TRENDS-in-MEDICINE

March 15, 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: Subscribe to ***Trends-in-Medicine*** for coverage of the **Conference on Retroviruses and Opportunistic Infections** (CROI) virtual meeting.

There is so much coronavirus news that there will be a separate ***Trends-in-Medicine*** coronavirus **update bulletin** that will go to all ***Quick Takes*** readers as well. All major medical conferences and FDA meetings are canceled or postponed through the end of April, though a couple are going to try a virtual meeting. Many of the meetings in May are also already getting canceled/postponed. The bulletin also has an alphabetical list of meetings that are postponed, those offering virtual sessions, and those still scheduled.

Be careful, be safe, and be well.

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

✓ Coronavirus (Covid-19) – This is now a pandemic, countries are closing borders, some are locking down completely, and the outbreak is spreading in the U.S., with flights from Europe, the U.K., and Ireland as well as China banned as of midnight March 16. The FDA canceled all non-essential meetings, including advisory committees, through the end of April. At the latest count, there were 3,499 cases of Covid-19 in the U.S., with 63 deaths, a 1.8% fatality rate.

✓ **The positive trials** – only one this week: ZELIRA THERAPEUTICS' ZLT-101 in a small Phase Ib/IIa trial in chronic insomnia.

✓ **The negative trials:**

- ASTRAZENCA and MERCK MSD's Lynparza (olaparib) + cediranib in a Phase III trial in relapsed ovarian cancer.
- BRISTOL-MYERS SQUIBB and ABBVIE's Empliciti (elotuzumab) in a Phase III trial in multiple myeloma.
- MEDDAY PHARMACEUTICALS' MD-1003 in a Phase III trial in non-active progressive MS.
- PFIZER and MERCK KGAA's Bavencio (avelumab) in a Phase III trial in untreated head and neck cancer.
- UNUM THERAPEUTICS' ACTR-707 – A Phase I trial in non-Hodgkin's lymphoma was put on a partial clinical hold for a safety issue.

SHORT TAKES

■ ABBOTT's MitraClip – A U.K. court found that **Edwards Lifesciences' Pascal**, a trans-catheter mitral valve repair (TMVR) infringes two MitraClip patents. This means Pascal is likely to be enjoined in the U.K., though Edwards is expected to appeal.

- ACCELERON PHARMA's ACE-083 – The company abandoned development after disappointing results in a Phase II trial in Charcot-Marie-Tooth disease. ACE-083 met the primary endpoint, significantly increasing total muscle volume vs. placebo, but the difference didn't significantly improve quality of life or function.

- ALMIRALL and ATHENEX's tirbanibulin (KX2-391, KX-01) – The FDA accepted for review a new drug application (NDA) for this ointment, a dual Src kinase and tubulin polymerization inhibitor, as a treatment for actinic keratosis. The PDUFA date is December 30, 2020.

- ALTASCIENCES bought Alliance Contract Pharma.

- AMAZON reportedly is working on a cure (a vaccine) for the common cold – project "Grand Challenge."

- ASTRAZENCA and MERCK MSD's Lynparza (olaparib) + cediranib – a combination of a PARP inhibitor and a VEGFR inhibitor – missed the primary endpoint in the Phase III GY004 trial in platinum-sensitive relapsed ovarian cancer, failing to prolong progression-free survival (PFS) vs. platinum-based chemotherapy.

- BAUSCH HEALTH stopped online prescribing for skin medications at the Dermatology.com website. Before getting a prescription, users had to complete a virtual medical consultation through RxDefine.

- Breast cancer – Two separate studies, published in the *Annals of Oncology*, suggest that insulin-like growth factor-1 (IGF-1) plays a role in the development of breast cancer.

- BRISTOL-MYERS SQUIBB and ABBVIE's Empliciti (elotuzumab), an anti-SLAMF7 – combined with Revlimid (lenalidomide) and dexamethasone – missed the primary endpoint in the Phase III ELOQUENT-1 trial, failing to prolong PFS vs. Rev/dex alone in multiple myeloma.

