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RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products, generic medication, medical products, and WHAT IS IN THE PIPELINE.

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NEWS……

Drug Issue	Date	News/Event
Zinbryta Off Market	03/02/2018	Biogen and AbbVie are voluntarily taking Zinbryta™ (daclizumab), a treatment for relapsing multiple sclerosis, off the market worldwide due to safety concerns. The decision have been made after European regulators flagged a lethal safety warning over cases of inflammatory encephalitis and meningoencephalitis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc.	Antiretroviral agent Combination of a non-nucleoside reverse transcriptase inhibitor (efavirenz (EFV)), and two nucleo(t)side reverse transcriptase inhibitors (lamivudine (3TC) and tenofovir disoproxil fumarate (TDF))	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/05/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one tablet taken orally once daily on an empty stomach, preferably at bedtime. • Prior to initiation and during treatment, patients should be tested for hepatitis B virus infection, and estimated creatinine clearance, urine glucose, and urine protein should be obtained **DOSAGE FORMS AND STRENGTHS** Tablets: 400 mg efavirenz, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil). **CONTRAINDICATIONS** • Previous hypersensitivity to any of the components. • Co-administration with elbasvir/grazoprevir. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** QTc prolongation has been reported with efavirenz use; consider alternative therapy in patients at risk for Torsade de Pointes or those taking concomitant medications which increase risk. • **Concomitant use:** Avoid with concurrent or recent use of nephrotoxic agents (e.g. high-dose or multiple NSAIDs) or agents known to reduce renal function or compete for active tubular secretion including acyclovir, cidofovir, ganciclovir, valacyclovir, valganciclovir, and aminoglycosides. • **Dermatologic:** Rash, including erythema multiforme, Stevens-Johnson syndrome, has been reported with efavirenz; discontinue use for severe rash associated with blistering, desquamation, mucosal involvement, or fever. • **Endocrine and metabolic:** (1) Lipid elevations may occur; monitoring recommended. (2) Accumulation and redistribution of body fat has been reported, including central obesity, dorsocervical fat enlargement, peripheral and facial wasting, breast enlargement, and cushingoid appearance.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc. (continuation)	Antiretroviral agent Combination of a non-nucleoside reverse transcriptase inhibitor (efavirenz (EFV)), and two nucleo(t)side reverse transcriptase inhibitors (lamivudine (3TC) and tenofovir disoproxil fumarate (TDF))	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/05/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** (1) Use not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C). (2) Lactic acidosis and severe hepatomegaly with steatosis have been reported, including fatal cases; suspend treatment if clinical or laboratory signs of hepatotoxicity or lactic acidosis develop, even in the absence of marked elevations in transaminases. (3) Hepatitis, including fulminant hepatitis progressing to liver failure, may occur and may result in transplantation or death; monitoring recommended and discontinuation may be required. (4) Hepatic decompensation, including fatalities, has been reported in HIV-1/hepatitis C virus co-infected patients receiving combination antiretroviral therapy and interferon-alfa with or without ribavirin; monitoring recommended and dose reduction or discontinuation may be warranted. • **Immunologic:** (1) Immune reconstitution syndrome has been reported with combination antiretroviral therapy; further evaluation and treatment may be required. (2) Autoimmune disorders, including Graves disease, polymyositis, and Guillain-Barré syndrome, have been reported in the setting of immune reconstitution; may occur many months after initiation of therapy. • **Musculoskeletal:** Bone mineral density (BMD) decreases, bone fractures, and osteomalacia (associated with proximal renal tubulopathy) have been reported with tenofovir; monitoring recommended for at-risk patients. • **Neurologic:** (1) CNS symptoms (e.g. dizziness, insomnia, impaired concentration, somnolence, abnormal dreams, hallucinations) may occur and usually emerge within the first few days of treatment initiation and resolve within 2 to 4 weeks. Dosing at bedtime may improve tolerability. (2) Seizures have been reported; use caution in patients with a history of seizures.