TRENDS-in-MEDICINE

August 9, 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…

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NOTE: Remember that most coronavirus news is being reported primarily in separate Coronavirus Update bulletins. Subscribe to ***Trends-in-Medicine*** for coverage of the **Gene Therapy for Ophthalmic Disorders** virtual conference.

Be careful, be safe, and be well.

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

✓ Acute flaccid myelitis (AFM) – With an outbreak expected this fall, the CDC is warning parents and doctors to consider it a medical emergency and not confuse it with Covid-19 or flu.

✓ BIOGEN and EISAI'S aducanumab (BIIB-037) – The FDA accepted the BLA for this Alzheimer's disease treatment and granted it priority review.

✓ DBV TECHNOLOGIES' Viaskin Peanut, a peanut allergy patch, was rejected by the FDA.

✓ **Positive trial news:**

- CYMABAY THERAPEUTICS' seladelpar – in primary biliary cholangitis (PBC).
- DICERNA PHARMACEUTICALS
  - and ROCHE's RG-6346 – in HBV.
  - nedosiran – in primary hyperoxaluria.
- IMMUNIC THERAPEUTICS' IMU-838 – in multiple sclerosis.
- MERCK MSD and PFIZER's Steglatro (ertugliflozin) – in Type 2 diabetes.
- NOVARTIS
  - Ilaris (canakinumab) – reduced the rate of joint replacements in a cardiovascular outcomes trial.
  - Kymriah (tisagenlecleucel) – in follicular lymphoma.
- PFIZER's Lorbrena (lorlatinib) – in ALK+ NSCLC.

✓ **Negative trial news:**

- KARUNA THERAPEUTICS' KarXT – in pain.
- LEVO THERAPEUTICS' intranasal carbetocin (LV-101) – in Prader-Willi syndrome.
- ROCHE's Tecentriq (atezolizumab) – in metastatic triple-negative breast cancer.

SHORT TAKES

- BIOSIGHT's aspacytarabine (BST-236), an antimetabolite, was granted fast track status by the FDA as a treatment for acute myeloid leukemia (AML).

- BRISTOL-MYERS SQUIBB's Opdivo (nivolumab) – In data presented at the virtual IASLC 2020 World Conference on Lung Cancer, first-line therapy with this PD-1 inhibitor + Yervoy (ipilimumab, a CTLA4 inhibitor) significantly prolonged survival vs. chemotherapy in the CheckMate-743 trial in mesothelioma (41% vs. 27% at 2 years).

- CYMABAY THERAPEUTICS' seladelpar, a PPARδ agonist, met the primary endpoint in the 265-patient Phase III ENHANCE trial in primary biliary cholangitis (PBC) – for which the FDA last month lifted a clinical hold – with significantly more seladelpar patients meeting the primary composite endpoint (78.2% at 10 mg and 57.1% at 5 mg vs. 12.5% on placebo) at 3 months.

- DBV TECHNOLOGIES' Viaskin Peanut – The FDA rejected this peanut allergy patch for children ages 4-11, issuing a complete response letter (CRL) that cited concerns about the impact of the patch-site adhesion on efficacy, the need for patch modification, and a new human factor study. The FDA also wants more clinical data on any modifications to the patch as well as additional chemistry, manufacturing, and controls (CMC) data. Yet, the FDA did not raise safety issues.

- GILEAD SCIENCES' Veklury (remdesivir) – In a multiyear deal, **Pfizer** agreed to manufacture and supply this IV antiviral treatment for Covid-19.

- HELIUS MEDICAL TECHNOLOGIES' Portable Neuromodulation Stimulator (PoNS) device was submitted to the FDA through the de novo pathway for treating gait deficit in multiple sclerosis patients.

- IMMUNIC THERAPEUTICS' IMU-838 – In top-line data from the Phase II EMPhASIS trial, this DHODH inhibitor met the primary endpoint in relapsing-remitting multiple sclerosis, significantly decreasing cumulative number of combined unique active (CUA) MRI lesions through Week 24 (by 62% with the 45 mg QD dose vs. placebo). IMU-838 also met the key secondary endpoints, including a reduction in CUA MRI lesions by 70% with the 30 mg QD dose.

- INCYTE's INCB-59872 – Development of this LSD-1 inhibitor for sickle cell disease, sarcoma, and other cancers was discontinued.

- JOHNSON & JOHNSON/ETHICON's NeuWave, a microwave ablation system for use with Auris Health's Monarch platform, a robotic-assisted bronchoscopy system, was granted breakthrough device designation by the FDA.