- CHEMTEST – Researchers in Argentina have developed a diagnostic kit that can diagnose dengue fever in 10 minutes, and Chemtest will produce the kits, which work like a pregnancy test.

- GLAXOSMITHKLINE's Zofran (ondansetron) and generic ondansetron – A meta-analysis of 24 trials with 3,482 children, published in *Pediatrics*, found that this antiemetic was the most effective antiemetic tested in stopping vomiting and reducing hospitalizations vs. placebo in youths with acute diarrhea and gastroenteritis.

- Immunotherapy – A mouse study by Australian researchers, published in the journal *Cell*, suggests that a very old drug for treating psychosis, prochlorperazine (PCZ), may have a new use – boosting the efficacy of checkpoint inhibitors and other antibodies in cancer patients. The researchers combined PCZ with Pfizer and Merck KGaA's Bavencio (avelumab) and found the combination shrank tumors better than either drug alone. And a combination of PCZ and Lilly's Erbitux (cetuximab) also reversed treatment resistance better than either drug alone.

- IPSEN's Somatuline Autogel (lanreotide autogel) – The results of the PRESTO nurse-preference trial, presented virtually at the European Neuroendocrine Tumor Society (ENETS) conference and simultaneously published in *Advances in Therapy*, showed that nurses prefer this somatostatin analog for neuroendocrine tumors and acromegaly.

- JOHNSON & JOHNSON's JNJ-61186372, a bispecific antibody, was granted breakthrough therapy designation by the FDA as a treatment for metastatic non-small cell lung cancer (NSCLC) in patients with EGFR exon 20 insertion mutations.

- KALA PHARMACEUTICALS' Eysuvis (loteprednol etabonate, KPI-121) met both primary endpoints in the 901-patient STRIDE-3 trial – required by the FDA after the Agency rejected this dry eye drug in August 2019 – significantly reducing ocular discomfort severity overall and in the subgroup of patients with more severe ocular discomfort at Day 15. The drug also met the secondary endpoint, reduction in conjunctival hyperemia.

- Liquid biopsy – A 19-patient study by Fox Chase Cancer Center researchers, published in the *International Journal of Molecular Sciences*, suggests that genomic profiles identified through circulating free DNA (cfDNA) – liquid biopsies from blood – are an effective way to track response to breast cancer treatment.

- MEDDAY PHARMACEUTICALS' MD-1003, an oral biotin, missed the primary and secondary endpoints in a second Phase III trial, SPI2, in non-active progressive multiple sclerosis (MS), failing to significantly slow functional disability or its progression – endpoints that were met in a previous Phase III trial.

- MERCK MSD extended its immunomodulatory drug discovery program with Sutro Biopharma by an additional year.

- NOVARTIS' Gilenya (fingolimod) – MRI data from the Phase III PARADIGMS trial in pediatric multiple sclerosis found that fingolimod patients had less brain MRI disease activity and a slower annualized rate of brain atrophy vs. interferon beta-1a (Biogen's Avonex) at 2 years.

- NUVASIVE's Attrax Putty – A study, published in *Spine*, showed that this bone graft substitute is effective in aiding in fusion in instrumented thoracolumbar posterolateral lumbar fusions (55% vs. 52% for autograft).

- PEPTCELL's FLU-v – The results of a Phase IIb trial, published in the ***Annals of Internal Medicine***, found that a single dose of this adjuvanted flu vaccine offered prolonged protection against multiple flu strains. *If the results hold up, a new flu vaccine with different strains would not need to be produced each year.*

- PFIZER and MERCK KGAA's Bavencio (avelumab) – After an interim analysis, the Phase III JAVELIN Head and Neck 100 trial in untreated locally-advanced squamous cell carcinoma of the head and neck was halted for futility. The independent data monitoring committee found the trial was unlikely to show a significant improvement in PFS.

