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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: MAY 2020

Date: 06/08/2020

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NEWS

Drug issue	Date	Details
FDA Alerts to Nitrosamine Impurity Findings in Certain Metformin Extended-Release Products	05/28/2020	The FDA announced that their testing has revealed levels of the nitrosamine impurity N-Nitrosodimethylamine (NDMA) above the agency's acceptable intake limit in several lots of the extended-release (ER) formulation of metformin. The FDA recommended the voluntary recall of metformin ER product to various manufacturers and will continue to work closely with manufacturers to ensure appropriate testing. For additional information, visit: https://www.fda.gov/news-events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Bafiertam™ (monomethyl fumarate) delayed-release capsules, for oral use	Banner Life Sciences	04/28/2020

THERAPEUTIC CLASS
Multiple sclerosis agent

FDA-APPROVE INDICATION(S)
Bafiertam™ is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
The recommended starting dose is 95 mg twice a day, orally, for 7 days. The maintenance dose after 7 days: 190 mg (administered as two 95 mg capsules) twice a day, orally.

DOSAGE FORMS AND STRENGTHS
Delayed-release capsules: 95 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate, or any of the excipients of Bafiertam™.
- Co-administration with dimethyl fumarate or diroximel fumarate.

WARNINGS AND PRECAUTIONS
- Anaphylaxis and angioedema: Can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Discontinue and do not restart if these occur.
- Progressive Multifocal Leukoencephalopathy (PML): Has occurred. Withhold at the first sign or symptom suggestive of PML.
- Herpes zoster and other serious opportunistic infections: Have occurred. Consider withholding in cases of serious infection until the infection has resolved.
- Lymphopenia: Bafiertam™ may decrease lymphocyte counts. Obtain a CBC including lymphocyte count before initiating, after 6 months, and every 6 to 12 months thereafter. Consider interruption of if lymphocyte counts <0.5 x10^9/L persist for more than 6 months.

WARNINGS AND PRECAUTIONS
- Liver injury: Have been reported. Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating and during treatment, as clinically indicated. Discontinue if clinically significant liver injury induced by Bafiertam™ is suspected.
- Flushing: May cause flushing.

ADVERSE REACTIONS
Most common adverse reactions: flushing, abdominal pain, diarrhea, and nausea.

DRUG INTERACTIONS
- Dimethyl Fumarate or Diroximel Fumarate: Both dimethyl fumarate and diroximel fumarate are metabolized to monomethyl fumarate. Therefore, Bafiertam™ is contraindicated in patients currently taking dimethyl fumarate or diroximel fumarate. Bafiertam™ may be initiated the day following discontinuation of either of these drugs.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Bafiertam™ (monomethyl fumarate) delayed-release capsules, for oral use	Banner Life Sciences	04/28/2020

THERAPEUTIC CLASS
Multiple sclerosis agent

FDA-APPROVE INDICATION(S)
Bafiertam™ is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
The recommended starting dose is 95 mg twice a day, orally, for 7 days. The maintenance dose after 7 days: 190 mg (administered as two 95 mg capsules) twice a day, orally.

DOSAGE FORMS AND STRENGTHS
Delayed-release capsules: 95 mg.

Orphan status: N/A

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tabrecta™ (capmatinib) Tablets, for oral use	Novartis Pharmaceuticals Corporation	05/06/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Tabrecta™ is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose is 400 mg orally twice daily.

Dose adjustments recommended for adverse reactions.

DOSAGE FORMS AND STRENGTHS
Tablets: 150 mg and 200 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue in patients with ILD/pneumonitis.
- Hepatotoxicity: Monitor liver function tests. Withhold, reduce dose, or permanently discontinue based on severity.
- Risk of photosensitivity: May cause photosensitivity. Advise patients to limit direct ultraviolet exposure.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite.

DRUG INTERACTIONS
- Strong CYP3A inhibitors: Co-administration increased capmatinib exposure, which may increase the incidence and severity of adverse reactions of Tabrecta™. Closely monitor patients for adverse reactions during co-administration.