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc. (continuation)	Antiretroviral agent Combination of a non-nucleoside reverse transcriptase inhibitor (efavirenz (EFV)), and two nucleo(t)side reverse transcriptase inhibitors (lamivudine (3TC) and tenofovir disoproxil fumarate (TDF))	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/05/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Psychiatric:** Serious psychiatric events (e.g. suicidality, severe depression, aggression, paranoia, mania) have been reported with efavirenz use; history of injected drug use, psychiatric disorders, or concomitant use of psychiatric medication may increase risk. Immediate medical evaluation is recommended for serious psychiatric symptoms. • **Renal:** (1) Use not recommended in patients with impaired renal function (CrCl less than 50 mL/min) or ESRD requiring hemodialysis. (2) Renal impairment, including acute renal failure and Fanconi syndrome, have occurred with tenofovir disoproxil fumarate therapy; monitoring recommended. (3) Proximal renal tubulopathy may occur; monitoring recommended. **ADVERSE REACTIONS** Most common adverse reactions: rash and dizziness. **DRUG INTERACTIONS** • Symfi Lo™ should not be administered with other antiretroviral medications for the treatment of HIV-1 infection. • Co-administration of Symfi Lo™ can alter the concentrations of other drugs and other drugs may alter the concentration of Symfi Lo™. The potential for drug-drug interactions should be considered before and during therapy. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Women should avoid pregnancy during EFV therapy, a component of Symfi Lo™, and for 12 weeks after discontinuation. • **Females of reproductive potential:** Females of reproductive potential should undergo pregnancy testing before initiation. Barrier contraception in combination with another method of contraception is recommended during treatment and for 12 weeks after discontinuation.

New FDA Approved Products

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Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc. (continuation)	Antiretroviral agent Combination of a non-nucleoside reverse transcriptase inhibitor (efavirenz (EFV)), and two nucleo(t)side reverse transcriptase inhibitors (lamivudine (3TC) and tenofovir disoproxil fumarate (TDF))	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/05/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Lactation:** Breastfeeding not recommended due to potential for HIV transmission. • **Pediatric use:** Increased risk of pancreatitis in pediatric patients with prior antiretroviral nucleoside exposure, history of pancreatitis, or other significant risk factors for pancreatitis; exercise caution and discontinue use if suspected. • **Renal impairment:** Not recommended in patients with CrCL less than 50 mL/min or patients with end-stage renal disease requiring hemodialysis. • **Hepatic impairment:** Not recommended for patients with moderate or severe hepatic impairment. Use caution in patients with mild hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cimduo™ (lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc.	Antiretroviral agent Combination of two nucleo(t)side reverse transcriptase inhibitors	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/28/2016	**DOSAGE AND ADMINISTRATION** The recommended dose • Prior to initiation and during treatment, patients should be tested for hepatitis B virus infection, and estimated creatinine clearance, urine glucose, and urine protein should be obtained. **DOSAGE FORMS AND STRENGTHS** Tablets: 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil). **CONTRAINDICATIONS** • Previous hypersensitivity to any of the components of this product. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Avoid concurrent or recent use of nephrotoxic agents. • **Endocrine and metabolic:** Fat redistribution and accumulation of body fat, including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and cushingoid appearance, has been reported. • **Gastrointestinal:** Pancreatitis may occur, particularly in pediatric patients with prior antiretroviral nucleoside exposure, history of pancreatitis, or existing risk factors; discontinuation required. • **Hepatic:** (1) Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, has been reported; interrupt treatment if suspected. (2) Hepatic decompensation may occur with concomitant interferon alfa or ribavirin use; monitoring recommended and dose reduction or discontinuation may be required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cimduo™ (lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc. (continuation)	Antiretroviral agent Combination of two nucleo(t)side reverse transcriptase inhibitors	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/28/2016	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) Immune reconstitution syndrome has been reported with combination antiretroviral therapy; monitoring recommended. (2) Autoimmune disorders have been reported in the setting of immune reconstitution syndrome. (3) Early virologic failure and high rates of resistance substitutions have been reported with triple nucleoside therapy; monitoring recommended. • **Musculoskeletal:** (1) Decreases in bone mineral density have been reported; monitoring recommended. (2) Osteomalacia and hypophosphatemia associated with proximal renal tubulopathy has been reported. • **Renal:** (1) New onset or worsening renal impairment, including acute renal failure and Fanconi syndrome, has been reported; monitoring recommended. (2) Proximal renal tubulopathy manifesting as persistent or worsening bone pain, extremity pain, facture, or muscle pain or weakness may occur; monitoring recommended. (3) Use not recommended in patients with renal impairment (CrCl less than 50 mL/min) or end stage renal disease requiring hemodialysis. **ADVERSE REACTIONS** Most common adverse reactions: headache, pain, depression, diarrhea, and rash. **DRUG INTERACTIONS** • **Atazanavir:** Atazanavir should be co-administered with ritonavir when coadministered with Cimduo™. • **HIV-1 Protease Inhibitors:** Monitor for evidence of tenofovir toxicity when Cimduo™ is co-administrated with atazanavir/ritonavir, darunavir/ritonavir, or lopinavir/ritonavir. • **Sorbitol:** Avoid chronic administration of sorbitol with Cimduo™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cimduo™ (lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Mylan Pharmaceuticals Inc. (continuation)	Antiretroviral agent Combination of two nucleo(t)side reverse transcriptase inhibitors	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg **Black box warning** Post-treatment acute exacerbation of hepatitis B virus (HBV): Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and human immunodeficiency virus (HIV-1) and have discontinued lamivudine and tenofovir disoproxil fumarate. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.	02/28/2016	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Cimduo™ during pregnancy. Healthcare providers are encouraged to register patients. • **Lactation:** Breastfeeding not recommended due to potential for HIV transmission. • **Renal impairment:** Not recommended in patients with CrCL less than 50 mL/min or patients with end-stage renal disease requiring hemodialysis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trogarzo™ (ibalizumab-uiyk) Injection, for intravenous use / TaiMed Biologics USA Corp.	Antiretroviral agent Humanized monoclonal antibody; CD4-directed post-attachment HIV-1 inhibitor --- Note: Orphan drug designation	treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen	03/06/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 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. **DOSAGE FORMS AND STRENGTHS** Injection: 200 mg/1.33 mL (150 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Immune reconstitution syndrome has been reported when used in combination with other antiretroviral agents. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea, dizziness, nausea, and rash. **DRUG INTERACTIONS** No drug interaction studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Trogarzo™ during pregnancy. Healthcare providers are encouraged to register patients. • **Lactation:** Women infected with HIV should be instructed not to breastfeed due to the potential for HIV transmission. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** No studies have been conducted in geriatric patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ilumya™ (tildrakizumab-asmn) Injection, for sucutaneous use / Sun Pharmaceutical Industries Inc.	Antipsoriatic Anti-IL-23p19 monoclonal antibody	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	03/20/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg at Weeks 0, 4, and every twelve weeks thereafter. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/mL solution in a single-dose prefilled syringe. **CONTRAINDICATIONS** • Serious hypersensitivity reaction to tildrakizumab or to any of the excipients. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Hypersensitivity reactions (e.g, angioedema and urticaria) have been reported; discontinue use if a serious reaction occurs. (2) Increased risk of infection may occur; discontinuation may be necessary if infection develops. (3) Do not initiate therapy in patients with active infection; consider risks and benefits in patients with a history of recurrent infection or patients with a chronic infection. (4) Screen patients for tuberculosis (TB) prior to initiating therapy; initiate latent TB treatment prior to administration and consider anti-TB therapy prior to initiation in patients with a past history of latent or active TB in which adequate treatment cannot be confirmed. (5) Do not initiate therapy in patients with active TB. (6) Consider completing all age appropriate immunizations prior to therapy initiation; avoid use of live vaccines with therapy. **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory infections, injection site reactions, and diarrhea. **DRUG INTERACTIONS** • **Live Vaccines:** Avoid use of live vaccines in patients treated with Ilumya™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ilumya™ (tildrakizumab-asmn) Injection, for sucutaneous use / Sun Pharmaceutical Industries Inc. (continuation)	Antipsoriatic Anti-IL-23p19 monoclonal antibody	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	03/20/2018	**USE IN SPECIFIC POPULATIONS** • No clinically significant differences in the pharmacokinetics of tildrakizumab were observed based on age (≥18 years). • No specific studies have been conducted to determine the effect of renal or hepatic impairment on the pharmacokinetics of tildrakizumab.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Otiprio™ (ciprofloxacin) Otic Suspension / Otonomy, Inc.	Otic fluoroquinolone antibacterial	Treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement surgery, and for the treatment of acute otitis externa (AOE) due to *Pseudomonas aeruginosa* and *Staphylococcus aureus* **New indication:** For the treatment of AOE in patients 6 months of age and older due to *Pseudomonas aeruginosa*and *Staphylococcus aureus*	03/02/2018	AOE also known as swimmer's ear, is a common condition involving infection and inflammation of the external ear canal typically caused by bacterial infection. Topical antibiotics are considered the standard of care treatment for AOE with the typical regimen of ear drops requiring several administrations to the affected ear each day for up to 10 days. Otiprio™ is the first single-dose antibacterial approved by the FDA for treating AOE.
