TRENDS-in-MEDICINE

October 4, 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 Covid-19 section starts on Page 4. Subscribe to ***Trends-in-Medicine*** for coverage of the North American Neuroendocrine Tumor Society (NANETS) virtual conference.

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

- ✓ **President Trump** has Covid-19, was treated with Regeneron Pharmaceuticals' REGN-COV2 antibody cocktail, and is getting 5 days of Gilead Sciences' Veklury (remdesivir) plus dexamethasone.
- ✓ ASTRAZENECA's AZD-1222 – This Covid-19 vaccine trial is still on FDA hold.
- ✓ MESOBLAST's Ryoncil (remestemcel-L) was rejected by the FDA for treating steroid-refractory acute pediatric GVHD.
- ✓ **Positive trial results:**
  - ALNYLAM PHARMACEUTICALS' lumasiran – in pediatric primary hyperoxaluria type 1.
  - BIOGEN's Spinraza (nusinersen) – in spinal muscular atrophy (SMA).
  - ILIAD BIOTECHNOLOGIES' BPZE-1 – a whooping cough vaccine.
  - NOVARTIS' Zolgensma (onasemnogene abeparvovec-xioi) – in SMA.
  - NOVO NORDISK's Ozempic (semaglutide) – improved kidney function in Type 2 diabetics.
  - OVID THERAPEUTICS and TAKEDA's soticlestat (OC-935, TAK-935) – in CDKL5 deficiency disorder and duplication 15q (Dup15q) syndrome.
  - POXEL's PXL-770 – in NASH.
  - ROCHE and SAREPTA THERAPEUTICS' SRP-9001 – in DMD.
  - ROCHE and PTC THERAPEUTICS' Evrysdi (risdiplam) – in SMA.
- ✓ **Negative trial results:**
  - IRONWOOD PHARMACEUTICALS' IW-3718 – in GERD.
  - MYOVANT SCIENCES' Relumina (relugolix) – in metastatic prostate cancer.
  - SYNTHETIC BIOLOGICS' SYN-010 – in IBS-C.

SHORT TAKES

■ ABBVIE's elezanumab was granted fast track status by the FDA as a treatment for spinal cord injuries.

- ALNYLAM PHARMACEUTICALS' lumasiran – Top-line data from the 39-patient Phase III ILLUMINATE-B trial in children age <6 with primary hyperoxaluria type 1, this RNAi therapeutic, which inhibits glycolate oxidase, successfully lowered oxalate levels.

- AMAG PHARMACEUTICALS is being acquired by **Covis Group**.

- ASTRAZENECA's Farxiga (dapagliflozin) was granted breakthrough therapy designation by the FDA for reduction of worsening of renal function or risk of cardiovascular or renal death in chronic kidney disease (CKD) patients with or without Type 2 diabetes.

- BIAL is buying **Lysosomal Therapeutics**, which is developing Parkinson's disease treatments, including a glucocerebrosidase enzyme activator.

- BRIDGEBIO PHARMA and ORIGIN BIOSCIENCES' fosdenopterin (BBP-870, ORGN-001) – The FDA accepted a new drug application (NDA) for this cyclic pyranopterin monophosphate (CPMP) substrate replacement therapy as a treatment for molybdenum cofactor deficiency (MoCD) Type A and granted it priority review. The PDUFA date was not announced but likely is around the end of March 2021.

- Drug-coated balloons (DCBs) – Preclinical studies, published in the ***Journal of Biomaterials***, found that drug delivery by a DCB (a) depends on the coating micromorphology and (b) does not have a class effect.

- Flu vaccines – A poll by C.S. Mott Children's Hospital on children's health found a third of parents responding do not plan to have their child/children (age 2-18) get a flu vaccine this fall. Fewer than half the parents said their child's regular healthcare provider is strongly recommending a flu vaccine this year. One in 7 also said they are keeping their child/children away from healthcare sites due to concerns about Covid-19.

