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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
Keytruda™ (pembrolizumab)	08/31/2017	**Keytruda™ (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement - Two Clinical Trials on Hold** The FDA issued this statement to inform the public, health care professionals, and oncology clinical investigators about the risks associated with the use of Keytruda™ in combination with dexamethasone and an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of patients with multiple myeloma. Keytruda™ is currently approved by the FDA for treatment of: Melanoma, Lung Cancer, Head and Neck Cancer, Classical Hodgkin Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High (MSI-H) Cancer. However, Keytruda™ is not approved for treatment of multiple myeloma. The statement is based on review of data from 2 clinical trials (KEYNOTE-183 and KEYNOTE-185) evaluating the use of Keytruda™ combined with other treatments in patients with multiple myeloma. The FDA required that all patients in these trials be discontinued from further investigation with this drug, because interim results from both trials demonstrated an increased risk of death for patients receiving Keytruda™ when it was combined with an immunomodulatory agent as compared to the control group. This does not apply to patients taking Keytruda™ for an approved indication. Patients on Keytruda™ for an approved use should continue to take their medication as directed by their health care professional. Other multiple myeloma clinical trials of Keytruda™, other PD-1/PD-L1 cancer drugs and other combinations are currently undergoing clinical evaluation. The FDA will be working directly with sponsors of Keytruda™ and other PD-1/PD-L1 cancer drugs, as well as clinical investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The agency will communicate any new information to the public as soon as it is able.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Idhifa™ (enasidenib) Tablets, for oral use / Celgene Corporation	First-in-class, targeted inhibitor of mutant isocitrate dehydrogenase 2 (IDH2)	Treatment of patients with relapsed or refractory acute myeloid leukemia (AML) with an IDH2 mutation **Black Box Warning** Patients treated with enasidenib have experienced symptoms of differentiation syndrome, which can be fatal if not treated. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.	08/01/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg orally once daily until disease progression or unacceptable toxicity. Administer at the same time each day. Treat for a minimum of 6 months if possible to allow for clinical response. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg or 100 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Differentiation syndrome has been reported and may be life-threatening or fatal without appropriate treatment; if suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution. • **Reproductive:** May cause fetal harm when administered to pregnant women; avoid pregnancy during use regardless of which partner is receiving treatment and for a minimum of 1 month after therapy. **ADVERSE REACTIONS** Most common adverse reactions: nausea, vomiting, diarrhea, elevated bilirubin, and decreased appetite. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, advise the patient of the potential risk to a fetus. • **Lactation:** Advise women not to breastfeed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Idhifa™ (enasidenib) Tablets, for oral use / Celgene Corporation (continuation)	First-in-class, targeted inhibitor of mutant isocitrate dehydrogenase 2 (IDH2)	Treatment of patients with relapsed or refractory acute myeloid leukemia (AML) with an IDH2 mutation **Black Box Warning** Patients treated with enasidenib have experienced symptoms of differentiation syndrome, which can be fatal if not treated. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.	08/01/2017	**USE IN SPECIFIC POPULATIONS** (continuation) • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No dose adjustment necessary based on age. • **Differentiation syndrome:** Interrupt therapy if severe pulmonary symptoms occur requiring intubation or ventilatory support or renal dysfunction persisting for over 48 hours following corticosteroid initiation; resume therapy with improvement to Grade 2 or below. • **Noninfectious leukocytosis (WBC greater than 30 x 10(9)/L):** Interrupt therapy if no improvement with hydroxyurea is seen; resume at 100 mg orally once daily when WBC is less than 30 x 10(9)/L. • **Hepatic impairment:** Bilirubin greater than 3 times ULN for 2 weeks or more without elevated transaminases or other hepatic disorders → Reduce dose to 50 mg orally daily; resume at 100 mg orally daily if bilirubin elevation resolves to less than 2 times ULN

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mavyret™ (glecaprevir and pibrentasvir) Tablets, for oral use / AbbVie Inc.	Fixed-dose combination of glecaprevir, an NS3/4A protease inhibitor, and pibrentasvir, an NS5A inhibitor	Treatment of all major genotypes (GT1-6) of chronic hepatitis C **Black Box Warning** Risk of Hepatitis B Virus Reactivation in Patients Coinfected with HCV and HBV. Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with glecaprevir/pibrentasvir. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.	08/03/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food. The recommended treatment duration of treatment depends on HCV genotype, presence or absence of cirrhosis, and previous therapy. See full prescribing information for details. Prior to initiation, test all patients for evidence of current or previous hepatitis B virus (HBV) infection by measuring HBV surface antigen and hepatitis B core antibody. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg glecaprevir and 40 mg pibrentasvir. **CONTRAINDICATIONS** • Severe hepatic impairment (Child-Pugh C). • Concomitant use with atazanavir or rifampin. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Hepatitis B virus (HBV) reactivation has occurred in patients coinfected with hepatitis C virus (HCV) during treatment for HCV with direct-acting antiviral agents, including cases of fulminant hepatitis and hepatic failure with fatalities. Screen all patients for evidence of current or prior HBV infection before initiation. Monitor HCV/HBV coinfected patients for HBV flare-ups or reactivation during treatment and post-treatment followup, and treat as clinically indicated. • **Concomitant use:** Concomitant use with carbamazepine, efavirenz, or St. John's wort is not recommended. • **Hepatic:** Use is not recommended in patients with moderate hepatic impairment (Child-Pugh B). **ADVERSE REACTIONS** Most common adverse reactions: headache and fatigue.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mavyret™ (glecaprevir and pibrentasvir) Tablets, for oral use / AbbVie Inc. (continuation)	Fixed-dose combination of glecaprevir, an NS3/4A protease inhibitor, and pibrentasvir, an NS5A inhibitor	Treatment of all major genotypes (GT1-6) of chronic hepatitis C **Black Box Warning** Risk of Hepatitis B Virus Reactivation in Patients Coinfected with HCV and HBV. Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with glecaprevir/pibrentasvir. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.	08/03/2017	**DRUG INTERACTIONS** • Carbamazepine, efavirenz, and St. John's wort may decrease concentrations of glecaprevir and pibrentasvir. • Coadministration of carbamazepine, efavirenz containing regimens, and St. John's wort with MAVYRET is not recommended. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** No adequate human data are available to establish whether or not MAVYRET poses a risk to pregnancy outcomes. • **Lactation:** It is not known whether the components of MAVYRET are excreted in human breast milk, affect human milk production, or have effects on the breastfed infant. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No dosage adjustment of MAVYRET is warranted in geriatric patients. • **Renal impairment:** No adjustment necessary. • **Hepatic impairment:** No adjustment necessary in mild hepatic impairment (Child-Pugh A). Use not recommended in moderate hepatic impairment (Child-Pugh B). Use is contraindicated in severe hepatic impairment (Child-Pugh C).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyxeos™ (cytarabine and daunorubicin) Injection, for intravenous use / Jazz Pharmaceuticals plc	Liposomal combination of cytarabine, a nucleoside metabolic inhibitor, and daunorubicin, an anthracycline topoisomerase inhibitor **Note:** Orphan drug designation	Treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) **Black Box Warning** Do not interchange with other DAUNOrubicin- and/or cytarabine-containing products. DAUNOrubicin and cytarabine, liposome has different dosage recommendations than DAUNOrubicin hydrochloride injection, cytarabine injection, DAUNOrubicin citrate liposome injection, and cytarabine liposome injection. Verify drug name and dose prior to preparation and administration to avoid dosing errors.	08/03/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for induction is Vyxeos™ (daunorubicin 44 mg/m2 and cytarabine 100 mg/m2) liposome via intravenous infusion over 90 minutes on days 1, 3, and 5 and on days 1 and 3 for subsequent cycles of induction, if needed. The recommended dose for consolidation is Vyxeos™ (daunorubicin 29 mg/m2 and cytarabine 65 mg/m2) liposome via intravenous infusion over 90 minutes on days 1 and 3. **DOSAGE FORMS AND STRENGTHS** For injection: 44 mg daunorubicin and 100 mg cytarabine encapsulated in liposomes as a lyophilized cake in a single-dose vial for reconstitution. **CONTRAINDICATIONS** • History of serious hypersensitivity to daunorubicin, cytarabine or any component of the formulation. