TRENDS-in-MEDICINE

June 14, 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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Remember that coronavirus news is being reported in regular separate Coronavirus Update bulletins. Thus, very little coronavirus news is included in this ***Quick Takes***.

NOTE: Subscribe to ***Trends-in-Medicine*** for coverage of the virtual meetings of the European Hematology Association (EHA) and the American Diabetes Association (ADA).

Be careful, be safe, and be well.

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

✓ **Positive trial news included:**

- ABBVIE's Rinvoq (upadacitinib) – in a head-to-head trial against Bristol-Myers Squibb's Orencia (abatacept) in rheumatoid arthritis.
- BIOGEN's Spinraza (nusinersen) – in the NURTURE trial in pre-symptomatic SMA patients.
- DBV TECHNOLOGIES' Viaskin Peanut (VP-250) – in children with other food allergies.
- MEDTRONIC's Symplicity – in the SYMPLICITY Registry for renal denervation.
- PFIZER's abrocitinib – in children and adolescents with atopic dermatitis.
- SAREPTA THERAPEUTICS' SRP-9003 – in limb-girdle muscular dystrophy Type 2E.

✓ **Negative trial news included:**

- DENALI THERAPEUTICS and SANOFI's DNL-747 – in a monkey study intended as the basis for a human trial in Alzheimer's disease.
- MERCK MSD's Keytruda (pembrolizumab) – in combination with chemotherapy in first-line advanced/metastatic urothelial carcinoma.

SHORT TAKES

- AGIOS PHARMACEUTICALS and Thermo Fisher Scientific expanded their partnership, adding development of a second oncology companion diagnostic for identifying patients with low-grade glioma who have IDH1 and IDH2 mutations that could be treatable with Agios' vorasidenib (AG-881), an IDH inhibitor.

- ASTRAZENECA reportedly flirted with the idea of merging with Gilead Sciences but quickly dropped the idea.

- CELLTRION's Truxima (rituximab-abbs) – a biosimilar of Roche's Rituxan for treating cancer – was prequalified by the World Health Organization, only the second biosimilar to get that designation.

- COGNITION THERAPEUTICS' Elayta (CT-1812) – The company got a $75.8 million grant from the National Institutes of Health (NIH) to support a 540-patient, 3-year Phase II trial of this sigma-2 receptor blocker – which purportedly prevents amyloid beta oligomers from binding to synapses – in Alzheimer's disease, which will be conducted in coordination with the Alzheimer's Clinical Trials Consortium.

- CORWAVE's Membrane LVAD – Preclinical data, presented at the American Society for Artificial Internal Organs virtual meeting, showed that this *pulsatile* left ventricular assist device, which uses wave membrane technology, met critical technical milestones – hemocompatibility, 6-month durability, and hemodynamic performance.

- CSL BEHRING is buying Vitaeris, which will give it clazakizumab, an anti-IL-6, in Phase III development to treat chronic active antibody-mediated transplant rejection.

- CULLINAN ONCOLOGY's CLN-619 – The company is collaborating with PDI Therapeutics to get this anti-MICA into human testing as a cancer treatment.

- DBV TECHNOLOGIES' Viaskin Peanut (VP-250) – The results of a 356-patient Phase III trial in children age 4-11, presented at the virtual European Academy of Allergy and Clinical Immunology (EAACI), on this epicutaneous immunotherapy (EPIT) for peanut allergy, showed that it was effective whether or not the patient had other food allergies. This is important since about a third of patients with a peanut allergy also have another food allergy, and when people have multiple food allergies, those allergies tend to be more severe.

- DENALI THERAPEUTICS and SANOFI's DNL-747 – In a toxicity study in monkeys, this RIPK1 inhibitor showed dose- and duration-dependent adverse events that were off-target and molecule-specific, making it difficult and potentially dangerous to increase the dose in humans, so the companies paused ongoing Phase I trials in Alzheimer's disease and amyotrophic lateral sclerosis (ALS) and are focusing on another molecule, DNL-788 instead.

- GALAPAGOS is collaborating with e-therapeutics to develop new therapeutic approaches to idiopathic pulmonary fibrosis (IPF).

