Highlights of FDA Activities – 4/1/17 – 4/30/17

FDA Drug Safety Communications & Drug Information Updates:

Erythropoiesis Stimulating Agents: Drug Information Update – REMS No Longer Necessary 4/13/17
Based on an evaluation of REMS program which showed providers were aware of the product risks and the products were being prescribed consistently with their intended and approved use, the FDA has determined a REMS program and prescriber/hospital certification is no longer necessary for these products.

Codeine and Tramadol Medicines: Drug Safety Communication - Restricting Use in Children, Recommending Against Use in Breastfeeding Women 4/20/17
The FDA is restricting the use of codeine and tramadol in pediatric patients and recommending against its use in breastfeeding women. These controlled substances can cause slowed or difficulty breathing and death in children, particularly in children younger than 12 years, and should not be used in this age group. Products containing codeine (single-ingredient products) and tramadol (all products) have been approved only for use in adults. The FDA is also recommending that breastfeeding mothers should avoid the use of codeine and tramadol due to possible harm to their infants.

Illegal Cancer Treatments: FDA Warning - Fraudulent Claims of Diagnosis, Treatment, Prevention or Cure 4/25/17
The FDA issued warnings to 14 U.S. based companies that have been illegally selling more than 65 products that have been falsely claimed to treat, diagnose, prevent or cure cancer. The illegally sold products were a variety of product types, such as pills, topical creams, ointments, oils, drops, syrups, teas and diagnostics products. The complete list can be found on the FDA website.

General Anesthetic and Sedation Drugs: Drug Safety Communication- FDA Approves Label Changes for use in Young Children 4/27/17
The FDA has issued changes in the labeling regarding the use of general anesthetic and sedation drugs in children younger than 3 years old. A new warning states that long term exposure or use of general anesthetics and sedatives over multiple procedures may negatively affect brain development in children under 3 years old. Studies in young animals and pregnant animals showed that long term exposure to general anesthetics and sedative drugs caused loss of nerve cells in the developing brain of the animals, these changes resulted in behavioral or learning problems.

Major Product Recalls Announced Through MedWatch:

Sterile Compounded Products by Isomeric Pharmacy Solutions: Recall – Lack of Sterility Assurance 4/6/17
Isomeric Pharmacy Solutions recalled all lots of sterile products compounded and packaged by Isomeric following an FDA inspection that brought attention to concerns of a lack of sterility assurance. Products were distributed between 10/4/16 and 2/7/17.

Standard Homeopathic Company Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets: Recall - Mislabeling 4/13/17
Standard Homeopathic Company recalled all lots of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets sold in retail stores to the consumer label. The FDA has found varying amounts of belladonna alkaloids that may differ from the amount stated on the product label. The company stopped making and shipping the medicine nationwide in October 2016.

Phenobarbital 15 mg tablets, USP by C.O. Truxton: Recall- Labeling Error on Declared Strength 4/21/17
C.O. Truxton has announced the recall of phenobarbital 15 mg tablets. This is due to a complaint that a bottle labeled as phenobarbital 15 mg was actually found to contain phenobarbital 30 mg tablets. The recalled products are 1000 bottle count, lot number 70952A, NDC 0463-6160-10, UPC 7 0463616010 6, expiration date 11/17.

25% Dextrose Injection, USP (Infant) by Hospira: Recall - Particulate Matter 4/24/17

Hospira recalled one lot of 25% Dextrose Injection, USP, (Infant) pre-filled syringes due to the presence of particulate matter, identified as human hair. The affected lot is NDC: 0409-1775-10, Lot 58382EV, Exp Date: 1OCT2017.

