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RX BENEFIT MANAGEMENT

PharmNOTES

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

From: APRIL 2018

Date: 05/07/2018

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Table of Contents

NEWS……

Drug Issue	Date	News/Event
Serious immune system reaction with seizure and mental health medicine lamotrigine (Lamictal™)	04/25/2018	Lamotrigine is used (1) for the treatment of seizures, and (2) for maintenance treatment of bipolar disorder (to help delay the occurrence of mood episodes such as depression, mania, or hypomania). The FDA warns that lamotrigine can cause a rare but serious reaction that activates the immune system in an excessive and uncontrolled manner. The reaction is called hemophagocytic lymphohistiocytosis (HLH). HLH can result in severe inflammation throughout the body and lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly. As a result, the FDA is requiring a new warning about this risk be added to the prescribing information of lamotrigine. Health care professionals should be aware that prompt recognition and early treatment is important for improving HLH outcomes and decreasing mortality. Diagnosis is often complicated because early signs and symptoms such as fever and rash are not specific. HLH may also be confused with other serious immune-related adverse reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Evaluate patients who develop fever or rash promptly, and discontinue lamotrigine if HLH or another serious immune-related adverse reaction is suspected and an alternative etiology for the signs and symptoms cannot be established. Advise patients to seek immediate medical attention if they experience symptoms of HLH during lamotrigine treatment. A diagnosis of HLH can be established if a patient has at least five of the following eight signs or symptoms: (1) Fever and rash; (2) Enlarged spleen; (3) Cytopenias; (4) Elevated levels of triglycerides or low blood levels of fibrinogen; (5) High levels of blood ferritin; (6) Hemophagocytosis identified through bone marrow, spleen, or lymph node biopsy; (7) Decreased or absent Natural Killer (NK) Cell activity; (8) Elevated blood levels of CD25 showing prolonged immune cell activation. In addition, both health care professionals and patients are encouraged to report side effects involving lamotrigine to the FDA MedWatch program.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tavalisse™ (fostamatinib) Tablets, for oral use / Rigel Pharmaceuticals, Inc.	Blood modifier agent Spleen tyrosine kinase (SYK) inhibitor	Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	04/17/2018	**DOSAGE AND ADMINISTRATION** The recommended initial dose is 100 mg orally twice daily with or without food. After 4 weeks, increase to 150 mg twice daily, if needed, to achieve platelet count at least 50 x 10^9 /L as necessary to reduce the risk of bleeding. • Manage adverse reactions using dose reduction, interruption of treatment, or discontinuation. • Discontinue after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg, 150 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Hypertension, including hypertensive crisis, may occur; monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. • **Gastrointestinal:** Diarrhea has been reported and may be severe; monitoring recommended. Management with supportive care measures recommended; interruption, dose reduction, or discontinuation of treatment may be required. • **Hematologic:** Neutropenia has been reported, including febrile neutropenia; monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. • **Hepatic:** Elevated liver function tests, particularly ALT and AST, have been reported; monitoring recommended and interruption, dose reduction, or discontinuation of treatment may be required. • **Reproductive:** Fetal harm may occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tavalisse™ (fostamatinib) Tablets, for oral use / Rigel Pharmaceuticals, Inc. (continuation)	Blood modifier agent Spleen tyrosine kinase (SYK) inhibitor	Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	04/17/2018	**ADVERSE REACTIONS** Most common adverse reactions: diarrhea, hypertension, nausea, respiratory infection, dizziness, ALT/AST increased, rash, abdominal pain, fatigue, chest pain and neutropenia. **DRUG INTERACTIONS** • **Strong CYP3A4 Inhibitors:** Concomitant use with a strong CYP3A4 inhibitor increases exposure to R406 (the major active metabolite). • **Strong CYP3A4 Inducers:** Concomitant use is not recommended. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Advise women of the risk to a fetus. • **Females of reproductive potential:** Fetal harm may occur. Verify pregnancy status prior to initiating. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established. Not recommended for use in patients less than 18 years of age because adverse effects on actively growing bones were observed in nonclinical studies. • **Geriatric use:** No overall differences in effectiveness were observed in these patients compared to younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Crysvita™ (burosumab-twza) Injection, for subcutaneous use / Ultragenyx Pharmaceutical Inc.	