- RUBIUS THERAPEUTICS' RTX-134 – The company halted development of this investigational treatment for phenylketonuria (PKU) after determining the ongoing trial data were "uninterpretable" and is getting out of rare disease drug development to focus on cell therapies for oncology and autoimmune disorders.

- SIERRA ONCOLOGY's SRA-737 – U.K. researchers may have found a new use for this CHK1 inhibitor. In a study, published in the journal ***Cancer Research***, the researchers reported that combining it with a B-family polymerase inhibitor lead to insurmountable DNA damage that causes cancer cells to die.

- SYNEOS HEALTH – ***Reuters*** reported that this contract research organization (CRO) is up for sale.

- TAKEDA's Ninlaro (ixazomib), an oral proteasome inhibitor – in combination with Bristol-Myers Squibb/Celgene's Revlimid (lenalidomide) + dexamethasone – missed the primary endpoint in the Phase III TOURMALINE-MM2 trial in previously untreated multiple myeloma patients ineligible for stem cell transplant, failing to significantly prolong PFS vs. Revlimid/dexamethasone alone (35.3 months vs. 21.8 months).

- THERMO FISHER SCIENTIFIC is partnering with **Johnson & Johnson/Janssen** on development of an oncology companion diagnostic to identify patients for NSCLC trials.

- Triple-negative breast cancer (TNBC) – Vanderbilt-Ingram Cancer Center researchers reported in ***Science Translational Medicine***, that combining a BET inhibitor and a MEK inhibitor may be effective in TNBC patients, with MYCN a potential marker.

- UNUM THERAPEUTICS' ACTR-707 – A Phase I trial of this immunotherapy – in combination with Roche's Rituxan (rituximab), an anti-CD20 – in CD20+ B-cell non-Hodgkin's lymphoma was put on a partial clinical hold by the FDA – again – after a patient had a Grade 3 serious adverse event (a possible new malignancy) considered possibly related to the drug.

- ZELIRA THERAPEUTICS' ZLT-101 – The company reported that this medicinal cannabis met the primary endpoint in a 24-patient Phase Ib/IIa trial in chronic insomnia, significantly improving the insomnia severity index (ISI) score vs. placebo.

- ZYDUS CADILA is collaborating with **XOMA** to combine Zydus' IL-2 and XOMA's anti-IL-2. Zydus will have exclusive rights to the new combination immunotherapy in India, Brazil, Mexico, and other emerging markets, and XOMA has the rights elsewhere.

Very early research news

- Alzheimer's disease – Researchers at the University of California, San Francisco, reported in the journal ***Nature Medicine*** on a successful 400-patient study of the use of a ptau 181 blood test for diagnosing Alzheimer's disease.

- NSCLC – A study by Tulane University researchers, published in ***Science Advances***, identified a protein on tumor-derived extracellular vesicles that indicates if a NSCLC tumor is likely to metastasize, suggesting it might be used as a biomarker for development of a rapid, minimally-invasive test to help identify patients where more aggressive therapy could reduce mortality.

- Obesity – Researchers at the University of Pennsylvania have identified how Novo Nordisk's Saxenda (liraglutide 3 mg), a GLP-1 agonist for diabetes, causes patients to lose weight, and that could lead to a new diet drug. In data published in ***Science Translational Medicine***, the researchers showed that Saxenda's appetite suppressing effect is due to its action on a subset of neurons in the nucleus tractus solitarius (NTS) region of the brain.

- Schizophrenia – Through brain imaging, researchers at the University of Pennsylvania found that there are two kinds of schizophrenia – one with a reduction in grey matter (60% of patients studied), and another with normal grey matter volume (40% of patients studied). This could explain why antipsychotics don't work in some patients and/or it could lead to new therapies.