- ILIAD BIOTECHNOLOGIES' BPZE-1 – In data from a Phase IIb trial, presented at the virtual World Vaccine Congress, this pertussis (whooping cough) vaccine met both primary endpoints, showing both safety and induction of mucosal immunity with good tolerability. A single vaccination with BPZE-1 prevented 90% of colonization at 3 months.

- INTEGRA LIFESCIENCES is selling its Extremity Orthopedics business to **Smith & Nephew**.

- IONIS PHARMACEUTICALS is collaborating with **Genuity Science** on discovery and development of therapeutics for up to 20 diseases.

- IRONWOOD PHARMACEUTICALS' IW-3718 missed the primary endpoint in a pre-planned interim analysis of the Phase III trial (IW-3718-302) in refractory gastroesophageal reflux disease (GERD), failing to significantly improve heartburn severity vs. placebo. As a result, development is being discontinued.

- JOHNSON & JOHNSON/JANSSEN is collaborating with **Sema4** on optimizing oncology trials.

- LABCORP bought the exclusive rights for 5 years to **Genfit's NIS4 technology** to develop and commercialize a blood-based biomarker panel in the U.S. and Canada for diagnosing non-alcoholic steatohepatitis (NASH).

- LUMINEX got a $5.4 million contract from the Biomedical Advanced Research and Development Authority (BARDA) to develop and obtain FDA 510(k) clearance for an expanded high-throughput NxTAG Respiratory Pathogen Panel (RPP) that includes the SARS-CoV-2 virus and which differentiates SARS-CoV-2 from other respiratory illnesses (e.g., flu).

- MEDTRONIC is buying **Avenu Medical**, which will give it the Ellipsys Vascular Access System for use in kidney dialysis patients.

- MESOBLAST's Ryoncil (remestemcel-L) was rejected by the FDA as a treatment for steroid-refractory acute graft-versus-host disease in pediatric patients. The FDA issued a complete response letter (CRL) that said more efficacy data than a single-arm trial will be needed, even though Ryoncil had a positive review (9 to 1) by an FDA advisory committee.

- MYOVANT SCIENCES' Relumina (relugolix) – This gonadotropin-releasing hormone (GnRH) receptor antagonist missed an additional secondary endpoint in the Phase III HERO trial in metastatic prostate cancer, failing to show superiority on castration resistance-free survival vs. leuprolide acetate at Week 48 (74% vs. 75%), though it did perform about as well as leuprolide.

- NOVARTIS' Zolgensma (onasemnogene abeparvovec-xioi) – New interim data on this gene therapy from a Phase III trial in babies born with spinal muscular atrophy (SMA), presented at the World Muscle Society virtual meeting, found that 21 of 33 infants achieved motor skill milestones with 10.6 months of follow-up, something that the infants would not normally achieve. Most of the children who entered the study without requiring ventilation remained ventilator-free.

- NOVO NORDISK's Ozempic (semaglutide) – A post hoc analysis of the 8,416-patient SUSTAIN 1–7 trials, published in ***The Lancet Diabetes & Endocrinology***, found that Type 2

diabetics who took this weekly GLP-1 agonist had an improvement in kidney function – a reduction in both eGFR and urinary albumin-to-creatinine ratio – vs. placebo.

- ORGENESIS is merging with **Koligo Therapeutics**, a regenerative medicine company.

- OVID THERAPEUTICS and TAKEDA's soticlestat (OC-935, TAK-935) reduced seizures in the 12-patient Phase II ARCADE trial in patients with CDKL5 deficiency disorder and duplication 15q (Dup15q) syndrome. The results were clearly positive for the CDKL5 patients but less clear for the Dup15q patients.

- PFIZER invested in **CStone Pharmaceuticals** and will co-develop sugemalimab, an anti-PD-L1, in China.

- POXEL's PXL-770 met the primary endpoint in a Phase IIa trial in NASH, significantly decreasing liver fat on MRI vs. placebo at Week 12. The response was even greater in patients with Type 2 diabetes. PXL-770 also significantly improved liver enzymes, a key secondary endpoint.