- GTX MEDICAL BV's Go-2 Targeted Epidural Spinal Stimulation system, an implant to help patients with spinal cord injuries and paralysis to walk and to recover control over paralyzed muscles, was granted breakthrough device status by the FDA.

- HEMOVENT's Mobybox ECLS – A study, published in ***The Annals of Thoracic Surgery***, found that this extracorporeal life support system "provides excellent safety and physiologic efficacy in a 7-day (long-term) sheep experiment without visible clotting, hemolysis, or sustained reductions in fibrinogen or platelets."

- HITGEN is collaborating with Evotec on drug discovery research of anti-infectives.

- INNOVENT BIOLOGICS is collaborating with Roche on development of multiple cell therapies, including bispecific antibodies to treat hematologic and solid cancers.

- INSMED's brensocatib (INS-1007), a reversible DPP1 inhibitor, was granted breakthrough therapy designation by the FDA as a treatment for reducing exacerbations in adults with non-cystic fibrosis bronchiectasis.

- LILLY is collaborating with Evox Therapeutics on development of RNAi and antisense oligonucleotide drugs for treating neurological disorders using Evox's DeliverEX platform.

- MEDTRONIC's Symplicity – In the global, single-arm SYMPLICITY Registry, this renal denervation device consistently lowered blood pressure in patients with high-risk comorbidities, regardless of their cardiovascular risk score. The results on 2,652 patients, published in the ***Journal of the American College of Cardiology***, showed that at three years, systemic blood pressure was reduced 8.9 mmHg over-all and 8.7 mmHg for patient's age ≥65, 10.4 mmHg for patients with resistant hypertension, and 10.2 mmHg for Type 2 diabetics. On the positive side, renal denervation (RDN) worked in all subgroups, but on the negative side, the study did not help identify the patients who would be the best candidates for RDN.

- MERCK KGAA's Mavenclad (cladribine) – The company signed a value-based deal with Prime Therapeutics, a pharmacy benefit manager (PBM), under which compensation

for this multiple sclerosis (MS) drug will be dependent on the rate at which plan members discontinue two-year treatment with this adenosine analog or switch to a different MS therapy at any point over the typical course of treatment.

- MERCK MSD's Keytruda (pembrolizumab) – This PD-1 inhibitor, in combination with chemotherapy, missed both co-primary endpoints in the Phase III KEYNOTE-361 trial in first-line advanced/metastatic urothelial carcinoma, failing to prolong either overall survival or progression-free survival (PFS) vs. chemotherapy alone.

- NIMBUS THERAPEUTICS is moving four pre-clinical agents into the clinic – an AMPKβ2, a CTPS1, a Cbl-b, and a Werner syndrome ATP-dependent helicase (WRN) – for oncology, immunology, and metabolism.

- NOVO NORDISK is buying **Corvidia Therapeutics**, which will give it ziltivekimab, an anti-IL6 in Phase II testing for preventing major cardiovascular events in patients with chronic kidney disease who also have atherosclerosis.

- PFIZER's abrocitinib – The top-line results of the Phase III JADE TEEN trial of this JAK inhibitor in children and adolescents with atopic dermatitis met both primary endpoints, reducing redness and itchiness, but side effects – 62.8% of high-dose patients vs. 52.1% of placebo patients – may be an issue.

- SANOFI gave two gene therapies – SAR-422459 for Stargardt disease and SAR-421869 for Usher syndrome – back to **Oxford Biomedica**.

- SAREPTA THERAPEUTICS' SRP-9003 – In a high-dose cohort in a small trial in limb-girdle muscular dystrophy Type 2E, this gene therapy showed positive results – good expression, good tolerability, and positive functional signals out to one year.

- TAKEDA sold **Celltrion** a portfolio of over-the-counter and prescription drugs marketed only in Asia.

Very early research news

- Gene therapy – Researchers at Trinity College Dublin and University College London reported in the journal ***Stem Cell Reports*** that they have developed a gene therapy technique that could help patients with retinitis pigmentosa, using "mini retinas" – 3D organoids made out of induced pluripotent stem cells and stem cells taken from patients with RP2-mutated retinitis pigmentosa – to pump out the protein rhodopsin.

