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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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NEWS

Drug issue	Date	Details
Possible increased risk of cancer with Belviq, Belviq XR (lorcaserin)	01/14/2020	The FDA is alerting the public that results from a clinical trial assessing safety show a possible increased risk of cancer with the weight management medicine Belviq, Belviq XR (lorcaserin). At this time, the cause of the cancer is uncertain, and it cannot be concluded that lorcaserin contributes to the cancer risk. However, the FDA wants to make the public aware of this potential risk. The FDA is continuing to evaluate the clinical trial results and will communicate their final conclusions and recommendations when they have completed their review.
Clozaril, Fazaclo ODT, Versacloz (clozapine): FDA Strengthens Warning That Untreated Constipation Can Lead to Serious Bowel Problems	1/28/2020	The FDA is strengthening an existing warning that constipation caused by the schizophrenia medicine clozapine (Clozaril, Fazaclo ODT, Versacloz, generics) can, uncommonly, progress to serious bowel complications. This can lead to hospitalization or even death if constipation is not diagnosed and treated quickly. Recommendations for healthcare professionals: • Evaluate bowel function before starting a patient on clozapine. • Avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility. • Advise patients frequently of the significant risk of constipation and life-threatening bowel issues and the need to stay hydrated to prevent constipation. • Question patients about the frequency and quality of their bowel movements throughout treatment. • Advise patients to contact a health care professional right away if they have difficulty having a bowel movement or passing stools, do not have a bowel movement at least three times a week or less than their normal frequency, or are unable to pass gas. • Monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility such as nausea, abdominal distension or pain, and vomiting. • Consider prophylactic laxative treatment when starting clozapine in patients with a history of constipation or bowel obstruction. • Report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Ayvakit™ (avapritinib) Tablets, for oral use	Blueprint Medicines Corporation	01/09/2020

THERAPEUTIC CLASS
Antineoplastic agent; Tyrosine kinase inhibitor.

FDA-APPROVE INDICATION(S)
Ayvakit™ is a kinase inhibitor indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

DOSAGE AND ADMINISTRATION
The recommended dose is 300 mg orally once daily on an empty stomach, at least one hour before and two hours after a meal. Dose modifications are recommended for adverse reactions and drug interactions.

Patients must be selected for treatment with AYVAKIT based on the presence of a PDGFRA exon 18 mutation.

DOSAGE FORMS AND STRENGTHS
Tablets: 100 mg, 200 mg and 300 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Intracranial hemorrhage: Intracranial hemorrhage have been reported. Withhold treatment for Grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue treatment for recurrent Grade 1 or 2 reactions or first occurrence of Grade 3 or 4 reactions.
- Central nervous system (CNS) effects: CNS adverse reactions can occur. Depending on the severity, continue at same dose, withhold and then resume at same or reduced dose upon improvement, or permanently discontinue treatment.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: edema, nausea, fatigue/asthenia, cognitive impairment, vomiting, decreased appetite, diarrhea, hair color changes, increased lacrimation, abdominal pain, constipation, rash and dizziness.

DRUG INTERACTIONS
- Strong and Moderate CYP3A Inhibitors: Avoid co-administration with strong and moderate CYP3A inhibitors. If co-administration with a moderate inhibitor cannot be avoided, reduce dose of AYVAKIT.
- Strong and Moderate CYP3A Inducers: Avoid co-administration with strong and moderate CYP3A inducers.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise of the potential risk to a fetus and to use effective contraception during treatment and after the final dose.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or efficacy were observed between these patients and younger adult patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Ayvakit™ (avapritinib) Tablets, for oral use	Blueprint Medicines Corporation	01/09/2020

THERAPEUTIC CLASS
Antineoplastic agent; Tyrosine kinase inhibitor.

FDA-APPROVE INDICATION(S)
Ayvakit™ is a kinase inhibitor indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.

DOSAGE AND ADMINISTRATION
The recommended dose is 300 mg orally once daily on an empty stomach, at least one hour before and two hours after a meal. Dose modifications are recommended for adverse reactions and drug interactions.

Patients must be selected for treatment with AYVAKIT based on the presence of a PDGFRA exon 18 mutation.

DOSAGE FORMS AND STRENGTHS
Tablets: 100 mg, 200 mg and 300 mg.

