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: *Trends-in-Medicine* will be at the FDA advisory committee review on January 14, 2020, of **Nektar Therapeutics' oxycodegol (NKTR-181)** for chronic low back pain.

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

✓ BLUEPRINT MEDICINES' Ayvakit (avapritinib) was approved to treat GIST exon 18 mutation patients – at $32,000/month.

✓ LILLY is buying Dermira.

✓ MEDTRONIC

- Bought Stimgenics.
- Mazor X robot has a problem – it can come loose from the operating table.

✓ MERCK MSD's Keytruda (pembrolizumab) was approved to treat non-muscle invasive bladder cancer.

✓ **The positive trial data:**

- ADC THERAPEUTICS' loncastuximab tesirine (ADCT-402) in a pivotal Phase II trial in relapsed/refractory DLBCL.
- APELLIS PHARMACEUTICALS' pegcetacoplan in a Phase III trial in paroxysmal nocturnal hemoglobinuria (PNH).
- CONNECT BIOPHARMA's CBP-201 in a Phase Ib trial in atopic dermatitis.
- DBV TECHNOLOGIES' Viaskin Peanut in 3-year data from a Phase III extension study in peanut allergy.
- PFIZER and MERCK KGAA's Bavencio (avelumab) in an interim analysis of a Phase III trial in previously untreated locally-advanced/metastatic urothelial carcinoma.
- SALUDA MEDICAL's Evoke, a closed-loop spinal cord stimulator, in a pivotal trial in chronic back and leg pain.
- VBI VACCINES' Sci-B-Vac in a second Phase III trial in hepatitis B.

SHORT TAKES

■ 3DERM SYSTEMS' 3DermSpot, an autonomous artificial intelligence imaging system for detecting squamous cell carcinoma, melanoma, and basal cell carcinoma, was granted breakthrough device designation by the FDA.

■ ACCURAY's CyberKnife – A study, published in the ***International Journal of Radiation Oncology, Biology, Physics***, found that 69% of men with locally recurrent prostate cancer who received stereotactic body radiation therapy (SBRT) with CyberKnife did

not need androgen deprivation therapy (ADT) within the first five years. The disease-free survival rate was 60%, with low toxicity.

- ADAPTIVE BIOTECHNOLOGIES' clonoSEQ was granted expanded coverage by Medicare to include minimal residual disease monitoring for patients with chronic lymphocytic leukemia (CLL).

- ADC THERAPEUTICS' loncastuximab tesirine (ADCT-402) met the primary endpoint in a pivotal, 145-patient Phase II trial in relapsed/refractory diffuse large B-cell lymphoma (DLBCL), with an overall response rate of 45.5% (which includes 20% complete responses).

- AMAG PHARMACEUTICALS plans to divest two of its drugs: Vyleesi (bremelanotide injection) for hypoactive sexual desire, and Intrarosa (prasterone), a vaginal insert for painful sex in post-menopausal women.

- Antibiotics – A small Israeli study, published in ***Science***, found that giving patients two different antibiotics may give them broader coverage, but it also can speed the development of resistance. This could (should?) change the way doctors think about combination antibiotics.

- APELLIS PHARMACEUTICALS' pegcetacoplan showed superiority to Alexion Pharmaceuticals' Soliris (eculizumab) – the primary endpoint – in the head-to-head, 80-patient Phase III PEGASUS trial in paroxysmal nocturnal hemoglobinuria (PNH), with a significant improvement in hemoglobin at Week 16.

- ASTRAZENECA's Farxiga (dapagliflozin) – The FDA accepted a supplemental new drug application (sNDA) and granted priority review for this SGLT2 inhibitor for reduction in the risk of cardiovascular death or worsening heart failure in adults with heart failure with reduced ejection fraction (HFrEF), regardless of whether or not they have Type 2 diabetes.

- BAYER signed a 5-year collaboration with **Schrödinger** to develop a system for faster drug discovery.

- BIOGEN is partnering with **CAMP4 Therapeutics** to use its Gene Circuitry Platform in an effort to identify how to dial up (or down) the expression of disease-associated genes within microglial cells involved in neurological or neurodegenerative diseases.

- BRISTOL-MYERS SQUIBB/CELGENE's Istodax (romidepsin) – A study, published in ***Physiological Reports***, suggests that this lymphoma drug, a PAK1 inhibitor, may help second-degree burn victims as well by reducing/preventing chronic pain.