NEWS IN BRIEF

ASCENTAGE PHARMA's APG-2575

The company got approval from the FDA to start two single agent or combination trials of this oral selective Bcl-2 inhibitor in the U.S. for hematologic malignancies:

- A Phase Ib/II trial to treat relapsed/refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- A Phase Ib/II trial to treat Waldenström macroglubulinemia (the MAPLE-1 trial).

In addition, a Phase Ib trial in China was approved by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) in relapsed/refractory acute myeloid leukemia (AML).

REGULATORY NEWS

Regulatory tidbits

- Diabetes drugs. The FDA issued new draft guidance on recommendations for pharma on performance of safety assessments for new Type 2 diabetes drugs. The guidance calls for Phase III trials to enroll ≥500 patients with Stage 3/4 chronic kidney disease, 600 patients age 65, and 600 patients with established cardiovascular disease.
- Electrosurgical devices. The FDA issued 510(k) guidance for these devices and expanded their description. The guidance allows a device to have more than one use, provided one use involved tissue cutting or coagulation.
- Hand sanitizer. The FDA issued guidance on compounding of hand sanitizer by pharmacists during the coronavirus outbreak using approved ingredients.
- Healthcare information technology (HIT). As rules for health data access are phased in, the government plans no enforcement activity for the next six months. The Office of the National Coordinator for Health Information Technology (ONC) said most covered entities will have to be in compliance within 24 months, and electronic health information export capability has to be available within 36 months.
- Insulin.
  - A bill passed the Minnesota Senate that would require insulin makers to provide insulin supplies to uninsured residents or those who can't afford the treatments. The legislation also requires manufacturers to send insulin to pharmacies for use in emergency cases.
  - The Centers for Medicare and Medicaid Services (CMS) proposed a pilot program that would allow Medicare Part D plans and insulin makers to negotiate and cap Part D subscribers' copays at $35/month.
  - The Utah legislature approved a bill that would limit cost-sharing for insulin to $30/month unless insurers waive deductibles, put insulin in the lowest insurance cost tier, create a program that creates a discounted insulin program for state workers, and allow pharmacists to dispense insulin without prescription renewal in some cases.
- Pharmaceutical manufacturing. A bipartisan bill was introduced in the Senate by Sen. Bob Menendez (D-NJ) and Sen. Marsha Blackburn (R-TN) that would provide $100 million to support pharmaceutical manufacturing in the U.S.
- Tariffs. The U.S. gave 27 companies, including Cardinal Health and Medline Industries, an import tariff exemption for medical products coming from China.
- Topical drugs. The FDA issued draft guidance for topical drug developers on evaluation of contact dermatitis risk, urging drug companies to evaluate local skin reactions in clinical trials and to use static scales to measure the reactions.

FDA approvals/clearances

- AERIN MEDICAL's RhinAer Stylus, a non-surgical device for treating chronic rhinitis, was granted 510(k) clearance.
- BOEHRINGER INGELHEIM's Ofev (nintedanib), a TKI, was granted expanded approval to treat chronic fibrosing interstitial lung diseases (ILD) with a progressive phenotype. This is the first drug approved for patients with this type of lung disease.
- BRISTOL-MYERS SQUIBB's Opdivo (nivolumab) + Yervoy (ipilimumab) – This combination of a PD-1 inhibitor and a CTLA4 inhibitor was granted accelerated approval to treat hepatocellular carcinoma patients previously treated with sorafenib (Bayer's Nexavar).
- FLUIDDA's Broncholab software, for helping to detect and track respiratory diseases, was cleared for use.
- KINEPICT HEALTH's Kinepict Medical Imaging Tool, software for better imaging of blood vessels, was granted 510(k) clearance.
- MEDACTA's Mecta-C Stand Alone, an anterior cervical fusion device for skeletally mature patients with degenerative disc disease, was cleared for use.
- NEUROPACE's RNS system, used to treat seizures in patients with epilepsy who have not responded to medication, was granted expanded MRI conditional labeling.

