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PharmNOTES

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

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NEWS

Drug issue	Date	Details
FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems	04/30/2020	The FDA is highlighting cautions against the use of hydroxychloroquine and chloroquine outside of the hospital setting or a clinical trial due to the risk of serious heart rhythm problems. To decrease the risk of these heart problems that can be life-threatening, the FDA is warning that hydroxychloroquine and chloroquine, either alone or combined with azithromycin, when used for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the emergency use authorization (EUA) issued by the agency on March 28, 2020. The FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19, and will communicate publicly when we have more information. For additional information, visit the FDA's Drug Safety Communications portal.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Sevenfact™ (coagulation factor VIIa (recombinant)-jncw) Injection, for intravenous use	HEMA Biologics, LLC	04/01/2020

THERAPEUTIC CLASS
Hematologic agent

FDA-APPROVE INDICATION(S)
Sevenfact™ is a coagulation factor VIIa concentrate indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors.

Limitation of use: Not indicated for treatment of congenital factor VII deficiency.

DOSAGE AND ADMINISTRATION
Sevenfact™ is for intravenous (IV) use after reconstitution only. The starting dose should be adjusted based on the type of bleeding and patient's weight (kg). Refer to full prescribing information for details.

DOSAGE FORMS AND STRENGTHS
Lyophilized powder in single-use vials containing 1 or 5 mg of coagulation factor VIIa (recombinant)-jncw; After reconstitution with a specified volume of Sterile Water for Injection, each mL contains 1 mg (1000 mcg) of coagulation factor VIIa (recombinant)-jncw.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Known allergy to rabbits or rabbit proteins.
- Severe hypersensitivity reaction to Sevenfact or any of its components.

WARNINGS AND PRECAUTIONS
- Hypersensitivity reactions: None have been reported, but are possible; Should symptoms occur, patients should discontinue treatment and seek appropriate medical intervention.
- Neutralizing antibodies: No patients tested positive for neutralizing antibodies, but may occur. If treatment with does not result in adequate hemostasis, then suspect development of neutralizing antibody as the possible cause and perform testing as clinically indicated.

ADVERSE REACTIONS
Most common adverse reactions: Headache, dizziness, infusion-site discomfort, infusion-site hematoma, infusion-related reaction and fever.

DRUG INTERACTIONS
- Clinical experience with pharmacologic use of FVIIa-containing products indicates an elevated risk of serious thrombotic events when used simultaneously with activated prothrombin complex concentrates.

USE IN SPECIFIC POPULATIONS
- Geriatric use: Safety and effectiveness in patients >65 years of age have not been evaluated in clinical trials. The presence of age-related comorbidities and the attendant risks associated with thrombotic and thromboembolic events should be considered when administering to patients older than 50 years of age.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Koselugo™ (selumetinib) Capsules, for oral use	AstraZeneca and Merck	04/10/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Koselugo™ is a kinase inhibitor indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

DOSAGE AND ADMINISTRATION
The recommended dose is 25 mg/m2 taken orally twice daily (see table 1), until disease progression or unacceptable toxicity. Must be taken on an empty stomach (no food 2 hours before each dose or 1 hour after each dose).

DOSAGE FORMS AND STRENGTHS
Capsules: 10 mg and 25 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Cardiomyopathy (decrease in left ventricular ejection fraction (LVEF) ≥ 10% below baseline): Assess EF prior to initiating treatment, every 3 months during the first year, then every 6 months thereafter, and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.
- Ocular toxicity: Conduct ophthalmic assessments prior to initiating, at regular intervals during treatment, and for new or worsening visual changes. Permanently discontinue for retinal vein occlusion (RVO). Withhold for retinal pigment epithelial detachment (RPED), monitor with optical coherence tomography assessments until resolution, and resume at reduced dose.
- Gastrointestinal toxicity: Advise patients to start an anti-diarrheal agent immediately after the first episode of loose stool and to increase fluid intake. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.

