TRENDS-in-MEDICINE

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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 Conference on Retroviruses and Opportunistic Infections (CROI).

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

- ✓ **ATHENEX's oral paclitaxel** (with encequidar) was rejected by the FDA to treat metastatic breast cancer.
- ✓ **Merck MSD's Keytruda** (pembrolizumab) – The indication in metastatic small cell lung cancer was withdrawn.
- ✓ **UNITED THERAPEUTICS' Trevyent** (treprostinil) – Development was halted in pulmonary arterial hypertension (PAH).
- ✓ **Positive trial news:**
  - **GALAPAGOS' Jyseleca** (filgotinib) – in two safety trials in rheumatoid arthritis.
  - **LILLY and INCYTE's Olumiant** (baricitinib) – in alopecia areata.
  - **LILLY's tirzepatide** – in Type 2 diabetes.
- ✓ **Mixed trial news: Amgen's Blincyto** (blinatumomab) – one positive, one negative trial in pediatric relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL).
- ✓ **Negative trial news:**
  - **ARENA PHARMACEUTICALS' olorinab** – in irritable bowel syndrome pain.
  - **NEUROCRINE BIOSCIENCES and TAKEDA's luvadaxistat** – in schizophrenia.

SHORT TAKES

- **ABBVIE** bought the exclusive right to buy **Mitokinin** if its PINK1 compound succeeds in investigational new drug (IND) trials in Parkinson's disease.
- **AGILENT TECHNOLOGIES** is buying **Resolution Bioscience**, which will give it Ctdx, a non-invasive liquid biopsy platform.
- **ARENA PHARMACEUTICALS' olorinab**, a CB_2 agonist, missed the primary endpoint in the 273-patient Phase IIb CAPTIVATE trial in irritable bowel syndrome pain, failing to significantly improve AAPS at Week 12. However, the company is not giving up, pointing to a trend to efficacy in patients with moderate-to-severe pain.
- **ATHENEX's oral paclitaxel (with encequidar)** – The FDA rejected this breast cancer drug, issuing a complete response letter (CRL) requiring a "new clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S."

Among the FDA concerns were: (1) safety – an increase in neutropenia-related sequelae with oral paclitaxel compared to IV paclitaxel, and (2) possible bias in the reading of the primary endpoint (objective response rate, ORR) at Week 19.

- **BIO-TECHNE** is buying **Asuragen**, a Texas company that makes genetic carrier screening and oncology testing kits.

- **BOSTON SCIENTIFIC** is buying the global surgical business of **Lumenis**, which will give it laser systems, fibers, and accessories for urology and otolaryngology procedures. Lumenis is keeping its aesthetics and ophthalmology businesses.

- **BRAINSTORM CELL THERAPEUTICS' NurOwn** – In a ***very*** unusual move, the FDA issued a statement that contradicts what BrainStorm said last week about the efficacy of this investigational treatment for amyotrophic lateral sclerosis (ALS), basically saying there is no significant benefit to the therapy, regardless of how the data are cut. The company had claimed that 37.4% of the NurOwn patients vs. 27.7% of placebo patients met the primary endpoint. The FDA said it was 32.6% vs. 27.7%, a difference that did not even approach significance.

- **COOK MEDICAL's Zenith Fenestrated+**, an endovascular graft for abdominal aortic aneurysms, was granted breakthrough device status by the FDA.

- **Diabetes** – A meta-analysis of 8 cardiovascular outcomes trials of Type 2 diabetics, published in the ***Journal of the Endocrine Society***, found that patients who took either an SGLT2 inhibitor or a GLP-1 agonist had a lower major adverse cardiac event (MACE) rate whether or not they were also on insulin. And patients on insulin at baseline had a greater risk of MACE vs. patients taking a non-insulin drug. The conclusion: *Start an SGLT2 inhibitor or a GLP-1 agonist as soon as possible.*

- **EMPIRICAL SPINE's LimiFlex Paraspinous Tension Band**, a spinal fusion alternative, was submitted to the FDA for approval through the premarket pathway.

- **FIBROGEN and ASTRAZENECA's roxadustat** – A new delay! First, the FDA review of the new drug application (NDA) for this HIF-PH inhibitor for anemia of chronic kidney disease was delayed due to Covid-19, and the PDUFA date was postponed 3 months – from December 20, 2020, to March 20, 2021. Now, the FDA has surprised the company with plans for the Cardiovascular and Renal Drugs Advisory Committee to review the drug – but without announcing the date, which suggests a final decision could be further delayed.