- KARUNA THERAPEUTICS' KarXT – The results of a 24-patient Phase Ib trial in healthy volunteers did ***not*** provide conclusive evidence that this oral coformulation of xanomeline (a novel muscarinic receptor agonist) and trospium (a muscarinic receptor antagonist) is effective in treating pain, and the company halted development in pain. However, testing in schizophrenia is continuing.

- KAZIA THERAPEUTICS' paxalisib was granted rare pediatric disease designation by the FDA as a treatment for diffuse intrinsic pontine glioma (DIPG).

- LEVO THERAPEUTICS' intranasal carbetocin (LV-101), a selective oxytocin-receptor agonist, missed the primary endpoint in the Phase III CARE-PWS trial in Prader-Willi syndrome, with the high dose (9.6 mg) failing to meet the endpoints. However, the low dose (which was a secondary endpoint) did show positive results. A pre-specified pooled analysis of the two doses also missed significance at Week 8 (p=0.055).

- LUNDBECK's Lu AF-11167 – The company terminated development of this PDE10Ai inhibitor for schizophrenia.

- NOVA EYE MEDICAL (formerly Ellex Medical Lasers) bought **Molteno Ophthalmic's Molteno3** glaucoma drainage device.

- NOVO NORDISK is ending development of two Phase I obesity drugs, not because they don't work but to focus instead on Ozempic (semaglutide) and AM-833, an amylin analog: a glucagon-GLP-1 co-agonist and a tri-agonist project.

- OXFORD BIOMEDICA's LentiVector platform was licensed to **Beam Therapeutics**.

- PFIZER's Lorbrena (lorlatinib), a next-generation ALK inhibitor, met the primary endpoint in the Phase IIII CROWN trial in previously untreated advanced ALK+ non-small cell lung cancer (NSCLC), significantly improving progression-free survival (PFS) vs. Pfizer's Xalkori (crizotinib).

- QUARTET HEALTH is partnering with **SilverCloud Health** to use SilverCloud's computerized cognitive behavioral therapy tools to offer digital mental health support to its patients nationwide.

- REDX PHARMA's RXC-006, a porcupine inhibitor for fibrotic diseases, including idiopathic pulmonary fibrosis (IPF), was licensed to **AstraZeneca.**

- ROCHE's Tecentriq (atezolizumab) – This PD-L1 inhibitor, in combination with paclitaxel, missed the primary endpoint in the 651-patient Phase III IMpassion131 trial in PD-L1+ metastatic triple-negative breast cancer, failing to significantly prolong PFS vs. paclitaxel alone.

- SGLT2 inhibitors – An American College of Cardiology consensus opinion, published in the ***Journal of the American College of Cardiology***, says that SGLT2 inhibitors and GLP-1 receptor agonists can be used by Type 2 diabetics to reduce the risk of a major adverse cardiovascular event.

- SPEEDX's ResistancePlus test – UCLA researchers reported in the journal ***Clinical Infectious Diseases*** that tests, including this one as well as others in development, can identify patients with gonorrhea who will respond successfully to a single dose of ciprofloxacin.

- TELADOC HEALTH is merging with Applied Health Signals' **Livongo Health**. Both companies focus on virtual health and chronic condition management.

- TOPCON HEALTHCARE bought the Henson line of perimetry products from **Elektron Eye Technology**.

- TRICIDA's veverimer (TRC-101) – The company said it expects the FDA to reject this non-absorbed, orally-administered polymer designed to treat metabolic acidosis, issuing a complete response letter. But the company hopes to resolve the issues in the CRL in time to get approval by the PDUFA date of August 22, 2020. (*That may be wishful thinking since the timeline is so tight.*)

- TYME TECHNOLOGIES' SM-88 (racemetyrosine), an oral investigational treatment for pancreatic cancer, was granted orphan drug status by the FDA.

- VIACYTE expanded its collaboration with **Gore** on development of subcutaneous treatment for Type 1 diabetes using ViaCyte's Encaptra Cell Delivery System and Gore's advanced material technologies.

- WISHBONE MEDICAL bought two spine device companies: **Back 2 Basics Direct** and **Orbbö Surgical**.

NEWS IN BRIEF

ABBVIE

- Is collaborating with **Voyager Therapeutics** on development of vectorized antibodies to treat Parkinson's disease, Alzheimer's disease, and more.