- Hepatocellular carcinoma (HCC) – Researchers at the National Cancer Institute have developed a blood test for identifying people at high risk of liver cancer based on their previous exposure to particular viruses. The test, which uses a specific exposure signature – containing links to 61 different viruses, including those not associated with any tumors – that they believe can accurately screen people with cancer from healthy volunteers or those with chronic liver diseases to identify people with the highest risk for HCC and who should get screened more frequently.

NEWS IN BRIEF

ABBVIE

- Is collaborating with **Genmab** to jointly develop and commercialize three of Genmab's bispecific antibodies for cancer – epcoritamab (CD3xCD20), DuoHexaBody-CD37, and DuoBody-CD3x5T4.

- Rinvoq (upadacitinib). In the head-to-head Phase III SELECT-CHOICE trial in rheumatoid arthritis, this JAK inhibitor met the primary endpoint, showing non-inferiority to Bristol-Myers Squibb's Orencia (abatacept), an IgG1 inhibitor, on DAS28-CRP at Week 12. Rinvoq also met the key secondary endpoints.

BIOGEN

- Aducanumab. A survey of 30 neurologists who collectively treat ~7,000 Alzheimer's disease patients/year – and who were "very familiar" with the data on this antibody found:
  - Most do not believe it should be approved.
  - If it is approved, many plan to prescribe it – initially for ~20% of patients – with use expected to grow to 40% in two years.
  - 94% believe it is at least somewhat tolerable.

- Spinraza (nusinersen). The results of the NURTURE trial in pre-symptomatic spinal muscular atrophy patients – presented at the virtual Cure SMA Research & Clinical Care Meeting – showed that early and sustained treatment with this antisense oligonucleotide for up to 4.8 years resulted in an amazing survival rate – 100% of the children were alive, and none required permanent ventilation. In addition, patients continue to maintain or gain motor function vs. the natural course of the disease, with 96% able to walk with assistance. NURTURE will continue to follow these patients out to 8 years of age.

ROCHE's risdiplam

New data on this SMN2 pre-mRNA splicing modifier for treating spinal muscular atrophy (SMA) were presented at the Cure SMA Research & Clinical Care virtual meeting, showing efficacy with no new safety issues:

- **SUNFISH trial** – 2-year data from Part 1 showed the drug significantly improved motor function (vs. expected natural history) after 24 months of treatment in patients age 2-25 in SMA Type 2 and Type 3 patients.

- **JEWELFISH trial** – Preliminary 12-month data in infants, children, and adults with SMA, showed rapid and sustained increases in SMN protein levels, with no new safety signals.

UCB

- Bought **Engage Therapeutics**, which gives it a potential epilepsy seizure therapy, Staccato, a drug-device combination that rapidly delivers alprazolam.

- **Bimekizumab.** In two Phase III trials, BE VIVID and BE READY, presented at the American Academy of Dermatology virtual meeting, this antil-IL-17A/F met the primary endpoints, clearing skin in adults with moderate-to-severe plaque psoriasis better than both placebo and Johnson & Johnson's Stelara (ustekimuamab), an anti-IL-12/23. Responses were rapid, with durability of PASI-100 and IGA results lasting out to one year.

  - In BE VIVID at Week 16, bimekizumab 320 mg Q4W showed superiority to both placebo and ustekinumab on PASI-90 and IGA 0/1 at Week 16, with 58.6% of bimekizumab patients achieving PASI-100 vs. 20.9% of ustekinumab patients.

  - In BE VIVID at Week 52, bimekizumab sustained skin clearance, showing superiority to ustekinumab, with PASI-100 achieved by 64.2% of bimekizumab patients vs. 38% of ustekinumab patients.

  - In BE READY, a pivotal withdrawal study, bimekizumab showed superiority to placebo on PASI-90 (90.8% vs. 1.2%) at Week 16.

  - In the second part of BE READY, two dosing regimens (Q4W and Q8W) were compared to withdrawal. At Week 52, PASI-90 was achieved by 86.8% of Q4W patients and 91% of Q8W vs. 16.2% of patients who withdrew.