- **GALAPAGOS' Jyseleca (filgotinib)** – Two safety trials in inflammatory diseases (e.g., rheumatoid arthritis), with a total of 240 evaluable patients, found that the number of patients with a ≥50% decrease in sperm count at Week 13 was comparable between drug and placebo (8 vs. 10 patients) – so no safety issue so far in those trials.

- **HOLOGIC** bought **Diagenode**, a European developer/manufacturer of diagnostic assays and epigenetics products.

- **Influenza** – The FDA's Vaccines and Related Biological Products Advisory Committee met virtually to consider strains to be included in the 2021/2022 influenza vaccines.

- **KRONOS' entospletinib** – The company reached agreement with the FDA for a 180-patient Phase III trial of this SYK inhibitor using a novel biomarker endpoint – measurable residual disease (MRD) negativity – in acute myeloid leukemia patients with an NPM1 mutation.

- **MEDABLE** and **Seqster** – both digital health companies – are collaborating on finding new ways to incorporate real-world data into clinical trials.

- **MERCK KGaA** in-licensed **Debiopharm's xevinapant** (Debio-1143), an IAPs inhibitor for locally-advanced squamous cell head and neck cancer, getting exclusive global development and commercialization rights.

- **NEUROCRINE BIOSCIENCES and TAKEDA's luvadaxistat (TAK-831, NBI-1065844)**, a DAAO inhibitor, missed the primary endpoint in the 256-patient Phase II INTERACT trial in schizophrenia, failing to improve the PANSS negative symptom factor score vs. placebo. However, there was an improvement in cognition, a secondary endpoint, so Neurocrine is not going up on luvadaxistat.

- **NOVARTIS' Kesimpta (ofatumumab)** – A 130-person study, presented at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum, found that 84% of MS patients and nurses preferred Kesimpta's self-administration with an injector pen over other MS drugs with different methods of administration (e.g., infusion).

- **NOXOPHARM's Veyonda (suppository idronoxil, NOX-66)** – New results from the 56-patient LuPIN trial in metastatic castration-resistant prostate cancer (mCRPC) showed that combining this S1P inhibitor with a radiopharmaceutical (^{177}lutetium-PSMA-617) led to a median overall survival of 19.7 months, a significant reduction in pain in 53% of men, and progression-free survival of 7.5 months.

- **ON TARGET LABORATORIES' pafolacianine sodium injection** – The FDA accepted an NDA and granted priority review for this IV fluorescent marker – a near-infrared dye combined with a ligand – for use in helping to identify ovarian cancer cells during resection surgery.

- **OVID THERAPEUTICS' soticlestat (TAK-935, OVA-935)** – Takeda bought back the global rights to this CH24H inhibitor for developmental and epileptic encephalopathies, including Dravet syndrome and Lennox-Gastaut syndrome, from Ovid, which licensed the drug from Takeda in 2017.

- **PFIZER** is partnering with **Iktos**, which will create an artificial intelligence-based chemical research solution for use in discovery programs.

- **PRESAGE BIOSCIENCES** has two new collaborations on use of its cancer testing platform: **Merck MSD** and **Maverick Therapeutics**.

- **SCYNEXIS' Brexafemme (ibrexafungerp)** – The company partnered with **Amplity Health** to get help with the launch of this treatment for vulvovaginal candidiasis if and when the drug is approved by the FDA. The PDUFA date is June 1, 2021. If approved, this would be the first new antifungal class in >20 years and the first non-azole treatment specifically for vaginal yeast infections.

- **SYNEOS HEALTH** extended its partnership with **Protocol First**, a research software provider, on ways to speed up clinical trials.

- **TAKEDA** is divesting four diabetes drugs sold in Japan to **Teijin Pharma**: Nesina (alogliptin), Liovel (alogliptin + pioglitazone), Inisync (alogliptin + metformin), and Zafatek (trelagliptin).

- **THERMO FISHER SCIENTIFIC** bought **Mesa Biotech**, a point-of-care diagnostic test developer.

- **UNITED THERAPEUTICS' Trevyent (treprostinil)** – The company is halting development of this treatment for pulmonary arterial hypertension (PAH).

- **VERISTAT** bought **SQN Clinical**, a European specialty contract research organization (CRO).

- **W.R. GRACE** is buying **Albemarle**'s Fine Chemistry Services business.

NEWS IN BRIEF

AMGEN

- Is buying **Five Prime Therapeutics**, which will give it bemarituxumab, an anti-FGFR2b antibody for gastric cancer.

- **Blincyto (blinatumomab).** Two studies, both published in ***JAMA***, offered mixed results for this BiTE in pediatric relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL). One trial showed an increase in event-free survival, but the other failed to show an increase in disease-free survival.