- Ended the collaboration begun by Allergan before it became part of AbbVie with **Editas Medicine** on treatments (including EDIT-101) for LCA10, a retinal disorder, returning all rights to Editas.

BIOGEN

- Is partnering with **Denali Therapeutics** to co-develop and co-commercialize Denali's small molecule inhibitors of leucine-rich repeat kinase 2 (LRRK2) for Parkinson's disease.

- and EISAI's aducanumab (BIIB-037). The FDA accepted the biologics license application (BLA) for this antibody treatment for Alzheimer's disease and granted it priority review. The PDUFA date is March 7, 2021, but an FDA advisory committee review is expected first.

DICERNA PHARMACEUTICALS

- and ROCHE's RG-6346. Dicerna reported positive results from an ongoing Phase I proof-of-concept trial of this GalXC RNAi therapeutic in chronic hepatitis B virus (HBV), with 9 of 10 patients concurrently taking a nucleoside analog (NUC) plus four doses of RG-6346 achieving a ≥1.0 $\log_{10}$ IU/mL reduction in hepatitis B surface antigen (HBsAg) at Day 112 (-1.39 $\log_{10}$ IU/mL with the low dose and -1.84 $\log_{10}$ at the highest dose).

- Nedosiran. In an interim analysis of the ongoing, open-label PHYOX3 extension study in primary hyperoxaluria, 9 of the 11 patients who reached Day 120 with monthly injections of nedosiran (82%) achieved normal or near-normal urinary oxalate levels.

MERCK MSD

- Is buying the global rights (except South Korea) to **Hanmi Pharmaceutical's efinopegdutide** (HM-12525A), a GLP-1/glucagon dual receptor agonist. Remember, Johnson & Johnson previously licensed it, tested it in obesity, and gave up. Merck wants to develop it for non-alcoholic steatohepatitis (NASH).

- and PFIZER's Steglatro (ertugliflozin). A study, published in the journal ***Diabetes, Obesity & Metabolism***, found that Type 2 diabetics, regardless of age, could improve their glycemic control, body weight, and systolic blood pressure by taking this SGLT2 inhibitor. The study also showed that diabetics age ≥65 on Steglatro had a higher incidence of volume depletion adverse events and genital mycotic infection vs. non-users.

NOVARTIS

- Arzerra (ofatumumab). The results of two Phase III trials – ASCLEPIOS-I and -II – were published in the ***New England Journal of Medicine***, showing that monthly subcutaneous

injections of this anti-CD20 is effective in B-cell depleting multiple sclerosis.

- **Ilaris (canakinumab).** In the 10,000-patient CANTOS cardiovascular trial, this anti-IL-1β had a surprise finding – that the rate of joint (hip or knee) replacements at 4 years was significantly lower with Ilaris vs. placebo. The results, published in the ***Annals of Internal Medicine***, showed the benefit was apparent at Year 1 and with all three doses tested.
- **Kymriah (tisagenlecleucel).** This CAR T therapy met the primary endpoint in the single-arm Phase II ELARA trial in in follicular lymphoma.

Acute flaccid myelitis (AFM)

The Centers for Disease Control and Prevention (CDC) is warning that this polio-like viral illness, which appears to strike every two years, is likely to hit again this fall, adding to the confusion in diagnosing Covid-19 and flu in children.

In a press conference with reporters CDC director Robert Redfield, MD, called AFM a "medical emergency that requires immediate medical care and monitoring." He expressed concern that parents might delay seeking medical attention for a child with AFM, thinking it is flu or Covid-19, saying a delay in care can be critical.

The key risk period for AFM is August through November, but that could be lengthened or shortened by Covid-19 and social distancing.

AFM is believed to be caused, mostly if not entirely, by the enterovirus-D68 (EV-D68).

In the last outbreak (2018), limb weakness occurred ~6 days *after* a fever or respiratory illness started, and the CDC said 25% of patients were not hospitalized until ≥2 days after limb weakness, but AFM can progress rapidly and even waiting a few hours can mean permanent paralysis and/or life-threatening respiratory failure.

Thomas Clark, MD, deputy director of the CDC's Division of Viral Diseases, is urging all clinicians to "remain vigilant for AFM and promptly evaluate patients…Clinicians should not delay hospitalizing patients when they suspect AFM…We are concerned that in the midst of the Covid pandemic that cases might not be recognized…or that concerned parents might be worried about taking their child to the doctor…We want parents to understand that…AFM is a medical emergency."