- COLOSPAN's CG-100, a temporary intraluminal bypass device reducing diverting stoma rates in gastrointestinal resection procedures, was granted an investigational device exemption (IDE) by the FDA, clearing the way for a pivotal trial in the U.S. and Europe.

- CONNECT BIOPHARMA's CBP-201 – In top-line data from a Phase Ib trial in Australia and New Zealand in moderate-to-severe atopic dermatitis, 50.0% of patients at the low dose (150 mg) of this anti-IL-4Rα and 42.9% of patients at the high dose (300 mg) achieved IGA0/1 (clear/almost clear skin), which compares favorably on both efficacy and safety to existing therapies.

- DBV TECHNOLOGIES' Viaskin Peanut – In top-line results from the 3-year, open-label Phase III PEPITES extension trial (PEOPLE) in children age 4-11 with peanut allergy, this patch therapy showed long-term efficacy, with 75.9% of patients increasing their peanut tolerability vs. baseline and 51.8% of patients able to tolerate ≥1,000 mg of peanut protein.

- DPP-4 inhibitors – A 14,187-patient study, published in the ***Journal of Diabetes and Its Complications***, found that the risk of bullous pemphigoid, a difficult skin condition, is increased in Type 2 diabetics taking a DPP-4 inhibitor, especially if they also use spironolactone or have dementia – but not if they are taking metformin.

- Ebola update – The World Health Organization (WHO) reported five new cases of Ebola in the Democratic Republic of the Congo, bringing the total to 3,382, including 2,232 deaths.

- ESTEVE is buying **Riemser**, a German pharmaceutical company that specializes in oncology, neurology, and infections, from **Ardian**.

- GALECTO is merging with **PharmAkea**.

- GILEAD SCIENCES' GS-9722 – Gilead licensed **Xencor**'s Xtend (extended half-life) technology and its Cytotoxic XmAb Fc technology for developing this anti-HIV antibody.

- IMMUNIC THERAPEUTICS' IMU-856, an oral small molecule modulator with an undisclosed target, was exclusively licensed from Daiichi Sankyo for treating intestinal diseases.

- JENAVALVE TECHNOLOGY's JenaValve Pericardial TAVR System, a self-expanding transcatheter aortic valve replacement system with a nitinol stent and a porcine pericardial valve, was granted breakthrough device designation by the FDA for use in aortic regurgitation-dominant mixed aortic valve disease and severe aortic regurgitation.

- LEAP THERAPEUTICS' DKN-01 – The rights to this anti-Dickkopf-1 (DKK1) cancer antibody in Asia (except Japan), Australia, and New Zealand, were exclusively licensed to **BeiGene**, which is expected to combine it with its PD-1 inhibitor, tislelizumab.

- LILLY is buying **Dermira** for $1.1 billion, which will give it lebrikizumab, an investigational anti-IL-13 for treating atopic dermatitis in Phase III development, as well as FDA-approved Qbrexza (glycopyrronium), a cloth towelette for treating primary axillary hyperhidrosis.

- LONZA is collaborating with **Allevi** on 3D bioprinting for drug research.

- MEDTRONIC bought **Stimgenics**, which developed the Differential Target Multiplexed spinal cord stimulation waveform, technology designed for use with its Intellis platform to treat chronic pain patients.

- MiNA THERAPEUTICS is collaborating with **AstraZeneca** on development of small activating RNA (saRNA) molecules to treat metabolic diseases.

- MODERNA's mRNA-1647 – The company announced positive 7-month interim safety and immunogenicity data after the third and final vaccination in a Phase I trial of this cytomegalovirus (CMV) vaccine.

- Naloxone – A study, published in the ***Journal of General Internal Medicine***, found that only 1.6% of high-dose opioid users with private insurance (including people who already survived an opioid overdose) filled a naloxone prescription (for either nasal or injectable naloxone) in the first 6 months of 2017 (the end of the study period).

- NOVO NORDISK launched the My$99Insulin Program, which allows patients enrolled with NovoCare.com to buy up to three vials (or 2 packs) of FlexPen/FlexTouch/PenFill pens of any combination of Novo Nordisk insulins for $99.

- Ovarian cancer – A study of ~250,000 women over 11.2 years, published in the ***Journal of the American Medical Association***, found no significant increase in ovarian cancer with the use of talc-based body powder products (talc) in the genital area (61 cases/100,000-person years vs. 55 cases per 100,000PY). There was also no difference based on how often a woman used the powder. And these findings hold up even for talc used in the time period before asbestos contamination was banned.