- Ptosis – A study, published in ***JAMA Ophthalmology***, found that oxymetazoline, a topical over-the-counter decongestant (e.g., Bayer's Afrin Sinus), a selective α1 adrenergic receptor agonist and α2 adrenergic receptor partial agonist, improved visual outcomes in ptosis (droopy eye) patients.

- SANTEN PHARMACEUTICAL bought **Eyevance Pharmaceuticals**, which develops ophthalmic programs targeting the ocular surface and anterior chamber of the eye. The purchase excludes two drugs: Visovanq (sterile vancomycin ophthalmic ointment) and Nexagon (ophthalmic gel).

- SOLID BIOSCIENCES' SGT-001 – The FDA lifted the clinical hold on the Phase I/II IGNITE trial of this AAV gene therapy for Duchenne muscular dystrophy (DMD), saying the company addressed its concerns about manufacturing and safety.

- SYGNATURE DISCOVERY, a contract research organization (CRO), bought another U.K. CRO, **XenoGesis**.

- SYNTHETIC BIOLOGICS' SYN-010 – The company (and Cedars-Sinai Medical Center) terminated a 12-week Phase IIb trial of this oral modified-release lovastatin in irritable bowel syndrome with constipation (IBS-C) after an interim analysis decided there was no hope of meeting the primary endpoint, an increase in complete spontaneous bowel movements/week.

Very early research news

- Pain – Researchers have speculated that a SARS-CoV-2 infection can block pain, which may explain why some people have Covid-19 and don't have any symptoms. But it also could lead to new research on pain relief medications.

NEWS IN BRIEF

Non-Covid-19 Vaccines to Watch

Company	Vaccine
BiondVax	Universal flu
GlaxoSmithKline	Meningococcal virus ABCWY
Johnson & Johnson	HIV
Merck MSD	15-valent pneumococcal
Novavax	Flu
Novavax	Respiratory syncytial virus (RSV)
Pfizer	20-valent pneumococcal
Pfizer	Respiratory syncytial virus (RSV)
Pfizer	Meningococcal virus ABCWY
Pfizer	*Clostridium difficile*
Takeda	Dengue fever

Source: FiercePharma

BIOGEN

- and EISAI's aducanumab. A Swedish study, published in ***Nature Structural and Molecular Biology***, tested four Alzheimer's disease antibodies against different epitopes of amyloid-beta – Lilly's solanezumab, Biogen and Eisai's aducanumab, Pfizer and Johnson & Johnson's bapineuzumab, and Roche's gantenerumab – and found that only aducanumab stemmed the formation of oligomers.

- Spinraza (nusinersen). Data presented at the World Muscle Society meeting on this antisense oligonucleotide in spinal muscular atrophy (SMA) included:

  - New findings from the ENDEAR/SHINE and NURTURE studies that reinforce the importance of early treatment, with the patients who were youngest when they got the first dose showing the best improvement in long-term motor function.

  - Spinraza rapidly lowered levels of plasma phosphorylated neurofilament heavy chain (pNF-H), a potential biomarker of disease activity in SMA. Lower baseline pNF-H levels were associated with an earlier ability to sit.

ROCHE

- and PTC THERAPEUTICS' Evrysdi (risdiplam). Updated data from Part 1 of the FIREFISH trial in spinal muscular atrophy (SMA), presented at the World Muscle Society virtual meeting, showed that nearly all infants treated with the highest dose of this oral survival motor neuron-2 (SMN2) splicing modifier were alive and did not require permanent ventilator support at 2 years. In addition, 59% of the children were able to sit unaided for ≥5 seconds. Among these infants, 100% maintained the ability to swallow, and 93% were able to feed orally.

- and SAREPTA THERAPEUTICS' SRP-9001. Two-year results for 4 DMD patients, presented at the World Muscle Society meeting, showed sustained benefits to this gene therapy, with the patients having a 7.0 point improvement from baseline on the North Star Ambulatory Assessment (NSAA).