- ORTHO CLINICAL DIAGNOSTICS' Vitros BRAHMS, a procalcitonin assay for detecting bacterial infections like sepsis and acute bronchitis, was granted 510(k) clearance.
- ROCHE
  - **cobas SARS-CoV-2 Test** for detecting coronavirus was granted Emergency Use Authorization (EUA).
  - **CINtec PLUS Cytology Test**, a next-generation test – and the first biomarker-based test – for triaging women with HPV+/Pap-negative test results – to help diagnose cervical cancer.
- SOLITON's Generation II Rapid Acoustic Pulse (RAP) device, which uses technology licensed from MD Anderson Cancer Center, was granted 510(k) clearance for use in tattoo removal.
- TRANSENTERIX's Intelligent Surgical Unit (ISU) that enables machine vision capabilities on the Senhance Surgical System was granted 510(k) clearance.

FDA recalls/warnings

- Fecal transplants – The FDA issued a safety alert about the risk of serious/life-threatening adverse events with fecal microbiota from stool banks used for transplantation, warning about the transmission of pathogenic organisms. The FDA has had reports of 6 patients given a fecal transplant for *Clostridium difficile* who developed serious infections, with four of these patients requiring hospitalization.
- MEDTRONIC's HeartWare HVAD was recalled (Class I) because the design of this left ventricular assist device (LVAD) allows users to insert the battery charger adapter into the incorrect port, damaging the controller.
- SMITHS MEDICAL's LogiCal and HemoDraw Plus – An urgent field safety notice was issued for these closed blood sampling system sets because of inaccurate pressure readings and pressure shifts.

European Regulatory News

- European Medicines Agency (EMA)
  - Is holding all of its committee and working party meetings virtually through April.
  - Postponed or changed to virtual all meetings and events with stakeholders through April.
  - Is waiving fees for scientific advice applications from developers for coronavirus therapeutics or vaccines.
- ABBOTT's FlexNav delivery system, for use during transcatheter aortic valve replacement (TAVR) procedures using the company's Portico valve, was granted a CE Mark.
- CERTEST BIOTEC's ViaSure SARS-CoV-2 Real Time PCR Detection Kit, which will use Becton Dickinson's BD Max system, was granted a CE Mark.
- DIANOSIC's CAVI-T, an intranasal, low-pressure balloon used to stop post-operative and spontaneous bleeding, was granted a CE Mark.
- ENDRA LIFE SCIENCES' Taeus Flip, a non-invasive ultrasound add-on imaging probe for use in detecting and analyzing non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD), was granted a CE Mark.
- GENEMATRIX's Neoflex COVID-19 diagnostic kit was granted a CE-IVD Mark and will be distributed worldwide.
- PHARMAMAR/GENOMICA's qCOVID-19 and CLART COVID-19 diagnostic test kits were granted CE Marks.
- KEYSTONE HEART's Triguard 3, a cerebral embolic protection device for use in transcatheter procedures, was granted a CE Mark.
- ROCHE's Venclyxto (venetoclax) was approved by the European Commission for use in combination with Gazyvaro (obinutuzumab) for the treatment of adults with previously untreated chronic lymphocytic leukemia (CLL).
- THERADIAG's i-Tracker Infliximab, i-Tracker Anti-Infliximab, i-Tracker Adalimumab, and i-Tracker Anti-Adalimumab test kits were granted CE Marks for use in biomonitoring biologics for disorders like rheumatoid and psoriatic arthritis and ulcerative colitis.
- TIVIC HEALTH's ClearUP, a hand-held device for temporary sinus pain relief, was granted a CE Mark.

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

- SANOFI and REGENERON PHARMACEUTICALS' Dupixent (dupilumab) – NICE issued a draft decision, rejecting this treatment for severe asthma, noting that the drug is effective in preventing exacerbations but too expensive.

