Clinical Pharmacy Newsletter

A Newsletter of Drug and Prescribing Information
Published by
Clinical Pharmacy Services Department, Govt. Head Quarters Hospital, Ooty
(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

VOLUME XXIII ISSUE03 JULY-SEPTEMBER 2018

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Promising Targeted Therapies for Atopic Dermatitis

Atopic dermatitis (AD) is a T-cell-driven, chronic inflammatory skin disease with a prevalence of up to 10% in adults and 25% in children. Classic atopic dermatitis presents during infancy with recurrent facial dermatitis, morphing during childhood into chronic inflammatory flexural patches and lichenified plaques. Researchers are now mapping the immune dysregulation behind AD, which is characterized by chronic activation of the Th2 immune response. Systemic T-cell-suppressing therapies, such as Azathioprine, Methotrexate, Mycophenolate mofetil, and Cyclosporine, are effective at controlling moderate to severe AD (all as off-label indications). However, these treatments are limited by side effects, including immunosuppression, risk for cancer, and multiorgan toxicity, especially when taken chronically.

The following is a brief review of four promising biologics for moderate to severe AD and a fifth category of "small molecules" capable of targeting and inhibiting the atopic Th2 immune response.

Dupilumab: A Human Monoclonal Antibody Against IL-2R-Alpha

Dupilumab, a human monoclonal antibody targeting the interleukin-4 receptor alpha (IL-4R-alpha), received US Food and Drug Administration (FDA) approval for the treatment of moderate to severe AD in adults, in part on the basis of its remarkable safety profile and efficacy similar to that of some broader and more toxic immunosuppressive agents.

Dupilumab inhibits signaling of the proinflammatory Th2 cytokines IL-4 and IL-13. It was the first biologic agent to treat adults with moderate to severe AD that was refractory to topical corticosteroid therapy. The indication for AD was based on randomized, placebo-controlled clinical trials (SOLO 1 and SOLO 2) involving adults in whom topical corticosteroid treatment had failed. Adults with moderate to severe AD (SOLO 1, n = 671; SOLO 2, n = 708) were randomly assigned to receive Dupilumab (300 mg subcutaneously) or placebo weekly or the same dose of Dupilumab every other week alternating with placebo, for 16 weeks.

The primary outcome measure was an Investigator's Global Assessment (IGA) score of 0 or 1 (clear or almost clear) and a score reduction of two or more points from baseline to week 16. Key findings include the following:

- The primary outcome measure was achieved in 38% of patients in SOLO 1 and 36% in SOLO 2 who injected Dupilumab every other week versus 10% in the placebo group. Weekly Dupilumab dosing did not improve efficacy.
- Dupilumab also improved secondary outcome measures, including > 75% improvement on the Eczema Area and Severity Index (EASI 75), improved pruritus and quality-of-life scores, and reduced symptoms of anxiety and depression.
- Injection-site reactions and conjunctivitis were more frequent in the Dupilumab versus placebo groups. Adverse events and laboratory values were otherwise similar in the treatment and placebo arms.

Lebrikizumab: Anti-IL-13 Monoclonal Antibody Targeting Soluble IL-13

IL-13 plays a central role in type 2 (Th2) inflammation, with levels of IL-13 mRNA correlating with AD severity. Lebrikizumab is still in clinical trials, including TREBLE, a randomized, placebo-controlled 12-week trial of topical corticosteroid plus Lebrikizumab every 4 weeks versus placebo involving 209 adults aged 18-75 years with moderate to severe AD. Key findings included the following:

- At week 12, significantly more patients who received Lebrikizumab 125 mg by subcutaneous injection every 4 weeks achieved EASI-50 (a 50% improvement) compared with the placebo group (82.4% vs 62.3%, respectively).
- Adverse event rates were similar between the Lebrikizumab and placebo groups.
- The benefit of Lebrikizumab was probably blunted by protocol-mandated use of topical corticosteroid in the placebo group.