The future of healthcare

Deloitte held a webinar to talk about the future of healthcare. It was pretty basic and general, but the online audience was given a number of poll questions, and their answers were interesting.

? *What does the future of health mean for you?*

- 32% – Better health outcomes
- 25% – New technology transforming care delivery
- 19% – Health costing less
- 12% – Consumers eating right and exercising
- 12% – More being done outside of the hospital

? *Which key trends have accelerated the most over the past several weeks of this pandemic?*

- 29% – The rate at which consumers have changed their behavior as it related to their health
- 24% – The degree to which access to healthcare has been expanded or enhanced with technology
- 15% – The rate at which science has identified breakthrough technologies or solutions
- 13% – Consumer willingness to share data
- 9% – The degree to which consumers have become more empowered in their own health
- 9% – The degree to which health and other data have been made more interoperable to drive decision-making

? *What are the most important drivers of the market shifts that will emerge in a post-Covid world?*

- 34% – Economic recession
- 24% – Business model innovation
- 22% – Tech advancements
- 15% – Regulatory change
- 5% – Employer demand

? *What type of business will prosper most in the future of health?*

- 41% – Technology companies that enable remote monitoring and diagnosis
- 24% – Telehealth companies
- 11% – Health systems
- 11% – Drug companies
- 7% – Health plans
- 6% – Retail health

Among the points the Deloitte principals made were:

✓ The ability to understand **data** is accelerating very rapidly, particularly things like the microbiome and brain circuits and psychology to treat mental health and cognitive issues.

- ✓ "Over the next number of years, we expect an explosion of both known and unknown **datasets** to become understandable and connected."
- ✓ "More than 80% of consumers feel fear and anxiety…**ER volume** has dropped 50% in a lot of healthcare systems."
- ✓ "In one survey 65% of consumers said that before they feel comfortable going to a hospital, hospitals need to improve **sanitation**."
- ✓ Healthcare clients "underestimate the impact of **5G** on what is possible."
- ✓ "New **biomarkers** that can diagnose things earlier" will be important.
- ✓ It is still early, but breakthroughs that will really reduce **costs of care** are coming.
- ✓ "I believe consumers feel the system has largely failed them …As a result, there is an amazing uptick in **consumers taking ownership** and acting themselves to manage their own care …There is a huge uptick in home diagnosis and monitoring devices."
- ✓ "**Virtual engagement** needs to be the gold standard…[but] I think we are seeing some pushback from providers [to that]."
- ✓ The winning **healthcare businesses of the future** "won't be around classic large pharma, health insurance, or brick and mortar hospitals…Organizations that will win have business models that have a combination of data capture/generation/connectivity, consumer centric offers [e.g., smart toothbrushes, virtual telehealth], and a supply chain [e.g., drone delivery of equipment to the home]." That is, multiple areas, not just 2 or 3.
- ✓ An example: A large hospital was thinking of building a new 300-bed facility. Deloitte urged it instead to invest in virtual elements and allow for **virtual care** both in the hospital and in the home. The hospital "thought that was too dramatic… So, they built a smaller expansion for the hospital but put real money into telehealth…It brought more volume to the brick and mortar…but also enabled them to get very sophisticated."
- ✓ A "**technological transformation** is coming."

REGULATORY NEWS

Regulatory tidbits

- **Breast cancer**. The House Insurance Committee passed a bill, introduced by Sen. Bob Mensch (R-PA) that would require insurance coverage of MRI and ultrasound breast exams for women with dense breast tissue.
- **Drug prices.** A coalition of 46 states, the District of Columbia, and four state territories filed a lawsuit in federal court in Connecticut against 26 drug companies and 10 pharmaceutical executives, accusing them of engaging in price-fixing conspiracies and market rigging for >80 generic drugs from 2009-2016.
- **FDA**
  - **CBER.** Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research (CBER), left Operation Warp Speed, the Trump administration's Covid-19 vaccine initiative just days after joining the project, saying he believes his efforts would be put to better use at the FDA.
  - **Opioids.** The FDA and the National Telecommunications and Information Administration are collaborating on a 120-day pilot program to reduce the online sale of illegal opioids.
  - **Samples.** Issued a guidance on distribution of drug samples during the Covid-19 public health emergency in response to questions that have come up. One change in the guidance: the FDA will not object to the delivery of prescription drug samples to patients' homes if that is requested by the patient's licensed healthcare professional.
  - **Staff.** John Farley, MD, MPH, was named director (previously he was acting director) of the FDA's Office of Infectious Diseases in the Center for Drug Evaluation and Research (CDER).