Orphan status: Orphan

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Renal impairment: No dose adjustment is recommended for patients with mild or moderate renal impairment. The recommended dose has not been established for patients with severe renal impairment or end-stage renal disease.
- Hepatic impairment: No dose adjustment is recommended for patients with mild or moderate hepatic impairment. The recommended dose of has not been established for patients with severe hepatic impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tepezza™ (teprotumumab-trbw), for intravenous use	Horizon Therapeutics plc	01/21/2020

THERAPEUTIC CLASS
Endocrine and metabolic agent; Monoclonal antibody

FDA-APPROVE INDICATION(S)
Tepezza™ is a monoclonal antibody (mAb) and a targeted inhibitor of the insulin-like growth factor 1 receptor (IGF-1R) indicated for the treatment of Thyroid Eye Disease (TED).

DOSAGE AND ADMINISTRATION
The recommended dose is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions (for a total of 8 infusions).

DOSAGE FORMS AND STRENGTHS
For Injection: 500 mg lyophilized powder in a single-dose vial for reconstitution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Infusion reactions: May cause infusion reactions. If an infusion reaction occurs, consideration should be given to pre-medicating with an antihistamine, antipyretic, corticosteroid and/or administering all subsequent infusions at a slower infusion rate.
- Exacerbation of pre-existing Inflammatory Bowel Disease (IBD): May cause an exacerbation of pre-existing IBD. Patients with pre-existing IBD must be monitor for flare of disease. If IBD exacerbation is suspected, consider discontinuation.
- Hyperglycemia: May occur. Glucose levels must be monitor in all patients. Patients with pre-existing diabetes should be under appropriate glycemic control before receiving Tepezza™.

ADVERSE REACTIONS
Most common adverse reactions: muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia and headache.

DRUG INTERACTIONS
No studies evaluating the drug interaction potential of have been conducted.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Based on animal data, may cause fetal harm.
- Females of reproductive potential: Advise of the potential risk to a fetus and to use effective contraception during treatment and after the final dose.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or efficacy were observed between these patients and younger adult patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tazverik™ (tazemetostat) Tablets, for oral use	Epizyme, Inc.	01/23/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Tazverik™ is a methyltransferase inhibitor indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.

DOSAGE AND ADMINISTRATION
The recommended dose is 800 mg taken orally twice daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 200 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Secondary malignancies: Tazverik™ increases the risk of developing secondary malignancies, including T-cell lymphoblastic lymphoma, myelodysplastic syndrome, and acute myeloid leukemia.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: pain, fatigue, nausea, decreased appetite, vomiting, and constipation.

DRUG INTERACTIONS
- Strong and moderate CYP3A inhibitors: Co-administration increases tazemetostat plasma concentrations, which may increase the frequency or severity of adverse reactions. Co-administration should be avoided and if cannot be avoided, reduce the dose of Tazverik™.

DRUG INTERACTIONS (continuation)
- Strong and moderate CYP3A inducers: Co-administration may decrease tazemetostat plasma concentrations, which may decrease the efficacy. Co-administration should be avoided and if cannot be avoided.
- CYP3A substrates: Co-administration can result in decreased concentrations and reduced efficacy of CYP3A substrates.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise of the potential risk to a fetus and to use effective contraception during treatment and after the final dose.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness in pediatric patients aged less than 16 years have not been established.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tazverik™ (tazemetostat) Tablets, for oral use	Epizyme, Inc.	01/23/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Tazverik™ is a methyltransferase inhibitor indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.

DOSAGE AND ADMINISTRATION
The recommended dose is 800 mg taken orally twice daily with or without food until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
Tablets: 200 mg.

Orphan status: Orphan

SAFETY PROFILE (continuation

USE IN SPECIFIC POPULATIONS (continuation)

- Geriatric use: Clinical studies did not include sufficient numbers of patients with epithelioid sarcoma aged 65 and over to determine whether they respond differently from younger subjects.
- Renal impairment: No dose adjustment recommended for patients with mild to severe renal impairment or end stage renal disease.
- Hepatic impairment: No dose adjustment recommended for patients with mild hepatic impairment. Has not been studied in patients with moderate or severe hepatic impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Palforzia™ (Peanut (Arachis hypogaea) Allergen Powder-dnfp), for oral use	Aimmune Therapeutics, Inc.	01/31/2020

THERAPEUTIC CLASS
Immunological Agent; Immunotherapy

FDA-APPROVE INDICATION(S)
Palforzia™ is an oral immunotherapy for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with peanut allergy.

