TRENDS-in-MEDICINE

August 30, 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: The weekly Covid-19 section is on Page 3. Subscribe to ***Trends-in-Medicine*** for coverage of the **European Association for the Study of the Liver**'s virtual International Liver Conference (ILC) and the **European Society of Cardiology** virtual conference.

Be careful, be safe, and be well.

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

✓ JOHNSON & JOHNSON's Invokana (canagliflozin), Invokamet, and Invokamet XR – The FDA removed the boxed warning about the risk of lower limb amputation with these SGLT2 drugs.

✓ TRICIDA's veverimer was rejected by the FDA as a treatment for metabolic acidosis in CKD patients, saying another trial is needed.

✓ **Positive trial news:**

- MERCK KGaA's Mavenclad (cladribine) – in a head-to-head study vs. two other leading therapies in multiple sclerosis, Biogen's Tecfidera and Teva's Copaxone.
- NOVARTIS' asciminib (ABL-001) – in Ph+ CML vs. Pfizer's Bosulif (bosutinib).
- OVID THERAPEUTICS and TAKEDA's soticlestat – in children with Dravet syndrome and Lennox-Gastaut syndrome overall, but really only in Dravet patients.
- ROIVANT SCIENCES/DERMAVANT SCIENCES' tapinarof cream 1% – in plaque psoriasis.

✓ **Negative trial news:**

- ABBVIE/ALLERGAN and UROGEN PHARMA's intravesical formulation of Botox (onabotulinumtoxinA) – in OAB and urinary incontinence.
- BRISTOL-MYERS SQUIBB's Idhifa (enasidenib) – in relapsed/refractory IDH2+ AML.
- ONCONOVA THERAPEUTICS' rigosertib – in higher-risk MDS.

SHORT TAKES

■ ACADIA PHARMACEUTICALS is buying CerSci Therapeutics, which will give it ACP-044, a non-opioid painkiller for incisional, inflammatory, and neuropathic pain.

■ AMGEN's obicetrapib (AMG-899) – The rights to this CETP inhibitor, which was put in mothballs in 2017, were sold to **NewAmsterdam Pharma**.

■ BAVARIAN NORDIC – The U.S. government signed a contract worth up to $539 million, much of which is devoted to production of 13 million doses of a freeze-dried version of its smallpox vaccine, Jynneos.

- BAYER extended its partnership with **One Drop**, a digital health provider currently focused on diabetes.

- BEIGENE exclusively licensed the rights to co-develop **Singlomics Biopharmaceuticals**' Covid-19 antibodies, including DXP-593 and DXP-604, outside of greater China.

- BIONANO GENOMICS bought **Lineagen**, a pediatric neurodevelopment testing company with genetic diagnostics for disorders such as autism spectrum disorder.

- BOEHRINGER INGELHEIM returned the rights to a Kv3 program, including AUT-00206 for schizophrenia, that it had licensed from **Autifony Therapeutics**.

- CELLTRION is collaborating with **Intract Pharma** on development of an oral infliximab – an oral biosimilar of Johnson & Johnson's Remicade – for inflammatory bowel disease.

- HOLOGIC is buying **Acessa Health**, which will give it the ProVu system for treating uterine fibroids.

- LILLY's Retevmo (selpercatinib) – The results of the Phase I/II LIBRETTO-001 trial in RET mutated non-small cell lung cancer (NSCLC), which led to its FDA approval, were published in the ***New England Journal of Medicine***, showing that this RET kinase inhibitor produced durable objective responses and had good safety.

- LIPOCINE's Tlando (undecanoate) – The FDA was expected to make a decision on this oral testosterone for hypogonadism by August 28, but the Agency informed the company that it needs more time, though it didn't say how much more time. Remember, the FDA rejected Tlando last year, saying there were efficacy questions. The data were reanalyzed, and the drug was resubmitted to the FDA.

- LYGENESIS – A study by University of Pittsburgh School of Medicine researchers, published in the journal ***Liver Transplantation***, found that functioning human liver cells can be grown in the abdominal lymph nodes of pigs. The next step is to try to transplant those liver cells to humans with failing livers.