FDA approvals

- BRISTOL-MYERS SQUIBB's Opdivo (nivolumab) was granted expanded approval to treat unresectable advanced/recurrent/metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.
- CHEMBIO DIAGNOSTICS' DPP Zika IgM System, a Zika virus detection system which delivers numerical results in 15 minutes, was granted 510(k) clearance.
- MERCK MSD's Gardasil9 was granted accelerated approval for an expanded indication: the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58. The required confirmatory trial is already underway.
- MIRUS' 3DR, a printed lumbar interbody fusion system, was granted 510(k) clearance.
- MYLAN and BIOCON BIOLOGICS' Semglee (insulin glargine) – a biosimilar of Sanofi's Lantus – was approved for both Type 1 and Type 2 diabetics.

- VIELA BIO's Uplizna (inebilizumab-cdon), a B-cell targeting anti-CD19, was approved as an IV treatment for neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive.
- VIIV HEALTHCARE's Tivicay PD (dolutegravir) was approved to treat HIV-1 in pediatric patients age ≥4 weeks and weight ≥6.6 pounds.

FDA recalls/warnings

- Covid-19 – A warning letter relating to Covid-19 was sent to:
  - **www.outoftheboxremedies.com** – for selling fraudulent Covid-19-related products.
  - **EUCYT Laboratories** – for marketing an unapproved exosome product for treating/preventing Covid-19.
- LUPIN PHARMACEUTICALS' metformin extended-release – a generic of Watson's Fortamet – One lot was recalled due to potential contamination with NDMA.
- Transport media – **PrimeStore MTM, Zymo DNA/RNA Shield, and Spectrum Solutions Saliva Collection Device** – The FDA reminded laboratories and healthcare providers to be careful that the transport media used with SARS-CoV-2 is compatible with the testing platform and laboratory process that will analyze the sample. If the transport media is incompatible with the testing system, there is a risk of harmful cyanide gas being released, though no injuries have yet been reported to the FDA.

European Regulatory News

- *U.K.* PFIZER's Duavive (conjugated estrogens/bazedoxifene, Duavee in the U.S.) – The Medicines and Healthcare products Regulatory Agency (MHRA) announced that two batches of this menopause drug were voluntarily recalled due to packaging issues.
- DEXCOM's G6, a continuous glucose monitor, was granted a CE Mark.
- MEDTRONIC's MiniMed 780G, a next-generation insulin pump for Type 1 diabetics age 7-80 was granted a CE Mark.
- PERKINELMER's Delfia Xpress sFlt-1 kit was granted a CE-IVD Mark for use in predicting preeclampsia.
- PROMEGA's OncoMate MSI Dx Analysis System for measuring microsatellite instability in solid tumors was granted a CE Mark.
- SAHAJANAND MEDICAL TECHNOLOGY's Hydra, a transcatheter aortic valve replacement (TAVR) device for treating severe aortic stenosis, was granted a CE Mark.
- SURMODICS' SurVeil, a paclitaxel-coated balloon for treating peripheral artery disease (PAD), was granted a CE Mark.

