TRENDS-in-MEDICINE

July 26, 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: Remember that most coronavirus news is being reported primarily in separate Coronavirus Update bulletins. Subscribe to ***Trends-in-Medicine*** for coverage of the **American Society of Retina Specialists** (ASRS) virtual meeting.

Be careful, be safe, and be well.

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

- ✓ CYMABAY THERAPEUTICS' seladelpar – The FDA lifted the clinical hold on trials of this PPARδ agonist in NASH and PBC.
- ✓ Drug prices – President Trump signed four executive orders aimed at lowering drug prices.
- ✓ MODERNA's mRNA-1273 – **Arbutus Biopharma** won a patent ruling on this investigational Covid-19 vaccine.
- ✓ **Positive trial news:**
  - AMPLYX PHARMACEUTICALS' fosmanogepix – in invasive fungal infections caused by *Candida*.
  - BIOXCEL THERAPEUTICS' BXCL-501 – in both schizophrenia and bipolar disorder.
  - INCYTE and NOVARTIS' Jakafi (ruxolitinib) – in graft-versus-host disease.
  - ROCHE's Port Delivery System (ranibizumab, PDS) – in wet AMD.
  - UCB's bimekizumab – in moderate-to-severe plaque psoriasis.
- ✓ **Negative trial news:**
  - ACADIA PHARMACEUTICALS' Nuplazid (pimavanserin) – in major depressive disorder (MDD).
  - Dexmedetomidine (Pfizer/Hospira's Precedex and generics) – in preventing atrial fibrillation in cardiopulmonary bypass.
  - GENFIT's elafibranor – in NASH.

SHORT TAKES

- ABBOTT's Synthroid (levothyroxine) and generics – A new trial found that giving this thyroid medication to patients with subclinical hypothyroidism did not improve cardiac function in patients with an acute myocardial infarction.
- ACADIA PHARMACEUTICALS' Nuplazid (pimavanserin) – In preliminary Phase III data in major depressive disorder (MDD), this atypical antipsychotic – as adjunctive treatment to an antidepressant – missed the primary endpoint, failing to significantly improve depression. Acadia is abandoning development for MDD.

- AMAG PHARMACEUTICALS' ciraparantag (aripazine), a reversal agent for direct oral anticoagulants (DOACs) and low molecular weight heparin (LMWH), was exclusively licensed to **Norgine** for Europe, Australia, and New Zealand.

- AMPLYX PHARMACEUTICALS' fosmanogepix, an antifungal, met the primary endpoint in an open-label, 14-day, 21-patient Phase II trial in first-line treatment of invasive fungal infections caused by *Candida*, with significantly more patients achieving treatment success (*Candida* clearance from blood cultures) vs. placebo.

- BIOFOURMIS and **Chugai** are partnering on development of a digital solution for objectively assessing endometriosis-associated pain.

- CERAPEDICS' P-15L – The FDA approved a reduction in the number of patients in the ASPIRE investigational device exemption (IDE) trial of this i-Factor peptide-enhanced bone graft from 364 to 270.

- CYMABAY THERAPEUTICS' seladelpar – The FDA lifted the clinical hold imposed in November 2019 on all three investigational ongoing Phase II trials for this PPARδ agonist – in non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and primary sclerosing cholangitis (PSC) – after independent experts concluded there was no clinical, biochemical, or histological evidence of drug-related liver injury.

- Dexmedetomidine – The results of the 794-patient DECADE trial, published in ***The Lancet***, showed that giving this α2-adrenergic receptor (α2-AR) agonist (Pfizer/Hospira's Precedex or a generic) perioperatively had no effect on postoperative new-onset atrial fibrillation or delirium in cardiac surgery patients with cardiopulmonary bypass.

- G1 THERAPEUTICS' lerociclib, an oral CDK4/6 inhibitor, was exclusively licensed to **EQRx** for the U.S., Europe, and Japan.

- GENFIT's elafibranor – The Phase III RESOLVE-IT trial of this PPARα/δ agonist in NASH failed, and development for NASH was discontinued, but elafibranor is still being investigated for PBC.

- GILEAD SCIENCES bought 49.9% of **Tizona Therapeutics**, which is developing TTX-080, a first-in-class immunotherapy for cancer.

- GLAXOSMITHKLINE bought 10% of **CureVac**, which is developing an mRNA vaccine for Covid-19.

- Imaging – A study by researchers at University Hospitals Cleveland Medical Center/Case Western Reserve measured the impact of Covid-19 on imaging volume. From April 7-13, 2020, imaging volume dropped 55% overall: -68% outpatient, -48% emergency department, -31% inpatient, -93% mammograms, -61% nuclear medicine scans.