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Product is not interchangeable with other DAUNOrubicin- or cytarabine-containing products; do not substitute preparations. Verify drug name and dose prior to use. • **Cardiovascular:** (1) Use not recommended in patients with left ventricular ejection fraction less than normal. (2) Increased risk of cardiotoxicity, particularly with prior anthracycline therapy, preexisting cardiac disease, prior mediastinum radiotherapy, or concomitant use of cardiotoxic drugs; monitoring recommended and discontinuation may be warranted. (3) Increased risk of drug-induced congestive heart failure with total cumulative non-liposomal DAUNOrubicin doses higher than 550 mg/m(2); avoid use in patients who have reached the lifetime anthracycline exposure maximum cumulative limit.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyxeos™ (cytarabine and daunorubicin) Injection, for intravenous use / Jazz Pharmaceuticals plc (continuation)	Liposomal combination of cytarabine, a nucleoside metabolic inhibitor, and daunorubicin, an anthracycline topoisomerase inhibitor **Note:** Orphan drug designation	Treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) **Black Box Warning** Do not interchange with other DAUNOrubicin- and/or cytarabine-containing products. DAUNOrubicin and cytarabine, liposome has different dosage recommendations than DAUNOrubicin hydrochloride injection, cytarabine injection, DAUNOrubicin citrate liposome injection, and cytarabine liposome injection. Verify drug name and dose prior to preparation and administration to avoid dosing errors.	08/03/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Dermatologic:** Severe local tissue necrosis has been reported; avoid IM or subQ administration. • **Hematologic:** Serious or fatal hemorrhage events associated with prolonged severe thrombocytopenia, including fatal CNS hemorrhages, have been reported; monitoring recommended and platelet transfusion support may be required . • **Immunologic:** Serious or fatal hypersensitivity reactions, including anaphylaxis, have been reported; monitoring recommended and interruption or slowing of infusion rate or discontinuation may be required. • **Reproductive:** Drug may cause fetal harm. Use adequate contraception during treatment and for 6 months after discontinuation. • **Special populations:** Copper overload may occur in patients with Wilson's disease or other copper-related metabolic disorders; monitoring recommended and discontinue use if signs or symptoms of acute copper toxicity occur. **ADVERSE REACTIONS** Most common adverse reactions: hemorrhagic events, febrile neutropenia, rash, edema, nausea, mucositis, diarrhea, constipation, musculoskeletal pain, fatigue, abdominal pain, dyspnea, headache, cough, decreased appetite, arrhythmia, pneumonia, bacteremia, chills, sleep disorders, and vomiting. **DRUG INTERACTIONS** • **Cardiotoxic agents:** Monitor cardiac function more frequently when coadministered with cardiotoxic agents. Concomitant use of cardiotoxic agents may increase the risk of cardiotoxicity. • **Hepatotoxic agents:** Monitor hepatic function more frequently when coadministered with hepatotoxic agents. Concomitant use with hepatotoxic agents may impair liver function and increase the toxicity of Vyxeos™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyxeos™ (cytarabine and daunorubicin) Injection, for intravenous use / Jazz Pharmaceuticals plc (continuation)	Liposomal combination of cytarabine, a nucleoside metabolic inhibitor, and daunorubicin, an anthracycline topoisomerase inhibitor **Note:** Orphan drug designation	Treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) **Black Box Warning** Do not interchange with other DAUNOrubicin- and/or cytarabine-containing products. DAUNOrubicin and cytarabine, liposome has different dosage recommendations than DAUNOrubicin hydrochloride injection, cytarabine injection, DAUNOrubicin citrate liposome injection, and cytarabine liposome injection. Verify drug name and dose prior to preparation and administration to avoid dosing errors.	08/03/2017	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Vyxeos™ can cause embryo-fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating. Patients should be advised to avoid becoming pregnant. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 6 months after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential harm to a fetus. • **Lactation:** Advise not to breastfeed during treatment with Vyxeos™ and for at least 2 weeks after the last dose. • **Pediatric use:** Safety and effectiveness of Vyxeos™ in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety were observed between these patients and younger patients. • **Renal Impairment:** No dosage adjustment required. • **Hepatic impairment:** Dosage adjustment is not required for patients with a bilirubin level less than or equal to 3 mg/dL. • **Wilson's disease:** Copper overload may occur in patients with Wilson's disease or other copper-related metabolic disorders; monitoring recommended and discontinue use if signs or symptoms of acute copper toxicity occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
CaroSpir™ (spironolactone) Suspension, for oral use / CMP Pharma, Inc.	Potassium-sparing diuretic **Note:** Orphan drug designation	Treatment of heart failure, management of edema, and for use as an add-on therapy in the treatment of hypertension	08/04/2014	**DOSAGE AND ADMINISTRATION** • Heart Failure: Initiate treatment at 20 mg once daily. • Hypertension: Initiate treatment at 20 to 75 mg daily in either single or divided doses. • Edema associated with Hepatic Cirrhosis: Initiate therapy in a hospital setting and titrate slowly. The initial recommended daily dose is 75 mg in either single or divided doses. **DOSAGE FORMS AND STRENGTHS** Oral suspension: 25 mg/5 mL. **CONTRAINDICATIONS** • Hyperkalemia • Addison's disease • Concomitant use of eplerenone **WARNINGS AND PRECAUTIONS** • **Hyperkalemia:** Monitor serum potassium within one week of initiation and regularly thereafter. • **Hypotension and Worsening Renal Function:** Monitor volume status and renal function periodically. • **Electrolyte and Metabolic Abnormalities:** Monitor serum electrolytes, uric acid and blood glucose periodically. • **Gynecomastia:** Carospir™ can cause gynecomastia **ADVERSE REACTIONS** Most common adverse reactions: gynecomastia. **DRUG INTERACTIONS** • **Agents increasing serum potassium:** Concomitant administration can lead to hyperkalemia. • **Lithium:** Increased risk of lithium toxicity. • **NSAIDs:** May reduce the diuretic, natriuretic and antihypertensive effect of Carospir™. • **Digoxin:** Carospir™ can interfere with radioimmunologic assays of digoxin exposure.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
CaroSpir™ (spironolactone) Suspension, for oral use / CMP Pharma, Inc. (continuation)	Potassium-sparing diuretic **Note:** Orphan drug designation	Treatment of heart failure, management of edema, and for use as an add-on therapy in the treatment of hypertension	08/04/2014	**DRUG INTERACTIONS** (continuation) • **Cholestyramine:** Hyperkalemic metabolic acidosis has been reported with concomitant use. • **Acetylsalicylic Acid (ASA):** ASA may reduce the efficacy of spironolactone. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Spironolactone may affect sex differentiation of the male during embryogenesis. Avoid spironolactone in pregnant women or advise a pregnant woman of the potential risk to a male fetus. • **Lactation:**. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** Carospir™ is substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, monitor renal function. • **Renal Impairment:** Carospir™ is substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. • **Hepatic Impairment:** Carospir™ can cause sudden alterations of fluid and electrolyte balance which may precipitate impaired neurological function, worsening hepatic encephalopathy and coma in patients with hepatic disease with cirrhosis and ascites. In these patients, initiate Carospir™ in the hospital.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Besponsa™ (inotuzumab ozogamicin) for Injection, for intravenous use / Pfizer Inc.	CD22 monoclonal antibody and calicheamicin cytotoxic agent conjugate	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)
		
		Black Box Warning
		• Hepatotoxicity, including fatal and life-threatening VOD occurred in patients who received inotuzumab ozogamicin.
		• A higher post-HSCT non-relapse mortality rate occurred in patients receiving inotuzumab ozogamicin.
			08/17/2017	**DOSAGE AND ADMINISTRATION**
				• Pre-medicate with a corticosteroid, antipyretic, and antihistamine prior to all infusions.
				• Dosing regimen for Cycle 1 (21 days):
				  • Day 1: 0.8 mg/m2
				  • Days 8 and 15: 0.5 mg/m2
				• Dosing regimen for subsequent cycles depending on response to treatment (28 days):
				  • Day 1: 0.5 mg/m2
				  • Days 8 and 15: 0.5 mg/m2
				• Patients who have not achieve a CR or CRi (28 days):
				  • Day 1: 0.8 mg/m2
				  • Days 8 and 15: 0.5 mg/m2
				See full prescribing information for dosing details.
				
				DOSAGE FORMS AND STRENGTHS
				For injection: 0.9 mg lyophilized powder in a single-dose vial for reconstitution and further dilution.