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

- ROCHE's Kadcyla (ado-trastuzumab emtansine, T-DM1) – NICE recommended use of this anti-HER2 antibody as an adjuvant treatment for HER2+ early breast cancer in adults with residual invasive disease after neoadjuvant taxane-based and HER2-targeted therapy.
- SANOFI
  - Cablivi (caplacizumab) – In draft guidance, NICE rejected use of this bivalent anti-vWF nanobody, along with plasma exchange and immunosuppression, to treat an acute episode of acquired thrombotic thrombocytopenic purpura (TTP), saying the data do not show that the drug improves either overall survival or quality of life long term.
  - Sarclisa (isatuximab) – NICE rejected this anti-CD38 as a fourth-line treatment for multiple myeloma – in combination with pomalidomide (Bristol-Myers Squibb/Celgene's Pomalyst) and dexamethasone, saying the total benefit and the cost-effectiveness were not established.
- TEVA's Ajovy (fremanezumab) – In final guidance, NICE recommends use of this anti-CGRP as a migraine preventive in patients who have not responded to ≥3 prior therapies.

Regulatory news from other countries

- *China.*
  - ALPHAMAB's KN-026 – The company is collaborating with **Sanofi** on this anti-HER2 bispecific antibody in combination with Sanofi's Taxotere (docetaxel) in HER2+ breast cancer.
  - EDWARDS LIFESCIENCES' Sapien 3, a TAVR, was approved to treat patients with aortic stenosis who are not candidates for surgical aortic valve replacement.
  - THERMO FISHER SCIENTIFIC is partnering with Genetron Health on commercialization of next-generation sequencing-based diagnostics in China and to bring the Genetron S5, based on the Ion GeneStudio S5 system from Thermo Fisher, to public hospitals in China for use in diagnosis of genetic diseases, microbial testing, reproductive health testing, and cancer diagnostics.
- *Japan.* BGI GENOMICS' 2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit – The Ministry of Health, Labour, and Welfare granted permission for **Sysmex** to market this saliva-based Covid-19 test.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
June 16	**Merck MSD's Keytruda** (pembrolizumab) for solid tumors TMB-H ≥10 mutations	PDUFA date
June 17	Immediately-in-effect guidance on **Covid-19 diagnostic tests**	FDA Town Hall - virtual
June 17	**1. Salarius Pharmaceuticals' seclidemstat** (SP-2577) for Ewing sarcoma **2. Bristol-Myers Squibb/Celgene's marizomib** (NPI-0052) for relapsed/refractory multiple myeloma	FDA's Oncologic Drugs Advisory Committee's Pediatric Oncology subcommittee – meeting by teleconference and webcast
June 18	**1. Tessa Therapeutics' CD30 CAR T** for relapsed/refractory CD30+ lymphomas **2. Syndax Pharmaceuticals' SNDX-5613**, a menin inhibitor for relapsed/ refractory acute leukemia	FDA's Oncologic Drugs Advisory Committee's Pediatric Oncology subcommittee – meeting by teleconference and webcast
June 18	**Ultragenyx and Kyowa Kirin's Crysvita** (burosumab-twza) for tumor-induced osteomalacia	PDUFA date
June 18	**Epizyme's Tazverik** (tazemetostat) – expanded approval to treat relapsed/ refractory follicular lymphoma	PDUFA date
June 19	**Nabriva Therapeutics' Contepo** (fosfomycin), an IV antibiotic for complicated urinary tract infections	PDUFA date
June 19	**Evoke Pharma's Gimoti** (EVK-001) for female diabetic gastroparesis	PDUFA date
June 23	**Karyopharm's Xpovio** (selinexor) for diffuse large B-cell lymphoma	PDUFA date
June 25	**Zogenix's Fintepla** (fenfluramine, ZX-008) for Dravet syndrome	PDUFA date *Extended from March 25 due to company submission of new data*
June 26	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	PDUFA date *extended from March 26*
June 26	**Heron Therapeutics' HTX-011** (bupivacaine + meloxicam) for postoperative pain	PDUFA date *Extended by the FDA from March 26*
June 26	**Chiasma's Mycapssa** (octreotide) for acromegaly	PDUFA date
June 27-July 1	**AFDO annual educational conference**	FDA's National Center for Toxicological Research
June 30	**Modernizing FDA's Data Strategy**	FDA public meeting *Originally scheduled for March 27*
