TRENDS-in-MEDICINE

September 13, 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: The weekly Covid-19 section is on Page 5. Subscribe to ***Trends-in-Medicine*** for our coverage of the virtual meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), in association with the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS).

Be careful, be safe, and be well.

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

- ✓ ASTRAZENECA's AZD-1222 – This Covid-19 vaccine trial was put on hold after a patient developed transverse myelitis, but the hold was lifted 6 days later, with an all-clear but little additional information.
- ✓ GILEAD SCIENCES is buying **Immunomedics**.
- ✓ SAREPTA THERAPEUTICS' SRP-9001 – The FDA said this treatment for Duchenne muscular dystrophy will need an additional lab test run before it can move to Phase III.
- ✓ **Positive trial results:**
  - AMRYT PHARMA's Filsuvez (AP-101, Oleogel-S10) – in epidermolysis bullosa.
  - ASTRAZENECA's Fasenra (benralizumab) – in chronic rhinosinusitis with nasal polyps.
  - AVENU MEDICAL's Ellipsys Vascular Access System and BECTON DICKINSON's Wave-linQ 4F System – in vascular access in ESRD dialysis patients.
  - BAYER and ORION's Nubeqa (darolutamide) – in non-metastatic castration-resistant prostate cancer.
  - GALAPAGOS' ziritaxestat (GLPG-1690) – in diffuse cutaneous systemic sclerosis.
  - LILLY's Reyvow (lasmiditan) – in migraine.
  - MERCK MSD's
    - Gefapixant – the high dose in refractory/unexplained cough.
    - V114 – a 15-valent pneumococcal conjugate vaccine.
  - SANOFI and SOBI's BIVV-001 (rFVIIIFc-VWF-XTEN) – in severe hemophilia A.
  - SPERO THERAPEUTICS' tebipenem HBr (tebipenem pivoxil hydrobromide) – in adults with complicated urinary tract infections and acute pyelonephritis.
- ✓ **Negative trial results:**
  - CORBUS PHARMACEUTICALS' lenabasum – in systemic sclerosis.
  - SATSUMA PHARMACEUTICALS' STS-101 (dihydroergotamine nasal powder) – in migraine.
  - TAKEDA's Ninlaro (ixazomib) – in newly diagnosed multiple myeloma.

SHORT TAKES

- AMARIN's Vascepa (icosapent ethyl) – A federal appeals court upheld a lower court ruling that Amarin's patents on this fish oil product are not valid, based on obviousness.

- AMRYT PHARMA's Filsuvez (AP-101, Oleogel-S10) – This birch bark extract met the primary endpoint in the 223-patient Phase III EASE trial in epidermolysis bullosa, accelerating wound healing better than placebo. However, Filsuvez missed all six key secondary endpoints, including time to closure of the target wound within 90 days.

- ASPEN PHARMACARE is selling its injectable thrombosis business in Europe to **Mylan**.

- ASTRAZENECA's Fasenra (benralizumab) met the primary endpoint in the 413-patient, 53-week Phase III OSTRO trial of this anti-IL-5 in chronic rhinosinusitis with nasal polyps (CRSwNP), significantly improving both the size of the polyps and nasal blockage.

- AVEO ONCOLOGY's ficlatuzumab (AV-299) – Aveo regained the full worldwide rights to this hepatocyte growth factor for cancer from **Biodesix.**

- BOEHRINGER INGELHEIM is collaborating with **Click Therapeutics** on CT-155, a prescription digital therapeutic for use in helping schizophrenic patients modify their behavior for positive results.

- CORBUS PHARMACEUTICALS' lenabasum, a cannabinoid receptor type 2 agonist, missed the primary endpoint in the 52-week, 365-patient Phase III RESOLVE-1 trial in systemic sclerosis, with no significant difference on the ACR CRISS score vs. placebo with either dose. The trial also missed the key secondary endpoints.

- EXELIXIS is collaborating with **NBE-Therapeutics** on discovery and development of antibody-drug conjugates (ADCs) to treat cancer.