Latuda™ (lurasidone) Tablets / Dainippon Sumitomo Pharma America, Inc.	Atypical antipsychotic	Treatment of schizophrenia and bipolar depression **Patient population altered:** To include the treatment of major depressive episode associated with bipolar I disorder (bipolar depression) in pediatric patients (10 to 17 years of age)	03/05/2018	Latuda™ is also approved in the US for the treatment of adults with bipolar depression as monotherapy and adjunctive therapy with lithium or valproate, and for the treatment of adolescents (13 to 17 years of age) and adults with schizophrenia. The approval for the expanded indication of Latuda™ was supported by data from a Phase 3 clinical study of children and adolescents (10 to 17 years of age) with bipolar depression. In this study, Latuda was associated with statistically significant and clinically meaningful improvement in bipolar depression symptoms compared to placebo and was generally well-tolerated.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking moconlonal antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma **New dosage regimen:** To include 480 mg infused every four weeks for a majority of approved indications	03/05/2018	Opdivo™ dosing schedule now include 480 mg infused every four weeks (Q4W) for a majority of approved indications; in addition to the previously available option of 240mg every two weeks (Q2W). Opdivo™ also was approved for a shorter 30-minute infusion across all approved indications. The 480mg Q4W dosing schedule is approved for the following indications: • Metastatic melanoma (monotherapy or monotherapy phase after combination treatment with Yervoy [ipilimumab])· • Previously treated metastatic non-small cell lung cancer. • Advanced renal cell carcinoma following prior anti-angiogenic therapy· • Previously treated locally advanced or metastatic urothelial carcinoma following disease progression during or after platinum-based chemotherapy. • Classical Hodgkin lymphoma following relapse/progression after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or three or more lines of systemic therapy that includes autologous HSCT. • Recurrent/metastatic squamous cell carcinoma of the head and neck following platinum-based therapy. • Hepatocellular carcinoma after prior sorafenib therapy. • Adjuvant therapy for patients with completely resected melanoma with lymph node involvement or metastatic disease.
Hizentra™ (immune globulin subcutaneous (human)) Liquid / CSL Behring	Immunological agent Immune globulin	Treatment of primary immunodeficiency, and for the maintenance treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) **New indication:** Treatment of CIDP as maintenance therapy to prevent relapse of neuromuscular disability and impairment	03/15/2018	This approval makes Hizentra™ the first and only subcutaneous immunoglobulin (SCIg) for the treatment of CIDP. The approval was based on data from the Phase III PATH (Polyneuropathy And Treatment with Hizentra) study, which demonstrated that the percentage of patients experiencing CIDP relapse or withdrawal for any other reason during SCIg treatment was significantly lower with Hizentra™ versus placebo. Additionally, the PATH study demonstrated that patients on Hizentra™ reported fewer systemic adverse reactions (ARs) per infusion compared to IVIg treatment (2.7% versus 9.8%, respectively). In fact, 93% of the 4,225 total Hizentra™ infusions were free of any ARs.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Adcetris™ (brentuximab vedotin) Injection / Seattle Genetics, Inc.	Antineoplastic agent CD30-directed antibody-drug conjugate (ADC)	Treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and CD30-expressing mycosis fungoides **New indication:** To treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy	03/20/2018	The FDA approved Adcentris™ for fisrt-line treatment of Stage III or IV Classical Hodgkin Lymphoma (cHL). The approval was based on a clinical trial comparing Adcetris™ plus chemotherapy (Adriamycin [doxorubicin], vinblastine and dacarbazine, or AVD) to a chemotherapy-only regimen common for cHL treatment (AVD plus bleomycin, also known as ABVD). The trial measured modified progression-free survival (mPFS). In the trial of 1,334 patients, after patients received an average of six 28-day cycles of treatment, those treated with Adcetris™ plus AVD were 23% less likely to experience progression, death, or initiation of new therapy compared with those receiving ABVD. There were 117 (18%) patients on the Adcetris™ plus AVD arm who experienced disease progression, death, or began new therapy compared to 146 (22%) patients on the ABVD arm.
