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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Remember that all coronavirus news is being reported in regular separate Coronavirus Update bulletins. Thus, no coronavirus news is included in ***Quick Takes***.

All major medical conferences are canceled/postponed through the end of April. However, the American Association for Cancer Research (AACR) will have the first half of its ***virtual*** meeting on April 27-28, 2020.

Be careful, be safe, and be well.

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

- ✓ AMGEN and NOVARTIS' Aimovig (erenumab), a CGRP inhibitor for migraine, showed positive results in two trials – a real-world study in Germany and a open-label long-term study.
- ✓ ASLAN PHARMACEUTICALS' ASLAN-004 – Enrollment was paused in a study of this anti-IL-13Rα1 antibody in moderate-to-severe atopic dermatitis due to Covid-19.
- ✓ BEIGENE's tislelizumab (BGB-A317), a PD-1 inhibitor, combined with chemotherapy, met the primary endpoint in non-squamous NSCLC.
- ✓ MODERNA THERAPEUTICS' mRNA-1893 – Preliminary results in a Phase I trial of this Zika vaccine showed seroconversion rates of 94%-100%.

SHORT TAKES

- ALNYLAM PHARMACEUTICALS' vutrisiran was granted fast track status by the FDA as a treatment for the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis.
- ARCUS BIOSCIENCES – There have been reports that **Gilead Sciences** is looking to do a deal with Arcus, which has an anti-TIGIT (AB-154) that is being studied as a new checkpoint inhibitor.
- ASLAN PHARMACEUTICALS' ASLAN-004 – Enrollment was paused in a double-blind, placebo-controlled, multiple ascending dose (MAD) study of this anti-IL-13Rα1 antibody (licensed from CSL Behring) in moderate-to-severe atopic dermatitis due to Covid-19.
- BEIGENE's tislelizumab (BGB-A317) – This PD-1 inhibitor, combined with chemotherapy, met the primary endpoint in non-squamous non-small cell lung cancer (NSCLC), prolonging progression-free survival vs. chemotherapy alone. *Remember, it previously showed similar results in squamous NSCLC.*

- BELLICUM PHARMACEUTICALS' BPX-601 – The temporary halt in research by MD Anderson Cancer Center due to Covid-19 is causing a halt in a Phase I/II trial of this cell therapy for advanced solid tumors with high levels of PSCA because BPX-601 is made at the cell therapy manufacturing plant Bellicum sold earlier this month to MD Anderson.

- BIOCON BIOLOGICS – The company said that the FDA inspections of its two biosimilar plants in Bangalore, India, have gotten the all-clear from the FDA, resolving issues observed in an inspection last year.

- BIOFOURMIS bought **Gaido Health**, a cancer monitoring company, from **Takeda**.

- BIOGEN's aducanumab – Biogen sued **Creative Biolabs**, alleging that Creative is selling unauthorized copies of this Alzheimer's disease drug. Creative said it is a misunderstanding and the aducanumab it sells is going to labs for research. On another note, Biogen's filing of aducanumab with the FDA was expected early this year, but apparently it isn't ready yet and may take a few more months.

- Contract research organizations (CROs) – A study by Moody's found that the CRO industry is being disrupted by Covid-19, with pharmas canceling/suspending new/ongoing tests. Moody's predicts that trials will mostly be delayed, not canceled.

- FACTORY-CRO GROUP – a merger of Boston Biomedical Associates (BBA), Factory-CRO, Five Corners, and Mile-Stone Research Organization – changed its name to **Avania**.

- FORMA THERAPEUTICS' FT-4202, a PKR activator for sickle cell disease, was granted orphan drug status by the FDA.

- GALAPAGOS is collaborating with **Ryvu Therapeutics** on discovery and development of small molecules to treat inflammation.

- HUMA (formerly Medopad) bought **Tarilian Laser Technologies**, a wearable technology firm, and **BioBeats**, a digital health and artificial intelligence company.

- INSILICO is collaborating with **Boehringer Ingelheim** to apply generative artificial intelligence to the search for potential therapeutic targets.

- JOHNSON & JOHNSON called off the deal to buy **Takeda's TachoSil** patch, a fibrin sealant patch, after the Federal Trade Commission raised objections about the deal lessening market competition.

- LILLY's Trulicity (dulaglutide) – A study, published in ***Diabetes & Metabolic Syndrome: Clinical Research & Reviews***, found that dulaglutide, a GLP-1 agonist, reduced binge eating behavior, body weight, body mass index, percentage body fat mass, and HbA_{1c} in Type 2 diabetics with binge eating disorder better than gliclazide, a sulfonylurea.