- NOVARTIS' asciminib (ABL-001), a STAMP inhibitor, met the primary endpoint in the Phase III ASCEMBL trial in ≥3-line Philadelphia chromosome-positive chronic myelogenous leukemia (CML) patients, showing superiority to Pfizer's Bosulif (bosutinib) at Week 24 on major molecular response (MMR).

- ONCONOVA THERAPEUTICS' rigosertib, an IV RAS mimetic, missed the primary endpoint in the pivotal Phase III INSPIRE trial in higher-risk myelodysplastic syndromes (MDS), failing to significantly prolong survival when added to best supportive care (BSC) vs. BSC alone.

- OVID THERAPEUTICS and TAKEDA's soticlestat, a CH24H inhibitor, met the primary endpoint in the 139-patient Phase II ELEKTRA trial in children with Dravet syndrome and Lennox-Gastaut syndrome, but the benefit was mostly in the Dravet patients (with a 46% reduction in seizures vs. placebo and a 14.8% reduction vs. placebo in the Lennox-Gastaut patients).

- PHILIPS is buying **Intact Vascular**, which will give it the Tack endovascular system for treating peripheral artery disease.

- REGENXBIO's RGX-314 – The company was given a green light by the FDA to start a Phase II trial of this gene therapy for treating diabetic retinopathy.

- ROIVANT SCIENCES/DERMAVANT SCIENCES' tapinarof cream 1% – This topical aryl hydrocarbon receptor modulating agent (TAMA) met the primary endpoint in two identical Phase III trials – PSOARING-1 and PSOARING-2 – in plaque psoriasis, showing significant improvement in PGA 0.1, with a ≥2-grade improvement, vs. vehicle at Week 12. Tapinarof also showed significant improvement in PASI-75, a key secondary endpoint, in both trials.

- SULZER is buying **Haselmeier**, a drug delivery device company.

- TAKEDA is collaborating with **Engitix** on development of drugs using Engitix's extracellular matrix (ECM) technology to treat advanced fibrotic liver diseases, including non-alcoholic steatohepatitis (NASH).

- TRICIDA's veverimer (TRC-101) – As expected, the FDA rejected this oral, non-absorbed polymer, issuing a complete response letter (CRL) for this treatment for metabolic acidosis in chronic kidney disease (CKD). Likely another trial will be needed.

Very early research news

- Alzheimer' disease – A mouse study by researchers at the University of Kentucky's Sanders-Brown Center on Aging, published in the ***Journal of Neuroinflammation***, suggests a new target for treating/preventing Alzheimer's disease – Trem2 activation. In the study, Trem2 activation reduced amyloid-beta deposition and improved cognition – *in mice.*

- Obesity – In a mouse study published in ***Science Translational Medicine***, researchers from the Joslin Diabetes Center reported that they used CRISPR to tweak white fat cells to make them function more like brown fat cells – the "good" kind of fat. The result was a metabolism "adjustment" that caused the mice to burn more calories, absorb glucose better, and lose weight.

- **Psychiatric disorders** – A study, published in ***JAMA Psychiatry***, found that a blood test – panel of protein markers – could be used to predicted (with 93% accuracy) which high-risk youngsters would develop a psychiatric disorder by the age of 18.

NEWS IN BRIEF

ABBVIE

- Licensed **Morphic Therapeutics**' $\alpha_v\beta_6$ integrin inhibitors – including MORF-720 – for treating fibrotic diseases, such as idiopathic pulmonary fibrosis (IPF).
- Is collaborating with Harvard on evaluation and development of new therapies to treat emergent viral infections.
- **ALLERGAN and UROGEN PHARMA's formulation of Botox** (onabotulinumtoxinA) in an RTGel hydrogel for intravesical instillation in overactive bladder (OAB) and urinary incontinence patients missed the primary endpoint in the Phase II APOLLO trial, failing to reduce daily urinary incontinence episodes. UroGen suggested the failure may have been due to the botulinum toxin *not* effectively permeating the urothelium.