DOSAGE AND ADMINISTRATION
Palforzia™ is administered orally in three phases: Initial Dose Escalation, Up-Dosing, and Maintenance. The Initial Dose Escalation phase is given on a single day. The Up-Dosing phase consists of 11 increasing dose levels and occurs over several months. Initial Dose Escalation, and the first dose of each Up-Dosing level, are administered under supervision of a healthcare professional in a healthcare setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Refer to package insert for details.

DOSAGE FORMS AND STRENGTHS
Powder for oral administration supplied in 0.5 mg 1 mg, 10 mg, 20 mg and 100 mg Capsules or 300 mg Sachets.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Uncontrolled asthma.
- History of eosinophilic esophagitis or other eosinophilic gastrointestinal disease.

WARNINGS AND PRECAUTIONS
- Black Box Warning: Anaphylaxis – Can occur at any time during therapy. Injectable epinephrine must be prescribed and patient must: be instructed on its appropriate use and to seek immediate medical care upon its use, and receive education to recognize the signs and symptoms of anaphylaxis. Do not administer to patients with uncontrolled asthma. Dose modifications may be necessary after anaphylaxis. Patient must be observed during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level. Because of the risk of anaphylaxis, Palforzia™ is only available through a restricted program called the PALFORZIA REMS.
- Asthma: Ensure patients with asthma have their asthma under control prior to initiation. Therapy should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Palforzia™ has not been studied in patients with severe asthma.

WARNINGS AND PRECAUTIONS (continuation)
- Eosinophilic esophagitis: Palforzia™ is associated with eosinophilic esophagitis. Monitor patients for signs and symptoms and discontinue if eosinophilic esophagitis is suspected.
- Gastrointestinal reactions: If patients develop chronic or recurrent local gastrointestinal allergic symptoms, consider dose modification or discontinuation of treatment.

ADVERSE REACTIONS
Most common adverse reactions: abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

USE IN SPECIFIC POPULATIONS
- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Palforzia™ during pregnancy.
- Pediatric use: Safety and effectiveness have not been established in persons younger than 4 years of age.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Audenz™ (influenza A monovalent vaccine, adjuvanted) Injection, for IM use	Seqirus	01/07/2020

THERAPEUTIC CLASS
Vaccine

FDA-APPROVE INDICATION(S)
Audenz™ is an inactivated vaccine indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine, for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine.

DOSAGE AND ADMINISTRATION
The recommended dose is to administer two doses (0.5 mL each) 21 days apart.

DOSAGE FORMS AND STRENGTHS
Each dose of injectable emulsion (0.5 mL) is supplied in a prefilled single dose syringe.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- History of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, or after a previous dose of an influenza vaccine.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions can occur. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Audenz™ should be based on careful consideration of potential benefits and risks.

ADVERSE REACTIONS
Most common adverse reactions:
- Adults 18-64 years: injection site pain, fatigue, headache, malaise, myalgia, arthralgia, and nausea.
- Adults 65 years and older: injection site pain, fatigue, malaise, headache, and arthralgia.
- Infants and children, 6 months - 5 years: tenderness, irritability, sleepiness, change in eating habits, and fever.

ADVERSE REACTIONS (continuation)
- Children 6-17 years: injection site pain, myalgia, fatigue, malaise, headache, loss of appetite, nausea, and arthralgia.

DRUG INTERACTIONS
- No data are available to evaluate the concomitant administration with other vaccines.
- Immunosuppressive or corticosteroid therapies may reduce the immune response.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness in infants younger than 6 months have not been established.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Valtoco™ (diazepam) Nasal Spray / Neurelis, Inc.	Central nervous system agents; Anticonvulsant; Benzodiazepine	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (e.g. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older	01/10/2020	Valtoco™ is a new formulation of diazepam in nasal spray. Before this approval, diazepam was available in generic as an injection solution, oral solution, and oral tablet. In addition, diazepam was available under the brand name Valium™ as an oral tablet. --- Orphan status: Orphan. Controlled substance: CIV
Numbrino™ (cocaine hydrochloride) Nasal Solution / Lannett Company, Inc.	Local anesthetic	For the introduction of local anesthesia of the mucous membranes for diagnostic procedures and surgeries on or through the nasal cavities of adults	01/10/2020	Drug Already Marketed without Approved NDA. --- Controlled substance: CII
Monoferric™ (ferric derisomaltose) injection / Novo Nordisk Inc.	Iron supplement	Treatment of iron deficiency anemia in adult patients: • who have intolerance to oral iron or have had unsatisfactory response to oral iron • who have non-hemodialysis dependent chronic kidney disease	01/16/2020	Monoferric™ is new iron formulation for iron replacement as a single dose in one visit for patients with iron deficiency anemia.
Trijardy XR™ (empagliflozin, linagliptin and metformin hydrochloride) Extended-Release Tablets / Boehringer Ingelheim and Eli Lilly and Company	Antidiabetic	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease	01/27/2020	Trijardy XR™ is a new once-daily therapy combining 3 well-established drugs in one single tablet: empagliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor, linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Bynfezia Pen™ (octreotide acetate) injection / Sun Pharm Inds Ltd	Somatostatin analogue	• Reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses • Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients • Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients	01/28/2020	Bynfezia Pen™ is a new formulation of the somatostatin analogue octreotide in a pre-filled pen.
Ajovy™ (fremanezumab-vfrm) Injection	Antimigarine	Preventive treatment of migraine	02/27/2020	The FDA has approved an auto-injector device for Ajovy™ injection.

