TRENDS-in-MEDICINE

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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: Subscribe to ***Trends-in-Medicine*** for coverage of the virtual Wet AMD & DME Drug Development Summit and the virtual American Academy of Neurology (AAN) annual meeting. The Covid-19 Update starts on page 3.

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

- ✓ **CELLTRANS' Lantidra** (donislecel) – An advisory committee voted 12-4 that the benefits outweigh the risks of this gene therapy for brittle Type 1 diabetes.
- ✓ **JOHNSON & JOHNSON's Ad26.COV2.S** (JNJ-78436735) – The FDA and the CDC recommended a "pause" in the use of this Covid-19 vaccine, and it remains on a "voluntary" hold. For details see the ***Trends-in-Medicine*** bulletins.
- ✓ **PACIRA BIOSCIENCES' Exparel** (liposomal bupivacaine) – The company sued a major medical society and its journal for libel.
- ✓ **UNIQURE's etranacogene dezaparvovec** – An outside investigation found that this gene therapy was unlikely to have caused hepatocellular carcinoma (HCC).
- ✓ **Positive trial news:**
  - **ASTRAZENECA's Farxiga** (dapagliflozin) – in serum and urine metabolic parameters in Type 2 diabetes.
  - **MEDTRONIC's i-Port Advance** – in Type 1 diabetes.
  - **NOVOCURE's Tumor Treating Fields** (TTF) – in Stage 4 non-small cell lung cancer (NSCLC).
  - **Psilocybin** – vs. an SSRI in depression.
  - **SAGE THERAPEUTICS and BIOGEN's SAGE-324** – in essential tremor.
- ✓ **Negative trial news:** **GLAXOSMITHKLINE's feladilimab** (GSK-3359609) – in combination with a chemotherapy and/or a PD-1 inhibitor in advanced/metastatic head and neck squamous cell carcinoma.

SHORT TAKES

- **AMGEN's AMG-986**, an APJ agonist that was disappointing in heart failure, was out-licensed to **BioAge Labs**, which renamed it (BGE-105) and will test it as an muscle anti-aging agent.
- **AMNEAL PHARMACEUTICALS / IMPAX LABORATORIES** – A federal appeals court upheld a Federal Trade Commission (FTC) decision that Impax engaged in pay-for-delay by accepting $102 million in credits from Endo Pharmaceuticals to keep a generic opioid off the market while Endo launched a reformulated version of Opana ER (oxymorphone).

- **ANGIODYNAMICS' AlphaVac System**, an off-circuit multi-purpose mechanical aspiration thrombectomy device for treating peripheral arterial and venous clots, was submitted to the FDA under the 510(k) pathway.

- **AVANTOR** is buying **Ritter**, a German company that makes robotics consumables.

- **CELLTRANS' Lantidra (donislecel)** – The FDA's Cellular, Tissue, and Gene Therapies Advisory Committee, meeting virtually, voted 12-4 (with one abstention) that the benefits of this allogeneic pancreatic islet cellular gene therapy for brittle Type 1 diabetes outweigh the risks.

- **DANCO LABORATORIES' Mifeprex (mifepristone)** – In response to concerns raised by American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, Acting FDA Commissioner Janet Woodcock, MD, said the FDA will allow women to order this abortion pill through the mail during the pandemic and will not have to go into a clinic in person.

- **DIASORIN**, an Italian diagnostics company, is buying **Luminex**.

- **ENDOLOGIX** bought **PQ Bypass**, which gives it the Detour platform for percutaneous femoral-popliteal bypass.

- **Genetic testing** – Even before **Mirati Therapeutics' adagrasib** and **Amgen's sotorasib** – both $KRAS^{G12C}$ inhibitors – get approved by the FDA, the companies have each started a campaign to educate oncologists about the importance of KRAS (particularly $KRAS^{G12C}$) mutation testing in non-small cell lung cancer (NSCLC) patients.