Endocrine and metabolic agent Monoclonal antibody Fibroblast growth factor 23 (FGF23) blocking antibody --- Note: Orphan drug designation	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older	04/17/2018	**DOSAGE AND ADMINISTRATION** Recommended dose in pediatric XLH: • Starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. • Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus. Recommended dose in adult XLH: • Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks. **DOSAGE FORMS AND STRENGTHS** Injection: 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vial. **CONTRAINDICATIONS** • Do not use with oral phosphate and active vitamin D analogs. • Do not initiate if serum phosphorus is within or above the normal range for age. • Severe renal impairment or end stage renal disease **WARNINGS AND PRECAUTIONS** • **Hypersensitivity:** Discontinue if serious hypersensitivity reactions occur and initiate appropriate medical treatment. • **Hyperphosphatemia and Risk of Nephrocalcinosis:** For patients already taking Crysvita™, dose interruption and/or dose reduction may be required based on a patient's serum phosphorus levels. • **Injection Site Reactions:** Administration of Crysvita™ may result in local injection site reactions. Discontinue CRYSVITA if severe injection site reactions occur and administer appropriate medical treatment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Crysvita™ (burosumab-twza) Injection, for subcutaneous use / Ultragenyx Pharmaceutical Inc. (continuation)	Endocrine and metabolic agent Monoclonal antibody Fibroblast growth factor 23 (FGF23) blocking antibody --- Note: Orphan drug designation	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older	04/17/2018	**ADVERSE REACTIONS** Most common adverse reactions in pediatrics: headache, injection site reaction, vomiting, pyrexia, pain in extremity, vitamin D decreased. Most common adverse reactions in adults: back pain, headache, tooth infection, restless leg syndrome, vitamin D decreased, dizziness, constipation, blood phosphorus increased. **DRUG INTERACTIONS** • No drug interaction studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** No available data on use in pregnant women to inform a drug-associated risk of adverse developmental outcomes. • **Lactation:** There is no information regarding the presence of burosumab-twza in human milk, or the effects of burosumab-twza on milk production or the breastfed infant. • **Geriatric use:** Studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jynarque™ (tolvaptan) Tablets, for oral use / Otsuka Pharmaceutical Co., Ltd	Endocrine and metabolic agent Selective vasopressin V_2-receptor antagonist	To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	02/23/2018	**DOSAGE AND ADMINISTRATION** Recommended dosage is divided in three steps: 1. Initial dosage: o First dose: 45mg o Second dose: 15mg 8 hours later o Total daily dose: 60mg 2. Titration step: o First dose: 60mg o Second dose: 30mg 8 hours later o Total daily dose: 90mg 3. Target dosage: o First dose: 90mg o Second dose: 30mg 8 hours later o Total daily dose: 120mg Dose adjustment is recommended for patients taking moderate CYP3A inhibitors. Available only through a REMS Program, because of the risks of liver injury. **DOSAGE FORMS AND STRENGTHS** Tablets: 15 mg, 30 mg, 45 mg, 60 mg and 90 mg. **CONTRAINDICATIONS** • History of signs or symptoms of significant liver impairment or injury, does not include uncomplicated polycystic liver disease. • Concomitant use of strong CYP 3A inhibitors is contraindicated. • Uncorrected abnormal blood sodium concentrations. • Unable to sense or respond to thirst • Hypovolemia. • Hypersensitivity to tolvaptan or any of its components. • Uncorrected urinary outflow obstruction. • Anuria.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jynarque™ (tolvaptan) Tablets, for oral use / Otsuka Pharmaceutical Co., Ltd (continuation)	Endocrine and metabolic agent Selective vasopressin V_2-receptor antagonist	To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	02/23/2018	**WARNINGS AND PRECAUTIONS** • **Concomitant use:** Concomitant use with drugs that are moderate or strong CYP3A inhibitors increases tolvaptan exposure. Use with strong CYP3A inhibitors is contraindicated. Dose reduction of is recommended for patients while taking moderate CYP3A inhibitors. • **Hepatic:** Serious and potentially fatal liver injury has been reported. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. To reduce the risk of significant or irreversible liver injury, assess ALT, AST and bilirubin prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter. If patient present signs or symptoms consistent with hepatic injury or if ALT, AST, or bilirubin increase to >2 times ULN, immediately discontinue, obtain repeat tests as soon as possible (within 48-72 hours), and continue testing as appropriate. If laboratory abnormalities stabilize or resolve, Jynarque™ may be reinitiated with increased frequency of monitoring as long as ALT and AST remain below 3 times ULN. Do not restart in patients who experience signs or symptoms consistent with hepatic injury or whose ALT or AST ever exceeds 3 times ULN during treatment, unless there is another explanation for liver injury and the injury has resolved. • **Hypernatremia, dehydration and hypovolemia:** May require intervention. **ADVERSE REACTIONS** Most common adverse reactions: thirst, polyuria, nocturia, pollakiuria and polydipsia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jynarque™ (tolvaptan) Tablets, for oral use / Otsuka Pharmaceutical Co., Ltd (continuation)	Endocrine and metabolic agent Selective vasopressin V_2-receptor antagonist	To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	02/23/2018	**DRUG INTERACTIONS** Avoid concomitant use with: • Strong CYP 3A Inducers • OATP1B1/3 and OAT3 Transporter Substrates • BCRP Transporter Substrates • V2-Receptor Agonists **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Lactation:** Breastfeeding not recommended. • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established • **Geriatric use:** Clinical studies of tolvaptan did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. • **Hepatic impairment:** Because of the risk of serious liver injury, use is contraindicated in patients with a history, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Bydureon™ (exenatide) Extended-Release Injectable Suspension / AstraZeneca	Antidiabetic Glucagon-like peptide-1 (GLP-1) receptor agonist	To improve glycemic control in patients with type 2 diabetes **Labeling Revision:** Expanded use as add-on therapy to basal insulin in adults with type 2 diabetes with inadequate glycemic control	04/02/2018	Bydureon™ is approved for adults with type 2 diabetes (T2D) whose blood sugar remains uncontrolled on one or more antidiabetic medicines in addition to diet and exercise, to improve glycemic control. The expanded use is based on results from the 28-week DURATION-7 study, which examined the effect of Bydureon™ or placebo as add-on therapy to insulin glargine, with or without metformin, in adults with T2D. Mean HbA1c was reduced by 0.9% in the Bydureon™ group (n=231) compared to 0.2% in the placebo group (n=229) in patients with a mean baseline HbA1c of 8.5%. Furthermore, 32.5% of patients in the Bydureon™ group reached an HbA1c of <7.0% compared to 7.0% of patients in the placebo group.