LILLY

- **and INCYTE's Olumiant (baricitinib).** This oral JAK inhibitor met the primary endpoint in the 546-patient Phase III BRAVE-AA2 trial in alopecia areata, with both doses (2 mg and 4 mg) significantly improving scalp hair regrowth vs. placebo at Week 36.

- **Tirzepatide**, a once-weekly GIP/GLP-1 agonist, lowered HbA_{1c} and body weight significantly better than Novo Nordisk's Ozempic (semaglutide) in the 1,879-patient, 40-week Phase III SURPASS-2 trial in Type 2 diabetes, with HbA_{1c} reductions of 2.09-2.46% vs. 1.86%), body weight (-8.5% to -13.1% vs. -6.7%). HbA_{1c} <5.7% was achieved by 51% of high-dose tirzepatide patients vs. 20% of semaglutide patients.

MERCK MSD

- **Gefapixant.** The FDA accepted an NDA for this P2X3 receptor antagonist for refractory chronic cough (RCC) or unexplained chronic cough (UCC) in adults. The PDUFA date is December 21, 2021.

- **Keytruda (pembrolizumab).** Merck withdrew the indication for this PD-1 inhibitor in metastatic small cell lung cancer which last year failed to show a survival benefit in the required confirmatory trial.

PHILIPS

- **Ambient Experience.** At the European Congress of Radiology 2021 virtual conference, Philips announced the 2,000th installation – in Munster, Germany – of this clinical environment design program, aimed at improving the patient and staff experience and reducing stress and anxiety when patients undergo radiology exams. The program allows adults to choose lighting, video, and sound during scans.

- **Disney.** Philips announced a collaboration with Disney to relax children age 4-12 undergoing MRI scans. Children can choose modified Disney character loops to watch on the exam room wall as well as inside the machine.

- **Covid-19.** Philips reported that the Covid-19 pandemic is creating challenges for radiologists: radiology exams with advanced modalities increased by 43% in the past year, and 45% of radiologists reported symptoms of burnout.

REGULATORY NEWS

Regulatory tidbits

- **Bundling** – A RAND study, published in ***Health Affairs***, found that bundling can result in significant savings for both health insurers and patients. In one private payor program studied, the cost was reduced by an average of 10.7% ($4,229) for spinal fusion, total knee and hip replacements, and bariatric weight loss procedures.

- **Covid-19**
  - The Centers for Medicare and Medicaid Services (CMS) is requiring group health plans to cover Covid-19 testing without cost sharing, even if people do not have symptoms, suspected exposure, or prior authorization. The guidance requires point-of-care testing at local and state sites. But coverage of test for employment purposes is ***not*** required.
  - The FDA issued guidance for manufacturers on specifications for glass vials and stoppers used to deliver sterile drug products.

- **FDA inspections** – The Government Accountability Office (GAO) warned that the FDA inspection backlog (>1,000) is likely to grow over time. The GAO also criticized the FDA's practice of giving foreign sites 12 weeks notice of an inspection, which raises questions about whether foreign inspections are equivalent to (as tough as) inspections of U.S. facilities.

- **Home care** – **Amazon Care**, **Intermountain Healthcare**, and others formed a coalition, Moving Health Home, to push for CMS to make changes to its reimbursement for home care.

- **One Medical**, a concierge medical service, is being investigated by the House Select Subcommittee on the Coronavirus Crisis after National Public Radio (NPR) reported that it administered Covid-19 vaccinations to rich clients who did not meet the criteria for vaccine eligibility.

- **Organ donors** – A bipartisan bill was introduced that would promote living organ donations by: prohibiting denial of coverage, designating it as a serious health condition, and requiring the Department of Health and Human Services (HHS) to update educational materials. This isn't the first time similar legislation was introduced but previous attempts failed to get passed.

- **Pelvic mesh lawsuits** – A New Jersey appeals court overturned jury verdicts totaling ~$83 million in two separate lawsuits against Becton Dickinson/C.R. Bard and Johnson & Johnson/Ethicon over pelvic mesh, saying the trial judge was wrong not to allow the jury to know that the companies' products had 501(k) clearance. Both cases were sent back to state court for retrial.

- **Telehealth**
  - Rep. Anna Eshoo (D-CA), chair of the House Health Subcommittee, said she supports making Medicare coverage of telehealth permanent – which requires Congressional action. However, Rep. Frank Pallone, Jr. (D-NJ), chairman of the House Energy and Commerce Committee said he is concerned this would lead to overutilization of healthcare service as well as fraud and abuse.
  - The HHS Office of the Inspector General (OIG) is conducting at least 7 different national investigations of telemedicine services and healthcare providers that have been billing for telehealth since the start of the Covid-19 pandemic.