				
				CONTRAINDICATIONS
				None.
				
				WARNINGS AND PRECAUTIONS
				• **Black box warning:** (1) Hepatotoxicity, including severe, life-threatening, and potentially fatal hepatic veno-occlusive disease (VOD) has been reported. Increased risk with hematopoietic stem cell transplant (HSCT) following treatment, use of HSCT conditioning regimens containing 2 alkylating agents, and last total bilirubin level greater than ULN; monitoring recommended and dose interruption, reduction, or discontinuation may be required. (2) Higher post-hematopoietic stem cell transplant (HSCT) non-relapse mortality rate has been observed; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Besponsa™ (inotuzumab ozogamicin) for Injection, for intravenous use / Pfizer Inc. (continuation)	CD22 monoclonal antibody and calicheamicin cytotoxic agent conjugate	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **Black Box Warning** • Hepatotoxicity, including fatal and life-threatening VOD occurred in patients who received inotuzumab ozogamicin. • A higher post-HSCT non-relapse mortality rate occurred in patients receiving inotuzumab ozogamicin.	08/17/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Administration:** Infusion-related reactions have been reported; premedication and monitoring recommended. Interrupt infusion if reaction occurs and consider discontinuation. Permanent discontinuation required for severe or life-threatening reactions. • **Cardiovascular:** QT-interval prolongation has been reported. Increased risk with a history of or predisposition to QTc prolongation, concomitant use of QT-prolonging agents, and electrolyte disturbances; monitoring recommended. • **Hematologic:** (1) Myelosuppression, including thrombocytopenia, neutropenia, and febrile neutropenia, has been reported and may be associated with complications (eg, infection, bleeding or hemorrhagic events); monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. (2) Hemorrhagic events may occur; monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. • **Hepatic:** Increased risk for exacerbation of liver disease, including development of VOD, in patients with prior VOD or serious ongoing hepatic liver disease (eg, cirrhosis, nodular regenerative hyperplasia, active hepatitis); monitoring recommended and dose interruption, reduction, or discontinuation may be required. • **Immunologic:** Infections, including serious, life-threatening, and fatal cases, have been reported; monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. • **Reproductive:** Drug can cause fetal harm; adequate contraception required during treatment and for at least 8 months after discontinuation in females of reproductive potential and for 5 months in males with female partners with reproductive potential.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Besponsa™ (inotuzumab ozogamicin) for Injection, for intravenous use / Pfizer Inc. (continuation)	CD22 monoclonal antibody and calicheamicin cytotoxic agent conjugate	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **Black Box Warning** • Hepatotoxicity, including fatal and life-threatening VOD occurred in patients who received inotuzumab ozogamicin. • A higher post-HSCT non-relapse mortality rate occurred in patients receiving inotuzumab ozogamicin.	08/17/2017	**ADVERSE REACTIONS** Most common adverse reactions: thrombocytopenia, neutropenia, infection, anemia, leukopenia, fatigue, hemorrhage, pyrexia, nausea, headache, febrile neutropenia, transaminases increased, abdominal pain, gamma-glutamyltransferase increased, and hyperbilirubinemia. **DRUG INTERACTIONS** • **Drugs That Prolong the QT Interval:** Concomitant use of BESPONSA with drugs known to prolong the QT interval or induce Torsades de Pointes may increase the risk of a clinically significant QTc interval prolongation. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Besponsa™ can cause embryo-fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating. Advise females of reproductive potential to avoid becoming pregnant and to use effective contraception during treatment and for at least 8 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BESPONSA and for at least 5 months after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, advise the patient of the potential risk to a fetus. • **Lactation:** Advise not to breastfeed during treatment with and for at least 2 months after the last dose. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No differences in responses were identified between older and younger patients. No adjustment required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Duzallo™ (allopurinol and lesinurad) Tablets, for oral use / Ironwood Pharmaceuticals, Inc.	Xanthine oxidase inhibitor and URAT1 inhibitor fixed-dose combination	Treatment of hyperuricemia in patients with uncontrolled gout **Limitations of Use** Duzallo™ is not recommended for the treatment of asymptomatic hyperuricemia. **Black Box Warning** Acute renal failure has occurred with lesinurad, one of the components of lesinurad/allopurinol tablets.	08/21/2017	**DOSAGE AND ADMINISTRATION** The recommended dose one 200 mg lesinurad/300 mg allopurinol tablet per day on a medically appropriate dose of 200 mg allopurinol. **DOSAGE FORMS AND STRENGTHS** Tablets: (1) 200 mg lesinurad/200 mg allopurinol; (2) 200 mg lesinurad/300 mg allopurinol. **CONTRAINDICATIONS** • Severe renal impairment (estimated CrCl less than 30 mL/min), end stage renal disease, kidney transplant recipients, or patients on dialysis. • Tumor lysis syndrome or Lesch-Nyhan syndrome. • Known hypersensitivity to allopurinol, including previous occurrence of skin rash. • Carriers of HLA-B*58:01 allele due to significant increased risk of severe cutaneous adverse reactions. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Renal-related adverse events have been reported, including serum creatinine elevations and serious, acute renal failure, and are more frequent with lesinurad monotherapy; evaluate renal function prior to initiation and monitor during therapy. Interrupt therapy if serum creatinine is elevated to greater than 2 times the baseline value. • **Cardiovascular:** Major cardiovascular events have been reported, including cardiovascular deaths, nonfatal myocardial infarctions, and nonfatal strokes. • **Hematologic:** Bone marrow suppression has been reported with allopurinol; increased risk in patients with concomitant therapy with potential to cause bone marrow suppression.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Duzallo™ (allopurinol and lesinurad) Tablets, for oral use / Ironwood Pharmaceuticals, Inc. (continuation)	Xanthine oxidase inhibitor and URAT1 inhibitor fixed-dose combination	Treatment of hyperuricemia in patients with uncontrolled gout **Limitations of Use** Duzallo™ is not recommended for the treatment of asymptomatic hyperuricemia. **Black Box Warning** Acute renal failure has occurred with lesinurad, one of the components of lesinurad/allopurinol tablets.	08/21/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** (1) Reversible clinical hepatotoxicity has been reported with allopurinol, along with asymptomatic elevations in serum alkaline phosphatase or serum transaminase; monitoring recommended if suspected. (2) Preexisting liver disease; monitoring recommended. (3) Use is not recommended in severe hepatic impairment. • **Immunologic:** (1) Skin rashes have been reported with allopurinol use and may be followed by more severe and potentially fatal hypersensitivity reactions, including exfoliation, fever, lymphadenopathy, arthralgia, eosinophilia, Stevens-Johnson syndrome, toxic epidermal necrolysis, and generalized vasculitis resulting in hepatitis, renal impairment, seizures, and rarely fatalities; discontinue use at first appearance of a skin rash or signs of allergic reaction. (2) Increased risk of hypersensitivity reactions to allopurinol may occur in patients with decreased renal function receiving concomitant thiazides; monitoring recommended. • **Neurologic:** Drowsiness has been reported with allopurinol. • **Renal:** (1) Serum creatinine elevations have been reported, and in most cases were reversible; monitoring recommended. Interrupt therapy if serum creatinine is elevated to greater than 2 times the baseline value. (2) Renal: Acute uric acid nephropathy may occur; interrupt therapy if suspected. Monitoring recommended and therapy discontinuation may be necessary. (3) Renal impairment with an estimated CrCl less than 45 mL/min may increase risk for renal-related adverse events and may result in less efficacy; monitoring recommended. Do not initiate and discontinue use if estimated CrCl is persistently less than 45 mL/min. (4) Renal impairment with an estimated CrCl of 45 mL/min to less than 60 mL/min or serum creatinine elevations 1.5 to 2 times baseline value; more frequent monitoring recommended and therapy interruption may be necessary. (5) BUN elevations may occur with allopurinol use in patients with preexisting renal disease or poor urate clearance.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Duzallo™ (allopurinol and lesinurad) Tablets, for oral use / Ironwood Pharmaceuticals, Inc. (continuation)	Xanthine oxidase inhibitor and URAT1 inhibitor fixed-dose combination	Treatment of hyperuricemia in patients with uncontrolled gout **Limitations of Use** Duzallo™ is not recommended for the treatment of asymptomatic hyperuricemia. **Black Box Warning** Acute renal failure has occurred with lesinurad, one of the components of lesinurad/allopurinol tablets.	08/21/2017	**ADVERSE REACTIONS** Most common adverse reactions: cardiovascular system problem, skin rash, bone marrow depression, hepatotoxicity, hypersensitivity reaction, somnolence, acute renal failure, decreased function, serum creatinine raised. **DRUG INTERACTIONS** • **Mercaptopurine or Azathioprine:** Reduce mercaptopurine or azathioprine dose to approximately one-third to one-fourth of the usual dose and closely monitor for therapeutic response and the appearance of toxicity. • **Coumarin Anticoagulants:** Carefully monitor prothrombin time. • **Moderate CYP2C9 Inhibitors:** Use Duzallo™ with caution. • **CYP3A Substrates:** Monitor for efficacy of the CYP3A substrate. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Limited published data on allopurinol use in pregnant women do not demonstrate a clear pattern or increase in frequency of adverse development outcomes. • **Pediatric use:** Safety and effectiveness in pediatric patients under 18 years of age have not been established. • **Geriatric use:** No dose adjustment is necessary in elderly patients. • **Renal impairment**: Not recommended for patients with CrCl below 45 mL/min. • **Hepatic impairment:** Not recommended for patients with severe hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