BRISTOL-MYERS SQUIBB

- **Idhifa (enasidenib)** missed the primary endpoint in the confirmatory Phase III IDHENTIFY trial in relapsed/refractory acute myeloid leukemia (AML) patients with an IDH2 mutation, failing to significantly prolong overall survival vs. conventional care.
- Is buying **Forbius**, which will give it AVID-200, a TGF-β1/3 inhibitor, to use in immuno-oncology.

JOHNSON & JOHNSON

- **Invokana (canagliflozin), Invokamet, and Invokamet XR**
  - A study, published in ***The BMJ***, found that adults age ≥65 who had cardiovascular disease had a higher risk of lower limb amputation with this SGLT2 inhibitor vs. patients on a GLP-1 agonist.
  - The FDA *removed* the boxed warning on this SGLT2 inhibitor about an increased risk of foot and leg amputation. There is still a warning, but not a boxed warning.
- **Blue Knight.** J&J is collaborating with the U.S. Biomedical Advanced Research and Development Authority (BARDA) to prepare for potential health threats – Covid-19 and beyond – and 7 startups from J&J's global JLABS network were chosen to get support:
  - 7 Hills Pharma, which is working on an immune stimulant
  - Autonomous Therapeutics, which is working on prophylactic treatments against all coronaviruses
  - Epic Bio, which is working on Cas13d enzymes
  - GabiSmartCare, which has a respiratory remote monitoring system
  - Genome Biologics, which has a computational platform for finding links between approved drugs
  - Persephone Biosciences, which is developing a microbiome treatment
  - Specific Biologics, which is developing a gene editor delivered via nanoparticles

MERCK KGAA

- **Mavenclad (cladribine).** A head-to-head observational study, published in the journal ***Neurology***, found that oral Mavenclad reduced relapse rates better than Teva's Copaxone (glatiramer acetate) and Biogen's Tecfidera (dimethyl fumarate) in relapsing multiple sclerosis patients – but Biogen's Tysabri (natalizumab) was better than Mavenclad.
- Is collaborating with **Amoy Diagnostics** (AmoyDx) on a pan lung cancer PCR companion diagnostic for Tepmetko (tepotinib), an oral MET kinase inhibitor.

Where the Doctors Are and Aren't	
States with the MOST physicians per capita	**State with the LEAST physicians per capita**
Washington, DC	Idaho
Massachusetts	Wyoming
Rhode Island	Nevada
New York	Montana
Connecticut	Mississippi

Source: **WalletHub**

COVID-19 WEEKLY HIGHLIGHTS

- **Convalescent plasma.** A snap poll of pharma and biotech officials by ***Endpoints News*** about the emergency use authorization (EUA) granted by the FDA for convalescent plasma found:
  - 57.5% said the EUA *should not* have been issued.
  - 28.4% said it *should* have been issued but was announced "poorly."
  - 14.1% said it *should* have been issued and was handled fine.
- **Food.** A study, published on ***bioRxiv***, found that SARS-CoV-2 can survive on frozen and refrigerated meat and fish for up to 3 weeks. Experts warned that this does not mean

that there is any significant risk of catching Covid-19 from defrosting and eating the meat in your refrigerator.