- **GLAXOSMITHKLINE's feladilimab (GSK-3359609)** – The company ended two Phase II trials of this inducible T cell co-stimulatory (ICOS) agonist, on the recommendation of the independent data monitoring committee, which was based on their interim analysis of the studies: the INDUCE-3 trial in combination with Merck MSD's Keytruda (pembrolizumab) in advanced/metastatic head and neck squamous cell carcinoma and the INDUCE-4 trial in combination with Keytruda and chemotherapy in an undisclosed cancer.

- **JAZZ PHARMACEUTICALS' Xyway (calcium, magnesium, potassium, and sodium oxybates)** – The FDA granted priority review for a supplemental new drug application (sNDA) that would expand the approval to include treatment of adult idiopathic hypersomnia. The PDUFA date is August 12.

- **MEDLINE INDUSTRIES** reportedly is looking to sell itself.

- **MEDTRONIC's i-Port Advance** – A study, published in ***Diabetes & Metabolic Syndrome: Clinical Research & Reviews***, found that at 12 weeks this injection port improved patient satisfaction, HbA_{1c}, fasting blood glucose, and post-prandial glucose in patients with Type 1 diabetes.

- **MICROSOFT** reportedly is buying **Nuance Communications**.

- **NATIONAL RESILIENCE** is buying **Ology Bioservices**, which makes biologic drug substances.

- **NOVOCURE's Tumor Treating Fields (TTF)** – After an interim analysis of 210 patients, the independent data monitoring committee (DMC) recommended the Phase III LUNAR trial in Stage 4 NSCLC – after platinum failure – continue. The DMC also recommended the trial be shortened to 12 months and total enrollment be reduced from the planned 534 to ~276, with no additional patients enrolled in the placebo arm.

- **PACIRA BIOSCIENCES' Exparel (liposomal bupivacaine)** – The company is suing the American Society of Anesthesiologists, which publishes the journal ***Anesthesiology***, for libel, charging that three articles were published that contained "bias…[that] seriously disparaged" Exparel, a painkiller for use in surgery.

- **PRECISION BIOSCIENCES** – **Servier** returned the global rights to all the CAR T programs partnered with Precision – PBCAR-0191, PBCAR-19B, and other undisclosed agents.

- **Psilocybin** – In a 6-week, 59-patient Phase II trial, published in the ***New England Journal of Medicine***, found that psilocybin (the active ingredient in "magic" mushrooms), this psychedelic met the primary endpoint, reducing the symptoms of depression (on the QIDS-SR-16) as well as the SSRI antidepressant escitalopram. On some secondary endpoints, psilocybin performed better.

- **RELAY THERAPEUTICS** is buying **ZebiAI**, an artificial intelligence company.

- **SAGE THERAPEUTICS and BIOGEN's SAGE-324**, an oral neuroactive steroid (NAS) GABA A receptor positive allosteric modulator (PAM), met the primary endpoint in a 67-patient Phase II KINETIC trial in essential tremor, with a 36% reduction in upper limb tremor at Day 29 vs. -21% with placebo ($p=0.049$). But there was a 38% drop-out rate, and >50% of patients had a dose reduction because of tolerability issues.

- **SANOFI** bought a worldwide license to an oral, preclinical IL-17A inhibitor for inflammatory diseases from **C4X Discovery**.

- **SEAGEN and GENMAB's tisotumab vedotin** – The FDA granted priority review to the biologics license application (BLA) for this antibody-drug conjugate to treat recurrent/ metastatic cervical cancer on/after chemotherapy. The PDUFA date is October 10, 2021.

- **Sexually-transmitted diseases (STDs)** – Data from the Centers for Disease Control and Prevention (CDC) show that cases of STDs in the U.S. continue to climb in 2019 for the 6th year in a row. The CDC said there were 2.6 million reported cases of chlamydia, gonorrhea, and syphilis in 2019, an increase of almost 30% from 2015. The biggest increase was in congenital syphilis, which went up almost 3-fold from 2015 to 2019.

- **SIEMENS** reportedly is considering the sale of its ultrasound business.

- **STERLING PHARMA SOLUTIONS**, a contract development and manufacturing organization (CDMO), bought **ADC Biotechnology**, which specializes in antibody-drug conjugates.