- INCYTE and NOVARTIS' Jakafi (ruxolitinib) met the primary endpoint in the Phase III REACH3 trial in graft-versus-host disease, showing superior overall response rate at Week 24 vs. best available therapy. This JAK inhibitor also met both key secondary endpoints.

- IQVIA is collaborating with **JDRF** to use non-identified patient-level real-world data and analytics to address unmet needs in Type 1 diabetes.

- LEO PHARMA's orismilast, an investigational PDE4 inhibitor for psoriasis (oral) and atopic dermatitis (topical), was sold to Union Therapeutics, which is renaming it UNI-500.

- MODERNA's mRNA-1273 – Moderna lost a Patent Trial and Appeal Board ruling in a patent dispute with **Arbutus Biopharma** over the nanoparticle technology used in this investigational Covid-19 vaccine. *The fight isn't over, but this round went to Arbutus.*

- NEXELIS bought **AIT Bioscience**, a contract research organization (CRO).

- NOVARTIS' adriforant (ZPL-389) – Development of this oral H4 receptor antagonist for atopic dermatitis was discontinued.

- OSMOTICA PHARMACEUTICALS' Ontinua ER (arbaclofen) – The FDA accepted for review a new drug application (NDA) for this GABAB agonist to treat multiple sclerosis spasticity.

- PFIZER and BIONTECH's BNT-162 – The U.S. government agreed to pay $1.95 billion for up to 100 million doses of this Covid-19 vaccine if and when it is FDA approved. That's $20/dose. And the government optioned another 500 million doses.

- RADIUS HEALTH's elacestrant, an oral selective estrogen receptor degrader (SERD) in development to treat advanced ER+/HER2-negative breast cancer, was exclusively licensed to **Menarini**, which will be responsible for worldwide commercialization if the Phase III EMERALD trial is successful and the drug gets regulatory approval.

- SAREPTA THERAPEUTICS and ROCHE's SRP-9001 was granted fast track status and rare pediatric disease (RPD) designation by the FDA as a dystrophin gene therapy for treating Duchenne muscular dystrophy.

- STRYKER got a $225 million contract from the U.S. Defense Logistics Agency to provide patient monitoring and capital equipment systems to the U.S. military.

- UCB's bimekizumab – This IL-17A/F inhibitor met the primary endpoint in the Phase IIIb BE RADIANT trial in moderate-to-severe plaque psoriasis, showing superiority to Novartis' Cosentyx (secukinumab) on PASI-100 at Week 16. All key secondary endpoints were also met.

- ZEALAND PHARMA's dasiglucagon – A 10-patient study, published in the journal ***Diabetes***, found that postprandial hypoglycemia was improved in patients with a recent Roux-en-Y gastric bypass who took this glucagon analog vs. placebo.

Very early research news

- Atopic dermatitis – In research, published in the ***Journal of Allergy and Clinical Immunology***, Emma Guttman-Yassky, MD, PhD, a dermatologist at Mount Sinai, identified a single gene biomarker that can differentiate between atopic dermatitis and psoriasis using adhesive tape strips. This could become a non-invasive alternative to skin biopsy to correctly and accurately distinguish between these two inflammatory skin diseases.

NEWS IN BRIEF

BIOXCEL THERAPEUTICS' BXCL-501

This sublingual thin film formulation of dexmedetomidine met the primary and secondary endpoints in two Phase III trials:

- The SERENITY-I trial in schizophrenia, with 67% of patients on 120 µg and 87% of patients on 180 µg achieving >40% reduction in PEC score at 2 hours.

- The SERENITY-II trial in bipolar disorder, with 69% and 85% of patients responding.

ROCHE

- Expanded its partnership with **PicnicHealth** to generate scientific insights from real-world patient data.

- Is collaborating with **Jnana Therapeutics** on discovery and preclinical development of solute carrier (SLC) transporter drugs to treat immunological and neurological diseases.

- **Port delivery system (ranibizumab, PDS).** Detailed results of the Phase III ARCHWAY trial of this refillable port delivery system (PDS) for this anti-VEGF to treat wet age-related macular degeneration (AMD) showed that 98.4% of PDS patients were able to go 6 months without needing additional treatment while having vision outcomes equivalent to monthly intravitreal injections of Lucentis.

- RG-6217. Development of this Phase I antiviral for hepatitis B virus (HBV) has been discontinued.