- GILEAD SCIENCES' Veklury (remdesivir)
  - While the FDA expanded the EUA for this antiviral, newly published – but previously reported – data in ***JAMA*** which showed that 70% of moderately ill hospitalized patients who took a 5-day course had a shorter hospital stay vs. 65% of patients on a 10-day course. The news was the accompanying editorial that questioned the drug's benefit overall.
  - GS-441524. The National Institutes of Health is starting preclinical studies of this antiviral, sold on the black market for treating feline infectious peritonitis caused by a different coronavirus, that works similarly to remdesivir. Gilead has declined to test it, but MD Anderson Cancer Center researchers believe it works as well or better than remdesivir, with fewer side effects.
- Hospitals. According to Kaufman Hall's National Hospital Flash Report, data on >800 hospitals showed operating margins were down 28% in the first 7 months of 2020 compared to the same period in 2019. Without federal funding from the CARES Act, operating margins would have been down 96%.
- Prevention. A U.K. study, published in ***Science Focus***, suggests that Citrefine International's Citriodiol (p-menthane-3,8-diol), an active ingredient in its Mosi-guard Natural, a mosquito repellant, may also protect against SARS-CoV-2.
- Reinfection. The first *confirmed* case of a SARS-CoV-2 reinfection was reported in Hong Kong 4.5 months after the patient's first infection (which was resolved and mutationally different), and there is an unconfirmed report of at least one U.S. patient who was reinfected. The good news is that, so far at least, reinfections are very uncommon. The bad news is this suggests that vaccines may not offer long-term protection for some or even most people.
- Testing. The FDA granted an EUA to **Abbott's BinaxNow**, a 15-minute $5 Covid-19 *antibody* test on a card, not identical to but similar to a pregnancy test. A study found it had 97.1% sensitivity and 98.5% specificity. However, it is designed to be used by healthcare providers, not the general public. The company plans to produce millions of tests a month, and the U.S. government is buying 150 million tests.
- Vaccines
  - FDA Commissioner Stephen Hahn, MD, in an interview with the ***Financial Times***, said an EUA *might* be appropriate for a Covid-19 vaccine before the Phase III trial is completed if the benefits outweigh the risks. The company would have to submit data, and the FDA would weigh it. However, Dr. Hahn also said he would not rush a vaccine just to please President Trump.
  - ***Endpoints News*** has a good summary of the status of 28 vaccines. It is worth a read: https://endpts.com/28-players-are-in-or-about-to-jump-in-to-the-race-to-a-global-multibillion-dollar-market-for-a-covid-19-vaccine-heres-how-they-rank-so-far/
  - The CDC proposed guidelines for vaccine distribution – once one is available – and the priorities, in order, will be:
    - ✓ ~20 million healthcare workers – paid and unpaid – at hospitals, long-term care facilities, home-based care, pharmacies, etc.
    - ✓ ~80 million essential personnel, including workers in food, agriculture, transportation, education, energy, law enforcement, etc.
    - ✓ ~100 million people with medical conditions.
    - ✓ ~53 million seniors (age ≥65).
  - Some of the Covid-19 vaccines in development – including the Pfizer/BioNTech and Moderna vaccines – will need ultra-cold storage, which will affect shipping, storage, and use in undeveloped countries.
  - Liability may be an issue for vaccine makers, at least outside the U.S.
  - CanSino Biologics' Ad5-nCoV vaccine won't be tested in Canada after all because the Chinese government won't let the company ship the vaccine there.
  - Moderna's mRNA-1273 vaccine produced neutralizing antibodies in elderly patients (age >71) with two injections, given a month apart. The good news, it appears to work in those patients. The bad news: multiple doses may be needed, which makes it logistically more difficult.
  - Pfizer and BioNTech said their Phase III Covid-19 trial has passed the 50% enrollment mark.
  - Sanofi and Translate Bio reported that two doses of their mRNA vaccine produced positive antibodies in a preclinical (animal) study.

REGULATORY NEWS

Regulatory tidbits

- CMS. The Centers for Medicare and Medicaid Services (CMS):
  - **Covid-19**
    - ✓ Issued an emergency regulation requiring all hospitals to make *daily* reports on Covid-19 data (e.g., cases,

ICU bed capacity, availability of ventilators and personal protective equipment.

- ✓ Threatened to withhold funds from healthcare providers (hospitals, nursing homes) that do not confirm a Covid-19 diagnosis with a test.
- ✓ Finalized a policy that makes vascular access procedures "essential" for end-stage renal disease (ESRD) patients during Covid-19.

- **Disasters** – Amended the disaster policy for Medicare Advantage and Medicare Part D plans so that it applies to nearly all plans due to the pandemic.
- **Stark** – Postponed the final changes to the Stark Law on physician self-referrals until August 31, 2021.