Exparel™ (bupivacaine liposome) Injectable Suspension / Pacira Pharmaceuticals, Inc. 700	Local anesthetic Long-acting non-opioid local analgesic	For post-surgical local analgesia, and for use as a nerve block (interscalene brachial plexus block) to provide pain relief following shoulder surgeries **New indication:** To include administration via interscalene brachial plexus block to produce postsurgical regional analgesia	04/06/2018	With this approval, Exparel™ is the first long-acting, single-dose nerve block available for patients undergoing upper extremity surgeries, such as total shoulder arthroplasty or rotator cuff repair. The approval was based on data from a Phase 3 study of Exparel™ in brachial plexus block for shoulder surgeries, in which Exparel™ demonstrated statistical significance for the primary endpoint of cumulative pain scores over 48 hours as measured by the area under the curve. Exparel™ also achieved statistical significance versus placebo for the study's key secondary endpoints as follows: total postsurgical opioid consumption through 48 hours; opioid-free subjects through 48 hours; and time to first opioid rescue through 48 hours.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Rubraca™ (rucaparib) Tablets / Clovis Oncology, Inc.	Antineoplastic agent Poly (ADP-ribose) polymerase (PARP) inhibitor	Treatment of patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies; and for the 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 **New indication:** 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	`04/06/2018	The approval was based on results from the ARIEL3 study, which evaluated Rubraca™ in the ovarian cancer maintenance-treatment setting among three populations: (1) BRCA mutant (BRCAmut+), (2) HRD positive inclusive of BRCAmut+ and, (3) all patients treated in ARIEL3. The study enrolled a total of 564 patients. Both its primary and key secondary endpoints were achieved, extending investigator assessed progression-free survival (PFS) versus placebo in all patients treated, regardless of BRCA status. It is of note that biomarker testing is not required for patients to be prescribed Rubraca™ in this maintenance treatment indication.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Afinitor™ (everolimus) Tablets / Novartis AG	Antineoplastic agent mTOR inhibitor	Treatment of patients with advanced HR+, HER2- breast cancer; progressive neuroendocrine tumors of pancreatic origin (PNET); progressive neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin; advanced renal cell carcinoma; and subependymal giant cell astrocytoma (SEGA) and renal angiomyolipomas associated with tuberous sclerosis **New indication:** Adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex (TSC)-associated partial-onset seizures	04/10/2018	The approval was based on results form the EXIST-3 trial, which included 366 patients with TSC-associated partial-onset seizures, inadequate seizure control with ≥ 2 sequential anti-epileptic drug (AED) regimens, and a TSC diagnosis (modified Gomez criteria). The major efficacy measure was the percentage reduction in average weekly seizures during a 12-week treatment period compared with the average weekly seizures during the 8-week baseline period. The trial demonstrated statistically significant reductions in seizures with Afinitor™ compared with placebo. The proportion of patients with 50% reduction in seizure frequency during the 12-week treatment period compared with baseline also was higher with Afinitor compared with placebo. Everolimus is also approved for two other manifestations of TSC: (1) TSC-associated subependymal giant cell astrocytoma (SEGA) (2) TSC-associated renal angiomyolipoma
Tagrisso™ (osimertinib) Tablets / AstraZeneca	Antineoplastic agent Tyrosine kinase inhibitor (TKI) of epidermal growth factor receptor (EGFR)	Treatment of patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer **New indication:** For the 1st-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions or exon 21 L858R mutations), as detected by an FDA-approved test	04/18/2018	The approval was based on results from the Phase III FLAURA trial. The FLAURA trial compared Tagrisso™ to current 1st-line EGFR tyrosine kinase inhibitors, erlotinib or gefitinib, in previously untreated patients with locally advanced or metastatic EGFR-mutated (EGFRm) NSCLC. Tagrisso™ met the primary endpoint of progression-free survival (PFS). Overall survival data were not mature at the time of the final PFS analysis.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tafinlar™ (dabrafenib) Capsules / Novartis	Antineoplastic agent Kinase inhibitor	Ttreatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test **New indication:** In combination with Mekinist™ (trametinib) for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection	04/30/2018	The approval was based on results from a Phase III study (COMBI-AD), which inc;uded 870 patients with Stage III BRAF V600E/K mutation-positive melanoma treated with Tafinlar™ + Mekinist™ after complete surgical resection. Patients received the Tafinlar™ (150 mg BID) + Mekinist™ (2 mg QD) combination (n = 438) or matching placebos (n = 432)[1]. After a median follow-up of 2.8 years, the primary endpoint of relapse-free survival (RFS) was met. Treatment with the combination therapy significantly reduced the risk of disease recurrence or death by 53% as compared to placebo. Improvements were also observed in key secondary endpoints including overall survival (OS), distant metastasis-free survival (DMFS) and freedom from relapse (FFR).