Dietary Supplement Recalls & Public Notifications

In April, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	*Promoted Use*	*Hidden/Undeclared Drug Ingredient(s)*
Uproar*	Sexual Enhancement	Tadalafil[1]
Cummor*	Sexual Enhancement	Tadalafil[1]
Zrect for men*	Sexual Enhancement	Tadalafil[1]
Monkey Business*	Sexual Enhancement	Tadalafil[1]
Xrect*	Sexual Enhancement	Tadalafil[1]
Rectalis*	Sexual Enhancement	Tadalafil[1]
Tornado*	Sexual Enhancement	Tadalafil[1]
Zdaily*	Sexual Enhancement	Tadalafil[1]
BigNHard*	Sexual Enhancement	Tadalafil[1]
Enhancerol Natural Male Enhancement*	Sexual Enhancement	Tadalafil[1]
Zrect for women*	Sexual Enhancement	Flibanserin[2]
LabidaMAX*	Sexual Enhancement	Flibanserin[2]

*Recalled

[1]Sildenafil/tadalafil/vardenafil may interact with nitrates to lower blood pressure to dangerous levels

[2]Flibanserin interacts with alcohol resulting in an increased risk of severe hypotension and syncope

New Product Shortages Reported by the FDA:	*Date Initially Posted*
Potassium Phosphate Injection	4/14/17
Methotrexate Sodium Injection	4/24/17
Dextrose 50% Injection	4/27/17

Product Discontinuations/Withdrawals	*Date Posted*
Canakinumab (Ilaris) Lyophilized Powder for Injection (Novartis): 150 mg/vial lyophilized powder for injection, for subcutaneous use (NDC 0078-0582-61); this product has been replaced by canakinumab (Ilaris) 150 mg/mL injection solution (NDC 0078-0734-61).	4/27/17
Octreotide Acetate (Sandostatin) Injection (Novartis): 1000 mcg 5 mL in 1 vial, multi-dose (NDC 0078-0184-25), 200 mcg 5 mL in 1 vial, multi-dose (NDC) 0078-0183-25; octreotide acetate injection solution remains available from other manufacturers.	4/28/17

New Drug Approvals:	*Description*	*Date Approved*
Deutetrabenazine / Austedo / Teva	See attached	4/3/17
Valbenazine / Ingrezza / Neurocrine Biosciences	See attached	4/11/17
Infliximab-abda / Renflexis / Merck	Biosimilar to infliximab (Remicade)	4/21/17
Cerliponase alfa / Brineura / BioMarin Pharmaceutical, Inc.	See attached	4/27/17
Midostaurin / Rydapt/ Novartis	See attached	4/28/17
Brigatinib / Alunbrig / Takeda Pharmaceutical	See attached	4/28/17
Abaloparatide / Tymlos / Radius	See attached	4/28/17

New Indications:	***Description***	***Date Approved***
Sofosbuvir / Sovaldi / Gilead Sciences, Inc.	Indication expanded to include use in combination with ribavirin for treatment of hepatitis C virus (HCV) genotype 2 or 3, without or with mild cirrhosis in children ages 12 to 17 or weighing at least 77 pounds (35 kilograms).	4/7/17
Ledipasvir and sofosbuvir / Harvoni / Gilead Sciences, Inc.	Indication expanded to include treatment of HCV genotypes 1, 4, 5, or 6 without or with mild cirrhosis in children ages 12 to 17 or weighing at least 77 pounds (35 kilograms).	4/7/17
Anti-thymocyte globulin (rabbit) / Thymoglobulin / Genzyme Corp.	Indication expanded to include prophylaxis of acute rejection in patients receiving a kidney transplant	4/21/17
Regorafenib / Stivarga/ Bayer HealthCare Pharmaceuticals, Inc.	Indication expanded to include treatment of patients with hepatocellular carcinoma wo have been previously treated with sorafenib.	4/27/17

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Oxycodone HCl / Roxybond / Inspirion Delivery Sciences	Immediate-release tablets (5 mg, 15 mg, 30 mg) in an abuse deterrent formulation	4/20/17
Methotrexate / Xatmep / Silverate Pharmaceuticals	Oral solution (2.5 mg/mL) for the management of pediatric patients with acute lymphoblastic leukemia or active polyarticular juvenile idiopathic arthritis	4/25/17

