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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
Severe worsening of multiple sclerosis after stopping Gilenya™ (fingolimod)	11/20/2018	Gilenya™ is one of several medicines approved to treat relapsing Multiple Sclerosis (MS). The FDA is warning that when Gilenya™ is stopped, the disease can become much worse than before the medicine was started or while it was being taken. This MS worsening is rare but can result in permanent disability. Healthcare professionals should: • Inform patients before starting treatment about the potential risk of severe increase in disability after stopping Gilenya™. • Carefully observe patients for evidence of an exacerbation of their MS and treat appropriately when Gilenya™ is stopped. • Advise patients to seek immediate medical attention if they experience new or worsened symptoms of MS after Gilenya™ is stopped. • Test for new or enhancing lesions by magnetic resonance imaging (MRI) if an increase in disability occurs and begin appropriate treatment as needed. • Encourage patients to read the patient Medication Guide they receive with their Gilenya™ prescriptions, which explains the benefits and risks of the medicine. • Report adverse events or side effects related to the use of these product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.
Serious condition affecting the blood cells are not being recognized with Idhifa™ (enasidenib)	11/29/2018	Idhifa™ is FDA-approved for the treatment of patients with acute myeloid leukemia (AML) with a specific genetic mutation (isocitrate dehydrogenase (IDH)-2) whose disease has come back or has not improved after treatment with other chemotherapy medicines. The FDA is warning that signs and symptoms of the life-threatening side effect called differentiation syndrome are not being recognized in patients receiving Idhifa™. Although the Idhifa™ prescribing information and patient Medication Guide already contain a warning about differentiation syndrome, the FDA have become aware of cases of differentiation syndrome not being recognized and patients not receiving the necessary treatment. For this reason, the FDA is alerting health care professionals and patients about the need for early recognition and aggressive management of differentiation syndrome to lessen the likelihood of serious illness and death. Healthcare professionals should: • Describe to patients the symptoms of differentiation syndrome listed in the Medication Guide when starting Idhifa™ and at follow-up visits, and inform them to call their healthcare professional if such symptoms occur. • Encourage patients to read the Medication Guide they receive with their Idhifa™ prescriptions, which helps patients understand differentiation syndrome and provides other important information. • Report adverse events or side effects related to the use of these product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

NEWS……

Drug Issue	Date	News/Event
Serious risks of stroke and blood vessel wall tears with Lemtrada™ (alemtuzumab)	11/29/2018	Lemtrada™ is one of several medicines approved to treat relapsing Multiple Sclerosis (MS). The FDA is warning that rare but serious cases of stroke and tears in the lining of arteries in the head and neck have occurred in patients with MS shortly after they received Lemtrada™. Alemtuzumab is also available under the brand name Campath™ for the treatment of B-cell chronic lymphocytic leukemia, and the label of Campath™ will also be updated to include these risks. Healthcare professionals should: • Advise patients at every Lemtrada™ infusion to seek immediate emergency medical attention if they experience symptoms of ischemic or hemorrhagic stroke or cervicocephalic arterial dissection, and promptly evaluate patients who complain of symptoms consistent with these conditions. • Encourage patients to read the patient Medication Guide they receive with each Lemtrada™ prescription, which explains the benefits and risks of the medicine. • Report adverse events or side effects related to the use of these product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Udenyca™ (pegfilgrastim-cbqv) Injection, for subcutaneous use / Coherus BioSciences, Inc.	Blood modifier agent Colony stimulating factor Note: Biosimilar to Neulasta™ (pegfilgrastim)	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia **Limitations of use** Is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation	11/02/2018	**DOSAGE AND ADMINISTRATION** The recommended dose for patients with cancer receiving myelosuppressive chemotherapy is 6 mg administered subcutaneously once per chemotherapy cycle. Use weight based dosing for pediatric patients weighing less than 45 kg. Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy. **DOSAGE FORMS AND STRENGTHS** Injection: 6 mg/0.6 mL in a single-dose prefilled syringe for manual use only. **CONTRAINDICATIONS** • History of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products. **WARNINGS AND PRECAUTIONS** • **Fatal splenic rupture:** Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture. • **Acute respiratory distress syndrome (ARDS):** Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue Udenyca™ in patients with ARDS. • **Serious allergic reactions, including anaphylaxis:** Permanently discontinue Udenyca™ in patients with serious allergic reactions. • **Fatal sickle cell crises:** Have occurred. • **Glomerulonephritis:** Evaluate and consider dose-reduction or interruption of Udenyca™ if causality is likely. **ADVERSE REACTIONS** Most common adverse reactions: bone pain and pain in extremity.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lorbrena™ (lorlatinib) Tablets, for oral use / Pfizer Inc.	Antineoplastic agent Anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI)	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on: • crizotinib and at least one other ALK inhibitor for metastatic disease; or • alectinib as the first ALK inhibitor therapy for metastatic disease; or • ceritinib as the first ALK inhibitor therapy for metastatic disease	11/02/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg orally once daily. **DOSAGE FORMS AND STRENGTHS** Tablets: 25 mg or 100 mg. **CONTRAINDICATIONS** • Concomitant use with strong CYP3A inducers. **WARNINGS AND PRECAUTIONS** • **Risk of serious hepatotoxicity with concomitant use of strong CYP3A inducers:** Discontinue strong CYP3A inducers for 3 plasma half-lives of the strong CYP3A inducer prior to initiating Lorbrena™. • **Central nervous system (CNS) effects:** CNS effects include seizures, hallucinations and changes in cognitive function, mood (including suicidal ideation), speech, mental status, and sleep. Withhold and resume Lorbrena™ at same or reduced dose or permanently discontinue Lorbrena™ based on severity. • **Hyperlipidemia:** Initiate or increase the dose of lipid-lowering agents. Withhold and resume Lorbrena™ at same or reduced dose based on severity. • **Atrioventricular block:** Withhold and resume Lorbrena™ at same or reduced dose based on severity. • **Interstitial lung disease/pneumonitis:** Immediately withhold Lorbrena™ in patients with suspected ILD/pneumonitis. Permanently discontinue Lorbrena™ for treatment-related ILD/pneumonitis of any severity. • **Embryo-fetal toxicity:** Can cause fetal harm. **ADVERSE REACTIONS** Most common adverse reactions: edema, peripheral neuropathy, cognitive effects, dyspnea, fatigue, weight gain, arthralgia, mood effects, and diarrhea.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lorbrena™ (lorlatinib) Tablets, for oral use / Pfizer Inc. (continuation)	Antineoplastic agent Anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI)	Treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on: • crizotinib and at least one other ALK inhibitor for metastatic disease; or • alectinib as the first ALK inhibitor therapy for metastatic disease; or • ceritinib as the first ALK inhibitor therapy for metastatic disease	11/02/2018	**DRUG INTERACTIONS** • **CYP3A inducers:** Contraindicated with strong CYP3A inducers. Avoid concomitant use with moderate CYP3A inducers. • **CYP3A inhibitors:** Avoid concomitant use with strong CYP3A inhibitors; reduce Lorbrena™ dose if concomitant use cannot be avoided. • **CYP3A substrates:** Avoid concomitant use with CYP3A substrates, where minimal concentration changes may lead to serious therapeutic failures. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. • **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating. Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment and for at least 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the final dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yupelri™ (revefenacin) Inhalation Solution, for oral use / Theravance, Inc.	Long-acting muscarinic antagonist (LAMA)	Treatment of chronic obstructive pulmonary disease (COPD)	11/09/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one 175 mcg vial (3 mL) once daily. **DOSAGE FORMS AND STRENGTHS** Inhalation solution in a unit-dose vial for nebulization. Each vial contains 175 mcg/3 mL solution. **CONTRAINDICATIONS** • Hypersensitivity to revefenacin or any component of this product. **WARNINGS AND PRECAUTIONS** • Do not initiate Yupelri™ in acutely deteriorating COPD or to treat acute symptoms. • If paradoxical bronchospasm occurs, discontinue Yupelri™ and institute alternative therapy. • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately if symptoms occur. • Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to contact a healthcare provider immediately if symptoms occur. • Immediate hypersensitivity reactions may occur. If such a reaction occurs, therapy with Yupelri™ should be stopped at once and alternative treatments should be considered. **ADVERSE REACTIONS** Most common adverse reactions: cough, nasopharyngitis, upper respiratory tract infection, headache, and back pain.