DRUG INTERACTIONS
- Strong and moderate CYP3A inducers: Co-administration decreased capmatinib exposure, which may decrease Tabrecta™ anti-tumor activity. Avoid concomitant use.
- CYP1A2 substrates: Co-administration increased the exposure of a CYP1A2 substrate, which may increase the adverse reactions of these substrates. If co-administration is unavoidable where minimal concentration changes may lead to serious adverse reactions, decrease the CYP1A2 substrate dosage in accordance with the approved prescribing information.
- P-glycoprotein (P-gp) and Breast Cancer Resistance Protein (BCRP) substrates: Co-administration increased the exposure of a P-gp substrate and a BCRP substrate, which may increase the adverse reactions of these substrates. If co-administration is unavoidable where minimal concentration changes may lead to serious adverse reactions, decrease the P-gp or BCRP substrate dosage in accordance with the approved prescribing information.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tabrecta™ (capmatinib) Tablets, for oral use	Novartis Pharmaceuticals Corporation	05/06/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Tabrecta™ is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose is 400 mg orally twice daily.

Dose adjustments recommended for adverse reactions.

DOSAGE FORMS AND STRENGTHS
Tablets: 150 mg and 200 mg.

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS

- MATE1 and MATE2K substrates: Co-administration may increase the exposure of MATE1 and MATE2K substrates, which may increase the adverse reactions of these substrates. If co-administration is unavoidable where minimal concentration changes may lead to serious adverse reactions, decrease the MATE1 or MATE2K substrate dosage in accordance with the approved prescribing information.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Verify pregnancy status for females of reproductive potential prior to starting treatment.
- Females and males of reproductive potential: Advise patients of the potential risk to a fetus and to use effective contraception.
- Lactation: Advise not to breastfeed
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in the safety or effectiveness observed between these patients and younger patients.
- Renal impairment: No dose adjustment recommended for mild or moderate renal impairment. Has not been studied in patients with severe renal impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Retevmo™ (selpercatinib) Capsules, for oral use	Eli Lilly and Company	05/08/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Retevmo™ is indicated for the treatment of:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if appropriate)

DOSAGE AND ADMINISTRATION
The recommended dose is based on weight:

- <50 kg: 120 mg orally twice daily.
- ≥ 50 kg: 160 mg orally twice daily.

Dose adjustments recommended for severe hepatic impairment, adverse reactions, and drug interactions.

DOSAGE FORMS AND STRENGTHS
Capsules: 40 mg, 80 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS

- Hepatotoxicity: Hepatic adverse reactions have occurred. Monitor ALT and AST prior to initiating, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity.
- Hypertension: Have occurred. Do not initiate in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity.
- QT interval prolongation: Can cause concentration-dependent QT interval prolongation. Monitor patients who are at significant risk of developing QTc prolongation. Assess QT interval, electrolytes and TSH at baseline and periodically during treatment. Monitor QT interval more frequently when concomitantly administered with drugs known to prolong QTc interval. Withhold and reduce dose or permanently discontinue based on severity.
- Hemorrhagic events: Hemorrhagic events can occur. Permanently discontinue in patients with severe or life-threatening hemorrhage.

WARNINGS AND PRECAUTIONS

- Hypersensitivity: If occurs, withhold and initiate corticosteroids. Upon resolution, resume at a reduced dose and increase dose by 1 dose level each week until reaching the dose taken prior to onset of hypersensitivity. Continue steroids until patient reaches target dose and then taper.
- Risk of impaired wound healing: Impaired wound healing can occur in patients who receive drugs that inhibit the vascular endothelial growth factor (VEGF) signaling pathway. Therefore, Retevmo™ has the potential to adversely affect wound healing. Withhold for at least 7 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), increased glucose, decreased leukocytes, decreased albumin, decreased calcium, dry mouth, diarrhea, increased creatinine, increased alkaline phosphatase, hypertension, fatigue, edema, decreased platelets, increased total cholesterol, rash, decreased sodium, and constipation.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Retevmo™ (selpercatinib) Capsules, for oral use	Eli Lilly and Company	05/08/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Retevmo™ is indicated for the treatment of:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if appropriate)

DOSAGE AND ADMINISTRATION
The recommended dose is based on weight:

- <50 kg: 120 mg orally twice daily.
- ≥ 50 kg: 160 mg orally twice daily.

Dose adjustments recommended for severe hepatic impairment, adverse reactions, and drug interactions.