KedRAB™ (rabies immunoglobulin human) Injection, for wound infiltration intramuscular use / Kamada Ltd. and Kedrion S.p.A.	Human plasma derived anti-rabies immunoglobulin	Post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal • Should be administered concurrently with a full course of rabies vaccine	08/23/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for PEP consists of a single dose of KEDRAB™ and a full course of rabies vaccine. • Administer KEDRAB™ and the rabies vaccine as soon as possible after exposure. • Dosage: 20 IU/kg body weight The recommended dose for infiltrate is as much of the dose as possible into and around the exposure site (if visible). • Administer the remainder intramuscularly at sites distant from the site of vaccination **DOSAGE FORMS AND STRENGTHS** Single-use vials containing 2 mL or 10 mL ready-to-use solution with a potency of 150 IU/mL. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Allergic or hypersensitivity reactions may occur, particularly if injected into a blood vessel or with past history of systemic allergic reactions; monitoring recommended; immediate discontinuation required. • Bleeding disorders, preexisting; may result in bleeding complications due to intramuscular route of vaccine. • Concomitant use with live vaccines, such as measles, mumps, polio, or rubella. Do not use within 3 months of rabies immunoglobulin. Do not use measles vaccine within 4 months of Kedrab™ administration, and do not use other live attenuated virus vaccines within 3 months of administration. • Hemolysis may occur, particularly in patients with non-O blood type, underlying associated inflammatory conditions, or high cumulative doses of immune globulins.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
KedRAB™ (rabies immunoglobulin human) Injection, for wound infiltration intramuscular use / Kamada Ltd. and Kedrion S.p.A. (continuation)	Human plasma derived anti-rabies immunoglobulin	Post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal • Should be administered concurrently with a full course of rabies vaccine	08/23/2017	**WARNINGS AND PRECAUTIONS** (continuation) • Human plasma product; infectious agent risk, including viruses and theoretical risk of Creutzfeldt-Jakob disease. • Infectious agent transmission may occur, with potential exposure to viruses, the Creutzfeldt-Jakob agent, the variant Creutzfeldt-Jakob agent, and other pathogens Kedrab™. • Intramuscular use only; should not be administered intravenously because of potential for serious reactions. • Isolated immunoglobulin A deficiency; may increase risk for developing antibodies to IgA and for anaphylactic reactions with subsequent administration of IgA-containing blood products. • Repeated doses, should not be administered once vaccine treatment has been initiated; potential for interference with maximum active immunity expected from vaccine (HyperRab™ S/D). • Systemic allergic reaction to human immune globulin preparation. • Thrombocytopenia, preexisting; may result in bleeding complications due to intramuscular route of vaccine. • Thrombosis or thrombotic complications; increased risk with hypercoagulable states, prolonged immobilization, indwelling vascular catheters, advanced age, estrogen use, past history of venous or arterial thrombosis, cardiovascular risk factors, and hyperviscosity syndromes; monitoring recommended. **ADVERSE REACTIONS** Most common adverse reactions: injection site pain, headache, muscle pain, and upper respiratory tract infection. **DRUG INTERACTIONS** • Do not administer KEDRAB™ in the same syringe, or into the same anatomical site, as the rabies vaccine.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
KedRAB™ (rabies immunoglobulin human) Injection, for wound infiltration intramuscular use / Kamada Ltd. and Kedrion S.p.A. (continuation)	Human plasma derived anti-rabies immunoglobulin	Post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal • Should be administered concurrently with a full course of rabies vaccine	08/23/2017	**DRUG INTERACTIONS** (continuation) • Immunization with live vaccines: KEDRAB™ may interfere with the response to live vaccines, such as measles, mumps, polio or rubella; avoid immunization with live virus vaccines within 3 months after KEDRAB™ administration, or in the case of measles vaccine, within 4 months after KEDRAB administration **USE IN SPECIFIC POPULATIONS** • **Pregnancy: T**he risk of major birth defects and miscarriage in pregnant women who are exposed to KEDRAB is unknown. • **Lactation:** There is no information regarding the presence of KEDRAB in human milk, the effects on the breastfed infant, or the effects on milk production. • **Pediatric use:** The safety and effectiveness of KEDRAB in the pediatric population have not been established. • **Geriatric use:** Clinical studies of KEDRAB™ did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Clinical experience with has not identified differences in effectiveness between elderly and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Gocovri™ (amantadine hydrochloride) Extended-Release Capsules, for oral use / Adamas Pharmaceuticals, Inc.	Chrono-synchronous amantadine therapy **Note:** Orphan drug designation	Treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease	08/24/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is initially 137 mg orally once daily at bedtime for 1 week, then increase to 274 mg once daily at bedtime. **DOSAGE FORMS AND STRENGTHS** Extended release capsules: 68.5 mg and 137 mg **CONTRAINDICATIONS** • End-stage renal disease (ESRD) • Hypersensitivity to amantadine hydrochloride or to other components of the product **WARNINGS AND PRECAUTIONS** • **Falling Asleep During Activities of Daily Living:** Advise patients prior to treatment; ordinarily discontinue if occurs. • **Suicidality and Depression:** Monitor patients for depressed mood, depression, or suicidal ideation or behavior. • **Hallucinations/Psychotic Behavior:** Patients with major psychotic disorder should ordinarily not be treated with GOCOVRI™; observe patients for the occurrence of hallucinations throughout treatment, especially at initiation and after dose increases. • **Dizziness and Orthostatic Hypotension:** Monitor patients for dizziness and orthostatic hypotension, especially after starting GOCOVRI or increasing the dose. • **Withdrawal-Emergent Hyperpyrexia and Confusion:** Avoid sudden discontinuation. • **Impulse Control/Compulsive Behaviors:** Ask patients about increased gambling urges, sexual urges, uncontrolled spending or other urges; consider dose reduction or discontinuation if occurs.. **ADVERSE REACTIONS** Most common adverse reactions: hallucination, dizziness, dry mouth, peripheral edema, constipation, fall, and orthostatic hypotension.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Gocovri™ (amantadine hydrochloride) Extended-Release Capsules, for oral use / Adamas Pharmaceuticals, Inc. (continuation)	Chrono-synchronous amantadine therapy **Note:** Orphan drug designation	Treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson's disease	08/24/2017	**DRUG INTERACTIONS** • **Other Anticholinergic Drugs:** Doses should be reduced if atropine-like effects occur. • **Drugs Affecting Urinary pH:** Excretion increases with acidic urine; possible accumulation with urine change towards alkaline. • **Live Attenuated Influenza Vaccines:** Not recommended during use. • **Alcohol:** Concomitant use not recommended. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Lactation:** There is no information on the risk to a breastfed infant. May alter breast milk production or excretion. • **Pediatric use:** The safety and effectiveness of GOCOVRI™ in pediatric patients have not been established. • **Geriatric use:** No dose adjustment is recommended on the basis of age. However, GOCOVRI™ is known to be excreted by kidneys, and the risk of adverse reactions may be greater in patients with impaired renal function. Elderly patients are more likely to have decreased renal function, so care should be taken and it may be useful to monitor renal function. • **Renal Impairment:** (1) GOCOVRI™ is contraindicated for use in patients with end-stage renal disease (creatinine clearance values < 15 mL/min/1.73 m2). (2) For patients with moderate renal impairment (creatinine clearance between 30 and 59 mL/min/1.73 m2): a 50% dose reduction of dosage to a starting daily dose of 68.5 mg daily at bedtime for a week, to a maximum dosage of 137 mg daily at bedtime is recommended. (3) For patients with severe renal impairment (creatinine clearance between 15 and 29 ml/min/m2), a daily dose of 68.5 mg at bedtime is the recommended initial and maximum dosage.