPC) has maintained a good safety record since approval in 2010.

- NEUROPORE THERAPIES' NPT-520-34 was granted orphan drug status by the FDA as a treatment for ALS.

- ONCONOVA THERAPEUTICS' rigosertib – The company partnered with **Mission Bio** to study this cancer drug.

- REGENERON PHARMACEUTICALS' evinacumab, an ANGPTL3 antibody, met the primary endpoint in a pivotal Phase III trial in homozygous familial hypercholesterolemia (HoFH), decreasing LDL by 49% vs. a 2% increase with placebo. Adverse events were actually lower with evinacumab than placebo (66% vs. 81%).

- Renal denervation – A preclinical study, published in the journal ***Hypertension***, suggests that delivering at least 4 successful catheter-based renal artery ablations (four-quadrant ablation) may assure efficacy in treating resistant hypertension. The study also provided insight into the connection between the patient's anatomy and post-procedure efficacy.

- SAAMA TECHNOLOGIES, a clinical data and analytics company, is buying **Comprehend Systems**, which partnered with DP Clinical.

- SONNET BIOTHERAPEUTICS is buying **Relief Therapeutics SA**, which will give it atexakin alfa, a low-dose anti-IL-6 for treating chemotherapy-induced peripheral neuropathy that Relief got from Merck KGaA.

- SYAPSE was chosen to work with the FDA's Oncology Center of Excellence on helping with evaluation of real-world data.

- TUFTS HEALTH PLAN and **Harvard Pilgrim Health Care** are merging.

- V-WAVE's minimally-invasive, implanted interatrial shunt was granted breakthrough device designation by the FDA for use in heart failure patients.

- VITALINK, a clinical research site business, bought **Comprehensive Clinical Trials**, which conducts women's health trials.

- WIRB-Copernicus Group (WCG) bought **PharmaSeek**, which provides consulting, training, and patient recruitment for clinical research sites.

Animal health news

- HYPOPET's HypoCat – A Swiss study, published in the ***Journal of Allergy and Clinical Immunology***, found that this investigational injectable vaccine makes cats hypoallergenic by reducing or eliminating the allergens their bodies naturally produce.

Very early research news

- Pancreatic cancer – Australian researchers reported in ***Nature Communications*** on their finding that the protein perlecan is overproduced in pancreatic tumors. In a study in a mouse model of pancreatic cancer, reducing the levels of perlecan slowed the spread of the cancer and improved the response to chemotherapy.

NEWS IN BRIEF

ASTRAZENECA

- Adavosertib (AZD-1775). New research by University of Michigan researchers, published in the ***Journal of Clinical Oncology***, showed that this Wee1 inhibitor combined with radiation and gemcitabine increased both PFS and overall survival (21.7 months vs. a historical rate of 12-14 months) in advanced pancreatic cancer. *It is early Phase I data, but this old drug may be getting new life.*

- Calquence (acalabrutinib) was granted breakthrough therapy designation by the FDA as a treatment for adults with chronic lymphocytic leukemia (CLL).

- and MERCK MSD's Lynparza (olaparib), a PARP inhibitor, in combination with Roche's Avastin (bevacizumab) significantly improved PFS in first-line maintenance in ovarian cancer vs. Avastin alone in the >800-patient Phase III PAOLA-1 trial, initiated by European investigators. While women with no BRCA mutation were allowed in the trial, no data were released on how the drug performed in those women.

BOSTON SCIENTIFIC

- Synergy. The results of a Swiss real-world registry, published in ***JACC: Cardiovascular Interventions***, showed that this cardiac stent, which has a bioresorbable polymer on the abluminal surface only, had a higher acute stent thrombosis rate vs. Abbott's Xience (1.2% vs. 0.3%), but at 12 months there was no difference in stent thrombosis.

- Watchman. A study, published in ***Cardiovascular Revascularization Medicine***, found that operator experience does not affect technical success or major adverse cardiac events (MACE) in patients getting this left atrial appendage (LAA) closure device.

Duchenne muscular dystrophy (DMD) drugs – ICER's opinion

The Institute for Clinical and Economic Review (ICER) issued its final report on two DMD drugs, concluding that neither of them is cost-effective.

- **PTC Therapeutics' Emflaza (deflazacort)** – At $89,000/year, ICER concluded this is not more effective than prednisone. The panel voted 10-7 that Emflaza provides better motor function and less weight gain but concluded that the price is not justifiable.
- **Sarepta Therapeutics' Exondys 51 (eteplirsen)** – The panel voted 16 to 1 that the evidence is inadequate to conclude the drug is superior to supportive care alone, saying it does not improve patients enough to justify use at its high price (~$1 million/year).
- **Sarepta Therapeutics' golodirsen** – The panel was unanimously skeptical of this drug, which is under FDA review.