WARNINGS AND PRECAUTIONS (continuation)
- Cardiomyopathy (decrease in left ventricular ejection fraction (LVEF) ≥ 10% below baseline): Assess EF prior to initiating treatment, every 3 months during the first year, then every 6 months thereafter, and as clinically indicated. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.
- Ocular toxicity: Conduct ophthalmic assessments prior to initiating, at regular intervals during treatment, and for new or worsening visual changes. Permanently discontinue for retinal vein occlusion (RVO). Withhold for retinal pigment epithelial detachment (RPED), monitor with optical coherence tomography assessments until resolution, and resume at reduced dose.
- Gastrointestinal toxicity: Advise patients to start an anti-diarrheal agent immediately after the first episode of loose stool and to increase fluid intake. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.
- Skin toxicity: Monitor for severe skin rashes. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Koselugo™ (selumetinib) Capsules, for oral use	AstraZeneca and Merck	04/10/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Koselugo™ is a kinase inhibitor indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

DOSAGE AND ADMINISTRATION
The recommended dose is 25 mg/m2 taken orally twice daily (see table 1), until disease progression or unacceptable toxicity. Must be taken on an empty stomach (no food 2 hours before each dose or 1 hour after each dose).

DOSAGE FORMS AND STRENGTHS
Capsules: 10 mg and 25 mg.

Orphan status: Orphan

SAFETY PROFILE (continuation)

WARNINGS AND PRECAUTIONS (continuation)

- Increased creatinine phosphokinase (CPK): Increased CPK and rhabdomyolysis can occur. Obtain serum CPK prior to initiating, periodically during treatment, and as clinically indicated. If increased CPK occurs, evaluate for rhabdomyolysis or other causes. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.
- Increased vitamin E levels and risk of bleeding: The capsules contain vitamin E and daily intake of vitamin E that exceeds the recommended or safe limits may increase the risk of bleeding. An increased risk of bleeding may occur in patients co-administered vitamin K antagonists or anti-platelet agents.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: Vomiting, rash, abdominal pain, diarrhea, nausea, dry skin, fatigue, musculoskeletal pain, pyrexia, acneiform rash, stomatitis, headache, paronychia, and pruritus.

DRUG INTERACTIONS

- Strong or moderate CYP3A4 inhibitors or fluconazole: Avoid co-administration. If co-administration cannot be avoided, reduce the dose of Koselugo™ .

DRUG INTERACTIONS (continuation)

- Strong or moderate CYP3A4 inducers: Avoid concomitant use of strong and moderate CYP3A4 inducers.
- Vitamin E: Koselugo™ contains vitamin E and daily vitamin E intake that exceeds the recommended or safe limits may increase the risk of bleeding.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females of reproductive potential prior to initiating.
- Pediatric use: The safety and effectiveness have not been established in pediatric patients younger than 2 years of age.
- Geriatric use: Clinical studies did not include patients 65 years of age and older.
- Hepatic impairment: Selumetinib exposures increased in patients with moderate or severe hepatic impairment. Dose must be reduced for moderate hepatic impairment. Dose for severe hepatic impairment has not been established.
- Renal impairment: No dose adjustment recommended for renal impairment or those with End Stage Renal Disease.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Pemazyre™ (pemigatinib) Tablets, for oral use	Incyte Corporation	04/17/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Pemazyre™ is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose is 13.5 mg orally once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles. Treatment is to be continued until disease progression or unacceptable toxicity occurs.

The presence of an FGFR2 fusion or rearrangement must be confirmed prior to initiation.

DOSAGE FORMS AND STRENGTHS
Tablets: 4.5 mg, 9 mg, and 13.5 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Ocular toxicity: Can cause retinal pigment epithelial detachment. Perform ophthalmological examination including optical coherence tomography (OCT) prior to initiation, every 2 months for the first 6 months of treatment and every 3 months thereafter, and urgently at any time for visual symptoms.
- Hyperphosphatemia: Increases in phosphate levels are a pharmacodynamic effect of Pemazyre™. Monitor and withhold, reduce the dose, or permanently discontinue based on duration and severity of hyperphosphatemia.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: Hyperphosphatemia, alopecia, diarrhea, nail toxicity, fatigue, dysgeusia, nausea, constipation, stomatitis, dry eye, dry mouth, decreased appetite, vomiting, arthralgia, abdominal pain, hypophosphatemia, back pain, and dry skin.

DRUG INTERACTIONS
- Strong and moderate CYP3A inducers: Avoid concomitant use.

DRUG INTERACTIONS (continuation)
- Strong and moderate CYP3A inhibitors: Reduce the dose of Pemazyre™, if concomitant use cannot be avoided.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify pregnancy status of females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise patients of reproductive potential of the potential risk to the fetus and use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety or effectiveness were observed between these patients and younger patients.
- Renal impairment: No dose adjustment recommended for mild or moderate renal impairment. Recommended dose has not been established for severe renal impairment.
- Hepatic impairment: No dose adjustment is recommended for mild or moderate hepatic impairment. Recommended dose has not been established for patients with severe hepatic impairment.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tukysa™ (tucatinib) Tablets, for oral use	Seattle Genetics, Inc.	04/17/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Tukysa™ is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

DOSAGE AND ADMINISTRATION
The recommended dose is 300 mg taken orally twice daily.