- Drug prices. Upset with President Trump's executive orders on Medicare drug pricing, which likely would mean at least a 30% decrease in prices, pharma companies sent the White House a counteroffer – a 10% price discount.
- Flu vaccine – The Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices issued updated recommendations for the upcoming flu season, recommending that everyone age ≥6 months who doesn't have a contraindication should get a flu vaccine.
- Oncology. The FDA issued draft recommendations for studying cancer drugs in patients with central nervous system (CNS) metastases. Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the Center for Drug Evaluation and Research (CDER), said that more attention is needed to address CNS metastases but that clinical trial design "remains a challenge," adding, "We hope this helps sponsors design clinical trials that improve the ability to understand the therapy's benefit:risk profile across the patient population likely to use the drug. The development of therapeutic products for patients with CNS metastases is greatly needed."

FDA approvals

- B. BRAUN and PHILIPS' Onvision, an ultrasound guidance system for needle-tip tracking for helping anesthesiologists position needle tips accurately inside the body, was granted 510(k) clearance.
- CASSIOPEA's Winlevi (clascoterone cream 1%), a topical androgen receptor inhibitor for acne, was approved.
- ELEKTA's Geneva, a universal gynecological applicator for use in cervical cancer treatments, was granted 510(k) clearance.
- EMERGENT BIOSOLUTIONS' Narcan (naloxone), a nasal spray opioid reversal agent, was granted a longer shelf-life – 36 months instead of 24 months.
- GILEAD SCIENCES' Veklury (remdesivir) – The existing EUA for this antiviral was expanded to allow treatment for all hospitalized patients (adults and pediatric) with suspected or confirmed Covid-19, regardless of disease severity.
- GYROSCOPE THERAPEUTICS' Orbit, a subretinal syringe, was granted 510(k) clearance.
- HEALEON's Healeon Duet, a blood separation device for use during platelet-rich plasma (PRP) preparation, was granted 510(k) clearance.
- MEDTRONIC's Evolut was granted revised labeling to include recommendations that healthcare providers should consider when deciding on use of this transcatheter aortic valve replacement (TAVR), including things to consider before using the valve for bicuspid patients.
- PELVITAL's Flyte, a non-invasive intravaginal device for strengthening pelvic floor muscles to treat stress urinary incontinence, was cleared for use.
- PENUMBRA's Indigo CAT7, a new size for the Indigo aspiration system for peripheral blood clots, was cleared for use.
- ROCHE/FOUNDATION MEDICINE's FoundationOne Liquid CDx was approved for use in diagnosing all solid tumors.
- SURGENTEC's OsteoFlo NanoPutty, a quadphasic synthetic bone graft, was granted 510(k) clearance.

FDA recalls/warnings

- NANOMATERIALES' Zanilast+gel – All lots of this hand sanitizer were recalled due to contamination with 1-propanol. The FDA also has continued to warn about numerous other hand sanitizers being dangerously contaminated with wood alcohol.
- Personal protective equipment (PPE)
  - The FDA issued a warning to healthcare providers *not* to use gowns from Laws of Motion PPE because they do not meet the label specifications for use, making them a safety risk.
  - The FDA withdrew its EUA for passive, non-negative pressure protective barrier enclosures that don't have air filters or fans, saying they may actually *increase* airborne particle exposure. The FDA warned that healthcare providers should only use FDA-approved barriers with negative pressure and that these barriers are not a replacement for PPE.

- SMITHS MEDICAL's Medfusion 3500 and 4000 syringe pumps were recalled (Class I) due to the risk of a medication delivery error.
- Tuberculosis – The FDA said it does not plan to recall either of two generic TB drugs – rifapentine and rifampin – even though both were found to have possible contamination with MNP and CPNP.

European Regulatory News

- CIVCO RADIOTHERAPY's Comfort Marker 2.0, for applying temporary reference points on the skin of patients for use during radiotherapy, was granted a CE Mark.
- NATERA's Signatera, a ctDNA test for monitoring treatment and detecting residual disease in cancer patients, was granted a CE Mark.
- NOVACYT's Winterplex, a PCR-based respiratory panel for differentiating SARS-CoV-2 from respiratory syncytial virus (RSV) and influenza A and B, was granted a CE Mark.

