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Hot Off the Press: New Drugs of 2018



HOT OFF THE PRESS: NEW DRUGS OF 2018

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This program will provide a brief overview of new drug approvals for 2018 along with drug information resources that pharmacists can utilize to stay up-to-date. Among the many approvals included in this overview are new medications approved for disease states and conditions such as migraine prevention, opioid withdrawal, influenza, and cannabidiol for severe forms of epilepsy. Additionally, it will discuss drugs for rare diseases and important counseling points for patients.

Learning Objectives

Pharmacist

- 1 Identify drugs for rare diseases to include the first medication for smallpox treatment (TPOXX)
- 2 Recognize mechanism of action, dosing, drug interactions, and adverse drug reactions of new drug approvals
- 3 Identify drug information resources pharmacists can utilize to stay up-to-date with new drug approvals
- 4 Identify key counseling points for new drug approvals

Pharmacy Technician

- 1 Identify new medications approved in 2018
- 2 Identify drugs for rare diseases to include the first medication for smallpox treatment (TPOXX)
- 3 Recognize dosing, drug interactions, and adverse drug reactions of new drug approvals

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The number of new drug approvals has continuously increased over the years, and the U.S. Food and Drug Administration (FDA) has approved 59 in 2018.¹ This is the largest amount of drugs approved in the past 10 years (Table 1).² These approvals include orphan drugs to treat rare diseases and first time drugs for conditions like smallpox. Additionally, 34 (58%) of the new drugs were approved to treat rare diseases (Table 2).² Other drug approvals include those used to treat cancer, influenza, and human immunodeficiency virus (HIV). With pharmacists as the drug experts, it can be daunting to stay up-to-date with the latest new drug approvals.

Table 1: 10 Year History of Drug Approvals²

Year	Number of FDA Approvals
2009	26
2010	21
2011	30
2012	39
2013	27
2014	41
2015	45
2016	22
2017	46
2018	59

FDA indicates U.S. Food and Drug Administration

Table 2: Quick Glance at Orphan Drugs for Rare Diseases²

Drug Brand Name	Generic Name	FDA Approved Indication
Asparlas	calaspargase pegol-mknl	Acute lymphoblastic leukemia in pediatrics and young adults

Braftovi	encorafenib	Unresectable or metastatic melanoma
Copiktra	duvelisib	Relapsed or refractory chronic lymphocytic lymphoma and follicular lymphoma
Crysvita	burosumab-twza	x-linked hypophosphatemia (rare inherited form of rickets) in adults and children 1 year and older
Daurismo	glasdegib	Newly diagnosed acute myeloid leukemia
Diacomit	stiripentol	Seizures associated with Dravet syndrome in patients 2 years and older taking clobazam
Elzonris	tagraxofusp	Blastic plasmacytoid dendritic cell neoplasm
Epidiolex	cannabidiol	Rare, severe forms of epilepsy
Firdapse	amifampridine	Lambert-Eaton myasthenic syndrome in adults
Galafold	migalastat	Fabry disease in adults
Gamifant	emapalumab-lzsg	Primary hemophagocytic lymphohistiocytosis
Krintafel	tafenoquine	Prevention of relapse of Plasmodium vivax malaria
Lorbrena	lorlatinib	Anaplastic lymphoma kinase positive metastatic non-small cell lung cancer
Lumoxiti	moxetumomab pasudotox-tdfk	Hairy cell leukemia
Lutathera	lutetium Lu 177 dotatate	Cancer affecting the pancreas or gastrointestinal tract called gastroenteropancreatic neuroendocrine tumors
Mektovi	binimetinib	Unresectable or metastatic melanoma

Moxidectin	moxidectin	Onchocerciasis (parasitic tropical disease) due to <i>Onchocerca volvulus</i> in patients 12 years and older
Omegaven	fish oil triglycerides	Parenteral nutrition-associated cholestasis
Onpattro	patisiran	Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
Oxervate	cenegermin	Neurotrophic keratitis
Palyngiq	pegvaliase-pqpz	Rare and serious genetic disease phenylketonuria in adults
Poteligeo	mogamulizumab-kpkc	Two rare types of non-Hodgkin lymphoma
Revcovi	elapegademase-lvlr	Adenosine Deaminase-Severe Combined Immunodeficiency
Symdeko	tezacaftor/ivacaftor and ivacaftor	Cystic fibrosis in patients 12 years and older
Takhzyro	lanadelumab-flyo	Types 1 and II hereditary angioedema
Tavalisse	fostamatinib	Thrombocytopenia in adult patients with persistent or chronic immune thrombocytopenia
Tegsedi	Inotersen	Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
Tibsovo	ivosidenib	Relapsed or refractory acute myeloid leukemia
Tpoxx	tecovirimat	Smallpox
Trogarzo	ibalizumab-uiyk	HIV patients with limited treatment options
Ultomiris	ravulizumab	Paroxysmal nocturnal hemoglobinuria

Vitrakvi	larotrectinib	Cancers with a specific genetic biomarker
Vizimpro	dacomitinib	Metastatic non-small-cell lung cancer
Xospata	gilteritinib	Relapsed or refractory acute myeloid leukemia

First of Its Kind Approvals

The following discussion of novel medication approvals is important for pharmacists and technicians to become more familiar with the names of these medications and their indications, what makes them novel, dosages, interactions, and relevant counseling points. While some are included in Table 2 as Orphan Drugs and may not be encountered often in practice, others represent novel approaches to treating diseases and conditions that are more commonly encountered. These novel drugs have or will soon begin to surface in practice, find their places in guidelines and treatment recommendations, and continue to be tracked for post marketing data such as adverse events. Pharmacists play a vital role in all of these areas in addition to providing care and counseling to patients.

TPOXX (tecovirimat)

TPOXX (tecovirimat) is an antiviral medication that inhibits the viral envelope formation and prevents the spread of the virus. Also, it is the first drug approved for the treatment of smallpox.^{3,4} Even though the World Health Organization declared smallpox eradicated in 1980, there have been concerns that it could be used as a bioweapon. Smallpox is a contagious and potentially fatal disease that was mainly spread by direct contact between people, with symptoms including rash, fever, tiredness, headache, and backache. Smallpox can lead to serious complications including encephalitis, corneal ulcerations, and blindness. TPOXX was studied in 359 healthy study participants without smallpox infection, and it was given fast track and priority review status.³ Drug efficacy studies were conducted in animals infected with viruses similar to those causing smallpox, as human trials would be unethical.³ The most common adverse reactions in healthy adults were headache, nausea, abdominal pain, and vomiting. TPOXX should be taken within 30 minutes after a full meal of moderate or high fat, and the dosage for adults is 600 mg orally twice a day for 14 days.⁴ TPOXX dosing for pediatric patients is weight based (Table 3). Capsules can also be administered by opening and mixing the entire contents in 30 ml of liquid (e.g. milk) or soft food (e.g. apple sauce, yogurt). TPOXX may increase drug concentrations of the antidiabetic medication repaglinide, and patients should be monitored for signs and symptoms of

hypoglycemia. Additionally, TPOXX may decrease midazolam concentrations which may affect the efficacy of midazolam.