- Paclitaxel – A retrospective study using German health insurance claims data on ~38,000 patients, published in the ***European Journal of Vascular and Endovascular Surgery***, found that patients with peripheral artery disease (PAD) who were treated with paclitaxel-coated/eluting devices (stents and balloons) had better long-term survival, fewer major cardiovascular events, and better amputation-free survival vs. control (uncoated devices).

- SALUDA MEDICAL's Evoke – A pivotal study, published in ***The Lancet Neurology***, found that at 1 year this closed-loop spinal cord stimulator reduced or eliminated opioid use in patients with chronic back/leg pain in 55% of patients vs. 40% of patients using an open-loop stimulator. And 95.2% Saluda patients remained in the therapeutic window vs. 47.9% of open-loop patients.

- SANOFI is collaborating with **Nurix Therapeutics** on discovery and development of a pipeline of targeted protein degradation drugs for treating multiple therapeutic areas.

- SIGNANT HEALTH will connect its TrialMax electronic clinical outcome assessment platform to **Propeller Health**'s inhaler sensor and linked digital health platform for use by patients with asthma or chronic obstructive pulmonary disease (COPD).

- TYME TECHNOLOGIES' SM-88 – Tyme is collaborating with **Eagle Pharmaceuticals** to develop this oral metabolic-based therapy for treating metastatic pancreatic cancer.

- Vaping update – In the latest numbers from the Centers for Disease Control and Prevention (CDC), 57 people have died and 2,602 people have been hospitalized for e-cigarette or vaping-associated lung injury (EVALI).

- VBI VACCINES' Sci-B-Vac met the primary endpoint in a second Phase III trial in hepatitis B achieving seroprotection of 90.4% with 2 doses and 99.3% with 3 doses vs. 51.6% and 94.8% with GlaxoSmithKline's Engerix-B. Sci-B-Vac also met the key secondary endpoints.

- VERISTAT bought **The Clinical Trial Company**, a European contract research organization (CRO).

- Zika update – Zika has pretty much faded from the news, but researchers had some bad news about Zika this week. They reported that a study, published in ***JAMA Pediatrics***, of infants in Colombia who were exposed to Zika *in utero* but who appeared normal at birth (false negatives) found that over time, some had "a curvilinear pattern of decline" in adaptive and functional skills. In an accompanying editorial, CDC researchers said the clinical significance of this finding is not yet clear but emphasized the importance of long-term follow-up of *all* Zika-exposed infants.

Very early research news

- Amyotrophic lateral sclerosis (ALS) – A mouse study by University of California, San Diego, School of Medicine researchers, published in ***Nature Medicine***, suggests that using gene-silencing RNA to turn off mutated SOD1 might prevent the onset of ALS or at least block its progression.
- Anxiety – A large genetic study by Veterans Administration researchers, using the VA Million Veteran Program data – published in the ***American Journal of Psychiatry*** – found new evidence for an underlying biologic cause of anxiety, genetic variants. The researchers hope their work will eventually lead to more individualized therapies.
- Autism – A mouse study by researchers at Harvard Medical School and MIT, published in ***Nature***, offers an explanation for why autistic behavioral symptoms appear to lessen when an autistic child has an infection. The researchers found that IL-17a is released in an infection and suppresses a small region in the brain that was previously linked to social behavioral deficits (in mice). *Could an IL-17a be used to treat autism?*
- Colorectal cancer – Researchers at the University of Toronto reported in the ***Journal of Cell Biology*** that they have identified a protein (Importin-11) related to the Wnt/beta-catenin signaling pathway that may be a driver in many colorectal cancers.
- HIV – A monkey study, published in ***Nature Communications***, found that a combination of two antibodies taken 30 hours after virus exposure prevented infection in baby monkeys, and a single dose prevented HIV transmission from mother to baby.
- Melanoma – A mouse study by Sanford Burnham Prebys Medical Discovery Institute researchers, published in ***Nature Communications***, found that patients who don't respond to PD-1 inhibitors might be able to be sensitized to the drugs by inhibiting the protein Siah2. In the mice, inhibiting Siah2 strategy restricted T regulatory cells, allowing killer T cells to attack the cancer.