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yupelri™ (revefenacin) Inhalation Solution, for oral use / Theravance, Inc. (continuation)	Long-acting muscarinic antagonist (LAMA)	Treatment of chronic obstructive pulmonary disease (COPD)	11/09/2018	**DRUG INTERACTIONS** • **Anticholinergics:** May interact additively with concomitantly used anticholinergic medications. Avoid administration of YUPELRI with other anticholinergic-containing drugs. • **Transporter-related drug interactions:** Co-administration of Yupelri™ with OATP1B1 and OATP1B3 inhibitors (e.g. rifampicin, cyclosporine, etc.) may lead to an increase in exposure of the active metabolite. Therefore, co-administration with Yupelri™ is not recommended. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Not indicated for use in children. Safety and efficacy in pediatric patients have not been established. • **Hepatic impairment:** Avoid use in patients with any degree of hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Aemcolo™ (rifamycin), for oral use / Cosmo Technologies, Ltd.	Anti-infective agent Antibiotic	Treatment of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* in adults **Limitations of use** Aemcolo™ is not recommended for use in patients with diarrhea complicated by fever and/or bloody stool or due to pathogens other than noninvasive strains of E. coli. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Aemcolo™ and other antibacterial drugs, Aemcolo™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	11/16/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 388 mg (two tablets) orally twice daily for three days. **DOSAGE FORMS AND STRENGTHS** Delayed-Release Tablets: 194 mg rifamycin. **CONTRAINDICATIONS** • Known hypersensitivity to rifamycin, any of the other rifamycin class antimicrobial agents (e.g. rifaximin), or any of the components in Aemcolo™. **WARNINGS AND PRECAUTIONS** • **Risk of persistent or worsening diarrhea complicated by fever and/or bloody stool:** Aemcolo™ was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool or diarrhea due to pathogens other than noninvasive strains of *E. coli* and is not recommended for use in such patients. Discontinue use if diarrhea gets worse or persists more than 48 hours, and consider alternative antibacterial therapy. • ***Clostridium difficile*-associated diarrhea:** Evaluate if diarrhea occurs after therapy or does not improve or worsens during therapy. **ADVERSE REACTIONS** Most common adverse reactions: headache and constipation. **DRUG INTERACTIONS** No clinical drug-drug interactions have been studied. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness has not been established in pediatric patients less than 18 years of age. **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently than younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Gamifant™ (emapalumab-lzsg) Injection, for intravenous use / Novimmune SA	Immunological agent Interferon gamma (IFNγ) blocking antibody Note: Orphan drug designation	Treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy	11/20/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 1 mg/kg as an intravenous infusion over 1 hour twice per week. • Administer dexamethasone concomitantly with Gamifant™. **DOSAGE FORMS AND STRENGTHS** Injection: • 10 mg/2 mL (5 mg/mL) solution in a single-dose vial. • 50 mg/10 mL (5 mg/mL) solution in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Infections:** Monitor patients for signs and symptoms and treat promptly. Test for latent tuberculosis. Administer prophylactic treatment against Herpes Zoster, Pneumocystis jirovecii and fungal infections. • **Live vaccines:** Do not administer live or live attenuated vaccines to patients receiving Gamifant™. • **Infusion-related reactions:** Monitor patients for infusion-related reactions. Interrupt infusion for severe infusion reactions and institute appropriate medical management. **ADVERSE REACTIONS** Most common adverse reactions: infections, hypertension, infusion-related reactions, and pyrexia. **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Daurismo™ (glasdegib) Tablets, for oral use / Pfizer Inc.	Antineoplastic agent	In combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy **Limitation of use** Daurismo™ has not been studied in patients with the comorbidities of severe renal impairment or moderate-to-severe hepatic impairment. **Black box warning** Embryo-fetal toxicity	11/21/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg orally, once daily. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg, 25 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Blood donation:** Advise patients not to donate blood or blood products during treatment and for at least 30 days after the last dose. • **QTc interval prolongation:** Monitor electrocardiograms and electrolytes. If QTc prolongation occurs, interrupt treatment. **ADVERSE REACTIONS** Most common adverse reactions: anemia, fatigue, hemorrhage, febrile neutropenia, musculoskeletal pain, nausea, edema, thrombocytopenia, dyspnea, decreased appetite, dysgeusia, mucositis, constipation, and rash. **DRUG INTERACTIONS** • **Strong CYP3A4 inhibitors:** Consider alternative therapies that are not strong CYP3A inhibitors or monitor for increased risk of adverse reactions, including QTc interval prolongation. • **Strong CYP3A4 inducers:** Avoid concomitant use with Daurismo™. • **QTc prolonging drugs:** Avoid co-administration with Daurismo™. If co-administration is unavoidable, monitor for increased risk of QTc interval prolongation.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Daurismo™ (glasdegib) Tablets, for oral use / Pfizer Inc. (continuation)	Antineoplastic agent	In combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy **Limitation of use** Daurismo™ has not been studied in patients with the comorbidities of severe renal impairment or moderate-to-severe hepatic impairment. **Black box warning** Embryo-fetal toxicity	11/21/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Conduct pregnancy testing in females of reproductive potential within 7 days prior to initiating therapy. • **Females and males of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and at least 30 days after the last dose. Advise males of the potential risk of exposure through semen and to use effective contraception, including a condom, even after a vasectomy, to avoid drug exposure to a pregnant partner or a female partner of reproductive potential during treatment and for at least 30 days after the last dose. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vitrakvi™ (larotrectinib) Capsules and Solution, for oral use / Loxo Oncology, Inc.	Antineoplastic agent Tropomyosin receptor kinase (TRK) inhibitor Note: Orphan drug designation	Treatment of adult and pediatric patients with solid tumors that: • have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory alternative treatments or that have progressed following treatment.	11/26/2018	**DOSAGE AND ADMINISTRATION** The recommended dose varies depending on patient Body Surface Area (BSA): • BSA of at least 1.0m2: 100 mg orally twice daily. • BSA of less than 1.0m2: 100 mg/m2 orally twice daily. Patients must be selected for treatment with Vitrakvi™ based on the presence of a NTRK gene fusion. **DOSAGE FORMS AND STRENGTHS** • Capsules: 25 mg, 100 mg. • Oral Solution: 20 mg/mL. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Neurotoxicity:** Advise patients and caretakers of the risk of neurologic adverse reactions. Advise patients not to drive or operate hazardous machinery if experiencing neurotoxicity. Withhold and modify dosage, or permanently discontinue Vitrakvi™ based on severity. • **Hepatotoxicity:** Monitor liver tests including ALT and AST every 2 weeks during the first month of treatment, then monthly thereafter and as clinically indicated. Withhold and modify dosage, or permanently discontinue based on severity. • **Embryo-fetal toxicity:** Can cause fetal harm. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, nausea, dizziness, vomiting, increased AST, cough, increased ALT, constipation, and diarrhea.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vitrakvi™ (larotrectinib) Capsules and Solution, for oral use / Loxo Oncology, Inc. (continuation)	Antineoplastic agent Tropomyosin receptor kinase (TRK) inhibitor Note: Orphan drug designation	Treatment of adult and pediatric patients with solid tumors that: • have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory alternative treatments or that have progressed following treatment.	11/26/2018	**DRUG INTERACTIONS** • **Strong CYP3A4 inhibitors:** Avoid coadministration of strong CYP3A4 inhibitors with Vitrakvi™. If coadministration cannot be avoided, reduce the Vitrakvi™ dose. • **Strong CYP3A4 inducers:** Avoid coadministration of strong CYP3A4 inducers with Vitrakvi™. If coadministration cannot be avoided, increase the Vitrakvi™ dose. • **Sensitive CYP3A4 substrates:** Avoid coadministration of sensitive CYP3A4 substrates with Vitrakvi™. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating Vitrakvi™. • **Females and males of reproductive potential:** Advise female patients of reproductive potential to use effective contraception during treatment with Vitrakvi™ and for at least 1 week after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with Vitrakvi™ and for 1 week after the final dose. • **Lactation:** Advise not to breastfeed. • **Hepatic impairment:** Reduce the starting dose of Vitrakvi™ in patients with moderate (Child-Pugh B) to severe (Child-Pugh C) hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Truxima™ (rituximab-abbs) Injection, for intravenous use / Celltrion, Inc.	