- MEI PHARMA's ME-401 – **Kyowa Kirin** licensed the rights to co-develop and co-promote this PI3Kδ inhibitor in the U.S. and will have exclusive rights outside the U.S.

- MICROBIO/ONENESS BIOTECH/FOUNTAIN BIOPHARMA's FB-825 was licensed to **LEO Pharma**. Oneness will handle Phase IIa studies in atopic dermatitis in the U.S., and Microbio Shanghai will handle a Phase IIa trial in allergic asthma in China. LEO will assume responsibility in both indications after the Phase IIa trials.

- MODERNA THERAPEUTICS' mRNA-1893 – The preliminary results of a Phase I trial of this Zika vaccine showed seroconversion rates of 94% and 100%, based on dosage.

- NOVARTIS is partnering with **TScan Therapeutics** on development of cell therapies for solid tumors.

- REGENERON PHARMACEUTICALS' REGN-EB3, an Ebola treatment, was submitted to the FDA for priority review. The PDUFA date is October 25, 2020.

- REMEGEN's telitacicept (RC-18), a recombinant TACI-Fc fusion protein for treating systemic lupus erythematosus (SLE), was granted fast track status by the FDA.

- SUMITOMO DAINIPPON PHARMA/SUNOVION's SEP-363856 – The results of a 245-patient Phase II trial of this anti-$TAAR1/5\text{-}HT_{1A}$ in early-stage schizophrenia, published in the ***New England Journal of Medicine***, showed a significant improvement in the Positive and Negative Syndrome Scale (-17.2 points vs. -9.7 points with placebo). Notably, there was improvement in negative symptoms.

- VIR THERAPEUTICS and ALNYLAM's VIR-2218 – Interim results from a Phase I/II trial of this small interfering RNA (siRNA) showed a significant dose-dependent and durable reduction in hepatitis B surface antigen (HBsAg) through Week 24 in patients with chronic hepatitis B after two doses.

Very early research news

- Alzheimer's disease – A study, published in ***Nature Medicine***, found that glucose metabolism is linked to Alzheimer's disease pathology, suggesting new drug targets, a new approach.

- Pain – A mouse study by Australian researchers, published in the ***Journal of Biological Chemistry***, suggests that a mini-protein in tarantula venom could be an addiction-free alternative to opioids for pain relief.

- Stroke – In a rat study, published in the ***Proceedings of the National Academy of Sciences***, Swedish researchers restored mobility and sensation of touch in stroke-afflicted rats by reprogramming human skin cells to become nerve cells and implanting the cells into the brains of a rodent model of stroke.
- X-rays – A study, published in ***Science Advances***, found that a perovskite-based x-ray detector, developed by researchers at the Argonne National Laboratory and the Los Alamos National Laboratory, uses ultralow radiation but provides 100-times greater sensitivity in medical and dental images vs. standard x-rays. The perovskite detector arrays also could be printed using an inkjet system, which would lower the cost vs. silicon detector arrays.

NEWS IN BRIEF

AMGEN and NOVARTIS' Aimovig (erenumab)

- A 109-patient real-world study in Germany found that 80% of patients taking this CGRP inhibitor had a reduction in migraine intensity and 92% had fewer attacks.
- A 4.5-year interim analysis of an open-label Phase II trial in episodic migraine showed that long-term treatment with Aimovig resulted in sustained reduction in monthly migraine days.

ASTRAZENECA

- Posters released in conjunction with the canceled American Academy of Allergy, Asthma, and Immunology (AAAAI) meeting showed:
  - Fasenra (benralizumab). A post hoc analysis of the Phase III SIROCCO and CALIMA trials found that exacerbation history, oral corticosteroid use, history of nasal polyposis, forced vital capacity (FVC), and age at asthma diagnosis were associated with better efficacy with benralizumab in patients with uncontrolled asthma and moderate eosinophilia.
  - and AMGEN's tezepelumab. The results of the Phase IIb PATHWAY trial showed that this TSLP antibody reduced exacerbations in patients with severe, uncontrolled asthma, irrespective of baseline body mass index.
- Tagrisso (osimertinib). The Phase III ADAURA trial of this irreversible EGFR inhibitor in NSCLC was stopped early at the recommendation of the independent data monitoring committee due to overwhelming efficacy.

Insulin

- Novo Nordisk is offering free insulin for 90 days to people who have lost their health coverage after being laid off or experiencing a job status change during the Covid-19 pandemic.
- Lilly is offering insulin for $35/month for up to 20,000 people a month who are in need, whether or not they have insurance, except Medicare Part D beneficiaries.