Editorial Article

Fezakinumab: An Anti-IL-22 Monoclonal Antibody

IL-22 promotes epidermal hyperplasia, inhibits keratinocyte differentiation, impairs skin barrier formation, and induces proinflammatory cytokines. Hence, IL-22 blockade may have a therapeutic benefit in at least some subsets of AD. Recent concluded randomized, double-blind, phase 2a trial of Fezakinumab, administered intravenously every 2 weeks for 10 weeks, versus placebo. The primary outcome measure was the change in severity scoring of AD (SCORAD), an AD clinical severity index, from baseline to 12 weeks. Findings included the following:

- At 12 weeks, the mean reduction in SCORAD was 13.8 ± 2.7 in the Fezakinumab group versus 8.0 ± 3.1 in the placebo group.
- SCORAD improvement was strongest in patients with severe AD treated with Fezakinumab versus placebo, measured at 12 and 20 weeks.
- Rates of adverse events were similar in the Fezakinumab and placebo groups.
- Because Fezakinumab targets a novel inflammatory pathway (IL-22) independent of IL-4 and IL-13, it may help patients with moderate to severe AD that is refractory to Dupilumab therapy.

Nemolizumab: An Anti-IL-31 Receptor A Monoclonal Antibody

IL-31 is a pruritogenic cytokine expressed in peripheral nerves and keratinocytes. A pilot placebo-controlled clinical trial of nemolizumab injected subcutaneously every 4 or 8 weeks for the treatment of moderate to severe AD (n = 264) had the following findings:

- Pruritus, EASI scores, and sleeps disruption improved during a 12-week period.
- The greatest improvement was seen in patients who received 0.5 mg/kg nemolizumab every 4 weeks.
- The study included a 52-week double-blind extension, during which improvement in pruritus and EASI scores was maintained or increased.
- No new safety concerns were identified during long-term use.

Small Molecules

Biologics are not the only story when it comes to promising new therapies for AD. The topical phosphodiesterase-4 inhibitor Crisaborole received FDA approval in 2016 for the treatment of mild to moderate AD in adults and children aged 2 years or older, with modest efficacy and an excellent safety profile. Small molecules that are in clinical trials for AD include a Janus kinase 1/3 inhibitor (Tofacitinib); an oral phosphodiesterase-4 inhibitor (Apremilast); and drugs targeting the thymic stromal lymphopoietin (TSLP)-OX40 ligand pathway, which is thought to play a key role in Th2 immune activation.

Conclusion

An improved understanding of the complex immunology of AD has inspired a "gold rush" of targeted therapies to suppress the cytokines and T-cell subsets at the root of AD. Studies are under way to investigate the safety and efficacy of these Th2-axis-inhibiting biologics and small molecules in atopic adults and children. Over the next decade, patients struggling with AD can finally expect some well-deserved and durable relief.

For further reading:
https://www.medscape.com/viewarticle/898282

EVENT CORNER

Report on CEP for Pharmacy Teachers

Pharmacy Council of India, New Delhi Sponsored Continuing Education Program (CEP) for Pharmacy Teachers on Current perspectives and challenges in Teaching and Learning: Strategies for the effective implementation of revised pharmacy curriculum was organized by Pharmacy Education Unit, Center for Continuous and Life Long Learning for Professional Excellence (CCLPE) in association with Dept. of Pharmacy Practice, JSS College of Pharmacy, Ooty between 21st – 23rd September 2018.

Around 30 teachers of various PCI, New Delhi approved institutions participated in the program and deliberated on principles and methodologies of various teaching pedagogies and learning; insights on new B Pharm / M Pharmacy curriculum (PCI recommended); understanding the learning objectives / program outcome of B Pharm / M Pharm curriculum; principles of evaluation of answer scripts and setting the question papers including MCQs; and personality development and teacher-student relationship etc. About 16 topics were covered during the program and resources persons from academia, industry, regulatory and training academy participated in the said program.