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Deutetrabenazine / Austedo / Teva Pharmaceuticals	
Generic Name / Brand Name / Company	Deutetrabenazine / Austedo / Teva Pharmaceuticals
Date of approval	April 3, 2017
Drug Class (Mechanism of Action if novel agent)	Vesicular monoamine transporter 2 (VMAT2) inhibitor
Indication	Treatment of chorea associated with Huntington's disease
Comparative agent – Therapeutic interchange?	Tetrabenazine
Dosage forms/strengths. Common Dose/sig	Tablets: 6 mg, 9 mg, and 12 mg Starting dose: 6 mg once daily; titrate at weekly intervals by 6 mg per day to maximum dose of 48 mg per day (24 mg twice daily)
DEA Schedule	Not scheduled
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	Dutasteride, tetrabenazine
CLINICAL USE EVALUATION	
Common Adverse Effects	>8%: somnolence, diarrhea, dry mouth, fatigue
Severe Adverse Effects	Depression and suicidal thoughts, neuroleptic malignant syndrome
Severe Drug-Drug Interactions	MAOIs, reserpine: contraindicated Strong CYP2D6 inhibitors: reduced deutetrabenazine maximum dose; also reduced in poor CYP2D6 metabolizers Alcohol and other sedating drugs: additive sedation and somnolence
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosing adjustments are required for renal impairment. Deutetrabenazine is contraindicated in patients with hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications • Patients who are suicidal, or with untreated/inadequately treated depression • Hepatic impairment • Concomitantly with monoamine oxidase inhibitors, or within 14 days of discontinuing an MAOI • With reserpine, or within 20 days of discontinuing reserpine • With tetrabenazine Warnings • Depression and suicidality • Neuroleptic malignant syndrome • Akathisia, agitation, restlessness • Parkinsonism • Sedation • QTc prolongation • Hyperprolactinemia
Special administration technique or considerations	Divide daily dosage for twice daily administration at doses of 12 mg or greater. Administer with food. Swallow tablets whole; do not chew, crush, or break.
Prepared by	Terri Levien, Pharm.D.
Source	Austedo (deutetrabenazine) prescribing information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2017.

Valbenazine / Ingrezza / Neurocrine Biosciences, Inc	
Generic Name / Brand Name / Company	Valbenazine / Ingrezza / Neurocrine Biosciences, Inc
Date of approval	April 11, 2017
Drug Class (Mechanism of Action if novel agent)	Vesicular monoamine transporter 2 (VMAT2) inhibitor
Indication	Treatment of adults with tardive dyskinesia
Comparative agent – Therapeutic interchange?	Deutetrabenazine – currently off-label use
Dosage forms/strengths. Common Dose/sig	Capsule: 40 mg. Starting dose: 40 mg taken once daily. After one week increase to 80 mg once daily. Dose reduction based on tolerability should be considered if the patient is known to be a CYP2D6 poor metabolizer.
DEA Schedule	Not scheduled
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	Afrezza, tetrabenazine, vinorelbine
CLINICAL USE EVALUATION	
Common Adverse Effects	> 5%: somnolence.
Severe Adverse Effects	QTc prolongation
Severe Drug-Drug Interactions	MAOIs: avoid concomitant use Strong CYP3A4 inhibitors: reduced valbenazine dose Strong CYP2D6 inhibitors: reduced valbenazine dose Strong CYP3A4 inducers: avoid concomitant use
Severe Drug-Food Interactions	N/A
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	N/A
Used in Pediatric Areas	Safety and effectiveness has not been established in pediatric patients.
Renal or Hepatic Dosing	No dose adjustments necessary in mild to moderate renal impairment; use is not recommended in patients with severe renal impairment (Cl < 30 mL/min). Dose reduction to 40 mg once daily is recommended in patients with moderate or severe hepatic impairment (Child-Pugh score 7 to 15).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings and Precautions: • Somnolence • QT Prolongation: avoid in patients with congenital long QT syndrome or arrhythmias associated with a prolonged QT interval.
Special administration technique or considerations	Take with or without food.
Prepared by	Uzoma Mbogu, Pharm. D. Candidate of 2018, Washington State University
Source	Ingrezza (valbenazine) prescribing information. San Diego, CA: Neurocrine Biosciences, Inc.; April 2017.