- GALAPAGOS' ziritaxestat (GLPG-1690), an oral autotaxin inhibitor, met the primary endpoint in the 33-patient Phase IIa NOVESA proof-of-concept trial, significantly improving the modified Rodnan skin score (mRSS) at Week 24 in patients with diffuse cutaneous systemic sclerosis (dcSSc) – -8.3 vs. -5.7. The drug was well tolerated, with 94% of patients who completed the trial continuing in the long-term, open-label extension study.

- GILEAD SCIENCES is buying **Immunomedics**.

- GRIFOLS is buying its partner, **Alkahest**, which analyzes blood proteins in neurological drug discovery.

- INTELGENX is partnering with **ATAI Life Sciences** on development of novel formulations of pharmaceutical-grade psychedelics, using IntelGenx's polymeric film technologies.

- JAZZ PHARMACEUTICALS is collaborating with **Redx Pharma** on discovery and development of two investigational cancer drugs targeting the Ras/ Raf/MAP kinase (MAPK) pathway.

- JOHNSON & JOHNSON's Darzalex Faspro (subcutaneous daratumumab and hyaluronidase-fihj) – A supplemental biologics license application (sBLA) was submitted to the FDA for approval to treat newly diagnosed patients with light chain amyloidosis.

- JUNSHI BIOSCIENCES' toripalimab, a PD-1 inhibitor, was granted breakthrough therapy designation as a treatment for nasopharyngeal carcinoma. This is the first Chinese anti-PD-1 to get BTD designation.

- LEO PHARMA exclusively licensed **Elektrofi**'s technology for use in developing a subcutaneous antibody against an undisclosed dermatologic indication.

- LILLY's Reyvow (lasmiditan) – In data presented virtually at the PAINWeek conference, this oral 5-HT_{1F} receptor inhibitor met the primary endpoint – and all 17 other endpoints – in the Phase III CENTURION trial in migraine attacks, significantly improving freedom from migraine pain at 2 hours vs. placebo (65.2% for 200 mg and 65.4% for 100 mg vs. 41.3% for placebo), showing superiority to placebo on all measures. Patients taking 200 mg for a migraine attack had a 4.6 times greater chance of being pain-free at 2 hours vs. placebo.

- MEDTRONIC's Intrepid – The FDA granted breakthrough device status and approved the start of an early feasibility study of this transcatheter tricuspid valve replacement (TTVR) system for symptomatic tricuspid regurgitation.

- OTSUKA/ASTEX PHARMACEUTICALS formed a strategic collaboration with MD Anderson Cancer Center aimed at accelerating clinical evaluation of Astex's leukemia drugs.

- PPD, a contract research organization (CRO), is collaborating with **Lupus Therapeutics** to broaden its lupus research capabilities for clients.

- PTC THERAPEUTICS' PTC Pinpoint – The company announced a free genetic testing program (with counseling) for neurotransmitter disorders.

- RADIOLOGY PARTNERS is buying the radiology services business of **Mednax**.

- SANOFI and SWEDISH ORPHAN BIOVITRUM (SOBI)'s BIVV-001 (rFVIIIFc-VWF-XTEN) – The final results of the open-label Phase I/IIa EXTEN-A trial in men with severe hemophilia A, published in the ***New England Journal of Medicine***, showed that a single dose of this Factor VIII replacement therapy induced near normal factor activity for nearly a week. No inhibitor development was detected through 28 days post-dose, and it was well tolerated.

- SAREPTA THERAPEUTICS' SRP-9001 (AAVrh74.MHCK7.micro-dystrophin) – The FDA told the company it needs an additional lab test – a new "potency assay" that tests whether it gets into cells and actually increases production of dystrophin – on this gene therapy for Duchenne muscular dystrophy before it starts a planned Phase III trial.

- SATSUMA PHARMACEUTICALS' STS-101 (dihydroergotamine nasal powder) – Both doses (3.9 mg and 5.2 mg) missed the primary endpoint in the Phase III EMERGE trial in acute treatment of migraine, failing to provide freedom from pain and most bothersome symptom at 2 hours post-dose vs. placebo.