In 2018 there were 238 cases in 42 states. A CDC review of the medical charts for those patients found that:

- 94% of cases were in children
- 76% sought medical care within one day
- 64% presented to the emergency department
- 98% of AFM patients were hospitalized
- 54% of patients were admitted to an ICU
- 25% of hospitalized patients needed a ventilator
- "Many" have permanent disability

Asked why some kids get AFM and others do not, Dr. Clark said they don't know, "We have a lot to learn."

Asked if there is a vaccine in development for EV-D68, Dr. Redfield said, "There has been preclinical work begun at NIAID [the National Institute on Allergy and Infectious Diseases under Anthony Fauci, MD] looking at prototype vaccine approaches. That started in fall 2018."

REGULATORY NEWS

Regulatory tidbits

- **CMS.** The Centers for Medicare and Medicaid Services (CMS) proposed 6%-9% cuts in Medicare reimbursement for some specialty surgeries:
  - Cardiovascular surgeons -9%
  - Thoracic surgeons -8%
  - Vascular surgeons -7%
  - Neurosurgeons -7%
  - Ophthalmologists -6%
- **Covid-19.** In a "Shark Tank" type of competition, the National Institutes of Health chose 7 Covid-19 diagnostic tests to get further support and funding:
  - Fluidigm's saliva-based test
  - Ginkgo Bioworks
  - Helix OpCo's nasal swabs
  - Mammoth Biosciences, a CRISPR based technology
  - Mesa Biotech's Accula, a hand-held RT-PCR test
  - Quidel's Sofia, an antigen test kit
  - Talis Biomedical's Talis One, a viral RNA test
- **Drug ads.** Knowledge Ecology International filed a citizen petition requesting that the FDA ban music during risk/side effect information in drug ads on television, radio, and the internet.

- **Essential drugs.** President Trump signed an executive order (the "Buy American" order) requiring the government to buy "essential" drugs from American companies.
- **FDA guidances**
  - **Antifungals.** The FDA released final guidance on its new LPAD pathway for new antifungal and antibiotic drugs for limited patient populations.
  - **Pediatrics.** The FDA released final guidance with details on how pharma and sponsors should prepare and submit plans for pediatric studies.
- **GILEAD SCIENCES' Veklury (remdesivir).** A bipartisan group of 34 state attorneys general is urging the federal government to use its "march-in rights" to allow generic versions of this antiviral therapy for Covid-19.
- **Medicare premiums.** Due to Covid-19, CMS will allow insurers to offer premium reductions to individuals and small groups through the end of 2020.
- **NOVARTIS**, settling a long-running whistleblower investigation, said it is moving away from the paid speaker model for physician education in the U.S. and will stop using restaurants as venues as part of the settlement of a whistleblower lawsuit. *Watch for other drug and device companies to follow suit.*
- **Patient ID.** A bill passed the U.S. House of Representatives that contains an amendment that would revoke the rule that prohibits federal expenditures on, promulgation of, or adoption of a unique patient identifier system.
- **Purple Book.** The FDA updated its searchable Purple Book database of biological products licensed by the FDA's Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER).
- **Ranitidine.** The U.S. Department of Justice is investigating Sanofi and GlaxoSmithKline after their ranitidine (Zantac) was recalled for NDMA contamination.
- **Telehealth.** President Trump signed an executive order that would make some telehealth policies instituted for Covid-19 permanent, starting with Medicare beneficiaries in rural areas. For those patients, telehealth would become a permanent benefit, with copayments waived.