- **THERMO FISHER SCIENTIFIC** is buying **PPD**, a contract research organization (CRO).

- **UNIQURE's etranacogene dezaparvovec** – An outside investigation found that this gene therapy was unlikely to have caused the case of hepatocellular carcinoma (HCC) that caused the FDA to put a clinical hold on the HOPE-B trial in December 2020. It turned out the HCC patient had a history of hepatitis B and C, evidence of non-alcoholic fatty liver disease (NAFLD), and other risk factors. The clinical hold is still in place, but the data have been shared with the FDA.

- **ZOLL MEDICAL** bought **Respicardia**, which has neurostimulation technology for sleep apnea.

Very early research news

- **Gene therapy** – Researchers at MIT and the University of California, San Francisco have created an "on/off switch" for CRISPR that allows control of gene expression without changing DNA.

- **Oncology** – Researchers at Fox Chase Cancer Center reported in ***Nature Communications*** that they have discovered a way to trigger cancer cell death (ferroptosis) using a Trojan horse-type of approach.

- **Wound care** – Researchers at the University of Rhode Island have developed smart bandages that can provide non-invasive and continuous monitoring and detection of wound infections.

NEWS IN BRIEF

ALNYLAM PHARMACEUTICALS

- **Onpattro (patisiran).** The U.S. Department of Justice is investigating the marketing of this treatment for hereditary ATTR amyloidosis.

- **ALN-AGT.** The company reported positive interim results from an ongoing Phase I trial of this RNAi therapeutic in treating hypertension.

ASTRAZENECA

- Is collaborating with **Sanguina** on development of a custom version of the AnemoCheck Mobile, a smartphone app that provides non-invasive hemoglobin (Hgb) levels for patients with anemia of chronic kidney disease (CKD) through pictures of a fingernail bed (no blood required).

- The FTC cleared AstraZeneca's acquisition of **Alexion Pharmaceuticals**.

- **Farxiga (dapagliflozin).** A 133-patient study, published in ***The Journal of Clinical Endocrinology & Metabolism***, found that Type 2 diabetics treated with this SGLT2 inhibitor over three months had improved serum and urine metabolic parameters vs. patients treated with insulin degludec (Novo Nordisk's Tresiba) which were unchanged.

COVID-19 UPDATE

- **The numbers.**
  - **Globally**, there have been 141,103,621 cases and 3,017,182 deaths.
  - **In the U.S.**, there have been 31,668,353 cases, with 567,210 deaths (19% of the worldwide total, which compares to 23% this time last year).
  - **The U.S.** has the highest number of *cases* – more than the next two highest countries (Brazil and India) combined. The U.S. also has the highest number of deaths, just slightly less than the mortality in the next two highest countries (Brazil and Mexico) combined.
  - As of today, 82.5 million people in the U.S. have been **fully vaccinated** (25.1% of the population). Worldwide, 199 million people have been fully vaccinated.

- **Treatments**
  - **ASTRAZENECA's Farxiga (dapagliflozin)** – This SGLT2 inhibitor failed in the Phase III DARE-19 trial in 1,250 hospitalized Covid-19 patients, failing to prevent

organ dysfunction, improve all-cause mortality, or improve recovery vs. placebo at 30 days.

- **GILEAD SCIENCES' Veklury (remdesivir) –** The company halted its Phase III IV trial in high-risk non-hospitalized Covid-19 patients, citing enrollment difficulties.
- **LILLY's bamlanivimab –** The FDA withdrew the emergency use authorization (EUA) for this antibody at the request of Lilly.
- **MERCK MSD/ONCOIMMUNE's MK-7110 (CD24Fc) –** Merck gave up on this recombinant fusion protein for treating Covid-19, citing both manufacturing and regulatory issues.
- **REGENERON PHARMACEUTICALS' REGEN-COV (casirivimab + imdevimab) –** In a 1,505-patient trial in which this antibody combination was given by subcutaneous injection (instead of the usual infusion), reduced the risk of symptomatic infections by 81% in those who did not have Covid before the trial within 29 days (11 cases vs. 59 with placebo).