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cyltezo™ (adalimumab-adbm) Injection, for subcutaneous use / Boehringer Ingelheim Pharmaceuticals, Inc.	Anti-TNF-α monoclonal antibody **Note:** Adalimumab-adbm is a biologic product approved as biosimilar to adalimumab (Humira™)	Treatment of various inflammatory diseases including: • Rheumatoid arthritis (RA) • Psoriatic arthritis • Ankylosing spondylitis • Crohn's disease • Ulcerative colitis • Plaque psoriasis • Juvenile idiopathic arthritis **Black Box Warning** Patients treated with adalimumab-adbm are at increased risk of infections that may become serious and lead to hospitalization or death (eg. TB, invasive fungal infections, bacterial, viral, and those caused by opportunistic pathogens including Legionella and Listeria). Risks and benefits should be carefully considered prior to initiation in patients with chronic or recurrent infection. Evaluate for latent TB and treat if necessary prior to initiation. Monitor closely for signs and symptoms of infection. Lymphoma, Hepatosplenic T-cell lymphoma (HSTCL) and other malignancies have been reported in pediatric and adolescent patients.	08/25/2017	**DOSAGE AND ADMINISTRATION** • For Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis: 40 mg every other week. • For Juvenile Idiopathic Arthritis in ≥ 30 kg (66 lbs) patient is: 40 mg every other week. • For adult Crohn's Disease and Ulcerative Colitis: Initial dose (Day 1): 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days). Second dose two weeks later (Day 15): 80 mg. Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week. For Ulcerative Colitis only: Only continue in patients with evidence of clinical remission by eight weeks (Day 57). • For Plaque Psoriasis: 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose. **DOSAGE FORMS AND STRENGTHS** Injection: 40 mg/0.8 mL in a single-use prefilled glass syringe. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Black Box Warning:** (1) Serious and fatal infections (bacterial [Legionella and Listeria], TB, invasive fungal infections, viral, parasitic, and other opportunistic infections) have been reported; increased risk in patients who are older than 65 years, are using concomitant immunosuppressants, or have comorbid conditions; monitor and discontinue treatment if serious infection or sepsis develops. (2) Lymphoma and other malignancies, some fatal, have been reported in children and adolescents. (3) Hepatosplenic T-cell lymphoma been reported, fatal in some cases; most occurred in adolescent and young adult males with Crohn disease or ulcerative colitis and were primarily associated with concomitant azathioprine or 6-mercaptopurine use.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cyltezo™ (adalimumab-adbm) Injection, for subcutaneous use / Boehringer Ingelheim Pharmaceuticals, Inc. (continuation)	Anti-TNF-α monoclonal antibody **Note:** Adalimumab-adbm is a biologic product approved as biosimilar to adalimumab (Humira™)	Treatment of various inflammatory diseases including: • Rheumatoid arthritis (RA) • Psoriatic arthritis • Ankylosing spondylitis • Crohn's disease • Ulcerative colitis • Plaque psoriasis • Juvenile idiopathic arthritis **Black Box Warning** Patients treated with adalimumab-adbm are at increased risk of infections that may become serious and lead to hospitalization or death (eg. TB, invasive fungal infections, bacterial, viral, and those caused by opportunistic pathogens including Legionella and Listeria). Risks and benefits should be carefully considered prior to initiation in patients with chronic or recurrent infection. Evaluate for latent TB and treat if necessary prior to initiation. Monitor closely for signs and symptoms of infection. Lymphoma, Hepatosplenic T-cell lymphoma (HSTCL) and other malignancies have been reported in pediatric and adolescent patients.	08/25/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Cardiovascular:** Congestive heart failure, new-onset or worsening, has been reported; monitoring recommended. • **Concomitant Use:** Concomitant use with abatacept, anakinra, or live vaccines is not recommended. • **Dermatologic:** Melanoma and nonmelanoma skin cancers have been reported; monitoring recommended. • **Hematologic:** Hematological abnormalities (eg, pancytopenia, aplastic anemia) have occurred; may require discontinuation of therapy. • **Hepatic:** Chronic hepatitis B carriers may have increased risk of reactivation; fatal cases have occurred; monitoring for several months after discontinuation recommended; discontinuation and supportive treatment may be necessary • **Immunologic:** (1) Pediatric patients should be brought up to date on all immunization requirements prior to starting adalimumab-adbm treatment. (2) Autoantibody formation may occur and may develop into lupus-like syndrome; discontinue therapy if symptoms occur. (3) Active infection, including localized; discontinue or do not initiate adalimumab-adbm. (4) Use with caution in patients with a history of opportunistic infection or underlying conditions that predispose them to infection; monitoring recommended; discontinue if serious infection develops. (5) Use with caution in patients who have traveled to or reside in areas of endemic TB or mycoses; monitoring recommended; discontinue if serious infection develops. (7) Immunologic: Anaphylaxis and angioneurotic edema have been reported; discontinue. (8) Malignancies (lymphoma, leukemia, breast, colon, prostate, lung, skin) have been reported in adults; increased risk in patients with rheumatoid arthritis and other chronic inflammatory disease, particularly those with highly active disease and chronic exposure to immunosuppressant therapies. (9) Use caution when immunizing infants who were exposed to adalimumab-adbm in utero.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cyltezo™ (adalimumab-adbm) Injection, for subcutaneous use / Boehringer Ingelheim Pharmaceuticals, Inc. (continuation)	Anti-TNF-α monoclonal antibody **Note:** Adalimumab-adbm is a biologic product approved as biosimilar to adalimumab (Humira™)	Treatment of various inflammatory diseases including: • Rheumatoid arthritis (RA) • Psoriatic arthritis • Ankylosing spondylitis • Crohn's disease • Ulcerative colitis • Plaque psoriasis • Juvenile idiopathic arthritis **Black Box Warning** Patients treated with adalimumab-adbm are at increased risk of infections that may become serious and lead to hospitalization or death (eg. TB, invasive fungal infections, bacterial, viral, and those caused by opportunistic pathogens including Legionella and Listeria). Risks and benefits should be carefully considered prior to initiation in patients with chronic or recurrent infection. Evaluate for latent TB and treat if necessary prior to initiation. Monitor closely for signs and symptoms of infection. Lymphoma, Hepatosplenic T-cell lymphoma (HSTCL) and other malignancies have been reported in pediatric and adolescent patients.	08/25/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Latex Sensitivity:** Gray needle cover of 27 gauge pen and prefilled syringe contains latex. • **Neurologic:** Known association between intermediate uveitis and central demyelinating disorders (eg, CNS including multiple sclerosis and optic neuritis and peripheral nervous system including Guillain-Barré syndrome); new-onset or worsening of preexisting condition may occur; discontinuation may be necessary. • **Respiratory:** TB reactivation or new-onset may occur; evaluate risk factors and test for latent TB prior to initiating treatment and periodically thereafter. **ADVERSE REACTIONS** Most common adverse reactions: infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash. **DRUG INTERACTIONS** • **Abatacept:** Increased risk of serious infection. • **Anakinra:** Increased risk of serious infection. • **Live vaccines:** Avoid use with CYLTEZO™. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** The estimated risk of major birth defects and miscarriage is unknown. • **Lactation:** There are no reports of adverse effects of adalimumab products on the breastfed infant and no effects on milk production.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Benznidazole Tablets, for oral use / Chemo Research, S. L.	Antiprotozoal **Note:** Orphan drug designation	Treatment of Chagas disease, or American trypanosomiasis, a parasitic infection caused by *Trypanosoma cruzi*	08/29/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for pediatric patients 2 to 12 years of age is a total daily dose of 5 mg/kg to 8 mg/kg orally administered in two divided doses separated by approximately 12 hours for a duration of 60 days. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg (functionally scored), 12.5 mg. **CONTRAINDICATIONS** • History of hypersensitivity reaction to benznidazole or other nitroimidazole derivatives. • Concomitant use of disulfiram or use within the last 2 weeks. • Concomitant use of alcohol or propylene glycol-containing products or use for at least 3 days after benznidazole therapy. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** (1) Serious skin reactions, including acute generalized exanthematous pustulosis, toxic epidermal necrolysis, erythema multiforme, and eosinophilic drug reaction, have been reported; discontinue at first evidence of a serious skin reaction. (2) Skin rashes (eg, maculopapular, pruritic macules, eczema, pustules, generalized erythematous, allergic dermatitis, and exfoliative dermatitis) have been reported; if signs or symptoms of systemic involvement (eg, lymphadenopathy, fever, and/or purpura) occur, discontinue treatment. • **Genotoxicity:** Genotoxicity may occur. • **Hematologic:** Bone marrow depression (eg, neutropenia, thrombocytopenia, anemia and leukopenia) has been reported; monitoring recommended. • **Neurologic:** Can cause paresthesia or symptoms of peripheral neuropathy; if neurological symptoms occur, immediate discontinuation is recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Benznidazole Tablets, for oral use / Chemo Research, S. L. (continuation)	Antiprotozoal **Note:** Orphan drug designation	Treatment of Chagas disease, or American trypanosomiasis, a parasitic infection caused by *Trypanosoma cruzi*	08/29/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Reproductive:** Can cause fetal harm during pregnancy; advise use of effective contraception in women of reproductive potential during therapy and for at least 5 days after the last dose. **ADVERSE REACTIONS** Most common adverse reactions: abdominal pain, rash, decreased weight, headache, nausea, vomiting, neutropenia, urticaria, pruritus, eosinophilia, decreased appetite. **DRUG INTERACTIONS** • **Disulfiram:** Psychotic reactions have been reported in patients who are concurrently taking disulfiram and nitroimidazole agents. • **Alcohol and Products Containing Propylene Glycol:** Abdominal cramps, nausea, vomiting, headaches, and flushing may occur if alcoholic beverages or products containing propylene glycol are consumed during or following therapy with nitroimidazole agents which are structurally related to benznidazole. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm when administered to a pregnant woman. Pregnancy testing is recommended for females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment with benznidazole and for 5 days after the final dose. • **Lactation:** Breastfeeding is not recommended. • **Pediatric use:** Safety and effectiveness have been established in pediatric patients 2 to 12 years of age. • **Renal Impairment:** Use has not been evaluated in patients with renal impairment. • **Hepatic Impairment:** Use of has not been evaluated in patients with hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vabomere™ (meropenem and vaborbactam) Injection, for intravenous use / The Medicines Company	Carbapenem and beta-lactamase inhibitor combination	Treatment of complicated urinary tract infections (cUTIs)	08/29/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 4 grams (meropenem 2 grams/vaborbactam 2 grams) IV every 8 hours for up to 14 days. **DOSAGE FORMS AND STRENGTHS** For injection: Sterile powder for constitution in single-dose vials containing meropenem 1 gram (equivalent to 1.14 grams of meropenem trihydrate) and vaborbactam1 gram. **CONTRAINDICATIONS** • Demonstrated anaphylactic reactions to beta-lactam antibiotics. • Known hypersensitivity to meropenem, vaborbactam or other drugs in the same class **WARNINGS AND PRECAUTIONS** • **Concomitant Use:** Concomitant use with valproic acid or divalproex sodium is generally not recommended. • **Gastrointestinal:** C.difficile-associated diarrhea, including mild diarrhea to fatal colitis, has been reported; discontinue if suspected or confirmed. • **Hematologic:** Thrombocytopenia has been observed in renally-impaired patients treated with meropenem. • **Immunologic:** (1) Hypersensitivity reactions, including anaphylaxis, have been reported, especially in patients with history of sensitivity to multiple allergens or other beta-lactam antibiotics such as penicillins and cephalosporins; discontinue if allergic reaction occurs. (2) Overgrowth of nonsusceptible organisms may occur with prolonged use; reevaluate need for continued therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vabomere™ (meropenem and vaborbactam) Injection, for intravenous use / The Medicines Company (continuation)	Carbapenem and beta-lactamase inhibitor combination	Treatment of complicated urinary tract infections (cUTIs)	08/29/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Neurologic:** (1) Seizures and other CNS adverse effects have been reported, especially in patients with preexisting CNS disorders, bacterial meningitis, or compromised renal function; dose reduction or discontinuation may be necessary. (2) Neuromotor impairment (eg, seizures, delirium, headaches, or paresthesias) may occur, which may cause motor impairment and interfere with mental alertness; consider these effects with outpatient use. • **Renal:** (1) Renal impairment (CrCl 50 mL/min or less); dose reduction recommended. (2) Changing renal function; monitoring recommended and dose reduction may be needed **ADVERSE REACTIONS** Most common adverse reactions: headache, phlebitis/infusion site reactions, and diarrhea. **DRUG INTERACTIONS** • **Valproic Acid:** Co-administration of carbapenems to patients receiving valproic acid or divalproex sodium results in a reduction in valproic acid concentrations. • **Probenecid:** Probenecid competes with meropenem for active tubular secretion, resulting in increased plasma concentrations of meropenem. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Insufficient data to establish whether there is a drug-associated risk of major birth defects or miscarriages. • **Lactation:** No information is available on the effects of meropenem and vaborbactam on the breast-fed child or on milk production. • **Pediatric use:** Safety and effectiveness in pediatric patients has not been established. • **Geriatric use:** No dosage adjustment based on age is required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Kymriah™ (tisagenle-cleucel) Suspension for Intravenous Infusion / Novartis Pharmaceuticals Corporation	Chimeric antigen receptor T cell (CAR-T)	Therapy for use in pediatric and young adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) **Black Box Warning** Cytokine release syndrome (CRS) and neurological toxicities: (1) CRS including fatal or life-threatening reactions, occurred in patients receiving tisagenlecleucel. Do not administer tisagenlecleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab. (2) Neurological toxicities, which may be severe or life-threatening, can occur following treatment with tisagenlecleucel, including concurrently with CRS. Monitor for neurological events after treatment with tisagenlecleucel. Provide supportive care as needed. Tisagenlecleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.	08/30/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is based on the number of chimeric antigen receptor (CAR) positive viable T cells. For patients 50 kg or less: administer 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg body weight intravenously. For patients above 50 kg: administer 0.1 to 2.5 x 10^8 total CAR-positive viable T cells (non-weight based) intravenously. **DOSAGE FORMS AND STRENGTHS** A single-dose unit contains 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg of body weight for patients 50 kg or less, or 0.1 to 2.5 x 10^8 CAR-positive viable T cells for patients more than 50 kg, suspended in a patient-specific infusion bag. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Black box warning:** (1) Cytokine release syndrome (CRS), including fatal or life-threatening reactions, have been reported. Do not use in patients with active infections or inflammatory disorders Treat severe or life-threatening CRS with tocilizumab and/or corticosteroids. Monitoring for at least 4 weeks after treatment recommended. (2) Neurological toxicities, which may be severe or life-threatening, may occur after treatment, including concurrently with CRS. Monitoring recommended and provide supportive care as needed. (3) Tisagenlecleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS. • **Concomitant use:** Live virus vaccines are not recommended for at least 2 weeks prior to therapy, during therapy, and until immune recovery following therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Kymriah™ (tisagenle-cleucel) Suspension for Intravenous Infusion / Novartis Pharmaceuticals Corporation (continuation)	Chimeric antigen receptor T cell (CAR-T)	Therapy for use in pediatric and young adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) **Black Box Warning** Cytokine release syndrome (CRS) and neurological toxicities: (1) CRS including fatal or life-threatening reactions, occurred in patients receiving tisagenlecleucel. Do not administer tisagenlecleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab. (2) Neurological toxicities, which may be severe or life-threatening, can occur following treatment with tisagenlecleucel, including concurrently with CRS. Monitor for neurological events after treatment with tisagenlecleucel. Provide supportive care as needed. Tisagenlecleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.	