Continuing Education Program (CEP) for Pharmacy Teachers

Dr. S. Ponnusankar, Professor & Head, Dept. of Pharmacy Practice –is introducing the guest speakaer Dr Dixon Thomas to the audience

Dr. Deepan Suresh, delivering his lecture on the ECG interpretation

REPORT

Conferences Attended by Faculty

Ms. **M. Deepalakshmi**, Dr. **B. Swathi swaroopa**, Dr. **C. Keerthana**, Dr. **Aneena Suresh**, Mr. **Vishwas HN** attended **National Seminar** on "**Research Advances and Therapeutic Interventions in Neurodegenerative Disorders**" organised by Department of Pharmacology, at JSS College of Pharmacy, Ooty,The Nilgiris from 6th – 7th July 2018

Dr. **S. Ponnusankar**, Dr. **Khayati Moudgil**, Dr. **Keerthana C**, Dr. **Aneena Suresh**, Mr. **Vishwas HN attended** a **National conference** on "**Emerging and Re-emerging zoonotic viral diseae NIPAH: Current scenario"** at KMCH college of pharmacy on 14th August 2018

Dr. **S. Ponnusankar**, Dr. **K.P. Arun** attended a **National Conference** on "**2nd Leadership Developmen Conclave"** organised by Indian Association of Colleges of Pharmacy, Chennai at Le Meridian, Goa from 15th – 17th September 2018

Ms. **M. Deepalakshmi** attended a **National Conference** on **Indian Society of Gastro enterology 2018**, Midterm conference at GEM PARK Ooty from 15th – 16th September 2018

Dr. **Keerthana . C**, Dr. **Khayati Moudgil** attended a National Conference Continuing Education Programme (**CEP**) for Pharmacy Teachers on "**Current Perspectives and Challenges in Teaching and Learning Strategies for the Effective Implementation of Revised Pharmacy Curriculum**" organised by Pharmacy Education Unit Center for Continuous and Lifelong Learning for Professional Excellence (CCLPE) & Department of Pharmacy Practice. Sponsored by **Pharmacy Council of India, New Delhi** conducted at JSS College of Pharmacy, Ooty from 21st- 23rdSeptember, 2018

Papers Presented by Faculty

Ms. **M. Deepalakshmi** presented a paper on "**Clinical Pharmacists Intervention on IV to oral conversion in District Head Quarters Hospital- Ooty. An Interventional study**" at National conference orgainised by Department of Pharmacology, JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu from 6th - 7th July 2018

Dr. **Keerthana C** presented a paper on "**Phenytoin Induced Myelosuppression in an Epilepsy Patient"** at National conference organised by Department of Pharmacology, JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu from 6th - 7th July 2018

Faculty as Resource Persons

Dr. S Ponnusankar delivered a talk on **"Pharmaceutical Care - Challenges and Opportunities: A Secondary Care Public Hospital Experience"** at 9th National conference on Pharmacoeconomics and Outcomes Research organised by ISPOR India in collaboration with Ragavendra Institute of Pharmaceutical and Research and IPA. 20-21 July 2018 at RIPER.

Dr **S. Ponnusankar** delivered a talk on "**Clinical Pharmacy Services – Our Experience**" at Two days **National Workshop** on Clinical Pharmacy Services: Challenges and Opportunities Ahead organised by Narasaraopeta Institute of Pharmaceutical Sciences, Yellamanda (PO) Narasaraopet – 522 601. Guntur District Andhra Pradesh from 3rd - 4th August 2018

Dr **S. Ponnusankar** delivered a talk on "**Clinical Pharmacy Services: Opportunities Ahead**" at **National Conference** on Current Perspectives in Clinical Pharmacy and Pharmacotherapeutics Seven Hills College of Pharmacy, Tirupathi from 16th - 17th August 2018

Dr **S. Ponnusankar** delivered a talk on **"Continuing Education Program: aim and objectives"** at **National Conference** Continuous Education Program for Pharmacy Teachers – PCI organised and Sponsored by CCLPE & Department of Pharmacy Practice JSS College of Pharmacy, Ooty from 21st- 23rd September 2018