DOSAGE FORMS AND STRENGTHS
Capsules: 40 mg, 80 mg.

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS

- Acid-reducing agents: Concomitant use decreases selpercatinib plasma concentrations, which may reduce Retevmo™ anti-tumor activity. Avoid co-administration. If co-administration cannot be avoided, take Retevmo™ with food (with PPI) or modify its administration time (with H2 receptor antagonist or locally-acting antacid).
- Strong and moderate CYP3A inhibitors: Concomitant use increases selpercatinib plasma concentrations, which may increase the risk of Retevmo™ adverse reactions, including QTc interval prolongation. Avoid co-administration. If co-administration cannot be avoided, reduce the Retevmo™ dose.
- Strong and moderate CYP3A inducers: Concomitant use decreases selpercatinib plasma concentrations, which may reduce Retevmo™ anti-tumor activity. Avoid co-administration.
- CYP2C8 and CYP3A substrates: Retevmo™ is a moderate CYP2C8 inhibitor and a weak CYP3A inhibitor. Concomitant use with CYP2C8 and CYP3A substrates increases their plasma concentrations, which may increase the risk of adverse reactions related to these substrates. Avoid co-administration. If co-administration cannot be avoided, modify the substrate dosage as recommended in its product labeling.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Verify pregnancy status for females of reproductive potential prior to starting treatment.
- Females and males of reproductive potential: Advise patients of the potential risk to a fetus and to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness of established in pediatrics aged 12 years and older for MTC who require systemic therapy and for advanced RET fusion-positive thyroid cancer who require systemic therapy and are radioactive iodine-refractory (if appropriate). Safety and effectiveness have not been established in pediatrics for other indications.
- Geriatric use: No overall differences in the safety or effectiveness observed between these patients and younger patients.
- Renal impairment: No dose modification recommended for mild to moderate renal impairment. Recommended dose has not been established for severe renal impairment.
- Hepatic impairment: Reduce the dose for severe hepatic impairment. No dose modification recommended for mild or moderate hepatic impairment. Closely monitor patients with hepatic impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Qinlock™ (ripretinib) Tablets, for oral use	Deciphera Pharmaceuticals, Inc.	05/15/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Qinlock™ is indicated for treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

DOSAGE AND ADMINISTRATION
The recommended dose is 150 mg orally once daily.

Dose adjustments recommended for adverse reactions.

DOSAGE FORMS AND STRENGTHS
Tablets: 50 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Palmar-plantar erythrodysesthesia syndrome: Based on severity, withhold and resume at same or reduced dose.
- New primary cutaneous malignancies: Perform dermatologic evaluations when initiating and routinely during treatment.
- Hypertension: Do not initiate in patients with uncontrolled hypertension and monitor blood pressure during treatment. Based on severity, withhold and then resume at same or reduced dose or permanently discontinue.
- Cardiac dysfunction: Assess ejection fraction by echocardiogram or MUGA scan prior to initiating and during treatment, as clinically indicated. Permanently discontinue for Grade 3 or 4 left ventricular systolic dysfunction.

WARNINGS AND PRECAUTIONS
- Risk of impaired wound healing: Impaired wound healing complications can occur in patients who receive drugs that inhibit the vascular endothelial growth factor (VEGF) signaling pathway. Therefore, Qinlock™ has the potential to adversely affect wound healing. Withhold for at least 1 week prior to elective surgery. Do not administer for at least 2 weeks after major surgery and until adequate wound healing.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmarplantar erythrodysesthesia, vomiting, increased lipase, and decreased phosphate.

DRUG INTERACTIONS
- Strong CYP3A Inhibitors: Monitor more frequently for adverse reactions. (7.1) Strong CYP3A Inducers: Avoid concomitant use of strong CYP3A inducers

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Qinlock™ (ripretinib) Tablets, for oral use	Deciphera Pharmaceuticals, Inc.	05/15/2020

THERAPEUTIC CLASS
Antineoplastic agent; Kinase inhibitor

FDA-APPROVE INDICATION(S)
Qinlock™ is indicated for treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

DOSAGE AND ADMINISTRATION
The recommended dose is 150 mg orally once daily.

Dose adjustments recommended for adverse reactions.

DOSAGE FORMS AND STRENGTHS
Tablets: 50 mg.