Vaccines

- **Chinese vaccines –** A top Chinese official said the efficacy of their vaccines is "not high."
- The **European Union** reportedly doesn't plan to renew its Covid-19 vaccine contracts with AstraZeneca and Johnson & Johnson.
- **Mix-and-match**. A U.K. study (COM-COV) that is testing whether shots from different vaccines can be mixed now includes four vaccines: AstraZeneca, Moderna, Pfizer, and Novavax.
- **U.S. distribution –** The Biden administration rejected calls to change the population-based Covid-19 vaccine distribution program to give more doses to states/localities with spikes in cases.
- **JOHNSON & JOHNSON's Ad26.COV2.S (JNJ-7843-6735) –** The FDA and the CDC recommended a "pause" in the use of this Covid-19 vaccine, and it remains on hold over concern about cases of blood clots (and one death) post vaccination. The CDC's Advisory Committee on Immunization Practices (ACIP) met but said it did not have enough information yet to made a recommendation, putting off a decision and planning another meeting on April 23, 2021.
- **Russia's Sputnik V**
  - ✓ **India** became the 60th country to authorize use of this Covid-19 vaccine.
  - ✓ **Slovakia** said ~200,000 doses of this vaccine have a different dosage form than the vaccines the European Medicines Agency (EMA) is reviewing – and they have different characteristics than the vaccines tested for studies published in ***The Lancet***. The Russian Direct Invest-ment Fund demanded Slovakia return the doses and denied any problem with them.

Variants. A U.K. study, published in ***The Lancet Infectious Diseases***, found that the U.K. variant (B.1.1.7) is more infectious and more transmissible but not more likely to cause death or severe illness.

REGULATORY NEWS

Regulatory tidbits

FDA

- **Inspections.** The FDA issued guidance on how the Agency plans to conduct remote interactive evaluations of pharmaceutical and biomedical research sites during the pandemic.
- **Drug reviews**
  - ✓ Asked on a webinar if the FDA is getting tougher on drug reviews, Acting FDA Commissioner Janet Woodcock, MD, said, "I don't think so."
  - ✓ As it stands now, PDUFA VII will include a new program designed to speed reviews in all areas the way they are in oncology, Split Real-Time Application Review (STAR).
- **CDER.** Patrizia Cavazzoni, MD, a psychiatrist, was named the permanent director of the FDA's Center for Drug Evaluation and Research (CDER). Her degrees are from McGill University and the University of Ottawa. She has been at the FDA for 3 years. Before that she worked for 7 years at Pfizer, 6 months at Sanofi, and 9 years at Lilly.
- **Premarket review.** The FDA backtracked on a Department of Health and Human Services proposal that would have exempted 91 devices from premarket review.
- **Commissioner candidates.** In addition to Acting FDA Commissioner Janet Woodcock, MD, names that have been thrown around as possible candidates to be Commissioner include:
  - ✓ Luciana Borio, MD, an infectious disease specialist and vice president of In-Q-Tel
  - ✓ Florence Houn, MD, MPH, an internist, consultant, and former vice president for global regulatory science at Celgene

- ✓ Katherine Luzuriaga, MD, a pediatric allergist and immunologist and director of the University of Massachusetts Center for Clinical and Translational Science
- ✓ Michelle McMurry-Heath, MD, PhD, an immunologist and president/CEO of the Biotechnology Innovation Organization (BIO)
- ✓ Gayatri Rao, MD, JD, vice president/global product head at Rocket Pharmaceuticals
- ✓ Joshua Sharfstein, MD, associate dean for Public Health Practice and Training at Johns Hopkins Bloomberg School of Public Health

- **Fentanyl.** The U.S. Department of Justice said it will work with Congress to extend until December 2021 a temporary ban on all fentanyl *variants*.
- **Medicare.** In a bipartisan vote, the House of Representatives delayed until 2022 a 2% cut in Medicare payments to healthcare providers.
- **NIH.** The National Institutes of Health has replaced the Centers of Excellence for Influenza Research and Surveillance (CEIRS) with a new agency to track the flu, Covid-19, and other viruses with pandemic potential: the Centers of Excellence for Influenza Research and Response (**CEIRR**).
- **Vitamin D.** The U.S. Preventive Services Task Force (USPSTF) recommended against routine screening for vitamin D deficiency in adults who are asymptomatic, not pregnant, and have no conditions that are treated with vitamin D.