NOVARTIS

- CDZ-173, a small molecule PI3Kδ inhibitor for treating activated phosphoinositide 3-kinase delta syndrome (APDS), was outlicensed to **Pharming**.
- Comtan (entacapone) and Stalevo (entacapone + carbidopa/levodopa) – The FDA concluded that entacapone, a Parkinson's disease drug, is ***not*** associated with an increased risk of prostate cancer.

What will be the best selling drugs in 2024?

Prediction: Top Selling Drugs in History in 2024		
Company	**Drug**	**Total sales (in billions)**
AbbVie	Humira (adalimumab)	$240.5
Pfizer	Lipitor (atorvastatin)	$180.2
Amgen	Enbrel (etanercept)	$139.8
Roche	Rituxan (rituximab)	$136.1
Celgene	Revlimid (lenalidomide)	$123.6
Johnson & Johnson	Remicade (infliximab)	$117.2
Amgen	Epogen (epoetin alfa)	$115.9
Roche	Herceptin (trastuzumab)	$114.9
Roche	Avastin (bevacizumab)	$114.3
GlaxoSmithKline	Advair (fluticasone + salmeterol)	$113.6

* Source: EvaluatePharma

ZIPLINE MEDICAL's Zip Surgical Skin Closure

Positive results with this wound closure system in two single-center studies were published in two journals:

- In the ***Journal of Knee Surgery***, the results of a trial in patients undergoing same-day bilateral knee replacement showed that Zip patients had significantly better clinical and patient satisfaction vs. surgical staples, with greater range of motion at Week 2, less pain, and better scar quality.
- In the journal ***Cureus***, a 130-patient retrospective chart review of knee replacement patients who received Zip therapy found Zip was significantly less expensive for the clinic overall than surgical staples.

REGULATORY NEWS

Regulatory tidbits

- EMA/FDA. A joint analysis by the FDA and the European Medicines Agency (EMA) found that the two regulators are in accordance on approval of >90% of the 107 new drug applications filed at the agencies from 2014-2016. When the decisions did differ it was most commonly about efficacy. Other findings included:
  - More drugs were submitted to the FDA first.
  - The EMA more often reviewed applications with additional trials or more mature data from the same clinical trial. When EMA had that additional data, it was more likely than the FDA to grant standard approval or first-line use.
- EpiPen (epinephrine). A new law makes Illinois the first state to require insurers to cover these devices (any brand), effective January 1, 2020, when medically necessary for patients age ≤18.
- Postmarketing studies. A study, published in ***Milbank Quarterly***, questions the FDA's reliance on – and ability to enforce – postmarketing study requirements. While the Agency depends on postmarketing studies, it doesn't have the necessary enforcement powers, and can face an uphill battle to withdraw approval when a postmarketing study fails.

FDA approvals/clearances

- ABBVIE's Rinvoq (upadacitinib), an oral JAK inhibitor, was approved to treat moderate-to-severe rheumatoid arthritis.
- BINX HEALTH's binx *io*, a point-of-care PCR test for gonorrhea and chlamydia, was granted 510(k) clearance.
- CELGENE's Inrebic (fedratinib), a JAK2 inhibitor, was approved to treat adults with certain types of myelofibrosis.
- CVRx's Barostim Neo System, a neuromodulating device, was granted premarket approval for treating heart failure patients not able to use another heart failure device (e.g., cardiac resynchronization therapy, CRT).