Regulatory news from other countries

- *Canada.* NOVO NORDISK's Fiasp (insulin aspart) was granted expanded approval by Health Canada for use in children age ≥2 with Type 1 or Type 2 diabetes and for use in insulin pumps.
- *United Kingdom.* MYLAN's aripiprazole oral solution – The Medicines and Healthcare products Regulatory Agency (MHRA) issued a drug alert that this antipsychotic may contain crystalline precipitate, but it was not recalled over supply issues.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
March tba	**AstraZeneca's Imfinzi** (durvalumab) + tremelimumab for small cell lung cancer	PDUFA date (*estimated late March*)
March 12	U.S.-Japan **cellular and gene therapy conference**: Exosomes in cancer treatments and other diseases	FDA conference in conjunction with Japan's Ministry of Education, Culture, Sports, Science, and Technology ***Postponed due to Covid-19 – no new date announced***
March 15	**Astellas and Seattle Genetics' enfortumab vendotin**, an antibody-drug conjugate for treating metastatic/locally-advanced urothelial cancer	PDUFA date
March 17	**Eton Pharmaceuticals' EM-105** (reformulated lamotrigine) as adjunctive therapy for partial seizures in Lennox-Gastaut syndrome patients	PDUFA date
March 23	Identification of concepts and terminology for **multi-component biomarkers**	FDA workshop ***Postponed due to Covid-19 – no new date announced***
March 25	**Bristol-Myers Squibb/Celgene's ozanimod** (RPC-1063) for relapsing MS	PDUFA date
March 25	**Zogenix's Fintepla** (fenfluramine, ZX-008) for Dravet syndrome	PDUFA date
March 26	**IntelGenx Technologies' Rizaport** (RHB-103) for migraine	PDUFA date
March 27	Modernizing **FDA's data strategy**	FDA public meeting ***Postponed due to Covid-19 – no new date announced***
March 28	**Rockwell Medical's Triferic** (ferric pyrophosphate) for anemia	PDUFA date
March 30	Patient-focused drug development for **vitiligo**	FDA public meeting ***Postponed due to Covid-19 – no new date announced***
March 31	Use of patient preference information **in medical device regulatory decisions** – risk:benefit and beyond	FDA public workshop ***Postponed due to Covid-19 – possible virtual meeting***
April tba	**Lilly's empagliflozin + linagliptin + metformin extended-release**, a triplet for Type 2 diabetes	PDUFA date
April tba	**Puma Biotechnology's Nerlynx** (neratinib) – expanded approval as a ≥3-line treatment for HER2+ metastatic breast cancer	PDUFA date
April 1	FDA communications about the **safety of medical devices**	FDA public meeting ***Postponed due to Covid-19 – possible fall date***
April 2	Reducing the risk of **Zika virus transmission** in blood and blood components	FDA's Blood Products Advisory Committee ***Postponed due to Covid-19 – no new date announced***
April 3	Testing for **hepatitis B** surface antigen (HBsAg) in blood donations	FDA's Blood Products Advisory Committee ***Postponed due to Covid-19 – no new date announced***
April 3	Consultation on **International Council for Harmonisation** (ICH)	FDA and Health Canada joint meeting ***Still scheduled – and also webcast***
April 4	**Bristol-Myers Squibb/Celgene and Acceleron Pharma's Reblozyl** (luspatercept-aamt) – expanded approval to include very low-to-intermediate risk myelodysplastic syndrome-associated anemia in patients with ring sideroblasts who require red blood cell transfusions	PDUFA date
April 6	**America's Got Regulatory Science Talent Winners**	FDA presentation ***Likely postponed due to Covid-19***
April 7	**Medical device user fee amendments** for fiscal years 2023-2027	FDA public meeting ***Likely postponed due to Covid-19***
April 13-15	Good **simulation practices** in health technologies	FDA public workshop ***Likely postponed due to Covid-19***
April 14	Preparations for international cooperation on **cosmetics regulation**	FDA public meeting ***Likely postponed due to Covid-19***
April 16	**TransMedics' Organ Care System**, a portable ex-vivo organ perfuison/monitoring system for resuscitation, prervation, and assessment of donor hearts	FDA's Circulatory System Devices Advisory Committee ***Likely postponed due to Covid-19***
April 20-21	Annual **Sentinel** review	FDA public workshop ***Likely postponed due to Covid-19***
April 21	**GlaxoSmithKline's Trelegy Ellipta** (fluticasone furoate + umeclidinium + vilanterol inhalation powder) – claim for reduction in all-cause mortality in COPD	FDA's Pulmonary-Allergy Drugs Advisory Committee ***Likely postponed due to Covid-19***
April 22 *tentative*	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	FDA's Gastrointestinal Drugs Advisory Committee *This is not on the FDA calendar, but the company gave the date* ***Likely postponed due to Covid-19***