08/30/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hematologic:** (1) Febrile neutropenia has been reported and may be concurrent with cytokine release syndrome. (2) Prolonged cytopenias have been reported and may occur for several weeks following treatment; prolonged neutropenia has been associated with increased risk of infection. • **Hepatic:** (1) Hepatitis B Virus (HBV) reactivation can occur in patients receiving drugs directed against B cells, in some cases resulting in fulminant hepatitis, hepatic failure, and death; prescreen patients for HBV, hepatitis C virus and HIV. (2) Hepatitis has been reported in patients who are hepatitis B surface antigen (HBsAg) positive and patients who are HBsAg negative but hepatitis B core antibody positive; prescreen patients for HBV, hepatitis C virus and HIV. • **Immunologic:** (1) Increased risk of cytokine release syndrome in patients with high pre-infusion tumor burden (greater than 50% blasts in bone marrow), uncontrolled or accelerating tumor burden following lymphodepleting chemotherapy, active infections, and/or inflammatory processes. (2) Allergic reactions may occur including serious hypersensitivity reactions (eg, anaphylaxis); possibly due to dimethyl sulfoxide or dextran 40 contained in drug product. (3) Serious infections, including life-threatening or fatal infections, have been reported; monitoring recommended. (4) Hypogammaglobulinemia has been reported and may occur following treatment in patients with complete remission; monitoring recommended. (5) Immunologic: Agammaglobulinemia may occur following treatment in patients with complete remission; monitoring recommended. • **Malignancy:** Secondary malignancies or recurrence of leukemia may occur; monitoring recommended

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Kymriah™ (tisagenle-cleucel) Suspension for Intravenous Infusion / Novartis Pharmaceuticals Corporation (continuation)	Chimeric antigen receptor T cell (CAR-T)	Therapy for use in pediatric and young adult patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) **Black Box Warning** Cytokine release syndrome (CRS) and neurological toxicities: (1) CRS including fatal or life-threatening reactions, occurred in patients receiving tisagenlecleucel. Do not administer tisagenlecleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab. (2) Neurological toxicities, which may be severe or life-threatening, can occur following treatment with tisagenlecleucel, including concurrently with CRS. Monitor for neurological events after treatment with tisagenlecleucel. Provide supportive care as needed. Tisagenlecleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the KYMRIAH REMS.	08/30/2017	**ADVERSE REACTIONS** Most common adverse reactions: cytokine release syndrome, hypogammaglobulinemia, infections-pathogen unspecified, pyrexia, decreased appetite, headache, encephalopathy, hypotension, bleeding episodes, tachycardia, nausea, diarrhea, vomiting, viral infectious disorders, hypoxia, fatigue, acute kidney injury, and delirium. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** KYMRIAH™ is not recommended for women who are pregnant, and pregnancy after KYMRIAH™ administration should be discussed with the treating physician. • **Lactation:** There is no information regarding the presence of KYMRIAH™ in human milk, the effect on the breastfed infant, and the effects on milk production. • **Pediatric use:** The safety and efficacy of KYMRIAH™ have been established in pediatric patients 3 to 17 years of age. • **Geriatric use:** The safety and effectiveness of KYMRIAH™ have not been established in geriatric patients.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Epclusa™ (sofosbuvir and velpatasvir) Tablets / Gilead	Nucleotide analog polymerase inhibitor and pan-genotypic NS5A inhibitor fixed-dose combination	Approved for the treatment of chronic genotype 1-6 hepatitis C virus (HCV) infection **New indication:** Patient Population Altered to include use in patients co-infected with HIV	08/01/2017	The approval is based on data from the open-label, Phase 3 ASTRAL-5 study, which evaluated 12 weeks of treatment with Epclusa in 106 subjects with genotype 1-4 HCV infection who were co-infected with HIV and on stable antiretroviral therapy. In the study, 95% (101/106) of patients achieved the primary endpoint of SVR12, defined as an undetectable viral load 12 weeks after completing therapy.
Imbruvica™ (ibrutinib) Capsules / Pharmacyclics LLC; Janssen Biotech, Inc.	Bruton's tyrosine kinase (BTK) inhibitor	Treatment of mantle cell lymphoma, chronic lymphocytic leukemia, Waldenström's macroglobulinemia, small lymphocytic lymphoma, marginal zone lymphoma, and chronic graft versus host disease **New indication:** Treatment of adult patients with chronic graft versus host disease (cGVHD) after failure of one or more treatments. This is the first FDA-approved therapy for the treatment of cGVHD.	08/01/2017	cGVHD is a life-threatening condition that can occur in patients after they receive a stem cell transplant from blood or bone marrow, called hematopoietic stem cell transplantation (HSCT), to treat certain blood or bone marrow cancers. cGVHD occurs when cells from the stem cell transplant attack healthy cells in a patient's tissues. Symptoms of cGVHD can occur in the skin, eyes, mouth, gut, liver and lungs. The condition is estimated to occur in 30-70 percent of all patients who receive HSCT. The efficacy and safety of Imbruvica for the treatment of cGVHD were studied in a single-arm trial of 42 patients with cGVHD whose symptoms persisted despite standard treatment with corticosteroids. Most patients' symptoms included mouth ulcers and skin rashes, and more than 50 percent of patients had two or more organs affected by cGVHD. In the trial, 67% of patients experienced improvements in their cGVHD symptoms. In 48% of patients in the trial, the improvement of symptoms lasted for up to five months or longer. Common side effects of Imbruvica in patients with cGVHD include fatigue, bruising, diarrhea, low levels of blood platelets (thrombocytopenia), muscle spasms, swelling and sores in the mouth (stomatitis), nausea, severe bleeding (hemorrhage), low levels of red blood cells (anemia) and lung infection (pneumonia).

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Liletta™ (levonorgestrel) Intrauterine Device / Odyssea Pharma, Belgium; Actavis Pharma, Inc.	Hormonal intrauterine device (IUD)	For use by women to prevent pregnancy **New indication:** To extend the duration of use of Liletta™ 52 mg for the prevention of pregnancy for up to four years	08/06/2017	The approval was based on a review of additional efficacy and safety data from an ongoing U.S.-based Phase 3 hormonal IUD trial, ACCESS IUS (A Comprehensive Contraceptive Efficacy & Safety Study of an IUS [intrauterine system]), with 1,751 U.S. women receiving Liletta™. Liletta™ was shown to be greater than 99 percent effective in preventing pregnancy in a broad range of women, regardless of age, race, body mass index (BMI) or parity (whether or not the woman had given birth to at least one child).
Faslodex™ (fulvestrant) Injection / AztraZeneca	Estrogen receptor antagonist	Treatment of hormone receptor positive metastatic breast cancer **New indication:** Monotherapy for expanded use in hormone-receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer	08/28/2017	Faslodex™ was first approved in 2002 and has been used as a monotherapy for the treatment of postmenopausal women with HR+ MBC whose cancer has progressed following prior antiestrogen therapy. In 2016, Faslodex™ was approved in combination with palbociclib, for the treatment of women with HR+, HER2- advanced or MBC, whose cancer has progressed after endocrine therapy. Now, Faslodex™ receives approval as monotherapy for expanded use in women with hormone-receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer, who have gone through menopause and have not received previous endocrine therapy. The approval was based on pivotal data from the Phase III FALCON trial. This trial was designed to demonstrate superiority and included 462 postmenopausal women with HR+ metastatic or locally-advanced breast cancer. The results showed a statistically-significant increase in investigator-assessed median progression-free survival (PFS), representing a 20% reduction in the risk of disease progression or death determined by RECIST - median PFS of 16.6 months in patients who received Faslodex™, compared to 13.8 months in patients receiving the aromatase inhibitor ARIMIDEX™ (anastrozole) 1mg (HR: 0.797; 95% CI: 0.637-0.999; p=0.049).

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Victoza™ (liraglutide) Injection / Novo Nordisk	Glucagon-like peptide-1 (GLP-1) receptor agonist	To improve glycemic control in adults with type 2 diabetes mellitus, and to reduce the risk of heart attack, stroke and CV death in adults with type 2 diabetes and established CV disease **New indication:** To reduce the risk of 3 major adverse cardiovascular events (heart attack, stroke and CV death) in Type 2 Diabetes patients.	08/25/2017	Victoza™ was approved on January 2010, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Victoza™ is now approved to reduce the risk of 3 major adverse cardiovascular events in Type 2 Diabetes patients. Approval was based on the results from the LEADER trial, which demonstrated that Victoza™ significantly reduced the risk of a 3 component endpoint consisting of cardiovascular death, non-fatal heart attack or non-fatal stroke by 13% vs placebo (p=0.01) with an absolute risk reduction (ARR) of 1.9%.