REGULATORY NEWS

Regulatory tidbits

- 510(k) devices. The FDA added five types of Class II medical devices – reproduction accessories, reproductive media, instruments designed for press-fit osteochondral implants, interactive rehabilitation exercise devices, and therapeutic pelvic floor massagers – that will be exempted from the 510(k) requirements.

- Cannabis. The FDA issued draft guidance to encourage cannabis-related clinical research.

- Covid-19
  - The FDA relaxed regulations for producing **viral transport media** required for Covid-19 tests.
  - The Department of Health and Human Services (HHS) officially extended the public health emergency designation for Covid-19.
  - QUIDEL's Sofia SARS Antigen FIA tests – HHS is buying 750,000 of these tests along with 2,000 instruments to run them, to use in detecting Covid-19 in nursing homes.

- Drug prices. President Trump signed four executive orders:
  - Requiring Federal Community Health Centers to pass along their discounts on insulin and EpiPens (epinephrine) to consumers. The President said the price of insulin will come down to "pennies a day."
  - Allow states to safely import prescription drugs from Canada and other countries where they cost less.
  - Prevent middlemen (pharmacy benefit managers) from "bilking" consumers.
  - Medicare will be required to purchase drugs at the same price as other advanced countries.

  President Trump said the drug companies are coming to a meeting at the White House on July 28, 2020, to discuss implementation of these orders. He said the Medicare executive order for "favored nation" status will be put on hold until August 24, 2020, to give pharmas time to lower prices enough that this order will not be needed.

- **Drug shortages.** Premier urged the FDA and the Drug Enforcement Administration (DEA) to adopt a number of permanent reforms and regulatory waivers to prevent drug shortages, including:
  - FDA – Allow 503B compounding facilities to continue producing specific drugs that are not on the drug shortage list based on specific criteria, such as short-term or regional shortages or demand surges.
  - FDA – Permanently abandon the geographical limitation (the "one-mile radius" provision) for hospital compounding.
  - FDA – Adopt a time-based standard rooted in scientific evidence for sterility and stability of compounded products.
  - DEA – Overhaul the quota allocation process.
- **Opioids.** The FDA is now requiring that labeling for opioids be updated to recommend that, as a routine part of prescribing these painkillers, doctors should discuss the availability of naloxone with patients and caregivers.
- **Regenerative medicine.** The FDA extended its enforcement discretion policy for certain human cell, tissue, and cellular and tissue-based products (HCT/Ps) because of Covid-19, giving manufacturers and potential sponsors an additional six months to determine if they need to submit an investigational new drug (IND) or marketing application and to prepare applications. This only applies to products that don't raise significant safety concerns.
- **Right to try.** The FDA issued a proposed rule that would require sponsors and manufacturers to provide the FDA with an annual summary of any investigational drug provided to eligible patients under the Right to Try Act.

FDA approvals

- **ABBOTT's Patient Controller**, an iPhone app for managing the company's implanted neuromodulation devices, was cleared for use.
- **ASTRAZENECA's Breztri Aerosphere (PT-010, budesonide + glycopyrrolate + formoterol fumarate)** was approved to treat chronic obstructive pulmonary disease (COPD).
- **BECKMAN COULTER's PK7400 Automated Microplate System** and its reagents were granted 510(k) clearance for use by blood banks, plasma centers, and reference labs.
- **BECTON DICKINSON's BD Onclarity HPV Assay** was granted supplemental premarket approval for identifying and detecting 14 high-risk HPV types in one analysis as well as providing genotyping information.
- **BOSTON SCIENTIFIC's Watchman FLX**, a next-generation left atrial appendage (LAA) closure device, was cleared for use for reducing the risk of stroke in patients with non-valvular atrial fibrillation.
- **CANON MEDICAL's clear-IQ engine**, image reconstruction technology that uses artificial intelligence, was granted 510(k) clearance.
- **CHANNEL MEDSYSTEMS' Cerene**, a next-generation cryotherapy device for treating heavy menstrual bleeding, was cleared for use.
- **FUJIFILM's Eluxeo**, an endoscopic surgical system, was granted 510(k) clearance.
- **FX Shoulder**'s new titanium nitrate-coated humeral head and glenosphere shoulder implants were granted 510(k) clearance.
- **GILEAD SCIENCES/KITE PHARMA's Tecartus (brexucabtagene autoleucel, KTE-X19)** was approved as the first CAR T therapy for treating adults with relapsed/refractory mantle cell lymphoma.
- **GRÜNENTHAL/AVERITAS PHARMA's Qutenza (capsaicin)**, a non-opioid patch for treating neuropathic pain associated with diabetic peripheral neuropathy of the feet, was cleared for use.
- **INTEGRA LIFESCIENCES' CUSA (Clarity Ultrasonic Surgical Aspirator System)** was granted 510(k) clearance for use during neurosurgery for resection of soft-to-firm tumors.
- **JAZZ PHARMACEUTICALS' Xywav (calcium, magnesium, potassium, and sodium oxybates)** was approved to treat daytime sleepiness in patients with narcolepsy.
- **MICRO-X's Rover**, a mobile x-ray system designed for military medical facilities, was granted 510(k) clearance.
- **ORTHOFIX MEDICAL's JuniOrtho**, a fixation system for use in treating pediatric deformity and lower limb trauma reconstruction, was cleared for use.
- **QUEST DIAGNOSTICS' SARS-CoV-2 RNA test** was granted emergency use authorization (EUA) for used in pooled Covid-19 sampling.
- **THERMO FISHER SCIENTIFIC's ImmunoCAP Specific IgE alpha-Gal Allergen Component test**, a blood-based test that detects sensitization to alpha-gal carbohydrate in red meat and the risk of an anaphylactic reaction, was cleared for use.