Cerliponase alfa / Brineura / BioMarin Pharmaceutical Inc.	
Generic Name / Brand Name / Company	Cerliponase alfa/ Brineura/ BioMarin Pharmaceutical Inc.
Date of approval	April 27, 2017
Drug Class (Mechanism of Action if novel agent)	Hydrolytic lysosomal N-terminal tripeptidyl peptidase
Indication	Slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 150 mg/5 mL (30 mg/mL) solution in two single dose vials per packaged carton, along with a 5 mL single dose vial of intraventricular electrolytes. Dose: 300 mg once every other week as an intraventricular infusion followed by infusion of intraventricular electrolytes over approximately 4.5 hours. Administered to cerebrospinal fluid via a surgically implanted reservoir and catheter.
DEA Schedule	Not scheduled
Date of market availability	May 2017
Similar Medications (Look-Alike Sound-Alike)	Brintellix
CLINICAL USE EVALUATION	
Common Adverse Effects	≥8%: pyrexia, ECG abnormalities, decreased CSF protein, vomiting, seizures, hypersensitivity, increased CSF protein, hematoma, headache, irritability, pleocytosis, device-related infection, bradycardia, feeling jittery, and hypotension
Severe Adverse Effects	Hypersensitivity reactions, cardiovascular events, device-related complications, seizures
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Routinely test CSF samples to detect subclinical infection
Used in Pediatric Areas	Used in pediatric patients as young as 3 years old
Renal or Hepatic Dosing	No dosage adjustments necessary
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: • Patients with acute intraventricular access device-related complications • Patients with ventriculoperitoneal shunts Warnings • Inspect scalp for access-device related complications • Monitor vital signs before, during, and after; monitor ECG if history of cardiovascular disorder • Observe for hypersensitivity reactions
Special administration technique or considerations	• Aseptic technique must be strictly observed during preparation and administration. It must be administered by, or under the direction of a physician knowledgeable in intraventricular administration. The access device should be implanted 5 to 7 days prior to the first infusion. • Pre-treatment with antihistamines with or without antipyretics or corticosteroids is recommended 30 to 60 minutes before the start of the infusion.
Prepared by	Uzoma Mbogu, Pharm. D. Candidate of 2018, Washington State University
Source	Brineura (cerliponase) prescribing information. Novato, CA: BioMarin Pharmaceutical Inc.; April 2017.