Table 3: TPOXX Dosage in Pediatric Patients⁴

Weight	Dosage
13 kg to less than 25 kg	200 mg twice daily for 14 days
25 kg to less than 40 kg	400 mg twice daily for 14 days
40 kg or more	600 mg twice daily for 14 days

Epidiolex (cannabidiol)

Epidiolex is a novel medication because it is the first FDA approved drug that contains a purified drug substance cannabidiol [CBD] derived from marijuana.⁵ The exact mechanism by which Epidiolex provides anticonvulsant effects in humans is unknown. Evidence suggests that cannabidiol does not create anticonvulsant effects through interaction with cannabinoid receptors.⁵ It is approved for the treatment of seizures associated with two rare and severe forms of epilepsy known as Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older. Additionally, this is the first FDA approved drug for the treatment of Dravet syndrome.⁵ The Drug Enforcement Administration placed Epidiolex in schedule V of the Controlled Substances Act, which means it has a lower potential for abuse than other controlled substance drugs.⁶ Studies have shown that Epidiolex decreased seizure frequency by 17% to 23% when taken along with other antiepileptic medications compared with placebo.^{7,8} Epidiolex is an oral solution, and the starting dose is 2.5 mg/kg twice a day, and it can be increased to a maintenance dosage of 5 mg/kg twice a day after one week.⁷ Additionally, Epidiolex should be dose adjusted for patients with hepatic impairment. The most common adverse effects include tiredness, decreased appetite, diarrhea, elevated liver enzymes, weakness, rash, and infections. Serious adverse effects may include liver injury, sedation, suicidal thoughts and behavior, and hypersensitivity reactions. Patients may need a dose reduction of Epidiolex when it is administered with moderate or strong inhibitors of CYP3A4 and CYP2C19 since these medications may increase Epidiolex concentrations. Additionally, strong CYP3A4 or CYP2C19 inducers may decrease Epidiolex concentrations so a dose increase may be necessary. Epidiolex and the antiepileptic drug Onfi (clobazam) have a drug interaction that increases the active metabolites of both medications in the bloodstream. Onfi and alcohol may increase the risk of CNS adverse effects in patients taking Epidiolex. The dose of Epidiolex should be

gradually decreased if the medication is being discontinued to prevent increased seizures, as with all anticonvulsants.⁷

Pharmacists should counsel patients on the appropriate use of Epidiolex, which comes with two reusable 5 ml oral syringes.⁷ If the dose is less than 1 ml, then it is important to provide patients with 1 ml syringes. When patients use Epidiolex for the first time, they should remove the child-resistant cap and push the bottle adapter firmly into the bottle. The tip of the oral syringe should be inserted into the bottle adapter, and the bottle should be turned upside down to withdraw the Epidiolex dose. If there are air bubbles in the oral syringe, then the liquid should be pushed back into the bottle and withdrawn again. Epidiolex should be administered by placing the tip of the oral syringe against the inside of the cheek, and the plunger should be gently pushed until all of the medication is given. After the medication is administered, the child-resistant cap should be placed back on the bottle with the bottle adapter kept in place. Educate patients to keep Epidiolex out of reach of children. It should be stored at room temperature and used within 12 weeks of opening the bottle. The oral syringe should be cleaned with warm soapy water.⁷

Aimovig (ereunumab-aooe)

Aimovig is approved for the prevention of migraine and is self-injected subcutaneously. It is the first to be approved in a new class of drugs called calcitonin gene-related peptide receptor (CGRP-R) antagonists.⁹ Aimovig is a human monoclonal antibody that binds to the CGRP receptor and antagonizes the receptor function, which blocks CGRP that is released during migraine episodes. The recommended dose is 70 mg once a month and can go up to 140 mg once a month. The most common adverse drug reactions are injection site reactions and constipation. Since Aimovig is not metabolized by cytochrome P450 enzymes, interactions are not likely. Educate patients that if they are prescribed the 140 mg dose, then two separate injections should be administered, one after another with a different prefilled autoinjector or prefilled syringe at different sites. Aimovig should be stored in the refrigerator, but it should be left at room temperature for at least 30 minutes before injecting.⁹

Crysvita (burosumab-twza)

Crysvita is the first FDA approved drug to treat adults and children ages one year and older with x-linked hypophosphatemia, which is a rare inherited form of rickets that causes low phosphorous levels.¹⁰ It works by binding to and blocking a growth factor known as FGF23 to restore renal phosphate levels. It is administered subcutaneously by a healthcare provider, and oral phosphate and vitamin D medications should be discontinued one week before treatment. The starting dose for pediatric patients is 0.8 mg/kg of body weight

administered every two weeks, and the adult dose is 1 mg/kg every four weeks. The most common adverse effects in pediatric patients include headache, injection site reaction, vomiting, fever, pain in the extremities, and decreased vitamin D. Adults may experience back pain, headache, restless leg syndrome, decreased vitamin D, constipation, dizziness, and increased phosphorous levels. No drug interaction studies have been conducted with Crysvisa. Pharmacists should counsel patients that hypersensitivity reactions such as rash may occur with Crysvisa treatment.¹⁰

Elzonris (tagraxofusp-erzs)

Elzonris infusion is the first FDA approved treatment for the rare condition blastic plasmacytoid dendritic cell neoplasm, which is an aggressive and life-threatening form of blood cancer. It works by inhibiting protein synthesis and causes cell death. Elzonris is approved for individuals 2 years of age and older.¹¹ The dose of Elzonris is 12 mcg/kg administered as an IV over 15 minutes once a day on days 1 to 5 of a 21-day cycle. Common adverse effects reported in clinical studies include capillary leak syndrome (boxed warning), nausea, fatigue, peripheral edema, fever, and weight increase. No drug interaction studies have been conducted with Elzonris. Liver enzymes should be monitored, as they may increase during Elzonris therapy.