FDA recalls/warnings

- **Covid-19** – The FDA and the Federal Trade Commission (FTC) issued a joint warning letter to 21st Century Laser-Med Pain & Regenerative Medicine Institute (d/b/a Create

Wellness Clinics) for offering unapproved, unlicensed, uncleared, and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of Covid-19.

- FRESENIUS KABI's dexmedetomidine hydrochloride – Two lots were recalled due to cross contamination with lidocaine.
- LUMINEX's xMAP SARS-CoV-2 multi-antigen IgG assay was granted an EUA.
- MHR BRANDS/INHE MANUFACTURING's hemp oil products were recalled due to the potential for excess lead.
- Naloxone – The FDA issued a safety alert, requiring opioid manufacturers to add new recommendations about naloxone to their label prescribing information.
- STASON PHARMACEUTICALS, a California contract development and manufacturing organization (CDMO), got a warning letter for failing to secure data used to determine the strength of its drugs.

European Regulatory News

- ALLERGAN's Rayoqta (abicipar pegol) – The company withdrew the marketing application for this anti-VEGF to treat wet AMD.
- ASTRAZENECA's Calquence (acalabrutinib) – The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended approval to treat chronic lymphocytic leukemia (CLL).
- BLUEPRINT MEDICINES' Ayvakyt (avapritinib) – CHMP recommended approval to treat adults with unresectable/metastatic gastrointestinal stromal tumors (GIST) with a PDGF receptor alpha D842V mutation.
- BRISTOL-MYERS SQUIBB's Reyataz (atazanavir sulphate) – CHMP recommended adding a new ***contraindication*** against use with lomitapide.
- CENTUS BIOTHERAPEUTICS EUROPE's Equidacent (bevacizumab) – a biosimilar of Roche's Avastin – CHMP recommended approval to treat a number of cancers, including colon, rectum, breast, non-small cell lung, renal cell, epithelial ovarian, fallopian tube, primary peritoneal, and cervical.
- Dexamethasone – The EMA has started a review of this steroid as a treatment for Covid-19 patients on respiratory support.
- GALAPAGOS and GILEAD SCIENCES' Jyseleca (filgotinib) – CHMP recommended approval of this JAK1 inhibitor to treat adults with moderate-to-severe rheumatoid arthritis.
- GLAXOSMITHKLINE's Blenrep (belantamab mafodotin) – CHMP recommended approval to treat relapsed/refractory multiple myeloma.
- HERON THERAPEUTICS' Zynrelef (bupivacaine + meloxicam) – CHMP recommended approval to treat postoperative pain.
- INSMED's Arikayce liposomal (amikacin) – CHMP recommended approval to treat non-tuberculous mycobacterial lung infections in non-cystic fibrosis patients.
- NEUMODX MOLECULAR's NeuMoDx HPV assay, which detects HPV 16 and 18 in addition to 13 other types, was granted a CE Mark.
- NORLASE's Leaf laser was granted a CE Mark for treating glaucoma and retinal diseases.
- NOVARTIS' Adakveo (crizanlizumab) – CHMP recommended approval to prevent recurrent vaso-occlusive crises in sickle cell disease patients.
- ORTHOFIX MEDICAL's JuniOrtho, a fixation system for use in treating pediatric deformity and lower limb trauma reconstruction, was granted a CE Mark.
- OTSUKA PHARMACEUTICAL's Abilify MyCite (aripiprazole with an ingestible sensor) – The company withdrew its marketing application for treating schizophrenia and bipolar disorder with this antipsychotic.
- PANEXCELL CLINICAL LABORATORIES – CHMP recommended the marketing authorization for generic drugs tested by this company in Mumbai, India, be ***suspended*** after inspectors found irregularities in bioequivalence studies.
- PHASE SCIENTIFIC's Phasify, a viral RNA extraction kit, was granted a CE Mark.
- RECORDATI's Fortacin (lidocaine + prilocaine) – CHMP recommended removing the requirement for a prescription for this painkiller.
- STEMLINE THERAPEUTICS' Elzonris (tagraxofusp) – CHMP recommended ***against*** approval of this treatment for blastic plasmacytoid dendritic cell neoplasm.
- SWEDISH ORPHAN BIOVITRUM's (Sobi's) Gamifant (emapalumab) – CHMP recommended ***against*** approval for treating primary hemophagocytic lymphohistiocytosis in children age <18.
- Water quality – The EMA issued new guidance on pharmaceutical water quality.
- ZIMMER BIOMET recalled a batch of polyethylene orthopedic implants for knees, hips, and extremities due to potentially elevated endotoxin levels.