Midostaurin / Rydapt / Novartis	
Generic Name / Brand Name / Company	Midostaurin / Rydapt / Novartis
Date of approval	April 28, 2017
Drug Class (Mechanism of Action if novel agent)	Class III receptor tyrosine kinase inhibitor. Midostaurin acts as a kinase inhibitor blocking enzymes which promote cell growth.
Indication	• First-line treatment of adults with FLT3+ acute myeloid leukemia (AML) as detected by an FDA-approved test and administered in combination with cytarabine/daunorubicin induction and cytarabine consolidation. • Advanced systemic mastocytosis (SM) in adults which includes: aggressive SM, SM with associated hematological neoplasm, and mast cell leukemia. (May be used as a single agent.)
Comparative agent – Therapeutic interchange?	sorafenib (Nexavar), quizartinib (investigational), crenolanib (investigational), gilteritinib (investigational)
Dosage forms/strengths. Common Dose/sig	Capsules: 25 mg. AML: 50 mg orally twice daily with food. Advanced SM: 100 mg orally twice daily with food.
DEA Schedule	None
Date of market availability	Available
Similar medications (Look-Alike Sound-Alike)	midodrine, mifepristone, Ridactate, Rybix, Rydex, Rynex
CLINICAL USE EVALUATION	
Common Adverse Effects	AML, ≥ 20%: febrile neutropenia, nausea, mucositis, vomiting, headache, petechiae, musculoskeletal pain, epistaxis, device-related infusion, hyperglycemia, upper respiratory tract infection, hypocalcemia Advanced SM, ≥ 20%: nausea, vomiting, diarrhea, edema, musculoskeletal pain, abdominal pain, fatigue, upper respiratory tract infection, constipation, pyrexia, headache, and dyspnea
Severe Adverse Effects	Febrile neutropenia, renal insufficiency, infections and gastrointestinal disorders, anemia, lymphopenia, hyperglycemia
Severe Drug-Drug Interactions	Strong CYP3A4 inhibitors: avoid or monitor closely Strong CYP3A4 inducers: avoid
Severe Drug-Food Interactions	Grapefruit (CYP3A4 inhibitor)
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Prior to initiation of therapy for AML, presence of FLT3 mutation must be confirmed using FDA approved companion diagnostic, the LeukoStrat CDxFLT3 Mutation Assay. Complete blood count (ANC, hemoglobin, platelets) to determine dosage adjustments. Monitor for toxicity weekly for the first 4 weeks, every other week for the next 8 weeks, and monthly thereafter.
Used in Pediatric Areas	Safety and effectiveness has not been established in pediatric patients.
Renal or Hepatic Dosing	None. Moderate hepatic impairment (≤3x ULN total bilirubin) or renal impairment (CrCl ≥ 30 ml/min) did not affect pharmacokinetics. Not studied in severe impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with hypersensitivity to drug or excipients. • Pulmonary toxicity: monitor for symptoms of interstitial lung disease or pneumonitis. Discontinue if suspected. Fatal events have occurred.
Special administration technique or considerations	Administer with food. Do not open or crush capsules. Administer prophylactic antiemetics. If dose is missed or vomited, do not make up the dose.
Prepared by	Alice Knotts, PharmD Candidate 2018
Source	Rydapt (midostaurin) prescribing information. East Hanover, NJ: Novartis Pharmaceutical Corporation; April 2017.

Abaloparatide / Tymlos / Radius	
Generic Name / Brand Name / Company	Abaloparatide / Tymlos / Radius
Date of approval	April 28, 2017
Drug Class (Mechanism of Action if novel agent)	Parathyroid hormone analog
Indication	Treatment of osteoporosis in postmenopausal women who are considered to be at high risk for fracture.
Comparative agent – Therapeutic interchange?	Teriparatide
Dosage forms/strengths. Common dose/sig	Injection 3120 mcg/1.56 mL (2000 mcg/mL) in a single-patient-use prefilled pen which delivers 30 doses. Each dose contains 80 mcg drug in 40 mcL solution to be administered subcutaneously, once daily.
DEA Schedule	Not scheduled
Date of market availability	June 2017
Similar Medications (Look-Alike Sound-Alike)	Abatacept, Adapalene, Albiglutide, Aldactazide, Teriparatide, Tiamol, timolol, Tylan, Tylenol
CLINICAL USE EVALUATION	
Common Adverse Effects	>2%: hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain, vertigo, injection site reactions
Severe Adverse Effects	Not specified in labeling
Severe Drug-Drug Interactions	No interactions known
Severe Drug-Food Interactions	No interactions known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Consider monitoring serum calcium, especially in patients with impaired kidney function (hypercalcemia 4% with mild/moderate CKD). Measurement of urinary calcium excretion if urolithiasis or pre-existing hypercalcemia suspected.
Used in Pediatric Areas	Safety and effectiveness has not been established in pediatric patients.
Renal or Hepatic Dosing	No dose adjustment is recommended for patients with mild, moderate, or severe renal impairment. The total exposure (AUC) of a single 80 mcg dose increased ~2 fold in subjects with severe renal impairment, therefore cose monitoring for adverse effects is recommended. No dose adjustment is necessary for hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings: • Cumulative use of abaloparatide for more than 2 years during a patient's lifetime is not recommended due to unknown risk associated with osteosarcoma. • Avoid use in patients with increased risk for osteosarcoma • Orthostatic hypotension • Hypercalcemia • Hypercalciuria and urolithiasis
Special administration technique or considerations	• Patient is to administer abaloparatide once daily as a subcutaneous injection. Supplement with calcium and vitamin D if dietary intake is not sufficient. • Administer into the periumbilical region, rotating the administration site each day. • Injections should be completed at about the same time each day. • Administer the first several doses in a sitting or supine position and monitor for symptoms of orthostatic hypotension/dizziness which are more common in the first hour after administration.
Prepared by	Alice Knotts, Pharm. D. Candidate of 2018, Washington State University
Source	Tymlos (abaloparatide) prescribing information. Waltham, MA: Radius Health, Inc.; April 2017.