FDA approvals/clearances

- **ACTIV SURGICAL's ActivSight**, an imaging device for enhancing real-time visual data during surgical procedures, was granted 510(k) clearance.
- **ACUTUS MEDICAL's AcQCross**, a family of universal transseptal crossing devices, was cleared for use.
- **BECTON DICKINSON's Pristine**, a long-term hemodialysis catheter, was granted 510(k) clearance.
- **BRISTOL-MYERS SQUIBB's Opdivo (nivolumab)** was approved as a first-line treatment (in combination with chemotherapy) for patients with advanced/metastatic gastric cancer, gastroesophageal junction cancer, and esophageal cancer, regardless of PD-L1 expression status.
- **DONISI HEALTH's Gili Pro BioSensor system**, an artificial intelligence-run contactless monitor for estimating heart rate, respiratory rate, pulse rate, and breathing rate, was granted de novo clearance.
- **MASIMO's Radius PCG**, a hand-held, battery-operated device for measuring someone's respiration rate and their partial pressure of carbon dioxide within 15 seconds, was granted 510(k) clearance.
- **MYHOMEDOC's MyHomeDoc**, a telehealth system, was granted 510(k) clearance.
- **ROCHE and NOVARTIS' Xolair (omalizumab)** was granted expanded approval for delivery via a prefilled syringe for patient self-injection across all approved U.S. indications.

FDA recalls/warnings

- **Covid-19 –** The FDA and the FTC jointly issued a warning letter about the sale of unapproved products with fraudulent Covid-19 treatment claims to **Trinity Natural Health & Pain Management**.
- **MEDTRONIC**
  - **HeartWare HVAD** battery cables, data cables, adapter cables, and controller 2.0 ports were recalled (Class I) due to the risk of wear and tear of the connector plugs causing damage to the controller port metal pins – which could cause serious harm, including loss of consciousness, hospitalization, heart attack, or death.
  - **Evera, Viva, Brava, Claria, Amplia, Compia, and Visia** – implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) – were recalled (Class I) due to the risk of shortened battery life. The FDA said it received 444 complaints about these devices, with 18 injuries but no deaths.
- **PROQUIMES**, an active pharmaceutical ingredient manufacturer in Colombia, received a warning **letter** for failing to validate quality control procedures.
- **SMISSON-CARTLEDGE BIOMEDICAL's ThermaCor 1200 Rapid Thermal Infusion System Disposable Sets** were recalled (Class I) due to the risk of leaks that could expose patients to high levels of aluminum ions.

European Regulatory News

- **BRISTOL-MYERS Squibb's Opdivo (nivolumab)** was approved by the European Commission for use in combination with Exelixis and Ipsen's Cabometyx (cabozantinib) as a first-line treatment for advanced renal cell carcinoma.
- **HEMANEXT's Hemanext ONE Red Blood Cell** processing and storage system, which limits carbon dioxide and oxygen levels in stored RBCs, was granted a CE Mark.

- **HENSLER SURGICAL TECHNOLOGIES' Hensler Bone Press**, for harvesting autologous material for use in bone fusion surgery, was granted a CE Mark.
- **ONCOSEC MEDICAL's GenPulse**, a part of the company's electroporation device platform that is used to treat solid tumors, was granted a CE Mark.
- **SIEMENS HEALTHINEERS' Atellica VTLi Patient-Side Immunoassay Analyzer**, a point-of-care high-sensitivity cardiac troponin I test, was granted a CE Mark.
- **SNIBE DIAGNOSTIC's Maglumi HIV Ab/Ag Combi CLIA kit**, a fourth-generation chemiluminescence immunoassay for detecting the HIV-1 p24 antigen and HIV-1 and HIV-2 antibodies, was granted a CE Mark.