Galafold (migalastat)

Galafold is the first oral medication approved for adults to treat the rare and serious genetic disorder Fabry disease, which can cause kidney disease, enlargement of the heart, arrhythmias, stroke, and death.¹² Galafold works by binding to the active site of the alpha-galactosidase A protein and increases the activity of the body's deficient enzyme, which is lacking in Fabry disease. The most common adverse effects include headache, nasopharyngitis, urinary tract infection, nausea, and fever. The recommended dose of Galafold is 123 mg orally once every other day at the same time.¹³ Pharmacists should educate patients to take Galafold on an empty stomach and to avoid consuming food at least 2 hours before and 2 hours after taking the medication. There is a low risk of drug interactions since Galafold is not a known inhibitor of cytochrome P450 enzymes.¹³

Lucemyra (lofexidine hydrochloride)

This is the first non-opioid medication approved for the management of opioid withdrawal symptoms in adults to be used for up to 14 days.¹⁴ Lucemyra is a selective alpha 2-adrenergic receptor agonist that reduces the release of norepinephrine, which is believed to play a role in opioid withdrawal symptoms.¹⁴ The usual dosage of Lucemyra is three 0.18

mg tablets orally four times a day during peak withdrawal symptoms, with 5-6 hours between each dose. Lucemyra should be discontinued with a gradual dose reduction over a 2-4 day period. Common adverse reactions include orthostatic hypotension, bradycardia, hypotension, dizziness, sedation, and dry mouth. Lucemyra prolongs the QT interval and should be avoided in patients with congenital long QT syndrome. Additionally, ECG monitoring is recommended in patients taking methadone and Lucemyra as they can both prolong the QT interval. Lucemyra can also reduce the efficacy of oral naltrexone. Paroxetine can increase blood levels of Lucemyra, and patients should be closely monitored for orthostatic hypotension and bradycardia when these medications are used together or with other CYP2D6 inhibitors. Benzodiazepines, alcohol, and other sedating medications can cause CNS depression when used with Lucemyra. Pharmacists should educate patients for signs of hypotension and bradycardia, which include dizziness and lightheadedness. In a phase III randomized placebo controlled study, Lucemyra was found to decrease opioid withdrawal symptoms significantly ($p=0.0212$) compared to placebo.¹⁵

Lutathera (lutetium Lu 177 dotatate)

Lutathera is approved for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).¹⁶ This is the first radioactive drug approved for the treatment of GEP-NETs. The recommended dose of Lutathera is 7.4 GBq every 8 weeks for a total of 4 doses. Long-acting somatostatin analogs like long-acting octreotide should be discontinued at least 4 weeks before starting Lutathera. Short-acting octreotide should be administered as needed and discontinued at least 24 hours prior to starting Lutathera. The most common adverse effects include lymphoma, vomiting, nausea, increased liver enzymes, hyperglycemia, and hypokalemia. Educate patients to minimize radiation exposure to household members.¹⁶

Onpattro (patisiran)

Onpattro is the first medication approved to treat patients with polyneuropathy caused by the rare genetic disease hereditary transthyretin amyloidosis, which develops through the accumulation of an abnormal protein in the nerves, heart, and gastrointestinal tract.¹⁷ Onpattro is part of a brand new class of drugs called small interfering ribonucleic acid, and it is administered as an intravenous infusion. The recommended dosage is 0.3 mg/kg every three weeks for patients weighing less than 100 kg, and 30 mg for individuals weighing 100 kg or more. All patients should receive premedications 60 minutes prior to the infusion with a corticosteroid, acetaminophen, and antihistamines to prevent infusion-related reactions. Upper respiratory tract infections are another adverse effect that patients may experience. Patients may also experience decreases in vitamin A levels so supplementation is recommended. Pharmacists should counsel patients about common signs and symptoms

of infusion-related reactions such as flushing, dyspnea, chest pain, tachycardia, rash, and facial edema.¹⁷

Orilissa (elagolix)

This is the first new treatment for endometriosis approved in over 10 years.¹⁸ Orilissa is a gonadotropin-releasing hormone GnRH receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. The hormone GnRH signals the pituitary gland to release luteinizing hormone and follicle stimulating hormone. This stimulates estrogen production, which is known to exacerbate endometriosis. Orilissa suppresses these hormones. The dosage in patients with normal liver function or mild hepatic impairment is 150 mg once a day for up to 24 months or 200 mg twice a day for up to 6 months. Patients with moderate liver impairment should receive 150 mg once a day for up to 6 months. Orilissa should not be used in women with the following conditions:

- Pregnant
- Known osteoporosis
- Severe hepatic impairment
- Using strong organic anion transporting polypeptide inhibitors (e.g. cyclosporine and gemfibrozil)

The most common adverse effects to expect are hot flashes, night sweats, headache, nausea, insomnia, amenorrhea, anxiety, depression, and mood changes. Digoxin levels may increase when patients are also receiving Orilissa so monitoring is recommended. Rifampin may increase Orilissa blood levels. The dose of Orilissa should be decreased to 150 mg once a day for 6 months when used in combination with rifampin. Orilissa can also decrease concentrations of midazolam and rosuvastatin, so the doses of these medications may need to be increased. Pharmacists should educate patients to seek immediate medical attention if they experience suicidal thoughts or behavior. Patient education regarding the risk of bone loss is important, and adequate calcium and vitamin D are necessary.¹⁸

Oxervate (cenegermin-bkbj)

Oxervate is a recombinant human nerve growth factor topical ophthalmic solution approved for the treatment of a rare and serious disease known as neurotrophic keratitis that affects the cornea of the eye.¹⁹ It is the first topical biologic medication to be approved in ophthalmology. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons to support corneal innervation and integrity. The dosage of Oxervate is one drop in the affected eye(s) six times a day at 2-hour intervals for eight weeks. The most common adverse effects include eye pain, ocular hyperemia

(enlarged blood vessels in the whites of the eye), eye inflammation, and increased lacrimation (watery eyes). Pharmacists should educate patients that contact lenses should be removed before applying Oxervate and to wait 15 minutes after drop installation before reinserting contact lenses.¹⁹

Palynziq (pegvaliase-pqpz)

Palynziq injection is a novel enzyme therapy approved for adults with the rare and serious genetic condition phenylketonuria (PKU).²⁰ Baseline blood phenylalanine concentration should be taken before starting treatment. The recommended starting dose is 2.5 mg subcutaneously once a day.²¹ The dose of Palynziq can be increased to a maximum of 40 mg subcutaneously once a day in patients who have been taking Palynziq 20 mg once a day continuously for at least 24 weeks and have not achieved either a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood concentration less than or equal to 600 micromol/L.²¹ The most common adverse reactions are injection site reactions, arthralgia, hypersensitivity reactions, headache, pruritus, nausea, abdominal pain, vomiting, diarrhea, and fatigue. Patients taking other medications that are PEGylated products such as medroxyprogesterone acetate suspension (contains PEG 3350) along with Palynziq may experience hypersensitivity reactions and should be monitored closely for signs of anaphylaxis. Pharmacists should counsel patients that Palynziq may cause hypersensitivity reactions, and it is important to carry auto-injectable epinephrine with them at all times during treatment. Anaphylaxis is part of the boxed warning for Palynziq, and since it is a serious risk the medication is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). The Palynziq REMS requirements include the following:²¹