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Akynzeo™ for Injection (fosnetupitant and palonosetron), for oral use / Helsinn Healthcare SA	Antiemetic Substance P/neurokinin-1 (NK-1) receptor antagonist and serotonin-3 (5-HT3) receptor antagonist combination	For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy (chemotherapy-induced nausea and vomiting (CINV)) Note: Palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy	04/19/2018	The FDA has approved the intravenous formulation of Akynzeo™. Oral Akynzeo™ was previously approved by the FDA as a fixed combination oral agent in 2014. The approval of Akynzeo™ in IV formulation offers an alternative route of administration of the only fixed antiemetic combination targeting two distinct CINV pathways in a single dose.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Everolimus Tablets 0.25 mg, 0.5 mg and 0.75 mg / West-Ward Pharmaceuticals Corp.	Antineoplastic agent mTOR Kinase Inhibitor	04/12/2018	Generic for: Zortress
Ertapenem Sodium for Injection 1 gram (base)/vial / ACS Dobfar S.p.A.	Antibiotic Carbapenem	04/16/2018	Generic for: Invanz
Miglustat Capsules 100 mg / Amerigen Pharmaceuticals, Inc.	Endocrine and metabolice agent Glucosylceramide synthase inhibitor	04/17/2018	Generic for: Zavesca