- DYNOSENSE's Vital Signs Measuring System, a cloud-based vital signs measuring and recording platform, was cleared for use.
- THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT's pretomanid (PA-824) tablets were approved to treat – in combination with bedaquiline and linezolid – highly-resistant tuberculosis of the lungs (XDR-TB). The TB Alliance was also granted a Tropical Disease Priority Review Voucher.
- HARMONY BIOSCIENCES' Wakix (pitolisant) was approved to treat excessive daytime sleepiness in adults with narcolepsy. It is the first non-scheduled treatment for narcolepsy in the U.S.
- JOHNSON & JOHNSON's Situro (bedaquiline) was granted expanded approval to treat tuberculosis patients age ≥12.
- MERCK MSD's Asmanex HFA (mometasone furoate) and Dulera (mometasone furoate + formoterol fumarate) were both granted expanded approval to treat pediatric asthma – Asmanex HFA down to age 5 and Dulear BID in patients age ≥5.
- NEXXT SPINE's Nexxt Matrixx, a standalone cervical spine system for use with either autograft bone graft and/or allogeneic bone graft made of cancellous and/or corticocancellous bone as an adjunct to fusion for treating degenerative disc disease, was granted 510(k) clearance.
- REGENERON and BAYER's Eylea (aflibercept) – A single-dose 2 mg single-use pre-filled syringe of this anti-VEGF was cleared for use in treating four retinal conditions, including wet age-related macular degeneration (AMD).
- ROCHE/GENENTECH's Rozlytrek (entrectinib) was approved to treat ROS1+ metastatic non-small cell lung cancer (NSCLC) and NTRK gene fusion-positive solid tumors. Roche priced it at $17,050/month. *Remember, Bayer's Vitrakvi (larotectenib), another NTRK fusion agent licensed from Loxo Oncology, is priced at $32,800/month.*
- SHOCKWAVE MEDICAL's S4, a new/improved version of this below-the-knee intravascular lithotripsy device, was cleared for use.
- SOLCO BIOMEDICAL's 4CIS Chiron, a spinal fixation device, was cleared for use in all spinal surgery methods (e.g., mono- and poly-cannula operations, reduction and minimally invasive procedures) to prevent pull-out after surgery.
- TAVR – Treating low-risk patients with severe aortic stenosis with transcatheter aortic valve replacement (TAVR) was approved, and this applies to both **Medtronic's Evolut** and **Edwards Lifesciences' Sapien 3 and Ultra**.
- ZIMMER BIOMET's The Tether, a ropelike spinal implant for pediatric scoliosis, was approved for humanitarian device exemption (HDE) use.

FDA recalls/warnings

- EMCURE PHARMACEUTICALS received a warning letter for not properly investigating how microbial growth turned up in batches of its amikacin sulfate (an anti-infective) and prochlorperazine edisylate (a schizophrenia drug).
- FRESENIUS KABI's Volumat MC Agilia Infusion Pump and Vigilant Agilia Drug Library were recalled (Class I) because of potentially fatal software issues that cause a "low priority" message to appear when it should be an alarm.
- LANTECH PHARMACEUTICALS, a solvent recovery firm in India got a warning letter that its products may have contributed to some of the tainted sartans through its processing methods, which may have allowed cross-contamination of solvents.
- NATCO PHARMA received another Form 483 for its active pharmaceutical ingredient (API) plant in India, citing procedural and training issues.
- PFIZER's Relpax (eletriptan hydrobromide) – Two lots of this migraine drug were voluntarily recalled because they may be out of specification and contaminated with *Genus Pseudomonas* and *Burkholderia*.

European Regulatory News

- ***U.K. – Scotland.*** VERTEX PHARMACEUTICALS' Orkambi (lumacaftor + ivacaftor) and Symkevi (tezacaftor + ivacaftor) – The Scottish Medicines Consortium (SMC) rejected use of both of these cystic fibrosis drugs, saying they are not cost-effective with current pricing.
- **Biologics.** The EMA told companies they must declare fish peptone use in biologics (e.g., insulin) fermentation and the source of those peptones.
- EXTHERA MEDICAL's Seraph 100 Microbind Affinity, a blood filter for reducing pathogens during bloodstream infections as an adjunct to anti-infective treatment, was granted a CE Mark.
- GILEAD SCIENCES and GALAPAGOS' filgotinib – The EMA accepted for review a marketing authorization application (MAA) for this oral JAK1 inhibitor for treating rheumatoid arthritis.
- JOHNSON & JOHNSON/JANSSEN's Imbruvica (ibrutinib) was granted expanded approval by the European Commission to treat (1) treatment-naïve adults with CLL in combination with Roche's Gazyva (obinutuzumab) and (2) adults with Waldenström's macroglobulinemia in combination with Roche's Rituxan (rituximab).

- MISONIX's Nexus, an integrated ultrasonic surgical device, was granted a CE Mark for use in helping surgeons perform more efficient bone removal surgeries.
- RESTORATION ROBOTICS' ARTAS iX, a robotic hair restoration system, was granted a CE Mark.

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

- MERCK MSD's Keytruda (pembrolizumab) – NICE issued draft guidance that recommends first-line use of this PD-1 inhibitor to treat NSCLC in combination with chemotherapy through the Cancer Drugs Fund. However, NICE did not recommend routine prescribing by the National Health Service (NHS).