Dr. **K.P. Arun** delivered a talk on "**Teaching and Learning Principles: Learning Styles for the New Generation Students"** at **National Conference** Continuous Education Program for Pharmacy Teachers – PCI organised and Sponsored by CCLPE & Department of Pharmacy Practice JSS College of Pharmacy, Ooty from 21st- 23rd September 2018

Dr. **D Raja,** Mr. **C Jayakumar**, Dr. **G K Sadagoban** delivered a talk on "**Methods and Teaching and Learning Process Using ICT / IT - Our Experience with PharmD Info and E – Learn"** at **National Conference** Continuous Education Program for Pharmacy Teachers – PCI organised and Sponsored by CCLPE & Department of Pharmacy Practice JSS College of Pharmacy, Ooty from 21st- 23rd September 2018

Dr. **S. Ponnusankar** delivered a talk on "**Pharmaceutical Care program for the pharmacists"** at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

REPORT

Ms. **M. Deepalakshmi** delivered a talk on "**ADR reporting- Skills and opportunities**" at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Ms**. B.S. Roopa** delivered a talk on "**Safety of new drugs**" at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Dr. **G.K. Sadagoban** delivered a talk on "**Antibiotic Policy: Development and Current Scenario"** at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Dr. **C. Keerthana** delivered a talk on "**Fixed Dose Combination- Do we have sufficient evidence???"** at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Dr. **Aneena Suresh** delivered a talk on "**Public Health Services- opportunities for Pharmacist"** at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Dr. **Khayati Moudgil** delivered a talk on "**Drug Technical Advisory Board**" at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Mr. **Vishwas HN** delivered a talk on "**Over the Counter Medicines**" at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Research Awards / Recognitions

Dr. **S Ponnusankar** awarded as a **Chairperson** at National Seminar on Research Advances and Therapeutic Interventions in Neurodegenerative Disorders- NEUROGEN 2018 organised by Department of Pharmacology, JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu from 6th- 7th July,2018

Ms. **M. Deepalakshmi** awarded with Best E-Poster presentation award at National Seminar on Research Advances and Therapeutic Interventions in Neurodegenerative Disorders- NEUROGEN 2018 organised by Department of Pharmacology, JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu from 6th- 7th July,2018

Dr. **K.P.Arun** recognised a**s Joint Coordinator** at One day workshop on theoretical basis for *in silico* methods in Biopharmaceutics and pharmacokinetics organised by Conducted By Dept of Pharmaceutics & Pharmacy Practice at JSS college of Pharmacy, Ooty on August 13, 2018

Ms. **M. Deepalakshmi** and Dr**. Khayati Moudgil** recognised a**s Joint Coordinator** at **State Conference** Continuing Pharmacy Education Program for Practicing Pharmacist – PCI Sponsored organised by Department of Pharmacy Practice JSS College of Pharmacy, Ooty in Association with Indian Pharmaceutical Association IPA – The Nilgiris Branch on 25.09.2018

Mr. **Sumit Kumar Rai** (V Pharm.D Student) received **Best E-Case Presentation under** the guidance of Dr**. Khayati Moudgil** at **National Conference** "**Sustainable Development with Pharmacological Research & Innovations"** organised by Department of Pharmacology, JSS College of Pharmacy, Ooty, The Nilgiris, Tamil Nadu from 28th - 29th September 2018

Conferences Organized (including CME/CDE/CPE, etc.)