Regulatory news from other countries

- ***Japan.*** ASTRAZENECA's Imfinzi (durvalumab) was approved by the Ministry of Health, Labour, and Welfare to treat small cell lung cancer.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
August 28	**Lipocine's Tlando** (oral testosterone) for hypogonadism (resubmission)	PDUFA date **Postponed indefinitely**
August 31	**GlaxoSmithKline and Innoviva's Trelegy Ellipta** (fluticasone furoate + umeclidinium + vilanterol) – new label claim for reduction in all-cause mortality in COPD patients	FDA's Pulmonary-Allergy Drugs Advisory Committee virtual meeting
September 1	**Surgical N95 respirator guidance**	FDA webinar
September 2	Immediately-in-effect guidance on **coronavirus diagnostic tests**	FDA virtual town hall
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 10	**Multiple function device products**: policy and considerations	FDA webinar
September 10	Advancing the science of real-world data to address the **Covid-19 pandemic**	FDA webcast
Sept. 10-11	Review of postmarketing studies of **Purdue Pharma's reformulated OxyContin ER** (oxycodone hydrochloride extended-release)	Virtual meeting of the FDA's Anesthetic and Analgesic Drug Products Advisory Committee jointly with the Drug Safety and Risk Management Advisory Committee
Sept. 14-16	Quality management and robust **manufacturing**	FDA and Parenteral Drug Association joint virtual conference
September 15	**Bausch Health/Eton Pharmaceuticals' EM-100**, an eyedrop for treating ocular itchiness (resubmission)	PDUFA date *Postponed from August 10*
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 24	Safety and performance-based **pathway** criteria for devices (final guidance)	FDA webinar
September 25	Challenges in **inhaled antifungal** drug development	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 preference 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
October 2	Discussion of strains to be included in **flu virus vaccine** for 2021 southern hemisphere flu season	FDA's Vaccines and Related Biological Products Advisory Committee virtual meeting
October 6	Patient-focused drug development for **stimulant use disorder**	FDA virtual public meeting
October 7	**TransMedics' TransMedics Organ Care System** (OCS) – normothermic heart transplant transport	FDA's Circulatory System Devices Advisory Committee virtual meeting
October 9 **(tentative)**	**Alkermes' ALKS-3831** (olanzapine/samidorphan) for schizophrenia and bipolar disorder	FDA's Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee joint virtual meeting
October 13	Patient-focused drug development for **systemic sclerosis**	FDA virtual public meeting
October 13-14	Update and **strategic plan** for 2021-2025 for National Antimicrobial Resistance Monitoring System (NARMS)	FDA's Center for Veterinary Medicine webcast
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 22-23	Pediatric dose selection	FDA virtual public workshop
October 22	**Covid-19 vaccines** general discussion	FDA's Vaccines and Related Biological Products Advisory Committee virtual meeting
October 22	**Artificial intelligence** and machine learning in medical devices	FDA's Patient Engagement Advisory Committee virtual meeting

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
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 *Postponed from August 21*
October 30	Integrated assessment of **marketing applications**	FDA virtual public workshop
November 13	**Orthopedic device-related infections**	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 19	**CBD and other cannabinoids** – sex and gender differences in use and response	FDA's Office of Women's Health virtual Scientific Conference
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
2021		
January 20	**Merck MSD and Bayer's vericiguat** in HFrEF	PDUFA date
January 26	Non-clinical immunogenicity assessment of **generic peptide products**	FDA virtual public workshop
January 27	**Protalix BioTherapeutics and Chiesi's pegunigalsidase alfa** (PRX-102) for Fabry disease	PDUFA date
February 11	**Regeneron Pharmaceuticals' evinacumab** in severe homozygous familial hypercholesterolemia (HoFH)	PDUFA date
February 15	**G1 Therapeutics' trilaciclib** for small cell lung cancer	PDUFA date
March 7	**Biogen and Eisai's aducanumab** for Alzheimer's disease	PDUFA date