Dose adjustment is recommended for severe hepatic impairment.

DOSAGE FORMS AND STRENGTHS
Tablets: 50 mg and 150 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Diarrhea: Severe diarrhea, including dehydration, acute kidney injury, and death, has been reported. Administer antidiarrheal treatment as clinically indicated. Interrupt dose, then dose reduce, or permanently discontinue based on severity.
- Hepatotoxicity: Severe hepatotoxicity has been reported. Monitor ALT, AST and bilirubin prior to initiation, every 3 weeks during treatment and as clinically indicated. Interrupt dose, then dose reduce, or permanently discontinue based on severity.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: Diarrhea, palmar-plantar erythrodysesthesia, nausea, fatigue, hepatotoxicity, vomiting, stomatitis, decreased appetite, abdominal pain, headache, anemia, and rash.

DRUG INTERACTIONS
- Strong CYP3A inducers or moderate CYP2C8 inducers: Avoid concomitant use.

DRUG INTERACTIONS (continuation)
- Strong CYP2C8 inhibitors: Avoid concomitant use; reduce Tukysa™ dose if concomitant use cannot be avoided.
- CYP3A substrates: Avoid concomitant use, where minimal concentration changes may lead to serious or life-threatening toxicities.
- P-gp substrates: Consider reducing the dose of P-gp substrates, where minimal concentration changes may lead to serious or life-threatening toxicities.

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 patients of 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: Higher incidence of adverse reactions was observed in patients ≥ 65 years. No overall differences in the effectiveness were in patients ≥ 65 years compared to younger patients.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Tukysa™ (tucatinib) Tablets, for oral use	Seattle Genetics, Inc.	04/17/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Tukysa™ is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

DOSAGE AND ADMINISTRATION
The recommended dose is 300 mg taken orally twice daily.

Dose adjustment is recommended for severe hepatic impairment.

DOSAGE FORMS AND STRENGTHS
Tablets: 50 mg and 150 mg.

Orphan status: Orphan

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Renal impairment: The use of Tukysa™ in combination with capecitabine and trastuzumab is not recommended in patients with severe renal impairment, because capecitabine is contraindicated in patients with severe renal impairment. No dose adjustment is recommended for patients with mild or moderate renal impairment.
- Hepatic impairment: Tucatinib exposure is increased in patients with severe hepatic impairment. Reduce the dose of Tukysa™ for patients with severe (Child-Pugh C) hepatic impairment. No dose adjustment is required for patients with mild or moderate hepatic impairment.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Trodelvy™ (sacituzumab govitecan-hziy) Injection, for intravenous use	Immunomedics, Inc.	04/22/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Trodelvy™ is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adults with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

DOSAGE AND ADMINISTRATION
The recommended dose is 10 mg/kg administered by intravenous (IV) infusion once weekly on Days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity. Pre-medication is required.

Not to be substituted for or use with other drugs containing irinotecan or its active metabolite SN-38.

DOSAGE FORMS AND STRENGTHS
For injection: 180 mg lyophilized powder in single-dose vials for reconstitution.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Severe hypersensitivity reaction to Trodelvy™.

WARNINGS AND PRECAUTIONS
- Boxed warning: Neutropenia and diarrhea – (1) Severe neutropenia may occur. Withhold for absolute neutrophil count below 1500/mm3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay. (2) Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold until resolved to <Grade 1 and reduce subsequent doses.
- Hypersensitivity: Have been observed. Monitor patients for infusion-related reactions. Permanently discontinue if severe or life-threatening reactions occur.
- Nausea/Vomiting: Use antiemetic preventive treatment and withhold treatment for patients with Grade 3 nausea or Grade 3-4 vomiting at the time of scheduled treatment.

WARNINGS AND PRECAUTIONS (continuation)
- Patients with reduced UGT1A1 activity: Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia following initiation of treatment.
- Embryo-fetal toxicity: Can cause fetal harm.

ADVERSE REACTIONS
Most common adverse reactions: Nausea, neutropenia, diarrhea, fatigue, anemia, vomiting, alopecia, constipation, rash, decreased appetite, and abdominal pain.