Regulatory news from other countries

■ *China.*

- ASSEMBLY BIOSCIENCES and **BeiGene** are collaborating in China on three of Assembly's investigational core inhibitors – ABI-H0731, ABI-H2158, and ABI-H3733 – for treating hepatitis B virus.
- JW THERAPEUTICS is buying **Syracuse Biopharma**, the Chinese subsidiary of Eureka Therapeutics.

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2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
July 21 (est.)	**Seattle Genetics and GlaxoSmithKline's belantamab mafodotin**, an anti-BCMA for relapsed/refractory multiple myeloma	PDUFA date **No decision announced yet**
July 28	President Trump to meet with pharmaceutical company executives about his **executive orders designed to lower drug prices**	President Trump meeting at White House
July 29	Immediately-in-effect guidance on **coronavirus diagnostic tests**	FDA virtual Town Hall
July 30	**FDA hiring and retention** – interim assessment	FDA virtual public meeting
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
August 8	**Eagle Pharmaceuticals' Ryanodex** (dantrolene sodium) to treat heat stroke (resubmission)	PDUFA date **Postponed from July 8**
August 10 (est.)	**Bausch Health/Eton Pharmaceuticals' EM-100**, an eyedrop for treating ocular itchiness (resubmission)	PDUFA date
August 11	Independent third-party assessment of IND FDA-Sponsor Communication practices in **PDUFA VI**	FDA virtual public meeting
August 13	**Spinal device premarket review**	FDA virtual public workshop
August 17	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date *Postponed to November 16, 2020*
August 18-19	**Annual meeting**	Science Advisory Board to the National Center for Toxicological Research
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 Winlevi** (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 28	**CDER standard core sets** clinical outcome assessements and endpoints grant program	FDA public meeting *and* webcast
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. 28-29	Global summit on regulatory science: **Emerging Technologies**	FDA virtual summit **https://aralliance.org/gsrs/**
Sept. 29-30	Annual Scientific Computing Days: **Real-world evidence**	FDA and National Center for Toxicological Research (NCTR) *May be virtual*
September 30	**Patient-reported outcomes** (PROs) and medical device investigations	FDA virtual public meeting

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
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 16	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date *Postponed from August 17*
November 20	**Eiger BioPharmaceuticals' Zokinvy** (lonafarnib) for progeria and progeroid laminopathies	PDUFA date
November 25	**Revance Therapeutics' daxibotulinumtoxinA** for moderate-to-severe glabellar lines	PDUFA date
November 27	**Rhythm Pharmaceuticals' setmelanotide** for pro-opiomelanocortin deficiency obesity and leptin receptor deficiency obesity	PDUFA date
December tba	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	PDUFA date
December 3	**BioCryst Pharmaceuticals' berotralstat** (BCX-7353) for hereditary angioedema attacks	PDUFA date
December 20	**FibroGen and AstraZeneca's roxadustat** for anemia of chronic kidney disease	PDUFA date
December 20	**Myovant Sciences' Relumina** (relugolix) for advanced prostate cancer	PDUFA date
December 26	**Sumitomo Dainippon Pharma/Urovant Sciences' vibegron** for overactive bladder	PDUFA date
December 30	**Almirall and Athenex's tirbanibulin** (KX2-391, KX-01) for actinic keratosis	PDUFA date
January 20, 2021	**Merck MSD and Bayer's vericiguat** in HFrEF	PDUFA date