Department of Pharmacy Practice & Department of Pharmaceutics organised a **One-day workshop** on theoretical basis for *in* ***silico*** **methods** in Biopharmaceutics and pharmacokinetics on 13th August 2018 with a total number of 50 participants

Department of Pharmacy Practice organised a **National Conference on** Continuing Education Programme (**CEP**) for Pharmacy Teachers from 21st to 23rd September 2018 with a PCI Sponsored CEP approved to **Dr. S. Ponnusankar** funded by PCI about 3 lakhs with a total number of 30 participants

Department of Pharmacy Practice organised a **CME** funded by JSS Academy of Higher Education and Research, Mysuru about Rs 10,000 with a total number of 30 participants

DRUG PROFILE

VORAPAXAR

Class: Anti-Platelet, Protease-activated receptor-1 (PAR-1) antagonist

Indication: Patients with History of Myocardial Infarction (MI) or with Peripheral Arterial Disease (PAD)

Mechanism of Action:

Vorapaxar is a reversible antagonist of the PAR-1expressed on platelets. Vorapaxar inhibits thrombin-induced and thrombin receptor agonist peptide (TRAP)-induced platelet aggregation in in-vitro studies. Vorapaxar does not inhibit platelet aggregation induced by adenosine diphosphate (ADP), collagen or a thromboxane mimetic and does not affect coagulation parameters ex vivo.

Dosage form and Administration:

- Vorapaxar is available as yellow coloured, oval-shaped, film coated tablets of 2.08 mg (Equivalent to 2.5 mg of Vorapaxar sulphate), for oral use. Normal adult dose is Vorapaxar 2.08 mg orally once daily, with or without food.
- Dosing in Renal Impairment: No dose adjustment is required in patients with renal impairment
- Dosing in Hepatic Impairment: No dose adjustment is required in patients with hepatic impairment

Pharmacokinetics:

Vorapaxar pharmacokinetics are similar in healthy subjects and patients. Vorapaxar is absorbed from the gastrointestinal tract with a peak plasma concentration occurring at 1-2 hours post dosing. The mean absolute bioavailability is approximately 100%.

Vorapaxar is highly bound to human serum albumin. The mean volume of distribution is approximately 424 liters. Vorapaxar exhibits multi-exponential disposition with an effective half-life of 3-4 days and apparent terminal elimination half-life of 8 days.

Vorapaxar is extensively metabolized in liver by CYP3A4 and CYP2J2. The major active circulating metabolite is M20 (monohydroxy metabolite) and predominant metabolite identified is M19 (amine metabolite) are excreted through faeces and urine.

Adverse Reactions:

Major Adverse reactions during clinical trials were increased risk of bleeding. Other adverse reactions are Anemia (5%), Depression (2.4 %), Rashes, Eruptions & Exanthemas (2.2%), Diplopia (0.2%).

Contraindications:

- Pregnancy (Category B) - There is no adequate and well-controlled studies of Vorapaxar use in pregnant women. Based on data in rats and rabbits, Vorapaxar is predicted to have a low probability of risk of adverse developmental outcomes. No embryo/fetal toxicities, malformations or maternal toxicities were observed in rats exposed during gestation to 56 times the human systemic exposure at the recommended human dose (RHD). Available information related to use in pregnancy is limited; if unintentional exposure occurs during pregnancy, close monitoring of the mother and fetus is recommended. Vorapaxar should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.
- Vorapaxar is contraindicated in patients with history of stroke, Transient ischemic attack, Active Intra cranial hemorrhage or peptic ulcer bleed.

Precautions & Drug Interactions:

- Like other antiplatelet agents, Vorapaxar increases the risk of bleeding. Patients should be monitored carefully.
- Avoid use with CYP3A inhibitors (E.g., Ketoconazole, Itraconazole, Posaconazole, Clarithromycin, Nefazodone, Ritonavir, Saquinavir, Nelfinavir, Indinavir, Boceprevir, Telaprevir, Telithromycin and Conivaptan.
- Avoid use with CYP3A inducers (E.g., Rifamipcin, Carbimazole, Phenytoin, St. John's Wart)

Timing of onset of adverse cutaneous reactions associated with programmed cell death protein 1 inhibitor therapy

JAMA — Wang LL, et al. | October 05, 2018

Researchers assessed the timing of cutaneous drug reactions following initiation of programmed cell death protein 1 (PD-1) inhibitor therapy in this retrospective observational study. The findings suggested that various cutaneous adverse reactions secondary to PD-1 inhibitor use might present with delayed onsets, even after discontinuation of the medication. They advised that skin specialists ought to know about the possibility of delayed cutaneous adverse reactions.