FDA approvals/clearances

- **ASENSUS SURGICAL's Senhance** – This surgical robot was granted expanded clearance for use in general surgery. (*NOTE: Asensus used to be TransEnterix.*)

- **CONTROLRAD's ControlRad Select**, a set of add-on x-ray filters and image-processing algorithms, was cleared for use to reduce unnecessary radiation exposure.

- **FUSION ROBOTICS'** 3D imaging robotic targeting and navigation system was granted 510(k) clearance for use during spinal surgery.

- **KEMPHARM's Azstarys (serdexmethylphenidate, KP-415)** was approved as a once-daily treatment for attention-deficit/hyperactivity disorder (ADHD). It will be commercialized by **Corium**.

- **MEMIC INNOVATIVE SURGERY's Hominis Surgical System**, a robotically-assisted surgical device (RASD) to help facilitate transvaginal hysterectomy, was granted de novo approval. It has a small footprint and 360 degree articulation.

- **NEUROLIEF's Relivion**, a non-invasive neuromodulation system for treating migraines, was cleared for use.

- **ORIGAMI SURGICAL's StitchKit** – Three new types of sutures for this robotic surgery platform were granted 510(k) clearance.

- **PERIMETER MEDICAL IMAGING's Optical Coherence Tomography (OCT) platform**, a point-of-care OCT for use during surgical procedures, was granted 510(k) clearance.

- **PFIZER's Lorbrena (lorlatinib)** was granted expanded approval to include first-line treatment of ALK+ non-small cell lung cancer (NSCLC) – and the accelerated approval was converted to full approval.
- **QUIBIM's qp-Prostate**, an artificial intelligence-run MRI solution to aid in early detection of prostate cancer, was granted 510(k) clearance.
- **ROCHE's Actemra (tocilizumab)** was granted expanded approval to include use to slow the rate of decline in pulmonary function in adults with systemic sclerosis-associated interstitial lung disease (SSc-ILD). This is the first biologic approved to treat SSc-ILD.
- **VETEX MEDICAL's ReVene**, a thrombectomy catheter for clearing clots from peripheral vessels, was granted 510(k) clearance.
- **VYERA PHARMACEUTICALS** was sued by Blue Cross and Blue Shield of Minnesota, which accused the company and two former executives of intentionally monopolizing the market to raise the price of its toxoplasmosis drug, Daraprim (pyrimethamine), by preventing generic drug companies from obtaining ingredients and samples required for them to produce generic pyrimethamine.

FDA recalls/warnings

- **Covid-19**
  - The FDA and the Federal Trade Commission (FTC) sent a warning letter about fraudulent Covid-19 product claims to **Ageless Global**.
  - **KDunn and Associates** (dba HealthQuilt) and Kimberly Dunn, MD, PhD, received a warning letter for not complying with federal laws and regulations relating to protecting people participating in clinical trials of an investigational drug for Covid-19.
  - **Ivermectin (Merck MSD's Stromectol and others)** – The FDA warned consumers against using this antiparasitic off-label for Covid-19, saying it can interfere with other medications, cause serious reactions, and has not been shown to be effective.
- **MEDTRONIC's HeartWare Ventricular Assist Device (HVAD) Pump Implant Kits** were recalled (Class I) due to a delayed or failed restart after the pump is stopped. The FDA has received 29 complaints about this issue, including 19 serious injuries, 8 cases of patients who had a life-threatening event but recovered without long-term effects, and 2 deaths.
- **Registration certificates** – The FDA said companies that claim their device has an "FDA Registration Certificate" are lying and using deceptive advertising because the Agency does ***not*** issue certificates like that. Twenty-five companies got warning letters from the FDA about this.
- **Thermal imaging systems** – (also called telethermographic systems, infrared thermographs, thermal cameras, and "fever cameras") – The FDA warned that these systems may provide inaccurate readings of human body temperature when used improperly and have not been shown to be effective or accurate when used to take the temperature of multiple people at the same time and should not be used for mass temperature screenings.

European Regulatory News

- **Covid-19** – The European Medicines Agency (EMA) issued guidance clarifying what data will be needed to support approval of *modified* vaccines against SARS-CoV-2 variants. One requirement: the "adjusted" vaccine must use the same fundamental platform and technology as the original vaccine.
- **GUARDANT HEALTH's Guardant360**, a companion diagnostic liquid biopsy test for solid cancers, was granted a CE Mark.
- **MASIMO's Rad-G with Temperature**, a pulse oximeter that also measures temperature, was granted a CE Mark.