NEWS IN BRIEF

ALMIRALL

- Licensed all rights from **23andMe** to a bispecific antibody that blocks all three isoforms of IL-36.
- Is partnering with **WuXi Biologics** on use of the WuXiBody platform to develop antibodies for treating dermatological diseases.

BOEHRINGER INGELHEIM

- Is collaborating with **PhoreMost** on discovery of new drug targets, using PhoreMost's SITESEEKER, a next-generation phenotypic screening platform.
- Bought the worldwide rights to **Enleofen**'s preclinical IL-11 platform to develop therapies for non-alcoholic steatohepatitis (NASH).

IONIS PHARMACEUTICALS

- Is collaborating with **Aro Biotherapeutics**, giving Ionis rights to Aro's Centyrin technology for developing targeted cell- and tissue-specific delivery of antisense oligonucleotides (ASOs), with the goal of creating ASO-Centyrin conjugates.
- Is collaborating in a 3-year deal with **Empirico** to use its Precision Insights Platform to identify therapeutic targets for indications and tissues responsive to antisense technology.

MERCK MSD

- Is collaborating with **Taiho Pharmaceutical** and **Astex Pharmaceuticals** on development of small molecule inhibitors against several cancer targets, including KRAS.
- Keytruda (pembrolizumab) missed the primary endpoint in the Phase III KEYNOTE-604 trial in first-line small cell lung cancer, failing to show a survival benefit.

PFIZER

- and MERCK KGAA's Bavencio (avelumab). In a preplanned interim analysis of the Phase III JAVELIN Bladder 100 trial in previously untreated locally-advanced/metastatic urothelial carcinoma, this PD-L1 inhibitor met the primary endpoint, improving overall survival in both co-primary populations – all randomized patients and PD-L1+ tumor patients.
- Licensed the rights to a preclinical anti-elF4E (eukaryotic initiation factor 4E) for use in cancer treatment from **Effector Therapeutics**.
- SB-525. Pfizer was developing this hemophilia A gene therapy with **Sangamo Therapeutics** but is taking over the Phase III trials.

REGENERON PHARMACEUTICALS

- Garetosmab (REGN-2477), an anti-Activin A, missed the primary endpoint in the 44-patient, 28-week Phase II LUMINA-1 trial in fibrodysplasia ossificans progressiva (FOP), decreasing total lesion activity by 25% vs. placebo

(p=0.07). However, the company is still hopeful of FDA approval because new lesions were reduced by 90% vs. placebo.

- REGN-5678. An article, published in ***Science Translational Medicine***, describes the potential of costimulatory bispecific antibodies (e.g., REGN-5678) in combination with CD3 bispecifics.

ROCHE

- CHUGAI's CH-5126766. The worldwide development and commercialization rights to this RAF/MEK inhibitor were licensed to **Verastem Oncology** for treating KRAS-mutant solid tumors.
- Licensed use of Amunix Pharmaceuticals' XTEN platform for discovery and development of non-oncology therapeutics against undisclosed targets.

REGULATORY NEWS

Regulatory tidbits

- Compounded drugs. The FDA created a Compounding Quality Center of Excellence aimed at improving quality assurance and control of compounded drugs. Participation is voluntary, but the Center will offer educational programs and other learning tools to outsourcing facilities.
- FDA Commissioner Stephen Hahn, MD, has been noticeably quiet since taking office. Unlike his predecessor, he is not putting out daily memos/announcements. Yet, the Agency appears to be plugging alone on all cylinders. It likely will be another few months before we know how the FDA will change under his command.
- FDA inspections. The FDA issued updated guidance on pre-approval drug inspections, which includes new field reporting requirements, instructions for potential official action indicated (pOAI) reporting responsibilities, and redefined collaboration and shared responsibility between the Office of Regulatory Affairs and the FDA's Center for Drug Evaluation and Research (CDER) for determining and performing an inspection.
- Generic drugs
  - The FDA plans to withdraw 249 generic drug approvals because the sponsors failed to submit annual reports to the Agency. Drug companies will be able to file appeals, but they will have to show a "genuine and substantial issue of fact" that requires a hearing.
  - California Gov. Gavin Newsom wants to lower drug prices by having the state contract with generic drug companies to make prescription medications that the state would then sell to the public – under a California label.
- Ranitidine
  - Rep. Rosa DeLauro (D-CT) wrote to Health and Human Services (HHS) Sec. Alex Azar and FDA Commissioner Dr. Hahn, urging them to do what 41 countries have already done – ***ban all sales of ranitidine*** or issue a warning because of the possibility of contamination with N-nitrosodimethylamine (NDMA).
  - Emery Pharma, a testing lab, is urging the FDA to ***recall all ranitidine*** drugs after finding that the level of NDMA can increase if a drug is exposed to high heat, even after packaging.