- Prescribers must be certified and complete training
- Prescribers must prescribe auto-injectable epinephrine with Palynziq
- Pharmacies must be certified with the REMS program and can only dispense Palynziq to patients who are enrolled in the program

Poteligeo (mogamulizumab-kpkc)

Poteligeo is a monoclonal antibody that binds to a protein found in some cancer cells, and it is approved for two rare types of non-Hodgkin lymphoma in adult patients.²² It is the first biologic agent targeting CC chemokine receptor 4 (CCR4) to be approved in the U.S. Poteligeo is administered as an intravenous infusion 1 mg/kg over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle. The most common adverse effects include rash, infusion reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infections. No drug interaction studies have been conducted with Poteligeo. Pharmacists should educate patients about possible

adverse effects and advise females of reproductive potential to use effective contraception during treatment with Poteligeo and for at least three months following the last dose since it has the potential to be transmitted from the mother to the fetus.²²

Tavalisse (fostamatinib)

Tavalisse is a kinase inhibitor approved for adult patients with the rare disease chronic immune thrombocytopenic purpura (ITP), which is an autoimmune blood disorder where the body destroys its own blood platelets.²³ First in a new class of oral spleen tyrosine kinase (SYK) inhibitors, fostamatinib targets the underlying cause of the disease by preventing destruction of platelets. The starting dose for Tavalisse is 100 mg orally twice a day, and the dosage can be increased to 150 mg twice a day after four weeks. Tavalisse should be discontinued after 12 weeks if the platelet count does not increase to an appropriate level to avoid bleeding. Strong CYP3A4 inhibitors and inducers may affect exposure to the active metabolite of Tavalisse and should be monitored. Common adverse effects of Tavalisse treatment include diarrhea, hypertension, nausea, respiratory infection, dizziness, increased liver enzymes, abdominal pain, fatigue, chest pains, and neutropenia. Pharmacists should educate patients that it is important to monitor blood pressure while taking Tavalisse since it can cause hypertension. Recommend a home blood pressure monitoring system. Also, patients should keep all scheduled appointments to monitor liver enzymes and complete blood counts. Females of reproductive potential should use effective contraception during treatment with Tavalisse and for at least one month after receiving the last dose since there is a potential risk to a fetus.²³

Tegsedi (inotersen)

Tegsedi is an injection approved for the treatment of nerve damage in adults with the rare condition hereditary transthyretin-mediated amyloidosis.²⁴ This condition is caused by the buildup of abnormal deposits of amyloid in the tissues and organs. Tegsedi is the first approved RNA interference drug (RNAi) which exerts its action by reducing the production of the disease-causing TTR protein in the liver by blocking the activity of a gene. The recommended dose of Tegsedi is 284 mg administered by subcutaneous injection once a week. The most common adverse effects are injection site reactions, nausea, headache, fatigue, thrombocytopenia, and fever. There is a boxed warning for thrombocytopenia and glomerulonephritis. Since there is a risk of thrombocytopenia, antiplatelet medications, over-the-counter products (e.g. aspirin) affecting platelets, and anticoagulant medications should be used cautiously with Tegsedi. Nephrotoxic drugs can also impair renal function when used concomitantly with Tegsedi. Tegsedi is only available through a REMS program. Requirements include that prescribers must be certified by enrolling and completing the training. Also, patients must enroll in the program and pharmacies must be certified to dispense Tegsedi. Pharmacists should educate patients about how to administer Tegsedi,

and injection sites include the abdomen, upper thigh, or outer area of the upper arm. The prefilled syringe should reach room temperature prior to injection and should be removed from the refrigerator at least 30 minutes before administration.²⁴

Tibsovo (ivosidenib)

Tibsovo is the first drug in its class known as an isocitrate dehydrogenase-1 inhibitor (IDH1) for the treatment of adult patients with the rare condition of relapsed or refractory acute myeloid leukemia who have a specific genetic mutation that is detected by an FDA approved test.²⁵ The dosage is 500 mg orally once a day until the disease worsens or there are unacceptable toxic effects.²⁶ If patients are doing well on the therapy, then they should be treated for at least 6 months. Pharmacists should educate patients to avoid a high-fat meal with administration since it can increase the drug concentrations. There is a boxed warning for a condition known differentiation syndrome, which can be fatal if it is not treated. Symptoms of the condition include dyspnea, acute respiratory distress, lung inflammation, rapid weight gain, peripheral edema, or multi-organ dysfunction. Differentiation syndrome should be treated with corticosteroids and monitored closely. Common adverse effects associated with Tibsovo include fatigue, leukocytosis, arthralgia, diarrhea, dyspnea, edema, nausea, mucositis, QT prolongation, rash, fever, cough, and constipation. Tibsovo should not be administered with itraconazole or ketoconazole since it can decrease the antifungal efficacy. Also, Tibsovo may decrease the efficacy of hormonal contraceptives so alternative contraception methods should be used. Tibsovo is also a CYP3A4 inducer and may induce CYP2C9 which could make substrates of these enzymes less effective.²⁶

Trogarzo (ibalizumab uiyk)

Trogarzo is a monoclonal antibody that is approved for the treatment of human immunodeficiency virus type 1 (HIV-1) in combination with other antiretrovirals in patients with a multidrug resistant infection.²⁷ Trogarzo is a post-attachment inhibitor that works by attaching to a protein on the surface of the immune cells and blocks HIV from entering the cells. It is the first monoclonal antibody to treat HIV and is also the first HIV therapy with a novel mechanism of action to be approved in 10 years. This is a promising medication for patients who have run out of treatment options. Trogarzo is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% Sodium Chloride Injection, USP. Dose adjustments are not necessary when Trogarzo is administered with other medications. Drug-interaction studies have not been conducted, but based on the mechanism of action they are not expected. The most common adverse effects include diarrhea, dizziness, nausea, and rash. There is a warning for immune reconstitution inflammatory syndrome (IRIS) since it has been reported in patients receiving combination antiretroviral therapies. This occurs when there is

worsening of preexisting infections. Pharmacists should counsel patients to contact their healthcare provider if they experience any infection symptoms.²⁷ A recent phase 3 study examined the efficacy of Trogarzo in patients with multidrug-resistant HIV-1 infection where multiple antiretroviral therapies had previously failed. There were 40 patients enrolled and 31 completed the study.²⁸ The study found that 83% of the intention-to-treat population (includes the results of all patients who started the study) had a significant decrease in viral load ($P < 0.001$).²⁸

Vitrakvi (larotrectinib)

Vitrakvi is the first oral tropomyosin receptor kinase (TRK) inhibitor to be approved for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation; are metastatic where surgery could have negative outcomes; and have no adequate alternative treatment options. Gene sequencing is utilized to identify presence of the neurotrophic receptor tyrosine kinase gene fusion (NTRK fusion-positive). The recommended dosage in adults and pediatric patients with body surface area of at least 1 meter-squared is 100 mg orally twice a day. Patients with a body surface area of less than 1 meter-squared should receive 100 mg/m² orally twice a day. Strong CYP3A4 inhibitors and inducers can interact with Vitrakvi and should be avoided. If the medications are necessary, then the dose of Vitrakvi should be adjusted. The most common adverse reactions are fatigue, nausea, dizziness, vomiting, increased AST and ALT levels, cough, constipation, and diarrhea. Pharmacists should educate patients to avoid breastfeeding during Vitrakvi treatment and for one week following the final dose.