- SPERO THERAPEUTICS' tebipenem HBr (tebipenem pivoxil hydrobromide, SPR-994), an oral carbapenem antibiotic, met the primary endpoint in the pivotal Phase III ADAPT-PO trial in adults with complicated urinary tract infections and (cUTI) and acute pyelonephritis (AP), showing non-inferiority to IV ertapenem (Merck MSD's Invanz) on overall response (58.8% vs. 61.6%).

- VERTEX PHARMACEUTICALS' VX-765 – A mouse study, published in the journal ***Nature***, suggests that this caspase inhibitor, which failed in epilepsy, may have utility in Alzheimer's disease. In the mice, the drug "considerably" delayed loss of cognitive function.

Very early research news

- Stem cells – A mouse study, by researchers at the University of California, Davis, published in ***Stem Cells Translational Medicine***, suggests that blocking the soluble epoxide hydrolase (sEH) enzyme will make it possible for stem cells to repair damaged cardiac tissue. The researchers believe the study could lead to a new class of compounds to prevent the muscle thickening associated with heart failure.

NEWS IN BRIEF

BAYER

- Is collaborating with Recursion Pharmaceuticals for use of its artificial intelligence technology to develop treatments for fibrotic diseases.

- and ORION's Nubeqa (darolutamide). The final data from the Phase III ARAMIS trial were published in the ***New England Journal of Medicine***, showing that adding this androgen receptor inhibitor to androgen deprivation therapy (ADT) significantly improved overall survival vs. placebo in men with non-metastatic castration-resistant prostate cancer, with a 31% reduction in the risk of death. Updated results on secondary endpoints showed that Nubeqa + ADT delayed the time to pain progression (HR 0.65), time to first initiation of treatment with cytotoxic chemotherapy (HR 0.58), and time to first symptomatic skeletal event (HR 0.48). The adverse event data had no surprises.

End-stage renal disease (ESRD)

A 100-patient, single-center study, published in the ***Journal of Vascular and Interventional Radiology***, showed that two minimally-invasive technologies enabled ESRD patients to start dialysis sooner than would be the case with a surgical vascular access (an arteriovenous fistula, AVF):

Avenu Medical's Ellipsys Vascular Access System

Becton Dickinson's WavelinQ 4F System

The study found:

- Ellipsys had a 100% technical success rate, with 27.7% of patients requiring a secondary intervention.
- WavelinQ had a 97% technical success rate, with 26.5% of patients requiring a secondary intervention.
- Overall, 79.5% of Ellipsys patients and 58% of WavelinQ patients were able to successfully begin dialysis with their fistula.
- At 12 months, 82% of Ellipsys fistulas and 60% of WavelinQ fistulas were still functional.

MERCK MSD

- Gefapixant. The high dose (45mg BID) – but not the low dose (15 mg BID) – of this P2X3 receptor antagonist met the primary endpoint in two Phase III trials (COUGH-1 and COUGH-2) with a total of 2,044 patients in refractory/unexplained cough, significantly reducing cough frequency over 24 hours at Week 12 vs. placebo.

The high dose also met the secondary endpoints. The most common side effect was dysgeusia (taste disturbance) – 58% in one trial and 69% in the other - which lead to more discontinuations (15% vs. 3% in one trial and 20% vs. 5% in the other).

- **V114.** In two Phase III trials (PNEU-AGE and PNEU-TRUE), this 15-valent pneumococcal conjugate vaccine met the primary endpoint, showing non-inferiority to Pfizer's Prevnar-13 (13-valent pneumococcal conjugate vaccine) while also working on two additional serotypes (22F and 33F). V114 also was superior to Prevnar on serotype 3, a leading cause of invasive pneumococcal disease globally, in one of the studies.

PURDUE PHARMA's OxyContin (oxycodone extended-release)

The FDA's Anesthetic and Analgesic Drug Products Advisory Committee met jointly – and virtually – with the FDA's Drug Safety and Risk Management Advisory Committee to review the postmarketing studies of this reformulated opioid.