- GENENTECH is partnering with **Vaccibody** on development and commercialization of VB10.NEO, a neoantigen cancer vaccine.

COVID-19 WEEKLY HIGHLIGHTS

- **President Trump** has Covid-19 and is being treated at Walter Reed Army Medical Center. He first received Regeneron's REGN-COV2 – a two-antibody antiviral treatment given to the President in an N-of-1 trial – followed by Gilead Sciences' Veklury (remdesivir), and then dexamethasone was added.

  First Lady Melania Trump, several Republican Senators, and a number of people who were at the Rose Garden announcement of the nomination of Judge Amy Coney Barrett to the Supreme Court also tested positive for the virus, and they are all quarantining at home. Former Vice President Biden tested negative for the virus.

- Cruise ships. The Centers for Disease Control and Prevention (CDC) announced an extension of a No Sail Order for cruise ships with ≥250 passenger capacity through October 31, 2020, in U.S. waters. Reportedly, the CDC wanted to ban cruises until February 2021 but was overridden by the White House.

- FDA. Seven former FDA Commissioners – Robert Califf, MD; Scott Gottlieb, MD; Margaret Hamburg, MD; Jane Henney, MD; David Kessler, MD; Mark McClellan, MD, PhD; and Andrew von Eschenbach, MD – wrote an opinion piece in the ***Washington Post*** calling for separation of church and state when it comes to the FDA's scientific recommendations and pressure from President Trump and administration officials. They wrote, "At risk is the FDA's ability to make the independent, science-based decisions that are key to combating the pandemic and so much more."

- **Non-Covid-19 procedures**
  - A survey by ***Market Scope*** found a 33.7% decrease in ophthalmic procedure volume in the U.S. in 2Q20 vs. the same period last year, with retina down 24.9% and refractive surgery down 55.8%.
  - According to medical claims data from IQVIA for the week ending
    - ✓ September 11, 2020:
      - Elective procedures were down 47% vs. the same period last year but up 2% over the week ending September 4, 2020.
      - Orthopedic procedures were among the procedures making the fastest recovery.
    - ✓ September 18, 2020:
      - In-person physician visits were down ~19% from pre-Covid levels, but better than the previous week.
      - Telehealth visits accounted for 20% of total visits and appear to be stable at that level.

- Testing. **Hologic**'s high-throughput Covid-19 test for wider screening of asymptomatic people was granted an emergency use authorization (EUA) by the FDA.

- Treatments
  - **Gilead Sciences' Veklury (remdesivir)** – Gilead took back distribution of this antiviral from the government due to a drop in demand – though that could change again if President Trump does well after taking it.
  - **Merck MSD's Januvia (sitagliptin)** – A study, published in ***Diabetes Care***, found that patients with Type 2 diabetes and Covid-19 who took a combination of this DPP4 inhibitor + insulin had a mortality rate of 18% vs. 37% with insulin alone. The sitagliptin/insulin patients also had a lower risk of requiring mechanical ventilation and intensive care and were less likely to have a worsening of clinical outcomes vs. insulin alone.
  - **Regeneron Pharmaceuticals and Roche's REGN-COV2** – Data from the first 275 patients in an adaptive Phase I/II/III trial in non-hospitalized Covid-19 patients who got a single 8 g dose of this antibody cocktail showed this dose (the highest dose) lowered virus levels and relieved symptoms quicker than placebo (8 days vs. 13 days). The cocktail appeared to do best in patients with undetectable antibody levels at baseline.

Vaccines

- A study of 847 Covid-19 vaccine and treatment trials, published in ***JAMA Internal Medicine***, found that people age >65 were generally excluded, either directly or indirectly, from Covid-19 trials, even though 80% of deaths are in that age group.

- **AstraZeneca's AZD-1222**
  - ✓ The Phase III trial remains on clinical hold in the U.S. as the FDA investigates safety after a reported case of transverse myelitis, even though the U.K. and Japan have allowed trials there to resume.
  - ✓ The European Medicines Agency (EMA) started a rolling review of this vaccine.