Xofluza (baloxavir marboxil)

Xofluza is a first in class antiviral flu treatment approved in 20 years with a novel proposed mechanism of action and is indicated for patients 12 years and older who have been symptomatic for no more than 48 hours.^{29,30} It is a polymerase acidic endonuclease inhibitor and is taken as a single dose orally. Baloxavir is thought to block an enzyme within the flu virus,

stopping viral replication early in the influenza lifecycle. Xofluza dosing is weight based and patients 40 kg to less than 80 kg should receive a single oral dose of 40 mg. Individuals at least 80 kg should receive a single oral dose of 80 mg.²⁹ One dose can help with patient compliance. In two randomized, double-blind controlled clinical trials, Xofluza was studied in patients 12-64 years of age during the 2016-2017 flu season.³¹ Xofluza was dosed at 40 or 80 mg depending on the patient's weight and compared with Tamiflu 75 mg twice a day for five days. The studies demonstrated that Xofluza alleviated flu symptoms in a shorter time frame than placebo. Additionally, the second study showed there was no difference between Xofluza and Tamiflu at alleviating flu symptoms.³¹ Therefore, one dose of Xofluza

has a similar efficacy to five days of Tamiflu treatment. However, Xofluza has not been studied in young pediatric patients and those 65 years of age and older.²⁹ The most common adverse effects of Xofluza are diarrhea, bronchitis, nasopharyngitis, headache, and nausea. Pharmacists should educate patients to avoid dairy or products that contain calcium, aluminum, or iron at the time of Xofluza administration, as these products may decrease the efficacy of Xofluza.²⁹ Advise patients to always get their annual influenza vaccine, as this is the best way to prevent the flu.

Other Novel Drugs for 2018 and Reporting Adverse Drug Reactions

This year there were a variety of drugs approved to treat many conditions including cancer and blood disorders, women’s health, neurological disorders, and infectious diseases (Table 4). The FDA designated 41% of the new drug approvals as Fast Track, which speeds drug development through increased communications.² Breakthrough therapies were also approved for serious or life-threatening diseases. Also, 43 medications were given a priority review through an expedited time.² When new drugs are introduced to a larger population than what was studied in clinical trials, there will generally be more adverse effects identified as well as new ones not listed in the prescribing information. Pharmacists can play an active role in the postmarketing surveillance process by reporting adverse effects to the FDA’s MedWatch program.

Table 4: Additional 2018 Novel Drug Approvals³²⁻⁷²

Brand (generic)	Indication	Dosage	Drug Interactions	Common Adverse Effects	Key Counseling Point
Ultomiris (ravulizumab)	Paroxysmal nocturnal hemoglobinuria	Infusion	Not studied	Upper respiratory tract infection and headache	Must receive meningococcal vaccine at least 2 weeks before receiving first dose
Asparlas (calaspargase pegol-mknl)	Acute lymphoblastic leukemia	2,500 units/m ² intravenously no more frequently	Not studied	Increased bilirubin, pancreatitis, abnormal	Possible hypersensitivity reactions

		than every 21 days		clotting studies	
Motegrity (prucalopride)	Chronic idiopathic constipation	2 mg orally once a day CrCL less than 30 mL/min: 1 mg once a day	Oral erythromycin concentrations may increase but unlikely to be clinically significant Ketoconazole may increase Motegrity concentrations but unlikely to be clinically significant	Headache, abdominal pain, nausea, diarrhea, dizziness, vomiting, fatigue	Can cause suicidal thoughts and behavior; Educate patients to be aware of any changes in mood
Xospata (gilteritinib)	Relapsed or refractory acute myeloid leukemia	120 mg orally once a day	Combined P-gp and strong CYP3A4 inducers like rifampin should be avoided with Xospata	Myalgia, fatigue, diarrhea, edema, dyspnea, rash, pneumonia, nausea, cough, headache, hypotension, dizziness, vomiting	Women should avoid breastfeeding during treatment and for at least 2 months after final dose
Firdapse (amifampridine)	Lambert-Eaton myasthenic syndrome	15-30 mg orally daily in divided doses 3-4 times a day Renal and hepatic impairment	Drugs that lower seizure threshold and medications with cholinergic effects	Paresthesia, upper respiratory tract infections, abdominal pain, nausea, diarrhea, headache, elevated liver enzymes,	Can cause seizures

		starting dose 15 mg a day		back pain, hypertension, and muscle spasms	
Daurismo (glasdegib)	Newly- diagnosed acute myeloid leukemia	100 mg orally once a day	Strong CYP3A4 inhibitors, inducers, QTc prolonging drugs	Boxed warning for embryo-fetal toxicity; Daurismo can cause fetal death and birth defects	Use effective contracepti on during treatment and for at least 30 days after last dose
Gamifant (emapaluma b-lzsg)	Primary hemophagocytic lymphohistiocyto sis	1 mg/kg intravenous infusion over one hour twice a week and administer with dexamethaso ne	Possibly affects Cytochrome P450 substances	Infections, hypertension, infusion- related reactions, fever	Patients should not receive any live or live attenuated vaccines during Gamifant treatment
Aemcolo (rifamycin)	Traveler's diarrhea	388 mg (two tablets) orally twice a day for three days	Drug interaction studies not conducted; drug interactions not expected	Headache and constipation	Take each dose with a glass of liquid and do not take with alcohol
Yupelri (revefenacin)	Chronic obstructive pulmonary disease	One 175 mcg unit-dose vial administered once a day by nebulizer	Avoid anticholinergic s and OATP1B1 and OATP1B3 inhibitors (e.g. rifampicin, cyclosporine)	Cough, nasopharyngi tis, upper respiratory tract infections, headache, back pain	Do not inhale more than one dose at a time