Regulatory news from other countries

- ***Canada.*** The government is changing its drug pricing program and will no longer use the U.S. or Switzerland as a comparator.
- ***Japan.*** MITSUBISHI TANABE PHARMA is collaborating with **Jichi Medical University** on development of a gene therapy to treat hemophilia B with funding from the Japan Agency for Medical Research and Development's Cyclic Innovation for Clinical Empowerment program.

2019 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
August 14	**Galt Pharmaceuticals' Orphengesic Forte** (orphenadrine citrate + caffeine + aspirin), a non-opioid painkiller	PDUFA date ***No decision announced yet***
August 16	**Vanda Pharmaceuticals' Hetlioz** (tasimelteon) – expanded approval to treat jet lag	PDUFA date – *likely delayed due to deficiencies in filing*
August 19	**Nabriva Therapeutics' lefamulin**, a pleuromutilin antibiotic for treating community-acquired bacterial pneumonia	PDUFA date
August 19	**Sarepta Therapeutics' golodirsen** (SRP-4053), an exon skipping therapy for Duchenne muscular dystrophy	PDUFA date
August 22	Final guidance on marketing clearance of **diagnostic ultrasound systems and transducers**	FDA *webinar*
August 28	**Intellipharmaceutics' Rexista** (oxycodone), an abuse and alcohol-deterrent controlled-release opioid	PDUFA date
August 29	**Nektar Therapeutics/Inheris Biopharma's NKTR-181** for low back pain	PDUFA date *Extended by the FDA from May 28*
September 2	**Roche's Tecentriq** (atezolizumab) + **Celgene's Abraxane** (nab-paclitaxel) in front-line metastatic non-squamous NSCLC	PDUFA date
September 6	Gaps in therapies for **primary mitochondrial diseases**	FDA public workshop
Sept. 9-10	**Scientific computing**	FDA symposium
September 10	**Xeris Pharmaceuticals' Gvoke** (liquid glucagon autoinjection) for severe hypoglycemia	PDUFA date *Extended by the FDA from June 10*
September 10	Discussion of medical device **cybersecurity**	FDA's Patient Engagement Advisory Committee
Sept. 11-12	FDA **Science Forum**	FDA forum
September 12	**Ardelyx's tenapanor** for irritable bowel syndrome with constipation	PDUFA date
September 13	**Aimmune Therapeutics' AR-101** for peanut allergy risk reduction	FDA's Allergenic Products Advisory Committee
September 15	**Avadel Pharmaceuticals' AV-001** (once-nightly sodium oxybate), a hospital product	PDUFA date
Sept. 16-17	Identification and use of biomarker for development of **preventive vaccines**	FDA public workshop
Sept. 16-18	**Manufacturing innovation, quality, and compliance**	FDA and 2019 Parenteral Drug Association joint regulatory conference
September 17	Standards for future **opioid therapy approvals**	FDA public meeting
September 18	Implementing the FDA's **Predictive Toxicology Roadmap** – update	FDA public workshop
September 20	**Merck MSD's Pifeltro** (doravirine) and **Delstrigo** (doravirine + lamivudine + tenofovir disoproxil fumarate) – expanded use to treat HIV-1+ patients switching from a stable antiretroviral therapy	PDUFA date
Sept. 24-26	**Regulatory science**	FDA global summit ***in Italy***
September 26	**Johnson & Johnson/Janssen's Darzalex** (daratumumab) in combination with VTD to treat multiple myeloma	PDUFA date
September 26	Consideration of **ICER's report on additive cardiovascular disease therapies** – Amarin's Vascepa (icosapent ethyl) and Johnson & Johnson's Xarelto (rivaroxaban)	Midwest CEPAC meeting at the University of Missouri-St. Louis
September 27	**Intra-Cellular Therapies' lumateperone** for schizophrenia	PDUFA date *May be extended to December 27 due to new data submitted to the FDA*
September 28	**Amarin's Vascepa** (icosapent ethyl) – expanded approval to reduce cardiovascular risk in statin-managed patients with high triglycerides	PDUFA date *Expected to be extended to December 28, 2019*
October 6	**Clinuvel Pharmaceuticals' Scenesse** (afamelanotide) for preventing phototoxicity	PDUFA date
October 8	**Partners in Progress 2019:** Cancer patient advocates and FDA	FDA public workshop
October 14	**Flexion Therapeutics' Zilretta** (FX-006), an extended-release corticosteroid for osteoarthritis knee pain	PDUFA date
October 19	**Alexion Pharmaceuticals' Ultomiris** (ravulizumab-cwvz) for treating atypical hemolytic uremic syndrome	PDUFA date
October 19	**Clearside Biomedical's Xipere** (triamcinolone acetonide), a suprachoroidal injection for treating macular edema associated with uveitis	PDUFA date