- **Inovio Pharmaceuticals' INO-4800** – The start of a Phase II/III trial of this DNA vaccine for Covid-19 was put on a partial clinical hold by the FDA until some additional Agency questions are addressed. The issue reportedly is not an adverse event but Agency questions about the Cellectra delivery device, which uses an electrical pulse to allow the vaccine to enter cells. The hold does not affect an ongoing Phase I trial.

- **Johnson & Johnson's Ad26.COV2.S/JNJ-78436735** – Pre-print data on ***medRxiv*** from a Phase I/IIa trial of this vaccine showed it produced an immune response with one dose, and the low dose produced similar immunity to the high dose. The data on patients age ≥65 looked good, but it was a very small sample size. Adverse events were less frequent in the elderly than in younger participants (36% vs. 64%). Overall, the data, though not detailed, appeared to support going ahead with a single dose for the 60,000 person Phase III trial.

- **Moderna's mRNA-1273**
  - ✓ The company said it is unlikely to have Phase III data before Thanksgiving.
  - ✓ A 40-patient Phase I extension study, published in the ***New England Journal of Medicine***, found that two doses of the 100 µg dose of this Covid-19 vaccine spurred an immune response in older adults similar to the response in younger people, without an increased risk of severe side effects.

REGULATORY NEWS

Regulatory tidbits

Antibiotics. Sen. Michael Bennet (D-CO) and Sen. Todd Young (R-IN) introduced a bipartisan bill – the PASTEUR Act – that would support development of new antibiotics and promote appropriate use of existing antibiotics.

CATALYST PHARMACEUTICALS. A federal judge threw out the company's lawsuit accusing the FDA of illegally approving a rival treatment for Lambert-Eaton myasthenic syndrome [Jacobus Pharmaceuticals' Ruzurgi (amifampridine).

Drug prices

- California Gov. Gavin Newsom signed a bill into law that will allow the state to manufacture cheaper versions of **generic drugs**, including insulin. The state's Health and Human Services Agency must partnership with drugmakers on this.

- A report by the House Committee on Oversight and Reform found that Amgen, Mallinckrodt, and Novartis inhibited competition and used routine price hikes to keep their **monopoly pricing power** – Mallinckrodt on H.P. Acthar Gel (repository corticotropin injection), Novartis on Gleevec (imatinib), and Amgen on Enbrel (etanercept) and Sensipar (cinacalcet).

FDA

- Issued draft guidance for industry on the use of physiologically-based **pharmacokinetic (PK) analyses**, including the Agency's current thinking on mechanistic modeling of small molecules. Comments are being accepted until November 30, 2020.

- Issued final labeling guidance on patient communications about **breast implants**.

- Finalized guidance on development of novel drugs to treat **opioid use disorder**, clarifying efficacy endpoints and trial design issues.

- Issued draft guidance for **generic drug companies** outlining what will happen if they fail to respond to a complete response letter (CRL) issued for an abbreviated new drug application (ANDA) within one year.

- Issued a final rule allowing states, pharmacies, and wholesalers to **import** certain prescription drugs from Canada and other countries.

- Issued 2 draft guidances to facilitate development of adjuvant treatments for **renal cell carcinoma and bladder cancer**. The guidance is designed to eliminate variability

in study designs, eligibility criteria, conduct, and analyses, making it easier for the FDA to interpret the results.

- **Nursing homes.** The Centers for Medicare and Medicaid Services (CMS) changed its nursing home testing guidance over concerns by rural governors that low Covid-19 testing volumes would create high positive rates in their areas.
- **Opioids.** A study, published in the ***Annals of Internal Medicine***, questioned FDA handling of NDAs for opioids. The study found that:
  - 47 of 48 NDAs for opioids that were approved by the FDA from 1997-2018 were for existing (not really new) products.
  - Only 21 of 39 NDAs for an opioid for chronic pain had Phase III trial data to support the NDA.
- **Ventilators.** According to a ***Wall Street Journal*** report, the U.S. Department of Justice is investigating whether **Medtronic**'s acquisitions reduced competition among ventilator manufacturers, potentially having a negative impact on the number of the devices available.