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Moxetumomab pasudotox / AstraZeneca and MedImmune	04/03/2018	Treatment for: Hairy Cell Leukemia	Moxetumomab pasudotox is an investigational anti-CD22 recombinant immunotoxin in development for the treatment of adult patients with hairy cell leukemia (HCL) who have received at least two prior lines of therapy. Moxetumomab pasudotox have the opportunity to be a first-in-class treatment in the US for patients with relapsed or refractory HCL. The FDA has accepted the BLA and granted an orphan drug designation for moxetumomab pasudotox.	High High
Omadacycline / Paratek Pharmaceuticals, Inc.	04/04/2018	Treatment for: Pneumonia, Skin and Structure Infection	Omadacycline is an oral and intravenous (IV) broad spectrum aminomethylcycline tetracycline antibiotic in development for the treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). The FDA has accepted the NDA and granted a priority review for omadacycline.	High
Duvelisib / Verastem, Inc.	04/09/2018	Treatment for: Chronic Lymphocytic Leukemia, Follicular Lymphoma, Peripheral T-cell Lymphoma, non-Hodgkin's Lymphoma	Duvelisib is a first-in-class, oral, dual phosphoinositide-3-kinase (PI3K)-delta/PI3K-gamma inhibitor in development for the treatment chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), follicular lymphoma and peripheral T-cell lymphoma. The FDA has accepted the NDA and granted an orphan drug designation for duvelisib.	High High
ALKS 5461 (buprenorphine and samidorphan)	04/16/2018	Treatment for: Major Depressive Disorder	ALKS 5461 is a novel opioid modulator, combining a partial opioid agonist with an opioid antagonist to rebalance brain function in patients with treatment-resistant depression. The FDA has accepted the NDA for ALK 5461.	Moderate

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

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Brexanolone / Sage Therapeutics	04/23/2018	Treatment for: Postpartum Depression	Brexanolone (SAGE-547) is an allosteric modulator of both synaptic and extrasynaptic GABAA receptors in development for the treatment of postpartum depression (PPD). Sage Therapeutics has submitted a NDA for brexanolone.	Moderate
Gilteritinib / Astellas Pharma Inc.	04/23/2018	Treatment for: Acute Myeloid Leukemia	Gilteritinib is an inhibitor of the tyrosine kinases FLT3/AXL in development for the treatment of patients with FLT3 mutation-positive (FLT3mut+) relapsed or refractory acute myeloid leukemia (AML). Astellas Pharma Inc. has submitted a NDA for gilteritinib. The FDA granted an orphan drug designation for gilteritinib.	High High

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

References:

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