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Verify pregnancy status for females of reproductive potential prior to starting treatment.
- Females and males of reproductive potential: Advise patients of the potential risk to a fetus and to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: Clinical studies did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger patients.
- Hepatic impairment: No dose adjustment recommended for mild hepatic impairment. Recommended dose has not been established for moderate or severe hepatic impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Phexxi™ (lactic acid, citric acid and potassium bitartrate) Vaginal Gel	Evofem, Inc.	05/22/2020

THERAPEUTIC CLASS
Contraceptive

FDA-APPROVE INDICATION(S)
Phexxi™ is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

Limitation of use: Not effective for the prevention of pregnancy when administered after intercourse.

DOSAGE AND ADMINISTRATION
The recommended dose is to administer one (1) pre-filled single-dose applicator of PHEXXI (5 grams) vaginally immediately before (or up to one hour before) each episode of vaginal intercourse.

DOSAGE FORMS AND STRENGTHS
Each pre-filled single-dose vaginal applicator delivers 5 grams of gel containing lactic acid (1.8%), citric acid (1%), and potassium bitartrate (0.4%).

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Cystitis and pyelonephritis: Avoid use in women with a history of recurrent urinary tract infection (UTI) or urinary tract abnormalities

ADVERSE REACTIONS
Most common adverse reactions: vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain.

USE IN SPECIFIC POPULATIONS
- Pediatric use: Safety and effectiveness established in females of reproductive potential. Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of before menarche is not indicated.

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Fensolvi™ (leuprolide acetate) Injection / **Tolmar Pharmaceuticals, Inc.**	Endocrine-metabolic agent; Gonadotropin releasing hormone (GnRH) agonist	Treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP)	05/01/2020	Fensolvi™ is a new injectable formulation of leuprolide acetate. Other injectable formulations of leuprolide acetate were already available in the market generically and as branded (Lupron Depot™, Lupron Depot-PED™ and Eligard™). • Generic leuprolide acetate and Eligard™ are approved for palliative treatment of advanced prostate cancer. • Lupron Depot™ and Lupron Depot-PED is approved for treatment of children with CPP. Orphan status: N/A
Darzalex Faspro™ (daratumumab and hyaluronidase-fihj) Injection / **Janssen Pharmaceuticals, Inc.**	Combination of a CD38-directed cytolytic antibody and an endoglycosidase	Treatment of adult patients with multiple myeloma (MM)	05/01/2020	Darzalex Faspro™ is a combination of a CD38-directed cytolytic antibody (daratumumab) and an endoglycosidase (hyaluronidase) for subcutaneous administration. Darzalex Faspro™ is specifically indicated for MM: • In combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant • In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory MM who have received at least one prior therapy • In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy • As monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent Prior to this approval, Darzalex™ (daratumumab) was available as an injection solution for intravenous (IV) use. IV administered Darzalex™ is approved for the same indications as Darzalex Faspro™ but it is also approved for two additional indications: • In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant • In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor Orphan status: Orphan

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Elyxyb™ (celecoxib) Oral Solution / **Dr. Reddy's Laboratories, Inc.**	Non-steroidal anti-inflammatory drug (NSAID)	Acute treatment of migraine with or without aura in adults	05/05/2020	Elyxyb™ is a new dosage form of celecoxib in oral solution. Celecoxib was already available in the market as oral capsules, generically and as branded (Celebrex™). Celecoxib oral capsules are indicated for the management of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Orphan status: N/A
Ferriprox™ (deferiprone) Tablets / **Apopharma Inc.**	Iron chelator	Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate	05/19/2020	A twice-a-day Ferriprox™ 1000 mg formulation has been approved. This new formulation eliminates the mid-day dose, potentially reducing the pill burden compared to 500 mg tablets. Orphan status: Orphan
Impeklo™ (clobetasol propionate) Lotion / **Mylan**	Corticosteroid	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, in patients 18 years of age or older	05/19/2020	Impeklo™ is a new lotion formulation of clobetasol propionate. Clobetasol propionate was already available in the market in various topical formulations generically and as branded. Other topical formulations of clobetasol are approved for the same indication Impeklo™. Orphan status: N/A
Kynmobi™ (apomorphine hydrochloride) Sublingual Film / **Sunovion Pharmaceuticals Inc.**	Antiparkinson; Dopamine agonist	Acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease	05/21/2020	Kynmobi™ is a new dosage form or apomorphine hydrochloride in sublingual film. Apomorphine hydrochloride was already available in the market as an injections solution for subcutaneous use under the brand Apokyn™. Apokyn™ is approved for the same indication as Kynmobi™ . Orphan status: N/A