FDA approvals

- BAUSCH HEALTH/ETON PHARMACEUTICALS and DIURNAL's Alkindi Sprinkle (granular hydrocortisone formulation) was approved to treat pediatric adrenocortical insufficiency.
- BRISTOL-MYERS SQUIBB's Opdivo (nivolumab) + Yervoy (ipilimumab) – This PD-1/CTLA4 inhibitor combination was approved as a first-line treatment for adults with unresectable malignant pleural mesothelioma. This is the first new systemic therapy approved to treat mesothelioma in 16 years.
- CAPSOVISION's CapsoCam Plus – The FDA agreed to allow at-home use of this small bowel capsule endoscope during the Covid-19 pandemic.
- CONFORMIS' Cordera, a total hip replacement system, was granted 510(k) clearance.
- DANAHER/CEPHEID's rapid multiplex RT-PCR test for detecting and differentiating influenza A and B, respiratory syncytial virus (RSV), and SARS-CoV-2 within 35 minutes, was granted an EUA for point-ofcare use as well as in high and moderate complexity labora-tories.
- DIASORIN's hepatitis B serology tests (6 of them) were approved.
- JOHNSON & JOHNSON's Simponi Aria (golimumab) was approved to treat patients age ≥2 with active polyarticular juvenile idiopathic arthritis. The FDA also expanded the approval in psoriatic arthritis to include patients as young as 2.
- MASIMO's Rad-G Pulse Oximeter was granted 510(k) clearance.
- OXFORD IMMUNOTEC's T-SPOT.*TB*, a tuberculosis blood test, was granted expanded clearance for use on patients age ≥2.
- PFIZER's Xeljanz (tofacitinib) – both tablet and oral formulations – was granted expanded approval to treat polyarticular juvenile idiopathic arthritis in patients age ≥2.
- RADLOGICS' chest x-ray pneumothorax software was granted 510(k) clearance for use in determining whether a lung has collapsed.
- SHIONOGI's Fetroja (cefiderocol) was granted expanded approval to include treatment of hospital-acquired and ventilator-associated bacterial pneumonia.
- SPINEOLOGY's OptiMesh, an expandable interbody fusion system for use in lumbar spine fusions, was granted de novo clearance.
- SURGENTEC's 3D GraftRasp system for decortication of bone and the delivery of autograft, allograft, or synthetic bone graft was granted 510(k) clearance.
- TELEFLEX's Arrow EZ-IO, an intraosseous vascular access system, was granted expanded 510(k) clearance for use in patients age ≥12 and for up to 48 hours if alternate IV access is not reliably available.

FDA recalls/warnings

- ALLISON BREAST CENTER at Monument Radiology in Richmond VA – The FDA issued a Safety Communication, warning patients, radiologists, and healthcare professionals about quality problems with mammograms performed at this site on or after June 17, 2018, noting that the site is not properly licensed and that the site failed to notify women – as the FDA ordered – that there were problems with the quality of their mammograms.
- CARDIOQUIP's Modular Cooler-Heater – The FDA sent a letter to healthcare providers warning of a potential risk of infection when this device is used during cardiac surgery.
- Covid-19 – The FDA and the Federal Trade Commission (FTC) jointly sent a warning letter for selling unapproved products with fraudulent Covid-19 claims to **Tonic Therapeutic Herb Shop & Elixir Bar**.
- NEPHRON PHARMACEUTICALS' Budesonide Inhalation Suspension – The company received a warning letter about emails the CEO and a sales representative sent concerning this product and complaints submitted to the FDA about it.
- PANACEA BIOTEC received a warning letter for failing to properly identify microbes at one of its plants in India.