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

- **KYOWA KIRIN's Poteligeo (mogamulizumab)** – NICE rejected routine use of this antibody to treat mycosis fungoides and Sézary syndrome in the National Health Service (NHS) in England and Wales, saying that the clinical evidence is uncertain because it was studied in a trial in comparison to vorinostat (Merck MSD's Zolinza), an HDAC inhibitor which is neither approved nor used in the U.K.
- **LILLY's Olumiant (baricitinib)** – NICE recommended use of this oral JAK inhibitor to treat moderate-to-severe atopic dermatitis in patients who have not responded to ≥1 systemic immunosuppressant – and after Lilly agreed to an undisclosed discount.
- **REWALK ROBOTICS' ReStore Soft Exo-Suit** – At a NICE MedTech Innovation Briefing, experts discussed the potential for this robotic device to assist individuals with lower limb disabilities, so watch for a NICE decision on this device soon.

Regulatory news from other countries

- ***Canada.***
  - **ABBOTT's FreeStyle Libre**, a continuous glucose monitor, was granted expanded approval by Health Canada for use in pregnant women with or without diabetes in hospitals and professional healthcare settings.
  - **MISONIX's neXus Ultrasonic Surgical System** was cleared for use by Health Canada.
- ***China.*** **WUXI ADVANCED THERAPIES** bought **Oxgene**.

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 27	**Protalix BioTherapeutics and Chiesi's pegunigalsidase alfa** (PRX-102) for Fabry disease	PDUFA date *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*
2021 Events		
March 8	Patient-focused drug development for **vitiligo**	FDA virtual public meeting
March 10	University of California San Francisco presentation on applying what has been learned from **Covid-19** to clinical practice	FDA webcast
March 20	**FibroGen and AstraZeneca's roxadustat** for anemia of chronic kidney disease	PDUFA date *Extended by FDA from December 20, 2020* **and likely to be delayed again because the FDA now plans (but has not yet scheduled) an advisory committee review**
March 23	Benefits and risks of **dermal fillers**	FDA's General and Plastic Surgery Devices Advisory Committee virtual meeting
March 23	Roadmap to 2030 for new drug evaluation in **older adults**	FDA virtual public workshop
March 24-25	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	FDA's Arthritis Advisory Committee, meeting jointly with the Drug Safety and Risk Management Advisory Committee *This virtual meeting is unusual in that it will last 1.5 days*
March 26	**Covid-19 vaccines**	European Medicines Agency virtual public meeting
March 27	**Bristol-Myers Squibb and bluebird bio's idecabtagene vicleucel** (ide-cel, bb2121), a CAR T therapy for relapsed/refractory multiple myeloma	PDUFA date
March 29-30	The risk of **nitrosamine contamination** in drugs	FDA virtual workshop
March 30-31	**Oncology** drug development	FDA virtual workshop
April 14-16	**Biostatistics forum** to discuss statistical issues related to drugs and biologics	FDA virtual joint meeting with the Drug Information Agency (DIA)
April 15	**CellTrans' donislecel** for Type 1 diabetes	FDA's Cellular, Tissue, and Gene Therapies 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 14	**Apellis Pharmaceuticals' pegcetacoplan** for treating PNH	PDUFA date
May 18	**Sanofi's avalglucosidase alfa** for Pompe disease	PDUFA date
May 20	**Bristol-Myers Squibb's Opdivo** (nivolumab) – expanded approval as adjuvant therapy for resected esophageal or gastroesophagel junction cancer	PDUFA date
May 21	**ADC Therapeutics' loncastuximab tesirine** for relapsed/refractory DLBCL	PDUFA date
May 25	**Bristol-Myers Squibb's Opdivo** (nivolumab) – expanded approval for use in combination with chemotherapy as a first-line treatment for gastric cancer	PDUFA date
May 30	**Kadmon's belumosudil** for chronic graft-versus-host disease after hematopoietic stem cell transplant	PDUFA date
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 21	**Incyte's topical ruxolitinib** to treat atopic dermatitis	PDUFA date
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 2	**Provention Bio's teplizumab** (PRV-031) for preventing/delaying clinical Type 1 diabetes	PDUFA date
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

021 FDA Advisory Committees and Other Regulatory Dates of Interest *RED are new since last week*		
Date	**Topic**	**Committee/Event**
August tba	**Pfizer's TicoVac** for tick-borne encephalitis	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
October tba	**Pfizer and OPKO Health's somatrogon** for growth hormone deficiency	PDUFA date
October 18	**BeiGene's Brukinsa** (zanabrutinib) – expanded approval to treat Waldenström's macroglobulinemia	PDUFA date
December 21	**Merck MSD's gefapixant** for refractory chronic cough	PDUFA date