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Vesicare LS™ (solifenacin succinate) Oral Suspension / **Astellas**	Genitourinary agent; Anti-muscarinic/Anti-cholinergic	Treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older	05/26/2020	Vesicare LS™ is a new dosage form of solifenacin in oral suspension. Solifenacin was already available in the market as an oral tablet (branded Vesicare™), which is indicated for the treatment of adults with overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Orphan status: N/A
Sirturo™ (bedaquiline) Tablets / **Janssen Research & Development, LLC**	Anti-infective agent; Antimycobacterial	Treatment of pulmonary multi-drug resistant tuberculosis	05/27/2020	A new pediatric formulation of Sirturo™ (bedaquiline) has been approved: 20 mg tablet. The new 20 mg tablet can be administered with water for patients who are able to swallow the intact tablet and taken with food. For patients who have difficulty swallowing intact tablets, the tablet can be dispersed in water and administered. To aid with administration, the dispersed mixture in water can be further mixed with a beverage or soft food. Alternatively, the tablet can be crushed and mixed with soft food immediately prior to use and administered. Sirturo™ (bedaquiline) was already available in the market as a 100 mg tablet. Orphan status: N/A
Zilxi™ (minocycline) Topical Foam / **Foamix Pharmaceuticals Ltd**	Dermatological agent; Tetracycline	Treatment of inflammatory lesions of rosacea in adults	05/28/2020	Zilxi™ is a new formulation of minocycline in topical foam. Of note, this formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Zilxi™ should be used only as indicated. Topical minocycline was already available in the market as a 4% topical foam (Amzeeq™) for the treatment of moderate to severe acne vulgaris. Orphan status: N/A

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Oriahnn™ (elagolix/estradiol/norethindrone acetate and elagolix) Capsules / **AbbVie Inc.**	Endocrine and metabolic agent	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	05/28/2020	Oriahnn™ is a new combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin. Elagolix is also available as a single-ingredient product (Orilissa™) for the management of moderate to severe pain associated with endometriosis. Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Reblozyl™ (luspatercept-aamt) Injection / Celgene Corporation	Blood modifier agent; Erythroid maturation agent (EMA)	Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions	Treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)	04/03/2020
Farxiga™ (dapagliflozin) Tablets / AstraZeneca	Antidiabetic; Sodium-glucose cotransporter 2 (SGLT2) inhibitor	Treatment of type 2 diabetes mellitus: • as an adjunct to diet and exercise to improve glycemic control in adults • to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors	Treatment of heart failure: • to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV)	05/05/2020
Lynparza™ (olaparib) Tablets / AstraZeneca	Antineoplastic agent; Poly ADP ribose polymerase (PARP) inhibitor	Treatment of ovarian cancer, breast cancer, and pancreatic cancer	• In combination with bevacizumab as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability • Treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)	05/08/2020; 05/19/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Pomalyst™ (pomalidomide) Capsules / Bristol-Myers Squibb Company	Antineoplastic agent; Thalidomide analogue	Treatment of multiple myeloma	Treatment of AIDS-related and HIV-negative Kaposi sarcoma	05/14/2020
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer (NSCLC), advanced small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma	In combination with Yervoy™ (ipilimumab), for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations	05/15/2020
Rubraca™ (rucaparib) Tablets / Clovis Oncology, Inc.	Antineoplastic agent; Poly (ADP-ribose) polymerase (PARP) inhibitor	Treatment of ovarian cancer	Treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy	05/15/2020
Tecentriq™ (atezolizumab) Injection / Genentech, Inc.	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), and small cell lung cancer (SCLC)	• First-line (initial) treatment for adults with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations • In combination with bevacizumab (Avastin™) for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy	05/18/2020; 05/29/2020