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

- **ALEXION PHARMACEUTICALS' Ultomiris (ravulizumab)** – After the company offered an undisclosed discount, NICE recommended use of this long-acting C5 inhibitor to treat paroxysmal nocturnal hemoglobinuria (PNH) in adults with hemolysis with clinical symptoms suggesting high disease activity, or whose disease is clinically stable after receiving **Soliris** (eculizumab) for ≥6 months.

Regulatory news from other countries

- ***Canada*. ROCHE's Evrysdi (risdiplam)** was approved by Health Canada to treat spinal muscular atrophy (SMA) in patients age ≥2 months.

2021 FDA Advisory Committees and Other Regulatory Dates of Interest *RED are new since last week*		
Date	**Topic**	**Committee/Event**
Missed PDUFA dates with no new date		
November 25	**Revance Therapeutics' daxibotulinumtoxinA** for glabellar lines	PDUFA date *Delayed by FDA No new date announced*
December tba	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	PDUFA date missed *No decision announced yet*
January 28	**Amgen's Nplate** (romiplostim) – expanded approval to treat hematopoietic syndrome of acute radiation syndrome	PDUFA date *No decision announced yet*
February 2	**Mallinckrodt's StrataGraft**, a regenerative skin tissue therapy	PDUFA date *Decision delayed due to Covid-19*
April 12	**Fortress Biotech/Avenue Therapeutics' IV tramadol**	PDUFA date April 12 **No decision announced yet**
2021 Events		
April 20-22	**Drug-Induced Liver Injury** (DILI)	FDA/CDER and AASLD joint virtual conference
April 23	Antimicrobial drugs to treat **gonorrhea**	FDA virtual public workshop in conjunction with the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID)
April 23	Adverse events with Johnson & Johnson/Janssen's Covid-19 vaccine	CDC's Advisory Committee on Immunization Practices (ACIP) virtual meeting **Trends-in-Medicine will be covering this**
April 27	**Protalix BioTherapeutics and Chiesi's pegunigalsidase alfa** (PRX-102) for Fabry disease	PDUFA date *Extended from January 27 by FDA*
April 27-29	Review of 6 indications granted **accelerated approval**: Roche's Tecentriq (atezolizumab) in TNBC and urothelial cancer; Merck MSD's Keytruda (pembrolizumab) in urothelial carcinoma, gastric cancer, and hepatocellular carcinoma; Bristol-Myers Squibb's Opdivo (nivolumab) in hepatocellular carcinoma	FDA's Oncologic Drugs Advisory Committee virtual meeting
April 28-29	**Generic Drugs Forum**	FDA virtual conference
May tba	**Roche's Esbriet** (pirfenidone) – expanded approval to treat unclassifiable interstitial lung disease	PDUFA date
May 4	**Patient-generated health data** and medical devices	FDA virtual public meeting
May 5	FDA Product-Specific Guidances: **Generic Drugs**	FDA webinar
May 6	**ChemoCentryx's avacopan** to treat anti-neutrophil cytoplasmic antibody-associated vasculitis	FDA's Arthritis Advisory Committee virtual meeting
May 6	Patient Engagement & **Regenerative Medicine**	FDA's Center for Biologics Evaluation and Research (CBER) virtual workshop for patient advocates
May 11	Implementation of the **patient-reported outcomes tool** (PRO-CTCAE)	FDA's Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) virtual meeting
May 11-12	Review of **ongoing research**	Science Advisory Board to the National Center for Toxicological Research **Meeting closed to the public**
May 12	Discussion of the use of **real-world evidence** in pediatric trials	FDA's Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) virtual meeting
May 14	**Apellis Pharmaceuticals and SOBI's pegcetacoplan** for treating PNH	PDUFA date
May 14	**Regional International Council for Harmonisation (ICH)** of technical requirements for pharmaceuticals	FDA and Health Canada joint virtual public meeting
May 18	**Sanofi's avalglucosidase alfa** for Pompe disease	PDUFA date
May 18-19	Potential **medical error risks** with investigational drug container labels	FDA virtual public meeting
May 21	**ADC Therapeutics' loncastuximab tesirine** for relapsed/refractory DLBCL	PDUFA date
May 26-27	**2021 FDA Science Forum**	FDA virtual meeting
May 27	**Provention Bio's teplizumab** to treat Type 1 diabetes	FDA's Endocrinologic and Metabolic Drugs Advisory Committee virtual meeting
May 30	**Kadmon's belumosudil** for chronic graft-versus-host disease after hematopoietic stem cell transplant	PDUFA date *Extended 3 months by FDA to August 30*
May 30	**Bristol-Myers Squibb's Zeposia** (ozanimod) for ulcerative colitis	PDUFA date
June 1	**Scynexis' Brexafemme** (ibrexafungerp) for vulvovaginal candidiasis	PDUFA date
June 7	**Biogen and Eisai's aducanumab** for Alzheimer's disease	PDUFA date *Extended 3 months by FDA from March 7*
June 7-8	**Morphine milligram equivalents** – current applications and knowledge gaps	FDA Center for Drug Evaluation and Research (CDER) virtual public workshop
June 21	**Incyte's topical ruxolitinib** to treat atopic dermatitis	PDUFA date