Actemra™ (tocilizumab) Injection / Genentech	Humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody	Treatment rheumatoid arthritis; systemic juvenile idiopathic arthritis (SJIA); polyarticular juvenile idiopathic arthritis (PJIA); giant cell arteritis; and CAR T cell-induced severe or life-threatening cytokine release syndrome **New indication:** Treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS)	08/30/2017	FDA approved Actemra™ for the treatment of CAR T Cell-Induced severe or life-threatening CRS in patients two years of age and older. CRS, which is caused by an overactive immune response, has been identified as a potentially severe and life-threatening side effect of CAR T cell therapy for certain cancers. The approval is based on a retrospective analysis of pooled outcome data from clinical trials of CAR T cell therapies for blood cancers, which assessed the efficacy of Actemra™ in the treatment of CRS. The study population included 45 pediatric and adult patients treated with Actemra™, with or without additional high-dose corticosteroids, for severe or life-threatening CRS. Thirty-one patients (69%; 95% CI: 53%–82%) achieved a response, defined as resolution of CRS within 14 days of the first dose of Actemra™, no more than two doses of Actemra™ were needed, and no drugs other than Actemra™ and corticosteroids were used for treatment. No adverse reactions related to Actemra™ were reported. A second study confirmed resolution of CRS within 14 days using an independent cohort that included 15 patients with CAR T cell-induced CRS.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Austedo (deutetrabenazine) Tablets / Teva Pharmaceutical Industries Ltd.	Vesicular monoamine transporter 2 (VMAT2) inhibitor	Treatment of chorea associated with Huntington's disease and the treatment of tardive dyskinesia **New indication:** Treatment of tardive dyskinesia in adults.	08/30/2017	Tardive dyskinesia is a debilitating and often irreversible movement disorder characterized by repetitive and uncontrollable movements of the tongue, lips, face, trunk and extremities. The condition affects about 500,000 people in the United States and can be caused by certain medications used to treat mental health conditions or gastrointestinal conditions. Austedo was previously approved for the treatment of chorea associated with Huntington's Disease in April 2017. Now, FDA also approved Austedo™ tablets for the treatment of tardive dyskinesia in adults. The approval was based on results from two Phase III randomized, double-blind, placebo-controlled, parallel group studies assessing the efficacy and safety of Austedo™ in reducing the severity of abnormal involuntary movements associated with tardive dyskinesia.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Lynparza™ (olaparib) Capsules and Tablets / Aztra Zeneca	Poly ADP ribose polymerase (PARP) inhibitor	Treatment of advanced ovarian cancer	08/17/2017	Lynparza™ was first approved under the FDA's Accelerated Approval program in December 2014, as a capsule formulation, making it the first poly ADP-ribose polymerase (PARP) inhibitor approved. Now FDA approved a tablet formulation of Lynparza™ for maintenance treatment of ovarian cancer. FDA granted approval as follows: • New use of Lynparza™ tablets as a maintenance treatment of adult patients with recurrent, epithelial ovarian, fallopian tube or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy, regardless of BRCA status. • New use of Lynparza™ tablets (2 tablets twice daily) as opposed to capsules (8 capsules twice daily). • Lynparza™ tablets also now indicated (conversion from the current accelerated approval) for the use in adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCA) advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy; patients for this indication are selected for therapy based on an FDA-approved companion diagnostic. Two randomized trials supported the new approvals: • SOLO-2 (n=295) confirmed the benefit of Lynparza™ in gBRCA-mutated patients, demonstrating a 70% reduced risk of disease progression or death (HR 0.30 [95% CI, 0.22-0.41], P<0.0001) and improved median progression-free survival (PFS) to 19.1 vs 5.5 months for placebo by investigator-assessed analysis. • Another study (n=265) showed that Lynparza™ reduced the risk of disease progression or death by 65% and improved PFS compared with placebo in patients of any BRCA status (HR 0.35 [95% CI, 0.25-0.49], P<0.0001; median PFS of 8.4 months with Lynparza vs 4.8 months with placebo). Additionally, patients in this study, treated with Lynparza™ as a maintenance therapy, had a median overall survival (OS) of 29.8 months vs 27.8 months for placebo (HR 0.73 [95% CI, 0.55-0.95])

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Isoproterenol Hydrochloride Injection USP / Nexus Pharmaceuticals, Inc.	Sympathomimetic agent that acts directly on both β_1- and β_2-adrenergic receptors (nonselective β-agonist)	08/02/2017	Generic for: Isuprel™ Injection • 0.2 mg/mL and 1 mg/5 mL single-dose vials
Lanthanum Carbonate Chewable Tablets / Natco Pharma Limited	Phosphate binder	08/11/2017	Generic for: Fosrenol Chewable Tablets • 500 mg (base), 750 mg (base) and 1 gram (base)
Tacrolimus Injection /Hospira, Inc.	Calceineurin inhibitor, Immunosuopressive	08/25/2017	Generic for: Prograf Injection • 5mg (base)/mL

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Tlando™ (testosterone) / Lipocine Inc.	08/09/2017 08/14/2017	Treatment for: Hypogonadism – Male	08/09 – Lipocine had previously submitted an NDA for Tlando™ and received a Complete Response Letter (CRL) from the FDA in June 2016. The CRL identified a deficiency related to the dosing algorithm for the proposed label. With the goal of addressing this deficiency, the company successfully completed a dosing validation (DV) study, which confirmed the validity of a fixed dose approach without the need for dose titration to orally administer Tlando™. 8/14 – Lipocine announced that the FDA has acknowledged receipt of the Company's NDA resubmission for Tlando™.	Moderate
Bictegravir, emtricitabine and tenofovir alafenamide (BIC/FTC/TAF) / Gilead Sciences, Inc.	08/10/2017	Treatment for: HIV Infection	Gilead announces that the U.S. FDA has grantd priority review designation for the company's NDA for an investigational, fixed-dose combination of BIC/FTC/TAF for treatment of HIV-1 infection. Gilead filed the NDA for BIC/FTC/TAF with a Priority Review voucher on June 12, 2017. Bictegravir, emtricitabine and tenofovir alafenamide is an investigational integrase strand transfer inhibitor and emtricitabine/tenofovir alafenamide (FTC/TAF) combination in development for the treatment of HIV-1 infection in adults.	Moderate
ALKS 5461 (buprenorphine and samidorphan) / Alkermes plc	08/21/2017	Treatment for: Major Depressive Disorder	ALKS 5461 (buprenorphine and samidorphan) is a novel opioid modulator, combining a partial opioid agonist with an opioid antagonist to rebalance brain function in patients with treatment-resistant depression.	Moderate
LJPC-501 (angiotensin II) / La Jolla Pharmaceutical Company	08/28/2017	Treatment for: Hypotension, Shock	LJPC-501 (angiotensin II) is a synthetic human angiotensin II product in development for the treatment of hypotension in adults with distributive or vasodilatory shock who remain hypotensive despite fluid and vasopressor therapy.	Moderate

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Inbrija™ (levodopa) Inhalation Powder / Acorda Therapeutics, Inc.	08/29/2017	Treatment for: Parkinson's Disease	Acorda Therapeutics, Inc. received a Refusal to File (RTF) letter from the FDA regarding its NDA for Inbrija™. Inbrija™ (levodopa) is an oral inhalation formulation of the approved drug levodopa in development as a treatment for symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen. Upon its preliminary review, FDA determined that the NDA, submitted on June 26, 2017, was not sufficiently complete to permit a substantive review.	N/A
Vitaros™ (alprostadil) Cream / Apricus Biosciences, Inc.	08/29/2017	Treatment for: Erectile Dysfunction	Apricus Biosciences, Inc. recently filed its resubmission of a NDA for Vitaros™ with the FDA. Vitaros™ (alprostadil) is a novel, on-demand topical vasodilator cream in development for the treatment of erectile dysfunction.	Moderate
ZTlido™ (lidocaine) Patch / Scilex Pharmaceuticals, Inc.	08/29/2017	Treatment for: Postherpetic Neuralgia	Sorrento Therapeutics, Inc. resubmitted the NDA and responded to all of FDA comments related to the initial NDA submission for its lead product candidate, ZTlido™ (lidocaine patch 1.8%). ZTlido™ is a next-generation non-opioid transdermal anesthetic formulation (lidocaine patch) in development for the treatment of postherpetic neuralgia.	Moderate

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