FDA approvals/clearances

- ABBOTT's HeartMate 3 – Implantation of this left ventricular assist device (LVAD) was approved through a less invasive incision in a patient's chest wall as an alternative surgical technique.
- APPLIED BIOCODE's BioCode Respiratory Pathogen Panel for detecting *Bordetella pertussis* was granted 510(k) clearance, allowing it to run on the BioCode MDx-3000 system.
- ASTELLAS' Mycamine (micafungin), an antifungal, was granted expanded approved for treating invasive candidiasis in infants.
- BLUEPRINT MEDICINES' Ayvakit (avapritinib, BLU-285) was approved for treating gastrointestinal stromal tumor (GIST) patients with a PDGFRA exon 18 mutation. It was priced at $32,000/month (that's $384,000/year).
- Cleveland Clinic's 3D printed silicone stents, designed by Tom Gildea, MD, a pulmonologist at the Clinic, were cleared for use in patients with serious breathing disorders.
- ICECURE MEDICAL's MultiSense system for simultaneous treatment of tumors with up to 3 needles was cleared for expanded use in performing cryoablation of the ear, nose, throat, kidney, liver, and other neurologic indications.
- MERCK MSD's Keytruda (pembrolizumab), a PD-1 inhibitor, was approved to treat non-muscle invasive bladder cancer (NMIBC) that is non-responsive to Bacillus Calmette-Guerin (BCG).
- NOVO NORDISK's Fiasp (insulin aspart 100 u/mL) was approved for mealtime use by children with diabetes. It is the first and only fast-acting mealtime insulin injection that does not have a pre-meal dosing recommendation.

- PHOTONICARE's TOMi Scope, an OCT scanner for checking/diagnosing ear infections by determining the presence/absence of fluid in the middle ear, was granted 510(k) clearance.
- TELEFLEX's UroLift system was granted expanded approval for use in treating larger (80-100 cc) prostates.
- TERUMO/MICROVENTION's Flow-Redirection Endoluminal Device (FRED) was granted premarket approval for treating wide-neck intracranial aneurysms of the carotid artery.

FDA recalls/warnings

- GPT PHARMACEUTICALS received a warning letter over violations of current good manufacturing practice (cGMP) and data integrity issues at its plant in Hyderabad, India.
- MEDTRONIC's Mazor X – The company issued a field safety notice about this surgical robot for spinal procedures, warning that it could come loose from the operating table and even fall on a patient. Medtronic is working on a permanent correction to the problem but meanwhile offered updated instructions for setting the system up.
- NDMA contamination – The latest recalls due to NDMA contamination include:
  - **APPCO PHARMA's ranitidine.**
  - **DENTON PHARMA's (dba Northwind Pharmaceuticals) ranitidine.**
  - **MYLAN's nizatidine** (3 lots).
- TARO PHARMACEUTICALS' lamotrigine was recalled because of cross-contamination with enalapril.

European Regulatory News

- ***Finland*** – Supervision of medical devices, device trials, and operators was transferred from the National Supervisory Authority for Welfare and Health to the Finnish Medicines Agency (Fimea).
- ***U.K.*** – IPSEN's Dysport (clostridium botulinum type A toxin-haemagglutinin complex) was granted expanded approval for use in treating focal spasticity of the upper limbs in pediatric patients age ≥2 with cerebral palsy.
- ABBVIE's acquisition of **Allergan** was approved by the European Commission.
- BIONESS' StimRouter, a neuromodulation system, was granted an expanded CE Mark for use in treating fecal incontinence as well as overactive bladder and chronic pain.
- MEDTRONIC's Percept PC, a deep brain neurostimulator, was granted a CE Mark for use in Parkinson's disease, primary dystonia, essential tremor, obsessive-compulsive disorder (OCD), and epilepsy.

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

- Drug reviews – A paper, written by NICE staff and published in the ***British Medical Journal***, suggests that new, histology-independent cancer treatments need more clinical evidence before NICE approval. The NICE writers said the specific mutations targeted are often rare and the clinical evidence is based on immature data and small sample sizes, making the drugs difficult to evaluate.