2019 FDA Advisory Committees and Other Regulatory Dates of Interest – continued (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
October 20	**Foamix Pharmaceuticals' FMX-101** (minocycline foam) for acne	PDUFA date
October 21	**Eton Pharmaceuticals' ET-202** (phenylephrine) for low blood pressure	PDUFA date
October 24	**Melinta Therapeutics' Baxdela** (delafloxacin) for community-acquired bacterial pneumonia	PDUFA date
October 24	**GlaxoSmithKline/Tesaro's Zejula** (niraparib) – expanded approval to treat advanced fallopian tube, ovarian, or primary peritoneal cancer	PDUFA date
October 30	**Agile Therapeutics' Twirla** (AG200-15, 120 mg levonorgestrel + 30 mg ethinyl estradiol), a contraceptive	FDA's Bone, Reproductive, and Urologic Drugs Advisory Committee
October 31	**Adamis Pharmaceuticals' Zimhi** (injectable higher dose naloxone) for opioid overdose	PDUFA date
October 31	ICH Global meeting on ICH E8(R1) guideline on general **considerations for clinical trials**	FDA public meeting
November 2	**RedHill Biopharma's Talicia** (RHB-105) to treat *H. pylori* infection	PDUFA date
November 4	**Roche's Xofluza** (baloxavir marboxil) – expanded use as a single-dose treatment for patients at high risk of flu complications	PDUFA date
November 4	Genetic toxicology: How many doses of a **DNA Reactive (Ames+) drug** can be safely administered to healthy subjects	FDA workshhop
November 7	**Effective drug development –** opportunities and priorities for the FDA's Office of New Drugs	FDA public meeting
November 14	**Amarin's Vascepa** (icosapent ethyl) – expanded approval to reduce cardiovascular risk in statin-managed patients with high triglycerides	FDA's Cardiovascular and Renal Drugs Advisory Committee
November 16	**Agile Therapeutics' Twirla** (AG200-15, 120 mg levonorgestrel + 30 mg ethinyl estradiol), a contraceptive	PDUFA date
November 30	**Aquestive Therapeutics' Exservan** (riluzole oral film) for ALS	PDUFA date
December 4	**Celgene and Acceleron Pharma's luspatercept** for beta-thalassemia-associated anemia	PDUFA date
December 16	**Amgen's ABP-710**, a biosimilar of Johnson & Johnson's Remicade (infliximab)	PDUFA date
December 24	**Correvio Pharma's Brinavess** (vernakalant), an antiarrhythmic for the rapid conversion of recent onset atrial fibrillation	PDUFA date
December 27	**Durect's Posimir** (bupivacaine extended-release) for post-operative pain	PDUFA date
December 28	**Amarin's Vascepa** (icosapent ethyl) – expanded approval to reduce cardiovascular risk in statin-managed patients with high triglycerides	PDUFA date *Expected extension from September 28, 2019*

2020 FDA Advisory Committees and Other Regulatory Dates of Interest		
Date	**Topic**	**Committee/Event**
January 23	**Epizyme's tazemetostat** for metastatic/locally-advanced epithelioid sarcoma	PDUFA date
February 4	**Alnylam Pharmaceuticals' givosiran** for acute hepatic porphyria	PDUFA date
February 18	**Merck MSD's Keytruda** (pembrolizumab) – 6 sBLAs for a 30-minute Q6W infusion to treat melanoma, Hodgkin's lymphoma, primary mediastinal large B-cell lymphoma, gastric cancer, hepatocellular carcinoma, and Merkel cell carcinoma	PDUFA date
February 19	**Adverse event reporting** using ICH standards	FDA public meeting
February 21	**Esperion Therapeutics' bempedoic acid** monotherapy to treat hypercholesterolemia	PDUFA date
February 26	**Esperion Therapeutics' bempedoic acid in combination with ezetimibe** to treat hypercholesterolemia	PDUFA date
March 25	**Celgene's ozanimod** (RPC-1063) for relapsing multiple sclerosis	PDUFA date
April 4	**Celgene and Acceleron Pharma's luspatercept** for myelodysplastic syndrome-associated anemia	PDUFA date
April 30	**Sanofi's isatuximab** for relapsed/refractory multiple myeloma	PDUFA date
May 14	**Sunovion Pharmaceuticals' dasotraline** for moderate-to-severe binge eating disorders	PDUFA date