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Date	**Topic**	**Committee/Event**
April 23	**Lilly/Avid Radiopharmaceuticals' flortaucipir F18**, an IV radioactive diagnostic agent for PET imaging of the brain	FDA's Medical Imaging Drugs Advisory Committee ***Likely postponed due to Covid-19***
April 23	Reclassification of **facet screws** from unclassified to Class II	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee ***Likely postponed due to Covid-19***
April 24	**Classification to Class II of three devices** that are currently unclassified: semicon-strained toe joint prostheses; intracompartmental pressure monitors; and intra-abdominal pressure monitoring devices	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee ***Likely postponed due to Covid-19***
April 25	**Sanofi's MenQuadfi**, a meningococcal vaccine	PDUFA date
April 26	**Neurocrine Biosciences' opicapone** to treat Parkinson's disease	PDUFA date
April 27	**United Therapeutics' Trevyent** (treprostinil) to treat pulmonary arterial hypertension (PAH)	PDUFA date
April 29	Topic not announced yet	FDA's Pediatric Advisory Committee ***Likely postponed due to Covid-19***
April 30	**Sanofi's isatuximab** for relapsed/refractory multiple myeloma	PDUFA date
May 4	**2020 generic drug** regulatory science initiatives	FDA public workshop
May 8	Development of **antifungal drugs to treat Valley Fever** (coccidioidomycosis)	FDA public workshop
May 12	**Johnson & Johnson and Halozyme's Darzalex** (daratumumab) subcutaneous delivery for multiple myeloma	PDUFA date (*estimated*)
May 12-13	**Regulatory education for industry**	FDA conference
May 14	**Sunovion Pharmaceuticals' dasotraline** for moderate-to-severe binge eating disorders	PDUFA date
May 14	**Blueprint Medicines' Ayvakit** (avapritinib, BLU-285) for *fourth-line* GIST	PDUFA date *extended by FDA from February 14*
May 15	**Allergan's bimatoprost sustained-release** for treating glaucoma	PDUFA date (*estimated*)
May 15	**Clovis Oncology's Rubraca** (rucaparib) – expanded approval to treat advanced prostate cancer	PDUFA date
May 15	**DBV Technologies' Viaskin Peanut** for treating children with peanut allergy	FDA's Allergenic Products Advisory Committee
May 24	**Roche's risdiplam** (RG-7916) to treat spinal muscular atrophy	PDUFA date
May 25	**Evofem Biosciences' Amphora** (L-lactic acid + citric acid + potassium bitartrate), a hormone-free contraceptive (resubmission)	PDUFA date
May 26	**Regeneron Pharmaceuticals and Sanofi's Dupixent** (dupilumab) – expanded approval to include treatment of children age 6-11 with atopic dermatitis	PDUFA date
May 30	**Incyte's pemigatinib** for previously treated, locally-advanced/metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements	PDUFA date
June 2	**Immunomedics' sacituzumab govitecan** (IMMU-132) as a ≥3-line treatment for metastatic triple-negative breast cancer	PDUFA date
June 2	**Foamix Pharmaceuticals' FMX-103** (minocycline foam) to treat moderate-to-severe papulopustular rosacea	PDUFA date
June 4	**Merck MSD's Recarbrio** (imipenem + cilastatin + relebactam) – expanded approval to treat hospital-acquired Gram-negative bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)	PDUFA date
June 11	**Viela Bio's inebilizumab** for first-line monotherapy of neuromyelitis optica spectrum disorder	PDUFA date
June 18	**Epizyme's Tazverik** (tazemetostat) – expanded approval to treat relapsed/ refractory follicular lymphoma	PDUFA date
June 19	**Roche's Tecentriq** (atezolizumab) – expanded use as first-line treatment for advanced NSCLC with high PD-L1 expression and no ALK or EGFR mutations	PDUFA date
June 26	**Heron Therapeutics' HTX-011** (bupivacaine + meloxicam) for postoperative pain	PDUFA date *Extended by the FDA from March 26*
June 26	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	PDUFA date *extended from March 26*
June 27-July 1	**AFDO annual educational conference**	FDA's National Center for Toxicological Research
July 5	**Acacia Pharma's Byfavo** (remimazolam), an ultra-short-acting and reversible anesthetic for use in surgery and other invasive procedures	PDUFA date ***Extended by 3 months from April 5 by FDA due to new data submitted by the company***
July 13	**Averitas Pharma's Qutenza** (capsaicin patch) – expanded approval to treat neuropathic pain from diabetic peripheral neuropathy	PDUFA date
August 5	**DBV Technologies' Viaskin Peanut** for treating children with peanut allergy	FDA target action date