Tasigna™ (nilotinib) Capsules / Novartis	Antineoplastic agent Tyrosine kinase inhibitor	Treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) **Patient population altered:** To include treatment of first- and second-line pediatric patients one year of age or older with Philadelphia chromosome-positive chronic myeloid leukemia in the chronic phase	03/22/2018	The approval was based on two studies evaluating the efficacy and safety of nilotinib in pediatric patients (two years to less than 18 years of age). A total of 69 pediatric patients, either newly diagnosed (first-line) or who were resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy (second-line), received nilotinib. In newly diagnosed pediatric patients, the major molecular response (MMR) rate was 60.0% at 12 cycles, with 15 patients achieving MMR. The cumulative MMR rate among newly diagnosed pediatric patients was 64.0% by cycle 12, and the median time to first MMR was 5.6 months. In pediatric patients with resistance or intolerance to prior TKI therapy, the MMR rate was 40.9% at 12 cycles, with 18 patients being in MMR. The cumulative MMR rate among pediatric patients with resistance or intolerance was 47.7% by cycle 12, and the median time to first MMR was 2.8 months.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Blincyto™ (blinatumomab) Injection / Amgen Inc.	Antineoplastic agent CD19-directed CD3 T-cell engager	Treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), and minimal residual disease (MRD)-positive B-cell precursor ALL **New indication:** To treat adults and children with B-cell precursor ALL who are in remission but still have MRD	03/29/2018	The efficacy of Blincyto™ in MRD-positive ALL was shown in a clinical trial that included 86 patients in first or second complete remission who had detectable MRD in at least 1 out of 1,000 cells in their bone marrow. Efficacy was based on achievement of undetectable MRD in an assay that could detect at least 1 cancer cell in 10,000 cells after one cycle of Blincyto™ treatment, in addition to the length of time that the patients remained alive and in remission (hematological relapse-free survival). Overall, undetectable MRD was achieved by 70 patients. Over half of the patients remained alive and in remission for at least approximately 22 months.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Lucentis™ (ranibizumab) Injection / Genentech, Inc.	Ophtalmologic agent Humanized anti-VEGF antibody	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization	03/20/2018	FDA approved the Lucentis™ (ranibizumab injection) 0.3 mg prefilled syringe (PFS) as a new method of administering the medicine to treat all forms of diabetic retinopathy.