REGULATORY NEWS

Regulatory tidbits

- Accountable care organizations (ACOs). A survey of ACOs by the National Association of ACOs found that 56% are likely to leave the Medicare ACO program over concerns about having to repay losses stemming from the Covid-19 outbreak: 21% said they were very likely to leave, 14% said likely to leave, and 21% said somewhat likely to leave. Nearly 80% said they are very concerned about their ACO performance this year.
- Companion diagnostics. The FDA released final guidance explaining how to broaden labeling for companion diagnostics used with precision oncology treatments and how to facilitate their use with multiple treatments.
- FDA reviews. So far, the FDA says, it has been able to handle drug and device reviews and Covid-19, but that may not be able to continue.
  - The FDA said that despite Covid-19 reviews of new **drugs**, generics, biologics, and biosimilars are on schedule, but the Agency added, "It is possible that we will not be able to sustain our current level of performance indefinitely."
  - Review of **devices** is also currently on track, but the Agency said it is extending response due dates by 90 days for applications – 510(k) applications, humanitarian device exemptions (HDE) applications, premarket approval (PMA) applications, and De Novo classification requests – currently on hold.
  - Emergency use authorizations (**EUAs**) have been speeding through the Agency, but that may also slow down.
  - **Animal** drug and generic reviews are on schedule and not expected to slow down.
- Insulin. A bill was signed into law in Minnesota that provides diabetics who can't afford their insulin *and need the drug on an emergency basis* can get a one-time, 30-day insulin supply from pharmacies for a $35 copay.

- Manufacturing. The FDA cleared three overseas generic manufacturing facilities – **Dr. Reddy's Laboratories, Lupin Pharmaceuticals**, and **Biocon**.
- Supply chain. House Republicans introduced legislation – the Protecting our Pharmaceutical Supply Chain from China Act – that would give economic incentives to companies that manufacture drugs and medical devices in the U.S. and would ban federally-qualified health facilities from buying pharmaceuticals from China.

FDA approvals/clearances

- ASTURA MEDICAL's Sirion, a lateral lumbar interbody fusion device, was granted 510(k) clearance for use in spine surgery.
- AXONICS MODULATION TECHNOLOGIES' r-SNM, a next-generation rechargeable implantable sacral neurostimulator, was granted supplemental PMA approval for use in treating bowel and urinary dysfunction.
- CENTINEL SPINE's prodisc L lumbar, a total lumbar disc replacement device, was approved for use in two-level spine procedures.
- INCYTE's Pemazyre (pemigatinib), an oral FGFR1/2/3 inhibitor, was granted accelerated approval to treat previously treated/advanced cholangiocarcinoma (bile duct cancer) that has a fusion or other rearrangement of the FGFR2 gene.
- SEATTLE GENETICS' Tukysa (tucatinib) was approved for use in combination with chemotherapy – trastuzumab and capecitabine – as a ≥2-line treatment for advanced HER2+ breast cancer that cannot be removed with surgery or has metastasized. This is the first new drug approved under an international collaboration with the Australian Therapeutic Goods Administration (TGA), Health Canada, Singapore's Health Sciences Authority (HSA), and Switzerland's Swissmedic (SMC). For this drug, Project Orbis, a subgroup of the collaboration – the FDA, HSA, and Swissmedic – was used.
- UROGEN PHARMA's Jelmyto (mitomycin) was approved to treat low-grade upper tract urothelial cancer (UTUC).
- XENOCOR's Xenoscope, a disposable 5 mm articulating laparoscope, was cleared for use during thoracic and abdominal surgery.

FDA recalls/warnings

- AMNEAL PHARMACEUTICALS' nizatidine – Three lots of this heartburn medication were voluntarily recalled over concern that they might contain higher-than-acceptable levels of NDMA.
- AVET PHARMACEUTICALS' tetracycline – Eight lots of this antibiotic were recalled because they failed dissolution specifications.
- GENESIS II CHURCH OF HEALTH AND HEALING – At the request of the FDA, a federal judge issued a temporary injunction preventing the company from selling chlorine dioxide products, which it had been marketing to treat Covid-19.
- INTERNATIONAL LABORATORIES' clopidogrel – One lot of this blood thinner was recalled due to mislabeling.

European Regulatory News

- PROTEOMICS' PromarkerD test kit, a blood test that determines the risk of diabetic kidney disease for patients with Type 2 diabetes, was granted a CE Mark.