Lorbrena (lorlatinib)	Anaplastic lymphoma kinase positive metastatic non-small cell lung cancer	100 mg orally once a day	Contraindicated with strong CYP3A inducers	Edema, peripheral neuropathy, fatigue, diarrhea	Advise women not to breastfeed during treatment and for 7 days after the final dose
Revcovi (elapegademase-lvir)	Adenosine Deaminase-Severe Combined Immunodeficiency	Transitioning from Adagen to Revcovi: 0.2 mg/kg weekly intramuscularly Adagen naïve patients: 0.4 mg/kg weekly based on ideal body weight, divided into two doses intramuscularly	Not studied	Cough and vomiting	Adherence is important
Vizimpro (dacomitinib)	Metastatic non-small-cell lung cancer	45 mg orally once a day	Avoid proton pump inhibitors; administer at least 6 hours before or 10 hours after H2-receptor antagonists	Diarrhea, rash, decreased appetite, dry skin, cough	Patients should use moisturizers and minimize sun exposure

Copiktra (duvelisib)	Relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma and follicular lymphoma	25 mg orally twice a day	Avoid with strong CYP3A inducers	Diarrhea, neutropenia, rash, cough, nausea, pneumonia, anemia	Report any symptoms of infection (e.g. fever, chills)
Lumoxiti (moxetumomab pasudotox-tdfk)	Hairy cell leukemia	0.04 mg/kg intravenous infusion over 30 minutes on days 1, 3, and 5 of each 28 day cycle; premedicate with acetaminophen, antihistamine, and H2 receptor antagonist 30-90 minutes before each infusion	Not studied	Boxed warning for capillary leak syndrome (fluid and proteins leak out of tiny blood vessels) and hemolytic uremic syndrome (can cause anemia and kidney failure)	Report any signs of capillary leak syndrome (e.g. breathing trouble, hypotension, edema)
Takhzyro (lanadelumab)	Types 1 and II hereditary angioedema	300 mg every 2 weeks by subcutaneous injection	No studies have been conducted	Injection site reactions, upper respiratory tract infections, headache, rash, myalgia, dizziness, diarrhea	Takhzyro should be stored in the refrigerator
Diacomit (stiripentol)	Seizures associated with Dravet syndrome	50 mg/kg/day administered	Diacomit can increase clobazam blood	Tiredness, decreased appetite, agitation,	Capsules should be swallowed whole and

		orally in 2-3 divided doses	concentrations and clobazam dose may need adjustments	tremor, insomnia	not broken or opened
Omegaven (fish oil triglycerides)	Source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis	Adult dosage depends on many factors such as age, body weight, clinical status; maximum dose in pediatric patients is 1g/kg/day	Monitor for bleeding in patients taking antiplatelet or anticoagulant medications	Vomiting, agitation, bradycardia, apnea, and viral infection	Report any signs of infection
Krintafel (tafenoquine)	Prevention of malaria relapse	Single oral dose of 300 mg (two 150 mg tablets taken together) with food	Avoid coadministration of Krintafel with OCT2 and MATE substrates (e.g. dofetilide or metformin); monitor for toxicities if they must be taken together and dose adjustments may be needed	Dizziness, nausea, vomiting, headache, decreased hemoglobin	Take with food to increase absorption

Braftovi (encorafenib)	Unresectable or metastatic melanoma	450 mg orally once a day in combination with Mektovi	Avoid strong or moderate CYP3A4 inhibitors and inducers	Fatigue, nausea, vomiting, abdominal pain	Females with reproductive potential should use effective non-hormonal contraception during treatment and for 2 weeks after the final dose
Mektovi (binimetinib)	Unresectable or metastatic melanoma	45 mg orally twice a day in combination with Braftovi	No known drug interactions	Fatigue, nausea, diarrhea, vomiting, and abdominal pain	Patients should notify their healthcare provider if they experience signs of unusual bleeding
Moxidectin (moxidectin)	Onchocerciasis (eye and skin disease)	8 mg (four 2 mg tablets) as a single oral dose	Can be co-administered with CYP3A4 substrates	Tachycardia, pruritus, hypotension, abdominal pain, leukocytosis, diarrhea	Patients should lie down if they feel dizzy or light-headed
Symdeko (tezacaftor, ivacaftor)	Cystic fibrosis	One tablet (containing tezacaftor 100 mg/ivacaftor 150 mg) in the morning and one tablet (containing ivacaftor 150	Reduce Symdeko dose when co-administered with strong (e.g. ketoconazole) or moderate	Headache, nausea, sinus congestion, and dizziness	Take Symdeko with foods that contain fat

		mg) in the evening about 12 hours apart	(e.g. fluconazole) CYP3A inhibitors. Avoid food containing grapefruit or Seville oranges		
Ajovy (fremanezumab-vfrm)	Migraine prevention	225 mg monthly subcutaneously or 675 mg (3 injections) every 3 months subcutaneously	Unlikely	Injection site reactions, hypersensitivity reactions	Patients using injection every 3 months should administer as three consecutive injections (225 mg each)
Emgality (galcanezumab)	Migraine prevention	240 mg loading dose subcutaneously (2 consecutive injections of 120 mg each) followed by monthly injections of 120 mg	Unlikely	Injection site reactions, hypersensitivity reactions	Store prefilled syringe in the refrigerator
Akynzeo capsules (palonosetron and netupitant) Akynzeo injection (palonosetron)	Prevention of acute and delayed nausea and vomiting with cancer chemotherapy administered	Capsules: one capsule orally one hour before chemotherapy	Avoid CYP3A4 substrates for one week after Akynzeo administration CYP3A4 inducers like rifampin can	Headache, dyspepsia, fatigue, constipation, erythema, muscle weakness,	Monitor for signs of serotonin syndrome such as agitation, confusion,

n and fosnetupitant)	with dexamethasone	IV infusion: 30 minute infusion 30 minutes before chemotherapy	decrease netupitant concentrations	serotonin syndrome	tachycardia, sweating
Libtayo (cemiplimab-rwlc)	Treatment of metastatic cutaneous squamous cell carcinoma (CSCC) or advanced CSCC that are not candidates for curative surgery or radiation	350 mg as an IV infusion over 30 minutes every 3 weeks	Not studied	Fatigue, rash, diarrhea Immune-mediated adverse effects Infusion-related adverse effects, embryo-fetal toxicity	Females of reproductive potential should use effective contraception during treatment and for at least 4 months after last dose
Erleada (apalutamide)	First FDA approved treatment for non-metastatic castration-resistant prostate cancer	240 mg (four 60 mg tablets) orally once a day Use with gonadotropin-releasing hormone analog or should have had bilateral testicle removal	Erleada may decrease efficacy of drugs that are substrates of CYP3A4, CYP2C19, CYP2C9, UGT, P-gp, BCRP, or OATP1B1	Fatigue, hypertension, rash, diarrhea, nausea, weight loss, joint pain, decreased appetite, fracture, peripheral edema	Increased risk of falls and fractures