The panel concluded that:

- There is no clear evidence that the new formulation actually was associated with fewer overdoses or deaths.
- The new formulation did appear to reduce abuse via snorting and injecting.
- Studying overdoses is complicated because the quality of the evidence is poor.
- It isn't clear whether a decrease in prescribing and illegal trafficking was due to the reformulation.

The FDA is considering whether to change the drug's label, which currently says the drug is "expected to" reduce abuse via injecting and snorting.

TAKEDA

- Sold a portfolio of non-core prescription drugs, including cardiovascular and anti-inflammatory products, to Chephapharm.
- **Ninlaro (ixazomib)**, an oral proteasome inhibitor, missed the primary endpoint in the Phase III TOURMALINE-MM2 trial in newly diagnosed multiple myeloma, failing to significantly prolong progression-free survival (PFS) when added to lenalidomide (Bristol-Myers Squibb/Celgene's Revlimid) + dexamethasone vs. RevDex alone (35.3 months vs. 21.8 months).

COVID-19 WEEKLY HIGHLIGHTS

- **India.** There is concern about the high rate of infection in India but the low death rate reported. Is it under-reporting, slow reporting, or something else?
- **Testing.** Getting tested – and tested in a timely manner – may still be difficult, but it isn't because there aren't enough tests with FDA approval. The FDA has granted 243 tests emergency use authorizations (EUAs), including 195 molecular tests, 44 antibody tests, and 4 antigen tests.
- **Treatment**
  - CELLTRION GROUP's CT-P59 – a biosimilar of Johnson & Johnson's Remicade (infliximab) – had positive safety results in a Phase I trial in healthy volunteers. The aim is to use it to treat Covid-19 patients.
  - **Blood thinners.** The National Institutes of Health (NIH) has started two of three planned Phase III trials to test the safety and efficacy of blood thinners – aspirin, heparin, and Bristol-Myers Squibb and Pfizer's Eliquis (apixaban) to treat adults with Covid-19 since blood clots are a common complication.
- **Vaccine – Public acceptance.** The latest poll, this time by the Kaiser Family Foundation, taken between August 28 and September 3, 2020, found that both Republicans and Democrats are wary of taking a vaccine before the presidential election.
  - 60% were worried that the Trump Administration would pressure the FDA to rush an approval.
  - 50% of Democrats and 36% of Republicans said they would take a vaccine if one were approved.
  - 81% do not expect a vaccine to be approved before the election.
- **Vaccine – Data integrity.** The CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck MSD, Moderna, Novavax, Pfizer, and Sanofi jointly issued a letter, vowing not to seek approval or emergency use authorization for their vaccine candidates without conclusive positive data.
- **Vaccine – Durability.** Responding to questions at a Senate hearing NIH director Francis Collins, MD, said:
  - "My guess is [the Covid-19 vaccines] will be better than the flu vaccine…but we do not know if it [will be as good as the measles or polio vaccines]."
  - "It is entirely possible [that handwashing, masking, and distancing will mean fewer deaths from flu this season]."

■ Vaccine – Trials

- ASTRAZENECA's AZD-1222 – Trials were put on hold after one patient developed transverse myelitis. The company said there was an adverse event, providing no details. But after 6 days, the company said it was resuming trials with the permission of U.K. regulators. The lack of transparency is concerning, but the rapid resolution is a positive. There is a lot that still needs to be understood about this case and this potential side effect to the vaccine.
- PFIZER and BIONTECH
  - ✓ Are expanding their Phase III trial to include another 14,000 patients in an effort to improve diversity.
  - ✓ Are starting a Phase I/II trial of a fifth vaccine candidate.
  - ✓ Reported a "strong" immune response in animals to its mRNA vaccine.

■ Vaccine distribution – Premier offered four considerations for a successful Covid-19 vaccination program once a vaccine is approved and commercially available, saying that the actual vaccination program is "shaping up to become the top supply chain challenge of the pandemic."