Antineoplastic agent CD20-directed antibody Note: Biosimilar to Rituxan™	Treatment of adult patients with non-Hodgkin's lymphoma (NHL): • Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. • Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. • Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. **Black box warning** Fatal infusion reactions, severe mucocutaneous reactions, hepatitis b virus reactivation and progressive multifocal leukoencephalopathy	11/28/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is is 375 mg/m2. • Should only be administered by a healthcare professional with appropriate medical support to manage severe infusion reactions that can be fatal if they occur. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL) solution in single-dose vials. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Tumor lysis syndrome:** Administer aggressive intravenous hydration, anti-hyperuricemic agents, monitor renal function. • **Infections:** Withhold Truxima™ and institute appropriate anti-infective therapy. • **Cardiac adverse reactions:** Discontinue infusions in case of serious or lifethreatening events. • **Renal toxicity:** Discontinue in patients with rising serum creatinine or oliguria. • **Bowel obstruction and perforation:** Consider and evaluate for abdominal pain, vomiting, or related symptoms. • **Immunizations:** Live virus vaccinations prior to or during Truxima™ treatment not recommended. • **Embryo-fetal toxicity:** Can cause neonatal harm. **ADVERSE REACTIONS** Most common adverse reactions: infusion reactions, fever, lymphopenia, chills, infection and asthenia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Truxima™ (rituximab-abbs) Injection, for intravenous use / Celltrion, Inc. (continuation)	Antineoplastic agent CD20-directed antibody Note: Biosimilar to Rituxan™	Treatment of adult patients with non-Hodgkin's lymphoma (NHL): • Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. • Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. • Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. **Black box warning** Fatal infusion reactions, severe mucocutaneous reactions, hepatitis b virus reactivation and progressive multifocal leukoencephalopathy	11/28/2018	**DRUG INTERACTIONS** • Renal toxicity when used in combination with cisplatin. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. • **Females of reproductive potential:** Females of childbearing potential should use effective contraception while receiving Truxima™ and for 12 months following treatment. • **Lactation:** Advise not to breastfeed • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Firdapse™ (amifampridine phosphate), for oral use / Catalyst Pharmaceuticals, Inc.	Central nervous system agent Neuronal potassium channel blocker Note: Orphan drug designation	Treatment of Lambert Eaton myasthenic syndrome (LEMS) in adults	11/29/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily). • Starting dosage is 15 mg daily for patients with renal impairment, hepatic impairment, and in known N-acetyltransferase 2 (NAT2) poor metabolizers. • Dosage can be increased by 5 mg daily every 3 to 4 days. • Dosage is not to exceed a maximum of 80 mg daily. • The maximum single dose is 20 mg. **DOSAGE FORMS AND STRENGTHS** Tablets: 10 mg, functionally scored. **CONTRAINDICATIONS** • History of seizures . • Hypersensitivity to amifampridine or another aminopyridine **WARNINGS AND PRECAUTIONS** • **Seizures:** Can cause seizures. Consider discontinuation or dose-reduction in patients who have a seizure while on treatment. • **Hypersensitivity reactions:** If a hypersensitivity reaction such as anaphylaxis occurs, Firdapse™ should be discontinued and appropriate therapy initiated. **ADVERSE REACTIONS** Most common adverse reactions: paresthesia, upper respiratory tract infection, abdominal pain, nausea, diarrhea, headache, elevated liver enzymes, back pain, hypertension, and muscle spasms.