Regulatory news from other countries

- ***Canada.***
  - Health Canada issued final guidance on how software as a medical device (SaMD) is regulated.
  - ABBVIE's Rinvoq (upadacitinib) was approved by Health Canada to treat adults with moderately-to-severely active rheumatoid arthritis who do not respond adequately to or cannot tolerate methotrexate.
- ***China.***
  - ASTRAZENECA's Lokelma (sodium zirconium cyclosilicate) was approved by the National Medical Products Administration (NMPA) to treat adults with hyperkalemia.
  - SINOVAC BIOTECH's varicella-zoster virus vaccine was approved by the NMPA for use in children ages 1-12.
  - The first person has died from the **mystery virus** that has affected ~60 people in China in 2020. And researchers believe it is a new strain of coronavirus.
- ***South Korea.*** AVACTA GROUP and **Daewoong Pharmaceutical** agreed to establish a joint venture in South Korea and will collaborate on development of next-generation cell and gene therapies using Avacta's Affimer proteins.
- ***Taiwan.*** The legislature passed a bill that will separate medical device regulation from drugs, creating a separate registrant process for medtech products.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
January tba	**Aimmune Therapeutics' Palforzia** (AR-101) to treat peanut allergy	PDUFA date (*estimated to be in mid-January*)
January 14	**Nektar Therapeutics' oxycodegol** (NKTR-181) for chronic low back pain	FDA's Anesthetic and Analgesic Drug Products Advisory Committee, meeting jointly with the Drug Safety and Risk Management Advisory Committee
January 15	**AM: Esteve Pharmaceuticals' tramadol 44 mg + celecoxib 56 mg** for acute pain requiring an opioid analgesic **PM: Intellipharmaceutics' Aximris XR** (abuse-deterrent oxycodone extended-release), resubmission to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which no alternative treatment is adequate	FDA's Anesthetic and Analgesic Drug Products Advisory Committee, meeting jointly with the Drug Safety and Risk Management Advisory Committee
January 16	**Durect's Posimir** (bupivacaine extended-release) for post-surgical pain	FDA's Anesthetic and Analgesic Drug Products Advisory Committee **PDUFA date tba (extended from December 27, 2019)**
January 23	**Epizyme's tazemetostat** for metastatic/locally-advanced epithelioid sarcoma	PDUFA date
January 24	**Merck MSD's Dificid** (fidaxomicin) for *Clostridium difficile* infections	PDUFA date
February 4	Testing methods for **asbestos in talc** and cosmetic products containing talc	FDA public meeting
February 14	**Blueprint Medicines' Ayvakit** (avapritinib, BLU-285) for ***fourth-line*** GIST	PDUFA date
February 16	**Agile Therapeutics' Twirla** (AG200-15, 120 μg levonorgestrel + 30 μg ethinyl estradiol), a contraceptive patch	PDUFA date *Extended by the FDA from November 16, 2019*
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	**Alder BioPharmaceuticals' eptinezumab** (ALD-403), a CGRP inhibitor for migraine	PDUFA date
February 21	**Esperion Therapeutics' bempedoic acid** monotherapy to treat hypercholesterolemia	PDUFA date
Feb. 25-26	Discussion of the evolving role of **artificial intelligence in radiological imaging**	FDA public workshop
February 26	**Acacia Pharma's Barhemsys** (IV amisulpride) for post-operative nausea and vomiting (PONV)	PDUFA date
February 26	**Esperion Therapeutics' bempedoic acid in combination with ezetimibe** to treat hypercholesterolemia	PDUFA date
February 27	**BeiGene's zanubrutinib**, a BTK inhibitor for mantle cell lymphoma	PDUFA date
March 3	Development of **individualized therapeutics**	FDA workshop
March 8	**Horizon Therapeutics' teprotumumab** to treat active thyroid eye disease	PDUFA date
March 9	**Intarcia Therapeutics' ITCA-650** (exenatide implant) for Type 2 diabetes	PDUFA date
March 10	**Bristol-Myers Squibb's Opdivo** (nivolumab) **+ Yervoy** (ipilimumab) for advanced hepatocellular carcinoma	PDUFA date
March 10	Patient-focused drug development for **stimulant use disorder**	FDA public meeting
March 15	**Astellas and Seattle Genetics' enfortumab vendotin**, an antibody-drug conjugate for treating metastatic/locally-advanced urothelial cancer	PDUFA date
March 17	**Eton Pharmaceuticals' ET-105** (reformulated lamotrigine) as adjunctive therapy for partial seizures in Lennox-Gastaut syndrome patients	PDUFA date
March 23	Identification of concepts and terminology for **multi-component biomarkers**	FDA workshop
March 25	**Bristol-Myers Squibb/Celgene's ozanimod** (RPC-1063) for relapsing multiple sclerosis	PDUFA date
March 25	**Zogenix's Fintepla** (fenfluramine, ZX-008) for Dravet syndrome	PDUFA date
March 26	**Heron Therapeutics' HTX-011** (bupivacaine + meloxicam) for postoperative pain	PDUFA date
March 26 *postponed*	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	PDUFA date postponed, no new date
March 26	**IntelGenx Technologies' Rizaport** (RHB-103) for migraine	PDUFA date
March 27	**Modernizing FDA's data strategy**	FDA public meeting
March 28	**Rockwell Medical's Triferic** (ferric pyrophosphate) for anemia	PDUFA date
March tba	**AstraZeneca's Imfinzi** (durvalumab) + tremelimumab for small cell lung cancer	PDUFA date (*estimated late March*)