FDA approvals

- **ABIOMED's Impella**, a percutaneous heart pump, was granted emergency use authorization (EUA) for treating Covid-19 patients with heart and lung failure who are on a ventilator.
- **ADAPTIVE BIOTECHNOLOGIES' clonoSEQ** was granted expanded clearance for use in evaluating minimal residual disease in chronic lymphocytic leukemia through blood or bone marrow.
- **Covid-19**
  - The FDA issued a Surgical Masks Umbrella emergency use authorization (EUA), a blanket approval of surgical masks that meet specific performance requirements for use in healthcare settings by healthcare personnel to protect from Covid-19.
  - **Autobio Diagnostics' Anti-SARS-CoV-2 Rapid Test** – The FDA revoked the EUA for this antibody test due to per-formance/accuracy concerns.
- **GLAXOSMITHKLINE's Blenrep (belantamab mafodotin-blmf)**, an anti-BCMA, was approved as a ≥5-line monotherapy treatment for adults with relapsed/refractory multiple myeloma. It was given a boxed warning for eye toxicity.
- **GUARDANT HEALTH's Guardant360 CDx** was approved to identify patients with specific EGFR mutations in NSCLC patients who may benefit from AstraZeneca's Tagrisso (osimertinib), making it the first liquid biopsy companion diagnostic and the first combination of next-generation sequencing and liquid biopsy in one test.
- **JOHNSON & JOHNSON's Spravato (esketamine)** – A supplemental new drug application (sNDA) was approved, expanding use of this nasal spray, in combination with an oral antidepressant, to treat depressive symptoms in adults with major depressive disorder (MDD) and acute suicidal ideation/behavior.
- **LIFE SPINE's Plateau-A Ti**, an anterior lumbar spacer system for use in anterior spine fusions, was cleared for use.
- **MEDTRONIC's InterStim Micro Neurostimulator and InterStim SureScan MRI leads** – a sacral neuromodulation system – was cleared for use to treat overactive bladder, fecal incontinence, and non-obstructive urinary retention.
- **ROCHE**
  - **and PTC THERAPEUTICS' Evrysdi (risdiplam)**, an oral SMN2-directed RNA splicing modifier, was approved to treat spinal muscular atrophy in patients age ≥2 months.
  - **cobas EBV test**, the first Epstein-Barr virus quantitative test, was cleared for use.
- **SAMSUNG's Galaxy Watch 3** – An ECG monitoring app was cleared for use with this device.
- **SIEMENS HEALTHINEERS' Somatom On.site**, a mobile head CT scanner, was cleared for use. It will allow in-bed CT head scans of intensive care unit (ICU) patients.

- SURMODICS' Sublime, a radial access 0.014 rapid exchange percutaneous transluminal angioplasty dilation catheter, was granted 510(k) clearance.
- TREVENA's Olinvyk (oliceridine), an IV opioid agonist for short-term in-hospital use in the management of moderate-to-severe pain in adults, was approved.
- VIIV HEALTHCARE's Dovato (dolutegravir + lamivudine) was granted expanded approval as a complete regimen for treating HIV, replacing the current antiretroviral regimen in virologically suppressed adults with no history of treatment failure and no known resistance to the components of Dovato.

FDA recalls/warnings

- BECTON DICKINSON/CME AMERICA's BodyGuard Infusion Administration Sets – The recall (Class I) due to delivery inaccuracies was updated.
- Covid-19
  - The FDA and the Federal Trade Commission jointly sent a warning letter for selling unapproved/unauthorized products to mitigate, prevent, treat, diagnose, or cure Covid-19 to:
    - ✓ MMSTabs.com
    - ✓ Canadian Chaga
  - The FDA issued a warning letter about distribution of chloroquine phosphate products to **New Life International** and a second warning letter to **Fishman Chemical of North Carolina**, both for making unsupported claims.
- FERRING PHARMACEUTICALS' DDAVP Nasal Spray, Desmopressin Acetate Nasal Spray, and STIMATE Nasal Spray were recalled due to potency higher than specified (superpotency).

European Regulatory News

- BENTLEY INNOMED's BeYond, a venous self-expanding stent system for removing vein obstructions, was granted a CE Mark.
- DIASORIN's Liaison Testosterone xt, a test that can help detect fertility disorders, was granted a CE Mark.
- ENDOLOGIX's ALTO, an abdominal stent graft system for repairing endovascular aneurysms, was granted a CE Mark.
- NEUMODX MOLECULAR's Quantitative BK virus assay was granted a CE Mark for use in helping healthcare providers monitor infections in critical organ transplant patients.
- ROCHE's Rozlytrek (entrectinib) was approved by the European Commission to treat NTRK fusion+ solid tumors and ROS1+ NSCLC.
- SCHWIND's Schwind ATOS femtosecond laser was granted a CE Mark.

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

- KIOWA KIRIN's Poteligeo (mogamulizumab) – NICE recommended *against* use of this anti-CCR4 antibody as a second-line treatment for mycosis fungoides or Sézary syndrome saying the efficacy is "very uncertain" because the comparator in the pivotal trial was a drug not approved or used in the U.K. (vorinostat).
- Pain – In its first guidance on pain, NICE said general practitioners should not prescribe opioids for chronic pain because they might be "harmful" and lead to addiction. Instead, NICE suggested an antidepressant, exercise, cognitive behavioral therapy (CBT), or acupuncture. Comments will be accepted until August 14, 2020.