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Firdapse™ (amifampridine phosphate), for oral use / Catalyst Pharmaceuticals, Inc. (continuation)	Central nervous system agent Neuronal potassium channel blocker Note: Orphan drug designation	Treatment of Lambert Eaton myasthenic syndrome (LEMS) in adults	11/29/2018	**DRUG INTERACTIONS** • **Drugs that lower seizure threshold:** The concomitant use of Firdapse™ and drugs that lower seizure threshold may lead to an increased risk of seizures. • **Drugs with cholinergic effects:** The concomitant use of Firdapse™ and drugs with cholinergic effects (e.g., direct or indirect cholinesterase inhibitors) may increase the cholinergic effects of Firdapse™ and of those drugs, and increase the risk of adverse reactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Pediatric use:** Safety and effectiveness have not been established. • **Renal impairment:** Renal clearance is an elimination pathway for amifampridine and the inactive metabolite, 3-N-acetyl amifampridine, and exposure of amifampridine is higher in subjects with renal impairment. In patients with renal impairment, Firdapse™ should be initiated at the lowest recommended starting dosage (15 mg/day), and patients should be closely monitored for adverse reactions. Consider dosage modification or discontinuation Firdapse™ for patients with renal impairment as needed based on clinical effect and tolerability. The safety, efficacy, and pharmacokinetics of amifampridine have not been studied in patients with end-stage renal disease. • **Hepatic impairment:** Although the effects Firdapse™ have not been studied in patients with hepatic impairment, it is extensively metabolized by Nacetyltransferase 2 (NAT2) and hepatic impairment may cause an increase in exposure. Initiate Firdapse™ in patients with any degree of hepatic impairment at the lowest recommended starting dosage (15 mg/day) and monitor for adverse reaction. Consider dosage modification or discontinuation for patients with hepatic impairment as needed based on clinical effect and tolerability.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xospata™ (gilteritinib) Tablets, for oral use / Astellas Pharma US, Inc.	Antineoplastic agent FLT3/AXL kinase inhibitor Note: Orphan drug designation	Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test	11/28/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 120 mg orally once-daily. **DOSAGE FORMS AND STRENGTHS** Tablet: 40 mg. **CONTRAINDICATIONS** • Hypersensitivity to gilteritinib or any of the excipients. **WARNINGS AND PRECAUTIONS** • **Posterior reversible encephalopathy syndrome (PRES):** Discontinue Xospata™ in patients who develop PRES. • **Prolonged QT interval:** Interrupt and reduce Xospata™ dosage in patients who have a QTcF >500 msec. Correct hypokalemia or hypomagnesemia prior to and during Xospata™ administration. • **Pancreatitis:** Interrupt and reduce the dose in patients who develop pancreatitis. • **Embryo-fetal toxicity:** Can cause fetal harm when administered to a pregnant woman. **ADVERSE REACTIONS** Most common adverse reactions: myalgia/arthralgia, transaminase increase, fatigue/malaise, fever, noninfectious diarrhea, dyspnea, edema, rash, pneumonia, nausea, stomatitis, cough, headache, hypotension, dizziness and vomiting. **DRUG INTERACTIONS** • **Combined P-gp and strong CYP3A inducers:** Avoid concomitant use. • **Strong CYP3A inhibitors:** Consider alternative therapies. If the concomitant use of strong CYP3A inhibitors cannot be avoided, monitor patients more frequently for adverse reactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xospata™ (gilteritinib) Tablets, for oral use / Astellas Pharma US, Inc. (continuation)	Antineoplastic agent FLT3/AXL kinase inhibitor Note: Orphan drug designation	Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test	11/28/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Pregnancy testing is recommended for females of reproductive potential within seven days prior to initiating. • **Females and males of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after the last dose. Advise males of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Invokana™ (canagliflozin) Tablets / Janssen Research & Development, LLC	Sodium glucose co-transporter 2 (SGLT2) inhibitor	**Previous indication(s):** Treatment of type 2 diabetes (T2D) **New indication(s):** To reduce the risk of cardiovascular events (including heart attack, stroke or death) in adults with T2D and established cardiovascular disease	10/30/2018	Invokana™ is the first oral diabetes treatment approved with this indication. The CANVAS (CANagliflozin cardioVascular Assessment Study) Program evaluated the effect of Invokana™ on CV risk in a broad population of more than 10,000 adults with T2D who had established CV disease (65%) or were at risk for cardiovascular disease with two or more risk factors (35%). Overall, treatment with Invokana™ as compared with placebo in addition to standard of care reduced the combined risk of heart attack, stroke and CV death by 14% events occurred in 26.9 vs. 31.5 participants, respectively, per 1000 patient-years; HR: 0.86; 95% CI: 0.75 to 0.97; p<0.0001 for non-inferiority and p=0.0158 for superiority). In patients with established CV disease, treatment with Invokana™ reduced the combined risk of heart attack, stroke and CV death by 18 percent compared to placebo (events occurred in 34.1 vs. 41.3 participants, respectively, per 1000 patient-years; HR: 0.82; 95% CI: 0.72 to 0.95).