1. **National prioritization for who gets vaccinated first.** The CDC already issued a priority list, but even in the first category – healthcare workers – there are likely only to be 1-2 million doses at first and there are 17 million healthcare workers in the U.S., so which of them will get a vaccine?
2. **Dynamic allocation based on hotspots and priority populations.** In previous mass vaccinations, the federal government allocated vaccines to each state equally, based on population. This may appear impartial, but with Covid-19 it will lead to shortages in some communities while others sit on an unused supply. For example, 21% of Puerto Ricans are age ≥65 but only ~10% of Utah residents. Premier recommends a "more dynamic allocation strategy" that focuses on hotspots and areas with more elderly people.
3. **Potential subzero distribution, storage and handling plan.** The Moderna and Pfizer/BioNTech vaccines require cold storage at different temperatures and with different storage lives.
4. **Accurate and methodical patient tracking.** [NOTE: This is perhaps the biggest problem.] Most of the leading vaccines require at least two doses within a specific period of time. Premier recommends Congress change the law and allow unique patients identifiers. Without that, it is extremely likely that a not insignificant number of patients will not remember which vaccine they got, may not get a second dose, or will be lost in the system. Not only does that mean they won't be protected, but it also means that the first dose was wasted and that it will be difficult to tell whether the vaccine is working. In addition, Premier points out that historic adherence to multi-dose vaccine regimens is low (≤30%).

REGULATORY NEWS

Regulatory tidbits

■ Drug pricing. President Trump signed an executive order – a new version of one signed in August – that ties Medicare payments for outpatient and pharmacy drugs to the lowest price offered in comparable developed countries. The order also directs the Centers for Medicare and Medicaid Services (CMS) to conduct demonstration projects for Medicare Part B, which means lower prices could come before election day. The intent is to expand the order to Medicare Part D drugs.

■ Manufacturing

- FDA Commissioner Stephen Hahn, MD, and FDA Deputy Commissioner for Medical and Scientific Affairs Anand Shah, MD, wrote a piece that said medical manufacturing needs to be brought back to the U.S., saying the government should incentivizing manufacturers to return to the U.S. and should invest in novel technologies that can address acute spikes in demand during emergency situations.
- The FDA issued temporary guidance to help drug and biological product manufacturers transition from operations impacted by Covid-19 to normal manufacturing operations again.

■ Telehealth. At a Medicare Payment Advisory Commission (MedPAC) meeting, panel members said it will be difficult to re-implement strict rules for telehealth now that doctors and patients have seen its value, but other panel members worried about the tax burden. MedPAC staff proposed limiting the expansion of telehealth, ending reimbursement for audio-only visits, and perhaps placing a monthly cap on the number of telehealth services eligible for reimbursement.

FDA approvals

- CTL AMEDICA's Mondrian LIF, a lumbar interbody fusion cage for use in spine surgery, was granted 510(k) clearance.
- DIASORIN MOLECULAR's Simplexa Flu A/B and RSV Direct Gen II kit, a combination test for respiratory syncytial virus and influenza, was cleared for use with the company's Simplexa Covid-19 Direct kit or on its own.
- GLAXOSMITHKLINE and INNOVIVA's Trelegy Ellipta (fluticasone furoate + umeclidinium + vilanterol) was approved as the first once-daily triple-therapy-in-one inhaled treatment for adults with uncontrolled asthma on current maintenance therapy.
- HEMOSONICS' Quantra, a desktop remote viewer bleeding management software, was granted 510(k) clearance for use in the operating room, the intensive care unit, or the laboratory.
- KA IMAGING's Reveal, a portable dual-energy x-ray detector, was granted 510(k) clearance.
- MINNETRONIX MEDICAL's MindsEye, a neurosurgical access port, was cleared for use during deep brain surgeries.
- ROCHE
  - and BLUEPRINT MEDICINES' Gavreto (pralsetinib), a RET inhibitor, was approved to treat adults with metastatic RET fusion-positive non-small cell lung cancer (NSCLC).
  - cobas BKV test, a BK virus quantitative test which enables simultaneous testing of BK virus with cytomega-lovirus and Epstein-Barr virus for transplant patients, running on the cobas 6800/8800 Systems, was granted 510(k) clearance.
- THERMO FISHER SCIENTIFIC's Oncomine Dx Target Test, was granted premarket approval as a companion diagnostic for Roche's Gavreto (pralsetinib) for NSCLC.