Regulatory news from other countries

- ***China.*** G1 THERAPEUTICS' trilaciclib – The rights to this CDK4/6 inhibitor, a treatment for the side effects of chemotherapy, for China, Hong Kong, Macau, and Taiwan were sold to **Simcere Pharmaceutical**.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
tba	**GlaxoSmithKline and Innoviva's Trelegy Ellipta** (fluticasone furoate + umeclidinium + vilanterol) – expanded approval for improving lung function, quality of life, and symptom control in asthma	PDUFA date **Now expected "later this year"**
August 8	**Eagle Pharmaceuticals' Ryanodex** (dantrolene sodium) to treat heat stroke (resubmission)	PDUFA date *Postponed from July 8*
August 10 (est.)	**Bausch Health/Eton Pharmaceuticals' EM-100**, an eyedrop for treating ocular itchiness (resubmission)	PDUFA date
August 10	**Fennec Pharmaceuticals' Pedmark** (sodium thiosulfate) for preventing ototoxicity from cisplatin chemotherapy	PDUFA date
August 11	Independent third-party assessment of IND FDA-Sponsor Communication practices in **PDUFA VI**	FDA virtual public meeting
August 11	**Roche's Xolair** (omalizumab) – expanded approval to include treatment of chronic rhinosinusitis with nasal polyps	PDUFA date
August 12	Immediately-in-effect guidance on **coronavirus diagnostic tests**	FDA virtual Town Hall
August 13	**Spinal device premarket review**	FDA virtual public workshop
August 13	**Mesoblast's Ryoncil** (remestemcel-L) – ex-vivo culture-expanded adult human mesenchymal stromal cells suspension for IV infusion for steroid-refractory acute graft-versus-host disease in pediatric patients	FDA's Oncologic Drugs Advisory Committee virtual meeting
August 13	**Nanotechnology Task Force report** on FDA progress in nanotechnology since 2007	FDA 1-hour virtual seminar
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 22	**Tricida's veverimer** (TRC-101) for metabolic acidosis	PDUFA date
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
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 8	Classification of **facet screw systems** from unclassified to Class II *and* classification of non-invasive bone growth stimulators from Class III to Class II	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee virtual meeting
September 9	Classification of 3 devices from unclassified to Class II: semi-constrained toe joint prostheses, intracompartmental pressure monitors, and intra-abdominal pressure monitoring devices	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee virtual meeting
September 15	**Safety review** of 6 drugs, devices, and biologics – and acute dystonia associated with ADHD	FDA's Pediatric Advisory Committee virtual meeting
Sept. 17-18	Use of real-world evidence to assess the effectiveness of **preventive vaccines**	FDA virtual public workshop
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 virtual summit **https://aralliance.org/gsrs/**
September 29	**Patient preferene information use in** medical device regulatory decisions	FDA public meeting webcast
Sept. 29-30	Annual Scientific Computing Days: **Real-world evidence**	FDA and National Center for Toxicological Research (NCTR) *May be virtual*
September 30	**Patient-reported outcomes** (PROs) and medical device investigations	FDA virtual public meeting
September 30	**Mesoblast's Kyoncil** (remestemcel-L) for steroid-refractory acute graft-versus-host disease in pediatric patients	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**
October 6	Patient-focused drug development for **stimulant use disorder**	FDA virtual public meeting
October 14	Enhancing development of **radiopharmaceuticals and radiological devices**	FDA-NRC virtual workshop
October 18	**Roche's Herceptin** (trastuzumab) **+ Perjeta** (pertuzumab) – a fixed dose combination to treat HER2+ breast cancer	PDUFA date
October 19	Complex generic **drug-device combination products**	FDA/DIA virtual conference
October 24	**Spectrum Pharmaceuticals' Rolontis** (eflapegrastim) for treating chemotherapy-induced neutropenia	PDUFA date
October 25	**Regeneron Pharmaceuticals' REGN-EB3** for Ebola	PDUFA date
October 27	Antimicrobial drugs to treat **gonorrhea**	FDA virtual public workshop
October 30	**Integrated assessment of marketing applications**	FDA virtual public workshop
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
January 20, 2021	**Merck MSD and Bayer's vericiguat** in HFrEF	PDUFA date
January 26, 2021	Non-clinical immunogenicity assessment of **generic peptide products**	FDA virtual public workshop
March 7, 2021	**Biogen and Eisai's aducanumab** for Alzheimer's disease	PDUFA date