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Alunbrig™ (brigatinib) Tablets / Takeda Pharmaceutical Company Limited	Antineoplastic agent; Anaplastic lymphoma kinase (ALK) inhibitor	Treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test, who have progressed on or are intolerant to crizotinib	First-line treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test	05/22/2020
Dupixent™ (dupilumab) Injection / Sanofi and Regeneron Pharmaceuticals, Inc.	Interleukin-4 receptor alpha antagonist	• Treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable • Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitation of Use: Not for the relief of acute bronchospasm or status asthmaticus • Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)	Patient population altered: To included children aged 6 to 11 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	05/26/2020
Brilinta™ (ticagrelor) Tablets / AstraZeneca	Platelet aggregation inhibitor; P2Y12 platelet inhibitor	To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel • Brilinta™ also reduces the risk of stent thrombosis in patients who have been stented for treatment of ACS	To reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes mellitus (T2DM)	05/28/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Date	Generic for:
Ivermectin Lotion 0.5% / Taro Pharmaceuticals U.S.A., Inc.	Anti-infective agent; Anthelmintic	05/06/2020	Sklice
Desonide Topical Gel 0.05% / Teresina Holdings LLC	Dermatological agent; Corticosteroid	05/11/2020	Desonate Gel
Calcipotriene and Betamethasone Dipropionate Topical Suspension 0.005% / 0.064% / Tolmar Pharmaceuticals Inc.	Dermatological agent; Corticosteroid and Vitamin D	05/11/2020	Taclonex Scalp
Posaconazole Oral Suspension 40mg/ mL / Hikma Pharmaceuticals USA Inc.	Anti-infective agent; Antifungal	05/15/2020	Noxafil Oral Suspension
Icosapent Ethyl Capsules 1 gm / Hikma Pharmaceuticals USA Inc.	Antihyperlipidemic	05/21/2020	Vascepa

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
CC-486 (azacitidine) / Bristol Myers Squibb	05/01/2020	Treatment for: Acute Myeloid Leukemia	CC-486 (azacitidine) is an investigational oral hypomethylating agent in development for the maintenance treatment of adult patients in remission with acute myeloid leukemia. FDA has accepted the NDA for CC-486.	High
Eysuvis (loteprednol etabonate) / Kala Pharmaceuticals, Inc.	05/04/2020	Treatment for: Dry Eye Disease	Eysuvis (loteprednol etabonate) is an ophthalmic corticosteroid formulation in development for the temporary relief of signs and symptoms of dry eye disease. NDA re-submitted.	Moderate
Setmelanotide / Rhythm Pharmaceuticals, Inc.	05/13/2020	Treatment for: Obesity	Setmelanotide is an investigational, melanocortin-4 receptor (MC4R) agonist in development for the treatment of pro-opiomelanocortin (POMC) deficiency obesity and leptin receptor (LEPR) deficiency obesity. FDA has accepted the NDA for setmelanotide. FDA have granted orphan drug status to setmelanotide.	High High
Sutimlimab / Sanofi	05/14/2020	Treatment for: Cold Agglutinin Disease (CAD)	Sutimlimab is a first-in-class selective inhibitor of complement C1s in development for the treatment of hemolysis in adult patients with cold agglutinin disease (CAD). BLA submitted. FDA have granted orphan drug status to sutimlimab.	High High
Zokinvy (lonafarnib) / Eiger BioPharmaceuticals, Inc.	05/19/2020	Treatment for: Progeria and Progeroid Laminopathies	Zokinvy (lonafarnib) is an oral farnesyltransferase inhibitor (FTI) in development for the treatment of Progeria and Progeroid Laminopathies. FDA has accepted the NDA for Zokinvy (lonafarnib). FDA have granted orphan drug status to Zokinvy (lonafarnib).	High High

PIPELINE

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Zimhi (naloxone hydrochloride) Injection / Adamis Pharmaceuticals Corporation	05/20/2020	Treatment for: Opioid Overdose	Zimhi (naloxone hydrochloride) is a high-dose formulation of the approved opioid antagonist naloxone in development for the treatment of opioid overdose. NDA re-submitted.	Moderate
Dasiglucagon / Zealand Pharma A/S	05/22/2020	Treatment for: Hypoglycemia	Dasiglucagon is a glucagon analog in development for the treatment of severe hypoglycemia. FDA has accepted the NDA for dasiglucagon.	Moderate

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)