Methods

- Study participants were patients referred to an academic dermatology clinic by an oncologist from January 1, 2014 through February 28, 2018, with at least 1 skin biopsy specimen of a skin reaction associated with PD-1 inhibitor use.
- All participants had a biopsy-proven cutaneous reaction in response to using pembrolizumab, nivolumab, or nivolumab with ipilimumab as immunotherapy for cancer.
- Time to onset of biopsy-proven cutaneous reactions that occurred during or after use of pembrolizumab or nivolumab was the main outcome measure.

Results

- In this analysis, researchers identified 17 subjects (12 men, 5 women; mean [SD] age, 68.6 [11.1] years) who presented with cutaneous adverse reactions related to PD-1 inhibitor therapy; these reactions included bullous pemphigoid, lichenoid dermatitis, erythema multiforme, lupus, eczema and sarcoidosis.
- It was noted that 12 patients presented with reactions at least 3 months after beginning pembrolizumab or nivolumab therapy.
- After drug initiation, it took a median (range) of 4.2 months (0.5-38.0 months) for skin reactions to present.
- Cutaneous adverse reactions attributed to the PD-1 inhibitor therapy developed after the drug therapy was terminated in five cases.

RECENTLY APPROVED DRUGS BY FDA

S.No	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date
1.	Tpoxx	Tecovirimat	7/13/2018	To treat smallpox
2.	Krintafel	Tafenoquine	7/20/2018	For the radical cure (prevention of relapse) of Plasmodium vivax malaria
3.	Tibsovo	Ivosidenib	7/20/2018	To treat patients with relapsed or refractory acute myeloid leukemia
4.	Orilissa	Elagolix Sodium	7/23/2018	For the management of moderate to severe pain associated with endometriosis
5.	Omegaven	Fish Oil Triglycerides	7/27/2018	As a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis
6.	Mulpleta	Lusutrombopag	7/31/2018	To treat thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
7.	Poteligeo	Mogamulizumab-Kpkc	8/8/2018	To treat two rare types of non-Hodgkin lymphoma
8.	Galafold	Migalastat	8/10/2018	To treat treat adults with Fabry disease.
9.	Annovera	Segesterone Acetate And Ethinyl Estradiol Vaginal System	8/10/2018	New vaginal ring used to prevent pregnancy for an entire year
10.	Onpattro	Patisiran	8/10/2018	To treat the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adult patients
11.	Diacomit	Stiripentol	8/20/2018	To treat seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam
12.				
13.	Oxervate	Cenegermin-Bkbj	8/22/2018	To treat neurotrophic keratitis
14.	Takhzyro	Lanadelumab	8/23/2018	To treat types I and II hereditary angioedema
15.	Xerava	Eravacycline	8/27/2018	To treat complicated intra-abdominal infections in patients 18 years of age and older
16.	Pifeltro	Doravirine	8/30/2018	To treat HIV-1 infection in adult patients
17.	Ajovy	Fremanezumab-Vfrm	9/14/2018	For the preventive treatment of migraine in adults
18.	Ajovy	Fremanezumab-Vfrm	9/14/2018	For the preventive treatment of migraine in adults

19.	Copiktra	Duvelisib	9/24/2018	To treat relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma and follicular lymphoma
20.	Vizimpro	Dacomitinib	9/27/2018	To treat metastatic non-small-cell lung cancer
21.	Emgality	Galcanezumab-Gnlm	9/27/2018	For the preventive treatment of migraine in adults
22.	Libtayo	Cemiplimab-Rwlc	9/28/2018	To treat cutaneous squamous cell carcinoma (CSCC)

Available from: Novel Drug Approvals for 2018
https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm592464.htm

For clarifications/ feedback, write to:
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