Regulatory news from other countries

- ***Canada.*** GILEAD SCIENCES' Descovy (emtricitabine + tenofovir alafenamide) – A supplemental marketing application was submitted to Health Canada, seeking approval in tablet form as a pre-exposure prophylaxis for HIV-1 in people at risk for HIV but are HIV-negative.
- ***China.*** ZAI LAB's Zejula (niraparib) was granted priority review by the National Medical Products Administration (NMPA) as a maintenance treatment for adults with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete/partial response to first-line platinum-based chemotherapy.

2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week; items in GRAY shading are postponed/canceled*)		
Date	**Topic**	**Committee/Event**
April 15	**Ulcerative colitis** draft report to be released	ICER ***Postponed to May 15 due to Covid-19***
April 20-21	Annual **Sentinel** review	FDA public workshop *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 *Postponed due to Covid-19, no new date yet*
April 22	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	FDA's Gastrointestinal Drugs Advisory Committee *Postponed to June 9 due to Covid-19*
April 22	Technical issues related to development of **diagnostic tests for SARS-CoV-2**	FDA virtual Town Hall for clinical laboratories and manufacturers
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 *Postponed due to Covid-19, no new date yet*
April 23	Reclassification of **facet screws** from unclassified to Class II	FDA's Orthopaedic and Rehabilitation Devices Advisory Committee *Postponed due to Covid-19*
April 23 *tentative*	Revised **cystic fibrosis** report	ICER
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 *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 30	**Sanofi's isatuximab** for relapsed/refractory multiple myeloma	PDUFA date
April 30	**Cystic fibrosis**	ICER meeting *Indefinitely postponed due to Covid-19*
May 4	**2020 generic drug** regulatory science initiatives	FDA public workshop – now virtual only
May 5	**Medical device user fee** amendments for fiscal years 2023-2027	FDA public meeting *Postponed from April 7 and now postponed indefinitely*
May 7	Development of **antifungal drugs** to treat unmet medical need	FDA public workshop ***Postponed to August 4***
May 8	Development of **antifungal drugs to treat Valley Fever** (coccidioidomycosis)	FDA public workshop ***Postponed to August 5***
May 8	Overview and **research update** about Tumor Vaccines and Biotechnology Branch and Cellular and Tissue Therapy Branch	FDA's Cellular, Tissue, and Gene Therapies Advisory Committee *meeting by teleconference*
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 *Postponed*
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 14	**Artificial intelligence** for regulatory science research	FDA Grand Rounds lecture **(webinar)**
May 15	Ulcerative colitis draft report to be released	ICER ***Postponed from April 15 due to Covid-19***
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 *Canceled over product issues, not Covid-19*
May 24	Roche's risdiplam (RG-7916) to treat spinal muscular atrophy	PDUFA date *Extended 3 months to August 24*
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

more - 2020 FDA Advisory Committees and Other Regulatory Dates of Interest (*items in RED are new since last week*)		
Date	**Topic**	**Committee/Event**
June 2	**Immunomedics' sacituzumab govitecan** (IMMU-132) as a ≥3-line treatment for metastatic triple-negative breast cancer	PDUFA date
June 2	**Menlo Therapeutics/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 9	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	FDA's Gastrointestinal Drugs Advisory Committee *Postponed from April 22 due to Covid-19*
June 9	**Refocus Group's VisAbility Micro Insert for treating presbyopia**	FDA's Ophthalmic Devices Advisory Committee
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 25	**Zogenix's Fintepla** (fenfluramine, ZX-008) for Dravet syndrome	PDUFA date *Extended from March 25 due to company submission of new data*
June 26	**Intercept Pharmaceuticals' obeticholic acid** to treat liver fibrosis due to non-alcoholic steatohepatitis (NASH)	PDUFA date *extended from March 26*
June 26	**Heron Therapeutics' HTX-011** (bupivacaine + meloxicam) for postoperative pain	PDUFA date *Extended by the FDA from March 26*
June 27-July 1	**AFDO annual educational conference**	FDA's National Center for Toxicological Research
June 30	**Modernizing FDA's Data Strategy**	FDA public meeting ***Originally scheduled for March 27***
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 from April 5 by FDA due to new data submission*
July 13	**Averitas Pharma's Qutenza** (capsaicin patch) – expanded approval to treat neuropathic pain from diabetic peripheral neuropathy	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 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 24	**Roche's risdiplam** (RG-7916) to treat spinal muscular atrophy	PDUFA date *Extended from May 24*
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
October 25	**Regeneron Pharmaceuticals' REGN-EB3** for Ebola	PDUFA date

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Date	**Topic**	**Committee/Event**
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