Talzenna (talazoparib)	Treatment of HER2 negative breast cancer and an abnormal inherited BRCA gene with cancer that is advanced or metastatic	1 mg as single oral dose once a day Moderate renal impairment (CrCL 30-59 ml/min 0.75 mg once a day)	P-gp inhibitors including amiodarone, carvedilol, clarithromycin, itraconazole, and verapamil may increase Talzenna concentration	Fatigue, anemia, nausea, neutropenia, headache, thrombocytopenia, vomiting, alopecia, diarrhea, decreased appetite,	Females of reproductive potential should use effective contraception during treatment with Talzenna and for at least 7 months after the last dose
Annovera (segesterone acetate and ethinyl estradiol vaginal system)	Progestin/estrogen CHC that is a vaginal ring for one year of contraception with novel progestin component.	Insert for 21 days vaginally remove for 7 days and insert again	Enzyme inducers such as phenytoin, rifampin, and St. John's wort may decrease efficacy; may need back up contraception method with enzyme inducers	Boxed warning females over 35 years who smoke should not use Annovera; cigarette smoking increases the risk of serious cardiovascular adverse events	Remind patients that Annovera does not protect against HIV and other sexually transmitted infections
Biktarvy (bictegravir, emtricitabine, tenofovir)	Treatment of HIV-1 infection with no treatment history or to replace current regimen for virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable	One tablet once a day Avoid in patients with a CrCL below 30 ml/min and in those with severe hepatic impairment	Avoid with the antiarrhythmic dofetilide Do not administer with rifampin Take Biktarvy 2 hours before antacids	Diarrhea, nausea, headache Boxed warning for risk of severe acute exacerbations of hepatitis B	Educate on the importance of compliance as missing doses can cause resistance

	regimen for at least 3 months without treatment failure or known resistance		Avoid St. John's wort		
Pifeltro (doravirine)	Non-nucleoside reverse transcriptase inhibitor (NNRTI) in combination with other antiretroviral medications	One tablet orally once a day Dose adjustment with rifabutin: one tablet orally twice a day (12 hours apart)	Contraindicated with: enzalutamide (androgen receptor), carbamazepine, oxcarbazepine, phenobarbital, phenytoin, St. John's wort, mitotane	Nausea, dizziness, headache, fatigue, diarrhea, abdominal pain, abnormal dreams	Educate on the importance of compliance as missing doses can cause resistance
Doptelet (avatrombopag)	Treatment of thrombocytopenia in adults with chronic liver disease scheduled for a procedure	Dose based on patient's platelet count either 60 mg (3 tablets) orally once a day with food for 5 consecutive days or 40 mg (2 tablets) orally once a day with food daily for 5 consecutive days	Doptelet weakly induces CYP2C8 and CYP2C9	Fever, abdominal pain, nausea, headache, fatigue, peripheral edema, thromboembolic complications	Educate women to avoid breastfeeding during treatment and for at least 2 weeks after the last dose
Mulpleta (lusutrombopag)	Treatment of thrombocytopenia in adults with chronic liver disease	3 mg orally once a day Procedure should occur	Not studied	Headache, thromboembolic complications	Educate women to avoid breastfeeding during treatment

	scheduled for a procedure	2-8 days after the last dose			and for 28 days after the last dose
Olumiant (baricitinib)	Janus kinase inhibitor for treatment of adults with moderately to severely active rheumatoid arthritis who have not responded adequately to one or more TNF antagonist treatments	2 mg once a day	Should be avoided with strong organic anion transporter 3 inhibitors like probenecid	Boxed warning for risk of serious infection, cancer, and thrombosis	Patients should report any signs and symptoms of DVT or PE
Ilumya (tildrakizumab-asmn)	Treatment of adults with moderate-to-severe plaque psoriasis	100 mg at weeks 0, 4, and every 12 weeks after by subcutaneous injection	Avoid use of live vaccines during Ilumya treatment	Hypersensitivity reactions, infections, tuberculosis, injection site reactions, diarrhea	Educate patients to report any signs of infection
Seysara (sarecycline)	Novel tetracycline-class medication for the treatment of moderate to severe non-nodular inflammatory acne vulgaris in patients 9 years and older	Dose is once a day orally and weight based: 33-54 kg: 60 mg 55-84 kg: 100 mg 85-136 kg: 150 mg	Avoid coadministration with oral retinoids including isotretinoin and acitretin due to risk of increased intracranial pressure Separate Seysara administration from antacids	Teratogenic effects avoid during pregnancy Avoid in children under 8 years of age-can cause permanent tooth discoloration and enamel hypoplasia	Educate patients that Seysara should not be used in pregnant women or individuals trying to conceive

			and iron products	Adverse effects include dizziness and nausea	
Nuzyra (omadacycline)	<p>Tetracycline antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) to overcome tetracycline resistance</p> <p>First and only once daily IV and oral antibiotic approved to treat both CABP and ABSSSI in almost 20 years</p> <p>Can initiate IV treatment and switch to oral without changing medications</p>	<p>CABP: Loading dose: Day 1 200 mg IV infusion over 60 minutes</p> <p>Maintenance: 100 mg IV infusion over 30 minutes</p> <p>ABSSSI: Loading dose: Day 1: 200 mg IV infusion over 60 minutes</p> <p>Maintenance: 100 mg IV infusion over 30 minutes</p> <p>ABSSSI tablets only: Loading dose: Days 1 and 2: 450 mg orally once a day</p> <p>Maintenance: 300 mg orally once a day</p>	<p>Separate dairy products, antacids, or multivitamins by 4 hours from Nuzyra</p> <p>May require dose reduction of anticoagulants if being coadministered with Nuzyra</p>	Nausea, vomiting, infusion site reactions, hypertension, diarrhea, insomnia	Educate patients to fast for at least 4 hours and then take Nuzyra tablets with water. No food or drink (except water) should be consumed for 2 hours after oral dose
Xerava (eravacycline)	Tetracycline class antibiotic for the treatment of complicated	1 mg/kg by IV infusion over 60 minutes every 12 hours	Strong CYP3A inducers may decrease Xerava	Infusion site reactions,	Women should avoid breastfeeding

	intra-abdominal infections in patients 18 years and older	<p>for total of 4-14 days</p> <p>Severe hepatic impairment:</p> <p>1 mg/kg every 12 hours day 1, then 1mg/kg every 24 hours starting day 2</p> <p>The dose of Xerava should be increased to 1.5 mg/kg every 12 hours with concomitant use of strong CYP3A inducers</p>	efficacy and Xerava dose should be increased	nausea, vomiting	ng during treatment with Xerava and for 4 days after the last dose
Zemdri (plazomicin)	Aminoglycoside for the treatment of complicated urinary tract infections in patients 18 years and older	<p>15 mg/kg every 24 hours by IV infusion over 30 minutes with CrCL greater than or equal to 90 mL/min</p> <p>Renal dose adjustment based on CrCL:</p> <p>Greater than or equal to 60</p>	Unlikely	<p>Boxed warning: nephrotoxicity, ototoxicity, fetal harm</p> <p>Hypersensitivity reactions, <i>Clostridium difficile</i>-associated diarrhea</p>	Counsel pregnant women and those of childbearing potential that Zemdri can cause congenital deafness and should not be used in pregnant patients