European Regulatory News

- ABBOTT's FreeStyle Libre 3, the smallest continuous glucose monitor (CGM), was granted a CE Mark.
- AVROBIO's AVR-RD-02, a gene therapy for Gaucher disease, was granted orphan drug status by the European Commission.
- BGI GENOMICS – Two multiplexed tests for detecting and differentiating SARS-CoV-2, influenza A, and influenza B were granted CE Marks.
- BIOGX BV's RT-PCR-based test that can simultaneously detect influenza A and B, RSV, and SARS-CoV-2 was granted a CE-IVD Mark.
- BLUEPRINT MEDICINES' Ayvakyt (avapritinib) was approved by the European Commission to treat unresectable/metastatic PDGFRA D842V mutant gastrointestinal stromal tumors.
- KYOWA KIRIN's Crysvita (burosumab) was approved by the European Commission to treat X-linked hypophosphataemia (XLH) in older adolescents and adults.
- ORCHARD THERAPEUTICS' OTL-203 – The EMA granted fast track review to this gene therapy for mucopolysaccharidosis type I, granting it priority medicines (PRIME) designation.
- SANOFI's avalglucosidase alfa – The EMA accepted for review a marketing authorization application (MAA) for this long-term enzyme replacement therapy for treating Pompe disease (acid α-glucosidase deficiency).
- ZYMO RESEARCH's sample collection devices – fecal collection tube, saliva/sputum collection kit, and collection tube and swab – were granted CE Marks.

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

- SHIONOGI's Rizmoic (naldemedine) – NICE recommended use to treat opioid-induced constipation in adults who have had laxative treatment.

Regulatory news from other countries

- *Canada.* ABBOTT's ID NOW – The government entered an advance purchase agreement for 7.9 million of these rapid point-of-care Covid-19 tests.

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 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 8	**Arbor Pharmaceuticals' amphetamine sulfate immediate-release** for treating attention-deficit/hyperactivity disorder (ADHD)	FDA's Psychopharmacologic Drugs Advisory Committee joint *virtual* meeting with the Drug Safety and Risk Management Advisory Committee
October 8	Bioequivalence of complex **topical generic drugs** (*in vitro* and *in vivo*)	FDA webcast
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 9	**NanoDay Virtual Research Symposium**	FDA Nanotechnology Task Force 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 15	Final guidance on recognition and withdrawal of **voluntary consensus standards**	FDA webcast
October 15-16	New approaches for an integrated non-clinical/clinical **QT/proarrhythmic risk assessment**	FDA webcast
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 19	Digital Health Center of Excellence **Listening Session #1**	FDA webcast
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 27	**Medical device user fee** amendments for fiscal years 2023-2027	FDA virtual public meeting
October 27	**Neovasc's Neovasc Reducer System** for treating refractory angina pectoris	FDA's Circulatory System Devices Advisory Committee virtual meeting
October 30	Integrated assessment of **marketing applications**	FDA virtual public workshop
November 6	**Biogen and Eisai's aducanumab** in Alzheimer's disease	FDA's Peripheral and Central Nervous System Drugs Advisory Committee virtual meeting
November 12	Digital Health Center of Excellence **Listening Session #2**	FDA webcast
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 17	**Safety of medical devices**	FDA virtual public meeting
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

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
December tba	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	PDUFA date
December 3	**BioCryst Pharmaceuticals' Orladeyo** (berotralstat, BCX-7353) for hereditary angioedema attacks	PDUFA date
December 3	**Alnylam Pharmaceuticals' lumasiran** for primary hyperoxaluria type 1	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
February 28	**Roche's Gavreto** (pralsetinib) in RET-mutated medullary thyroid cancer	PDUFA date
March 7	**Biogen and Eisai's aducanumab** for Alzheimer's disease	PDUFA date
March 27	**Bristol-Myers Squibb and bluebird bio's idecabtagene vicleucel** (ide-cel, bb-2121), a CAR T therapy for relapsed/refractory multiple myeloma	PDUFA date