Toujeo SoloStar™ (insulin glargine [rDNA origin]) Injection / Sanofi-Aventis U.S. LLC	Long-acting basal insulin	To improve glycemic control in adults with type 1 and type 2 diabetes	03/26/201	FDA approved Toujeo Max SoloStar, the highest capacity long-acting insulin pen that will be available on the market. The new Max SoloStar pen holds 900 Units of Toujeo, and provides up to 160 Units/mL of Toujeo in a single injection. Due to its higher capacity, Max SoloStar may reduce the number of pens adults prescribed Toujeo use, allowing for fewer refills and related copays, depending on the person's insurance coverage. The maximum dose of up to 160 Units/mL may also help reduce the number of injections needed to deliver the required Toujeo dosage for some adults with diabetes.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Cinacalcet Hydrochloride Tablets 30 mg (base), 60 mg (base), and 90 mg (base)	Calcimimetic; Calcium regulator	03/08/2018	Generic for: Sensipar™

Source: https://www.drugs.com/generic-approvals.html

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Inbrija™ (levodopa) Inhalation Powder / Acorda Therapeutics, Inc.	02/20/2018	Treatment for symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen	Inbrija™ (levodopa) is an oral inhalation formulation of the approved drug levodopa. The FDA has accepted for filing the NDA for Inbrija™.	Moderate
Stannsoporfin / Mallinckrodt plc	02/23/2018	Treatment for hyperbilirubinemia	Stannsoporfin is a heme oxygenase inhibitor in development for the treatment of neonates at risk for developing severe hyperbilirubinemia, or severe jaundice. The FDA has accepted its NDA. If approved, the drug is expected to become the first and only pharmacologic option in the US indicated for treatment of neonates at risk for developing severe hyperbilirubinemia, or severe jaundice.	High
Lanadelumab - formerly SHP643 / Shire plc	02/23/201	Treatment for hereditary Angioedema	Lanadelumab is an investigational fully human monoclonal antibody that inhibits plasma kallikrein in development as a treatment for the prevention of angioedema attacks in patients with hereditary angioedema. The FDA accepted the BLA and granted priority review for lanadelumab (SHP643).	High
Eravacycline / Tetraphase Pharmaceuticals, Inc.	02/27/2018	Treatment for intraabdominal infection	Eravacycline is a fluorocycline antibiotic in development for the treatment of complicated intra-abdominal infections. The FDA has completed its initial 60-day review of the NDA for eravacycline.	Moderate
Lusutrombopag / Shionogi & Co., Ltd.	02/27/2018	Treatment for thrombocytopenia	Lusutrombopag is an investigational, once-daily, orally administered, small molecule thrombopoietin receptor agonist in development for the treatment of thrombocytopenia in patients with chronic liver disease who are at increased risk for bleeding associated with invasive procedures. The NDA has been accepted for filing and has been granted Priority Review by the FDA.	Moderate

Soruce: https://www.drugs.com/new-drug-applications.html

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Ulipristal acetate / Allergan plc	02/28/2018	Treatment for uterine fibroids	Ulipristal acetate is an oral selective progesterone receptor modulator (SPRM) in development for the treatment of uterine fibroids. The FDA has extended the NDA review.	Moderate
Remoxy ER (oxycodone) / Pain Therapeutics, Inc.	03/01/2018	Treatment for p**ain**	Remoxy ER (oxycodone) is a long-acting, abuse-resistant, narcotic analgesic formulation in development for the treatment of moderate to severe chronic pain. The FDA has accepted Remoxy NDA for review.	Moderate
Solriamfetol / Jazz Pharmaceuticals plc	03/02/2018	Treatment for narcolepsy, obstructive sleep apnea/hypopnea syndrome	Solriamfetol is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in development for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea. The FDA has accepted for filling the NDA for solriamfetol.	Moderate
Prucalopride / Shire plc	05/03/2018	Treatment for chronic idiopathic constipation	Prucalopride is a selective serotonin type 4 (5-HT4) receptor agonist in development for the treatment of chronic idiopathic constipation in adults. The FDA has accepted the NDA for prucalopride.	Moderate
TX-001HR (estradiol and progesterone) / TherapeuticsMD, Inc.	05/08/2018	Treatment for perimenopausal symptoms	TX-001HR is an investigational bio-identical hormone combination of estradiol and progesterone in development for the treatment of moderate-to-severe vasomotor symptoms due to menopause. The FDA has accepted the NDA for TX-001HRM	Moderate
Bremelanotide / AMAG Pharmaceuticals, Inc.	05/26/2018	Treatment for hypoactive sexual desire disorder	Bremelanotide is a melanocortin receptor agonist in development for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women. A NDA have been submitted to the FDA.	Moderate
Sotagliflozin / Lexicon Pharmaceuticals, Inc.	05/26/2018	Treatment for diabetes type 1	Sotagliflozin is an investigational dual SGLT1 and SGLT2 inhibitor for use in combination with insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus. A NDA have been submitted to the FDA.	Moderate

Soruce: https://www.drugs.com/new-drug-applications.html

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