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, and endometrial carcinoma	Treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy	01/08/2020	This approval was based on data from the KEYNOTE-057 trial, where Keytruda™ demonstrated a complete response rate of 41% (range: 31 to 51). Among the 39 patients who achieved a complete response, the median duration of response was 16.2 months (range: 0.0+ to 30.4+), and 46% had a response of 12 months or longer.
Ozempic™ (semaglutide) Injection / Novo Nordisk	Antidiabetic; Glucagon-like peptide-1 (GLP-1) analog	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)	To reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease	01/16/2020	This approval was based on results from the SUSTAIN 6 cardiovascular outcomes trial (CVOT) which examined the cardiovascular safety of adding Ozempic™ or placebo to standard of care in adults with T2DM and established cardiovascular disease. Results showed that Ozempic™ significantly reduced the risk of the occurrence of a three-component major adverse cardiovascular events (MACE) endpoint consisting of cardiovascular death, non-fatal heart attack or non-fatal stroke. The estimated relative risk reduction of MACE was 26% vs placebo (HR: 0.74; 95% CI: 0.58, 0.95; p-value <0.001 for non-inferiority; median observation time: 2.1 years) with the primary composite outcome occurring in 6.6% of patients treated with Ozempic™ vs 8.9% with placebo. In terms of safety, gastrointestinal adverse events were more frequent in the Ozempic™ group than in the placebo group., and the majority of gastrointestinal adverse events occurred during the first 30 weeks.

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date	Comments
Dificid™ (fidaxomicin) / Merck	Anti-infective agent; Antibacterial	Treatment of *Clostridioides difficile*-associated diarrhea (CDAD)	Patient population altered: To include children aged six months and older	01/24/2020	New indication was approved for the tablet formulation that was already available in the market. In addition, a new formulation (oral suspension) was approved for CDAD in children aged six months and older.

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Date	Generic for:
Hydrocodone Bitartrate Extended Release Capsules 10 mg, 15 mg, 20 mg, 30 mg, 40 mg and 50 mg / Alvogen Inc.	Analgesic; Opioid	01/21/2020	Zohydro ER

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Lumasiran / Alnylam Pharmaceuticals, Inc.	01/10/2020	Treatment for: Primary Hyperoxaluria Type 1 (PH1)	Lumasiran is an investigational, subcutaneously administered RNAi therapeutic targeting hydroxyacid oxidase 1 (HAO1) in development for the treatment of PH1. NDA was submitted to the FDA. The FDA granted a pediatric rare disease designation for lumasiran for PH1.	High
Mycapssa (octreotide) / Chiasma, Inc.	01/13/2020	Treatment for: Acromegaly	Mycapssa (octreotide) is an oral formulation of the somatostatin analog octreotide (currently available as an injection) in development for the treatment of acromegaly. NDA was re-submitted to the FDA.	Moderate
Belantamab mafodotin /	01/27/2020	Treatment for: Multiple Myeloma	Belantamab mafodotin is an anti–B cell maturation antigen (BCMA) monoclonal antibody-drug conjugate in development for the treatment of patients with relapsed or refractory multiple myeloma whose prior therapy included an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. FDA granted priority review to BLA of belantamab mafodotin	High
Selpercatinib / Eli Lilly and Company	01/29/2020	Treatment for: Non-Small Cell Lung Cancer, Thyroid Cancer	Selpercatinib is a RET kinase inhibitor in development for the treatment of patients with advanced RET fusion-positive non-small cell lung cancer (NSCLC), RET-mutant medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancer. FDA granted priority review to NDA of selpercatinib and orphan drug designation.	High High

References

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