Brigatinib / Alunbrig / Takeda Pharmaceutical	
Generic Name / Brand Name / Company	Brigatinib / Alunbrig / Takeda Pharmaceutical
Date of approval	April 28, 2017
Drug Class (Mechanism of Action if novel agent)	Anaplastic Lymphoma Kinase (ALK) Inhibitor
Indication	Treatment of patients with metastatic ALK-positive non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.
Comparative agent – Therapeutic interchange?	Alectinib, crizotinib, ceritinib
Dosage forms/strengths. Common Dose/sig	Tablets: 30 mg and 90 mg Dose: 90 mg orally once daily for the first 7 days; if tolerated, increase to 180 mg once daily.
DEA Schedule	Not scheduled
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	Beractant
CLINICAL USE EVALUATION	
Common Adverse Effects	≥25%: nausea, diarrhea, fatigue, cough, and headache
Severe Adverse Effects	Pneumonitis, hypertension, bradycardia, visual disturbances, hyperglycemia
Severe Drug-Drug Interactions	Avoid concomitant use with strong CYP3A inhibitors and strong CYP3A inducers. If the use of CYP3A inhibitors are unavoidable, reduce to dose of brigatinib. May reduce efficacy of CYP3A substrates (hormonal contraceptives).
Severe Drug-Food Interactions	Grapefruit (CYP3A4 inhibitor)
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	CPK, lipase and amylase, fasting serum glucose
Used in Pediatric Areas	Safety and effectiveness has not been established in pediatric patients
Renal or Hepatic Dosing	No dose adjustment is recommended for patients with mild and moderate renal impairment; has not been studied in severe renal impairment. No dose adjustment is recommended for patients with mild hepatic impairment; has not been studied in moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: None Warnings: • Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening respiratory symptoms, particularly during the first week of treatment. Withhold treatment for new or worsening respiratory symptoms • Hypertension: Blood pressure should be monitored after 2 weeks and then at least monthly during treatment. Withhold treatment, then reduce dose or permanently discontinue if hypertension is severe. • Bradycardia: Heart rate should be monitored regularly during treatment. If symptomatic, withhold treatment, then reduce dose or permanently discontinue. • Visual Disturbance: Advise patients to report visual symptoms. Withhold treatment and obtain ophthalmologic evaluation, then reduce dose or permanently discontinue. • Creatine Phosphokinase (CPK) Elevation: CPK levels should be regularly monitored during treatment. Treatment should be withheld based on severity, then resume or reduce dose. • Pancreatic Enzyme Elevation: Monitor lipase and amylase levels regularly during treatment. Based on the severity, withhold treatment, then resume or reduce dose.

	• Hyperglycemia: Assess fasting serum glucose prior to starting treatment and regularly during treatment. If not adequately controlled with optimal medical management, withhold treatment, then consider dose reduction or permanently discontinue, based on severity. • Embryo-Fetal Toxicity: Can cause fetal harm. Advise females to use a nonhormonal method of effective contraception.
Special administration technique or considerations	May be taken with or without food; swallow tablets whole, do not crush or chew. If dose is missed or vomiting, do not take additional dose. If administration is interrupted for14 days or longer for reasons other than adverse effects, resume therapy at the 90 mg dose for 7 days before increasing dose to previously tolerated dose.
Prepared by	Uzoma Mbogu, Pharm. D. Candidate of 2018, Washington State University
Source	Alunbrig (brigatinib) prescribing information. Cambridge, MA: Ariad Pharmaceuticals, Inc.; April 2017.