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Date	**Topic**	**Committee/Event**
August 7	**Trevena's Olinvo** (oliceridine) for moderate-to-severe pain in hospitalized patients	PDUFA date
August 10	**Gilead Sciences/Kite Pharma's KTE-X19** for relapsed/refractory mantle cell lymphoma	PDUFA date
August 13	**Deciphera Pharmaceuticals' ripretinib** (DCC-2618) for GIST	PDUFA date
August 17	**Bristol-Myers Squibb/Celgene/Juno Therapeutics' lisocabtagene maraleucel** (JCAR-017, liso-cel) for DLBCL	PDUFA date
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 27	**Cassiopea's clascoterone cream 1%**, a topical androgen receptor inhibitor for acne	PDUFA date
August 30	**MorphoSys and Incyte's tafasitamab** for use in combination with lenalidomide to treat relapsed/refractory diffuse large B-cell lymphoma	PDUFA date
September 27	**Aquestive Therapeutics' Libervant** (diazepam buccal film) for seizure clusters in epileptics	PDUFA date
Sept. 28-30	Global summit on regulatory science: **Emerging Techologies**	FDA summit **https://aralliance.org/gsrs/**
October 18	**Roche's Herceptin** (trastuzumab) **+ Perjeta** (pertuzumab) – a fixed dose combination to treat HER2+ breast cancer	PDUFA date
October 24	**Spectrum Pharmaceuticals' Rolontis** (eflapegrastim) for treating chemotherapy-induced neutropenia	PDUFA date
November 15	**Alkermes' ALKS-3831** (olanzapine + samidorphan) for bipolar I disorder and schizophrenia	PDUFA date
November 25	**Revance Therapeutics' daxibotulinumtoxinA** for moderate-to-severe glabellar lines	PDUFA date
December tba	**Pfizer and Lilly's tanezumab** to treat moderate-to-severe osteoarthritis pain	PDUFA date
December 3	**BioCryst Pharmaceuticals' berotralstat** (BCX-7353) for hereditary angioedema attacks	PDUFA date
December 20	**FibroGen and AstraZeneca's roxadustat** for anemia of chronic kidney disease	PDUFA date
December 26	**Sumitomo Dainippon Pharma/Urovant Sciences' vibegron** for overactive bladder	PDUFA date
December 30	**Almirall and Athenex's tirbanibulin** (KX2-391, KX-01) for actinic keratosis	PDUFA date