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
April tba	**Lilly's empagliflozin + linagliptin + metformin extended-release**, a triplet for Type 2 diabetes	PDUFA date
April tba	**Puma Biotechnology's Nerlynx** (neratinib) – expanded approval as a ≥3-line treatment for HER2+ metastatic breast cancer	PDUFA date
April 4	**Bristol-Myers Squibb/Celgene and Acceleron Pharma's Reblozyl** (luspatercept-aamt) – expanded approval to include very low to intermediate risk myelodysplastic syndrome-associated anemia in patients with ring sideroblasts who require red blood cell transfusions	PDUFA date
April 22 *tentative*	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	FDA's Gastrointestinal Drugs Advisory Committee
April 25	**Sanofi's MenQuadfi**, a meningococcal vaccine	PDUFA date
April 26	**Neurocrine Biosciences' opicapone** to treat Parkinson's disease	PDUFA date
April 27	**United Therapeutics' Trevyent** (treprostinil) to treat pulmonary arterial hypertension (PAH)	PDUFA date
April 30	**Sanofi's isatuximab** for relapsed/refractory multiple myeloma	PDUFA date
May 12	**Johnson & Johnson and Halozyme's Darzalex** (daratumumab) subcutaneous delivery for multiple myeloma	PDUFA date (*estimated*)
May 12-13	**Regulatory education for industry**	FDA conference
May 14	**Sunovion Pharmaceuticals' dasotraline** for moderate-to-severe binge eating disorders	PDUFA date
May 15	**Allergan's bimatoprost sustained-release** for treating glaucoma	PDUFA date (*estimated*)
May 24	**Roche's risdiplam** (RG-7916) to treat spinal muscular atrophy	PDUFA date
May 25	**Evofem Biosciences' Amphora** (L-lactic acid + citric acid + potassium bitartrate), a hormone-free contraceptive (resubmission)	PDUFA date
May 30	**Incyte's pemigatinib** for previously treated, locally-advanced/metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements	PDUFA date
June 2	**Immunomedics' sacituzumab govitecan** (IMMU-132) as a ≥3-line treatment for metastatic triple-negative breast cancer	PDUFA date
June 2	**Foamix Pharmaceuticals' FMX-103** (minocycline foam) to treat moderate-to-severe papulopustular rosacea	PDUFA date
June 11	**Viela Bio's inebilizumab** for first-line monotherapy of neuromyelitis optica spectrum disorder	PDUFA date
July 13	**Averitas Pharma's Qutenza** (capsaicin patch) – expanded approval to treat neuropathic pain from diabetic peripheral neuropathy	PDUFA date
August 5	**DBV Technologies' Viaskin Peanut** for treating children with peanut allergy	FDA target action date
August 27	**Cassiopea's clascoterone cream 1%**, a topical androgen receptor inhibitor for acne	PDUFA date
Sept. 28-30	Global summit on regulatory science: **Emerging Techologies**	FDA summit **https://aralliance.org/gsrs/**
October 24	**Spectrum Pharmaceuticals' Rolontis** (eflapegrastim) for treating chemotherapy-induced neutropenia	PDUFA date