2021 FDA Advisory Committees and Other Regulatory Dates of Interest *RED are new since last week*		
Date	**Topic**	**Committee/Event**
June 23	**FY2021 generic drug** science and research initiatives	FDA virtual public workshop
June 30	**Lupin Pharmaceuticals' Solosec** (secnidazole) – expanded approval to treat trichomoniasis	PDUFA date
July tba	**Bayer's finerenone** (BAY-94-8862) for Type 2 diabetes patients with CKD	PDUFA date
July tba	**AbbVie's Rinvoq** (upadacitinib) – expanded use to treat moderate-to-severe atopic dermatitis	PDUFA date
July 2	**Provention Bio's teplizumab** (PRV-031) for preventing/delaying clinical Type 1 diabetes	PDUFA date
July 15	**FibroGen's roxadustat** for anemia of CKD in dialysis and non-dialysis patients	FDA's Cardiovascular and Renal Drugs Advisory Committee
July 18	**Merck MSD's V114**, a 15-valent pneumococcal conjugate vaccine	PDUFA date
July 20	**Albireo Pharma's odevixibat** (A-4250) to treat pruritus in patients with progressive familial intrahepatic cholestasis (PFIC)	PDUFA date
July 25	**Iterum Therapeutics' sulopenem etzadroxil/probenecid** for uncomplicated urinary tract infections	PDUFA date
August tba	**Pfizer's TicoVac** for tick-borne encephalitis	PDUFA date
August 12	**Jazz Pharmaceuticals' Xyway** (calcium, magnesium, potassium, + sodium oxybates) – expanded use to treat adult idiopathic hypersomnia	PDUFA date
August 16	**Amgen's sotorasib** for KRAS G12C-mutated NSCLC	PDUFA date
August 18	**Sensen Bio's vicineum** for non-muscle invasive bladder cancer	PDUFA date
August 30	**Kadmon's belumosudil** for chronic graft-versus-host disease after hematopoietic stem cell transplant	PDUFA date *Extended from May 30 by the FDA*
September 15	**Merck MSD's belzutifan** (MK-6482) to treat von Hippel-Lindau disease-associated renal cell carcinoma	PDUFA date
October tba	**Pfizer and OPKO Health's somatrogon** for growth hormone deficiency	PDUFA date
October 10	**Seagen and Genmab's tisotumab vedotin** to treat recurrent/metastatic cervical cancer	PDUFA date
October 18	**BeiGene's Brukinsa** (zanubrutinib) – expanded approval to treat Waldenström's macroglobulinemia	PDUFA date
December 21	**Merck MSD's gefapixant** for refractory chronic cough	PDUFA date
2022 Events		
January 28	**Bristol-Myers Squibb/MyoKardia's mavacamten** for symptomatic obstructive hypertrophic cardiomyopathy	PDUFA date