July 5	**Acacia Pharma's Byfavo** (remimazolam), an ultra-short-acting and reversible anesthetic for use in surgery and other invasive procedures	PDUFA date *Extended from April 5 by FDA due to new data submission*
July 6	**BioSpecifics Technologies and Endo International's collagenase clostridium histolyticum** (CCH) for treating/removing cellulite from women's buttocks	PDUFA date
July 8	**Eagle Pharmaceuticals' Ryanodex** (dantrolene sodium) to treat heat stroke (resubmission)	PDUFA date
July 13	**Averitas Pharma's Qutenza** (capsaicin patch) – expanded approval to treat neuropathic pain from diabetic peripheral neuropathy	PDUFA date
July 16	**Osmotica Pharmaceuticals/Vertical Pharmaceuticals' RVL-1201** (oxymetazoline hydrochloride ophthalmic solution) for acquired blepharoptosis	PDUFA date
July 17	**2020 Clinical Outcome Assessments in Cancer Clinical Trials**	FDA-ASCO virtual public workshop
July 21	**Jazz Pharmaceuticals' JZP-258** for cataplexy and excessive daytime sleepiness associated with narcolepsy	PDUFA date
July 21 (est.)	**Seattle Genetics and GlaxoSmithKline's belantamab mafodotin**, an anti-BCMA for relapsed/refractory multiple myeloma	PDUFA date
July 23	**Reauthorization of the Prescription Drug User Fee Act** for 2023-2027	FDA virtual public meeting
July 31	**Ultragenyx Pharmaceutical's triheptanoin** (UX-007) to treat long-chain fatty acid oxidation disorders	PDUFA date
July 31	**GW Pharmaceuticals/Greenwich Biosciences' Epidiolex** (canabidiol) – expanded approval for use in treating seizures associated with tuberous sclerosis complex	PDUFA date
August 2 (est.)	**Theravance Biopharma and GlaxoSmithKline's Trelegy Ellipta** (fluticasone furoate + umeclidinium + vilanterol) – expanded approval for improving lung function, quality of life, and symptom control in asthma	PDUFA date
August 4	Development of **antifungal drugs** to treat unmet medical need	FDA public workshop *Rescheduled from May 7*
August 5	Development of **antifungal drugs to treat Valley Fever** (coccidioidomycosis)	FDA public workshop *Rescheduled from May 8*
August 5	**DBV Technologies' Viaskin Peanut** for treating children with peanut allergy	FDA target action date
August 7	**Trevena's Olinvo** (oliceridine) for moderate-to-severe pain in hospitalized 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**
August 10	**Gilead Sciences/Kite Pharma's KTE-X19** for relapsed/refractory mantle cell lymphoma	PDUFA date
August 10 (est.)	**Bausch Health/Eton Pharmaceuticals' EM-100**, an eyedrop for treating ocular itchiness (resubmission)	PDUFA date
August 16	**Jazz Pharmaceuticals and PharmaMar's lurbinectedin** for second-line relapsed small cell lung cancer	PDUFA date
August 17	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date Postponed to November 16, 2020
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 24	**Roche's risdiplam** (RG-7916) to treat spinal muscular atrophy	PDUFA date *Extended from May 24*
August 27	**Cassiopea's 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 30	**MorphoSys and Incyte's tafasitamab** for use in combination with lenalidomide to treat relapsed/refractory diffuse large B-cell lymphoma	PDUFA date
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 27	**Aquestive Therapeutics' Libervant** (diazepam buccal film) for seizure clusters in epileptics	PDUFA date
Sept. 28-30	Global summit on regulatory science: **Emerging Techologies**	FDA summit **https://aralliance.org/gsrs/**
October 18	**Roche's Herceptin** (trastuzumab) **+ Perjeta** (pertuzumab) – a fixed dose combination to treat HER2+ breast cancer	PDUFA date
October 24	**Spectrum Pharmaceuticals' Rolontis** (eflapegrastim) for treating chemotherapy-induced neutropenia	PDUFA date
October 25	**Regeneron Pharmaceuticals' REGN-EB3** for Ebola	PDUFA date
November 15	**Alkermes' ALKS-3831** (olanzapine + samidorphan) for bipolar I disorder and schizophrenia	PDUFA date
November 20	**Eiger BioPharmaceuticals' Zokinvy** (lonafarnib) for progeria and progeroid laminopathies	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 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 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