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma **New indication(s):** In combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC)	10/30/2018	This approval marks the first time an anti-PD-1 regimen has been approved for the first-line treatment of squamous NSCLC regardless of tumor PD-L1 expression status.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Empliciti™ (elotuzumab) Injection / Bristol-Myers Squibb Company and AbbVie	Signaling Lymphocyte Activation Molecule (SLAMF7)-directed immuno-stimulatory antibody	**Previous indication(s):** Combination treatment of patients with multiple myeloma **New dosage regimen:** For intravenous use in combination with pomalidomide and dexamethasone (EPd) for the treatment of adult patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor	11/06/2018	In ELOQUENT-3 trial, EPd demonstrated benefit in patients with relapsed or refractory multiple myeloma, doubling both median progression-free survival (PFS) and overall response rate (ORR) versus pomalidomide and dexamethasone (Pd).
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma **New indication(s):** Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib	11/09/2018	This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

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)	**Previous indication(s):** Treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and CD30-expressing mycosis fungoides **New indication:** In combination with CHP chemotherapy (cyclophosphamide, doxorubicin, prednisone), for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified	11/16/2018	The approval is based on the successful outcome of the phase 3 ECHELON-2 clinical trial that compared Adcetris™ plus CHP to CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone). This is the sixth FDA-approved indication for Adcetris™, which also has approval for adult patients with: (1) previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine (AVD), (2) cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation, (3) cHL after failure of auto-HSCT or failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates, (4) sALCL after failure of at least one prior multi-agent chemotherapy regimen, and (5) primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.
Venclexta™ (venetoclax) Tablets / AbbVie Inc.	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	**Previous indication(s):** Treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion who have received at least 1 prior treatment **New indication:** In combination with azacitidine or decitabine, or low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in patients who are age 75 years or older, or for those ineligible for intensive induction chemotherapy due to coexisting medical conditions	11/21/2018	This indication is approved under accelerated approval. This approval was based on results from the M14-358 study and the M14-387 study in people newly-diagnosed with AML including those who were ineligible for intensive induction chemotherapy. In M14-358, the rate of complete remission (CR) was 37% and the rate of CR with partial blood count recovery (CRh) was 24% for those who received Venclexta™ plus azacitidine. For those who received Venclexta™ plus decitabine, the rate of CR was 54% and the rate of CRh was 8%. M14-387 showed a CR rate of 21% and a CRh rate of 21% for those who received Venclexta™ in combination with low-dose cytarabine.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Sympazan™ (clobazam), for oral use / Aquestive Therapeutics, Inc.	Central Nervous System Agent; Anticonvulsant; Benzodiazepine	Adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older	11/01/2018	Sympazan™ is the first oral film FDA-approved to treat seizures associated with LGS. Previously, clobazam was marketed as ONFI™ and offered in two formulations – either tablet or oral suspension.
Dsuvia™ (sufentanil) Sublingual Tablets / AcelRx Pharmaceuticals, Inc.	Opioid analgesic	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	11/02/2018	Dsuvia™ must be used in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments.
Bryhali™ (halobetasol propionate) Lotion / Ortho Dermatologics	Corticosteroid	Treatment of plaque psoriasis in adults	11/06/2018	Bryhali™ is a potent to super-potent corticosteroid (halobetsasol propionate, 0.01%) in a novel vehicle lotion with safety established for dosing up to eight weeks.
Primatene Mist™ (epinephrine) Inhalation Aerosol / Amphastar Pharmaceuticals, Inc.	Bronchodilator Note: Over-the-counter (OTC)	For the temporary relief of the symptoms of mild asthma	11/08/2018	The new formulation of Primatene Mist™ approved November 2018 is a CFC-free metered dose inhaler (MDI) containing hydrofluoroalkane (HFA) propellants.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Abiraterone Acetate Tablets 250 mg / Apotex, Inc.; Hikma Pharmaceuticals LLC; Mylan Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.	Antineoplastic agent	10/31/2018	Generic for: Zytiga™ 250 mg

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Lasmiditan / Eli Lilly and Company	11/14/2018	Treatment for: Migraine	Lasmiditan is an investigational selective serotonin 5-HT1F agonist in development for the acute treatment of migraine with or without aura in adults. Eli Lilly and Company has submitted an NDA for lasmiditan.	Moderate
Quizartinib / Daiichi Sankyo	11/21/2018	Treatment for: Acute Myeloid Leukemia	Quizartinib is an oral FLT3-ITD (FMS-like tyrosine kinase-3-internal tandem duplication) inhibitor in development for the treatment of patients with acute myeloid leukemia (AML). The FDA accepted a NDA and granted Priority Review for quizartinib.	High

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

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)