FDA recalls/warnings

- Covid-19.
  - The FDA and the Federal Trade Commission jointly sent a warning letter to Pharmacy Plus (dba Vital Care Compounder) for selling unapproved products with fraudulent Covid-19 claims, ordering it to immediately halt sales.
  - The FDA revoked the registration of 340 foreign establishments that failed to identify a U.S. agent, but 131 of these list devices that are essential to the Covid-19 pandemic response.
- Opioids – The FDA issued warning letters to 17 website operators for illegally selling unapproved and misbranded opioids online.
- RLC LABS' Nature-Throid [sic] and WP Thyroid – A total of 483 lots of these thyroid drugs were recalled after the FDA found them to have sub-potent amounts of Liothyronine (T3) or Levothyroxine (T4).
- ROCHE's Tecentriq (atezolizumab) – The FDA issued an alert that the IMpassion131 trial found the combination of this PD-1 inhibitor with paclitaxel did not work in patients with previously untreated inoperable locally-advanced/ metastatic triple negative breast cancer (mTNBC). Tecentriq is approved for use in PD-L1+ mTNBC patients with Bristol-Myers Squibb's Abraxane (nab-paclitaxel), not paclitaxel, but the FDA said that approval could be revoked if additional trials don't show a proven benefit.

European Regulatory News

- *France.* ROCHE and NOVARTIS' Lucentis (ranibizumab) – The French government fined the companies >$525 million for using their position in the market to push this treatment for wet age-related macular degeneration (AMD) over Roche's Avastin (bevacizumab), which is significantly less expensive.
- BOSTON SCIENTIFIC's Vercise Genus, a fourth-generation deep brain stimulation (DBS) system for treating Parkinson's disease symptoms, was granted a CE Mark.
- IZI MEDICAL PRODUCTS' Kiva, a vertebral compression fracture treatment system, was granted a CE Mark.
- JOHNSON & JOHNSON/JANSSEN's Imbruvica (ibrutinib) was granted expanded approval by the European Commission to include treatment of previously untreated patients with chronic lymphocytic leukemia (CLL).
- MIKAJAKI's EyeLib, a fully automated eye health diagnostic platform, was granted a CE Mark.
- THERANICA's Nerivio, a smartphone-controlled wearable device used for acute migraine treatment, was granted a CE Mark.

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

- ASTRAZENECA's Tagrisso (osimertinib) – NICE reversed itself and recommended use of this TKI as a first-line therapy for previously untreated EGFR-mutated NSCLC and as a second-line treatment for T790M mutation subtype – after the company cut the price (by an undisclosed amount).

- OLYMPUS' PLASMA system – NICE's Medical Technologies Advisory Committee reviewed this device for treating benign prostate hyperplasia (BPH) and recommended NICE approve it.
- PORTOLA PHARMACEUTICALS' Ondexxya (andexanet alfa) – NICE decided to recommend use of this Factor X reversal agent, but only in adults with life-threatening or uncontrolled gastrointestinal bleeding and only for two Factor X agents – Johnson & Johnson's Xarelto (rivaroxaban) and Bristol-Myers Squibb's Eliquis (apixaban).

Regulatory news from other countries

- ***Japan.*** SYNTHETICMR's SyMRI, software that can deliver brain MRI sequences in minutes, was approved by the Pharmaceuticals and Medical Devices Agency.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
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 24	The Mayo Clinic experience with **point-of-care manufacturing**	FDA webcast
September 24	**Latino representation** in clinical oncology trials	FDA's Oncology Center of Excellence webcast
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
September 29	Overview of **naloxone access**	FDA webinar
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 2	Control of **nitrosamine** impurities in human drugs	FDA webinar
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 8	Assessing changes in the PK of drugs in **liver disease**	FDA virtual public workshop in collaboration with the University of Maryland Center of Excellence in Regulatory Science & Innovation
October 9	**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	**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
October 22-23	Pediatric dose selection	FDA virtual public workshop
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

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
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