		<p>to less than 90:</p> <p>15 mg/kg every 24 hours</p> <p>Greater than or equal to 30 to less than 60:</p> <p>10 mg/kg every 24 hours</p> <p>Greater than or equal to 15 to less than 30:</p> <p>10 mg/kg every 48 hours</p>			
Lokelma (sodium zirconium cyclosilicate)	Treatment of hyperkalemia	<p>Starting dose 10 g orally (suspension in water) three times a day for up to 48 hours</p> <p>Maintenance dose 10 g once a day</p>	<p>Since Lokelma can increase the gastric pH and affect the absorption of other drugs, other oral medications should be administered at least 2 hours before or 2 hours after Lokelma</p>	Mild to moderate edema	<p>Educate patients how to reconstitute : The entire packet contents should be emptied into a drinking glass containing about 3 tablespoons of water. Patients should stir well and drink</p>

					immediately
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Resources for Pharmacists to Stay Up-to-date

It can sometimes be challenging for pharmacists to find time to stay up-to-date with new drug approvals. The database Pubmed is a great free database to search for recently published clinical studies. DailyMed is a free one-stop-shop for pharmacists that contains prescribing information for many of the FDA approved drugs.⁷³ It also includes a feature to search by drug class and a pill identification tool. Other features through DailyMed include direct links for reporting adverse drug reactions, drug recall information, pregnancy and lactation safety, and consumer health information.⁷³ Social media platforms like Twitter and LinkedIn can also provide great free resources for keeping up with the pharmacy world. On Twitter, pharmacists can follow various news sites, pharmacy organizations, and journals to stay up-to-date. LinkedIn enables pharmacists to connect with colleagues and share drug information. Pharmacists should also sign up for free email alerts with FDA.gov and CenterWatch to get the latest information on new drug and biologic approvals and drug recalls. Pharmacists can select a variety of free or subscription resources to help stay up-to-date based on their practice setting. Joining a professional pharmacy organization such as the American Society of Health-System Pharmacists can enhance pharmacists' knowledge. Many pharmacy organizations are affiliated with journals and send these out to members on a monthly basis. Pharmacists can also participate in monthly journal clubs with their pharmacy staff to stay current on recently published clinical studies. Participating in continuing education beyond the minimum requirements for license renewal is a great way to stay abreast of new developments. This way pharmacists can select topics that are relevant to their practice setting or areas which they would like to enhance their knowledge base.

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Place your Florida license # on every quiz.

4. What did you like MOST about this lesson? _____

5. What did you like LEAST about this lesson? _____

6. How would you improve this lesson? _____

PLEASE MARK THE CORRECT ANSWER(S)

1. How many new drugs were approved in 2018?
 - A. 21
 - B. 39
 - C. 41
 - D. 59

2. Which of the following medications was approved for the treatment of smallpox?
 - A. TPOXX
 - B. Zemdri
 - C. Mektovi
 - D. Tibsovo

3. Which controlled substance schedule is Epidiolex classified as?
 - A. Schedule I
 - B. Schedule II
 - C. Schedule IV
 - D. Schedule V

4. Which of the following medications is a calcitonin gene-related peptide receptor (CGRP-R) antagonist?
 - A. Lucemyra
 - B. Onpattro
 - C. Aimovig
 - D. Orilissa

5. Which of the following medications is restricted through a REMS program?
 - A. Palynziq
 - B. Poteligeo
 - C. Tavalisse
 - D. Tibsovo
6. Which of the following orphan drugs treats x-linked hypophosphatemia?
 - A. Diacomit
 - B. Crysvida
 - C. Mektovi
 - D. Oxervate
7. Which of the following is the correct dose for Tegsedi?
 - A. 100 mg orally twice a day
 - B. 200 mg intravenously over a 30 minute infusion
 - C. 284 mg subcutaneous injection once a week
 - D. 500 mg subcutaneous injection once a day
8. Which of the following medications is an antiviral flu treatment?
 - A. Xofluza
 - B. Motegrity
 - C. Firdapse
 - D. Ultomiris
9. What is the correct dose of Xofluza in a patient weighing 85 kg?
 - A. Single oral dose of 40 mg
 - B. Single oral dose of 80 mg
 - C. 500 mg orally once a day
 - D. 100 mg orally twice a day
10. Which of the following is an important counseling point for Oxervate?
 - A. Patients should avoid a high-fat meal with administration
 - B. Contact lenses should be removed before applying
 - C. Patients should carry auto-injectable epinephrine with them during treatment
 - D. It is important to receive the meningococcal vaccine before the first dose
11. Which of the following is the dose of Xospata?
 - A. 2 mg orally once a day
 - B. 120 mg orally once a day
 - C. 2,500 units/m² intravenously
 - D. 7.4 GBq every 8 weeks

12. Which of the following adverse effects is part of the boxed warning for Tegsedi?
- A. Hepatitis
 - B. Pneumonia
 - C. Thrombocytopenia
 - D. Cirrhosis
13. Where can pharmacists report adverse drug reactions?
- A. FDA's MedWatch program
 - B. Orphan drug program
 - C. Fast Track program
 - D. Pubmed
14. Which of the following medications has a boxed warning for capillary leak syndrome?
- A. Copiktra
 - B. Takhzyro
 - C. Lumoxiti
 - D. Diacomit
15. Which of the following medications should be taken with foods that contain fat?
- A. Symdeko
 - B. Moxidectin
 - C. Mektovi
 - D. Braftovi
16. Which of the following medications should proton pump inhibitors be avoided with?
- A. Revcovi
 - B. Omegaven
 - C. Mektovi
 - D. Vizimpro
17. Which of the following is true about the DailyMed resource?
- A. There is a monthly fee of \$30
 - B. It contains prescribing information
 - C. It is part of the American Society of Health-System Pharmacists organization
 - D. Journals are sent out on a monthly bases

18. Which of the following medications is approved for the prevention of malaria relapse
- A. Braftovi
 - B. Symdeko
 - C. Revcovi
 - D. Krintafel
19. Which of the following is the dose of Vizimpro?
- A. 45 mg orally once a day
 - B. 90 mg orally three times a day
 - C. 150 mg orally once a day
 - D. 250 mg orally once a day
20. Which of the following medications treats hereditary angioedema?
- A. Yupelri
 - B. Gamifant
 - C. Daurismo
 - D. Takhzyro