DRUG INTERACTIONS
- UGT1A1 inhibitors or inducers: Avoid concomitant use.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify the pregnancy status of females of reproductive potential prior to the initiation.
- Females and males of reproductive potential: Advise patients of potential risk to a fetus and to use effective contraception.
- Lactation: Advise not to breastfeed.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Trodelvy™ (sacituzumab govitecan-hziy) Injection, for intravenous use	Immunomedics, Inc.	04/22/2020

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
Trodelvy™ is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adults with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

DOSAGE AND ADMINISTRATION
The recommended dose is 10 mg/kg administered by intravenous (IV) infusion once weekly on Days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity. Pre-medication is required.

Not to be substituted for or use with other drugs containing irinotecan or its active metabolite SN-38.

DOSAGE FORMS AND STRENGTHS
For injection: 180 mg lyophilized powder in single-dose vials for reconstitution.

Orphan status: N/A

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS (continuation)

- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in safety and effectiveness were observed between these patients and younger patients.
- Hepatic impairment: No adjustment to the starting dose is required for mild hepatic impairment. The safety of Trodelvy™ in moderate or severe hepatic impairment has not been established. No recommendations can be made for the starting dose in these patients.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
MenQuadfi™ (meningococcal (groups A, C, Y, W) conjugate vaccine) Injection, for intramuscular use	Safoni	04/23/2020

THERAPEUTIC CLASS
Vaccine

FDA-APPROVE INDICATION(S)
MenQuadfi™ is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. MenQuadfi™ vaccine is approved for use in individuals 2 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended dose is 0.5 mL dose for intramuscular injection.

- Primary Vaccination: Individuals 2 years of age and older - a single dose.
- Booster Vaccination: A single dose may be administered to individuals ≥15 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (Groups A, C, W, Y) conjugate vaccine.

DOSAGE FORMS AND STRENGTHS
Solution for injection in 0.5 mL single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS

- Severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi™ or any other tetanus toxoid-containing vaccine.

WARNINGS AND PRECAUTIONS

- Altered immunocompetence: Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi™. Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by N. meningitidis, including invasive disease caused by serogroups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi™.
- Syncope: Can occur. Procedures should be in place to prevent falling and injury and to manage syncope.
- Guillain-Barré Syndrome (GBS): Has been reported.
- Tetanus immunization: Immunization with MenQuadfi™ does not substitute for routine tetanus immunization.
- Limitations of vaccine effectiveness: Vaccination with MenQuadfi™ may not protect all vaccine recipients.

ADVERSE REACTIONS
Most common adverse reactions:

- 2-9 years of age: pain, erythema, and swelling at the injection site; malaise, myalgia, and headache.
- 10-17 years of age: injection site pain, myalgia, headache, and malaise.
- 18- 55 years of age: injection site pain, myalgia, headache, and malaise.
- ≥56 years of age: pain at the injection site, myalgia, headache, and malaise.

DRUG INTERACTIONS

- Other vaccines: Lower geometric mean antibody concentrations (GMCs) for antibodies to the pertussis antigens filamentous hemagglutinin (FHA), pertactin (PRN) and fimbriae (FIM) were observed when MenQuadfi™ was co-administered with Tdap and HPV, compared to concomitant administration of Tdap and HPV (without MenQuadfi™).
- Immunosuppressive treatments: Immunosuppressive therapies may reduce the immune response to MenQuadfi™.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
MenQuadfi™ (meningococcal (groups A, C, Y, W) conjugate vaccine) Injection, for intramuscular use	Safoni	04/23/2020

THERAPEUTIC CLASS
Vaccine

FDA-APPROVE INDICATION(S)
MenQuadfi™ is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. MenQuadfi™ vaccine is approved for use in individuals 2 years of age and older.

DOSAGE AND ADMINISTRATION
The recommended dose is 0.5 mL dose for intramuscular injection.

- Primary Vaccination: Individuals 2 years of age and older - a single dose.
- Booster Vaccination: A single dose may be administered to individuals ≥15 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (Groups A, C, W, Y) conjugate vaccine.

DOSAGE FORMS AND STRENGTHS
Solution for injection in 0.5 mL single-dose vial.

Orphan status: N/A

SAFETY PROFILE (continuation)

USE IN SPECIFIC POPULATIONS

- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to MenQuadfi™ during pregnancy.
- Pediatric use: Safety and effectiveness have not been established in individuals younger than 2 years of age.

(continuation)

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Ongentys™ (opicapone) Capsules, for oral use	Neurocrine Biosciences, Inc.	04/24/2020

THERAPEUTIC CLASS
Antiparkinsonian

FDA-APPROVE INDICATION(S)
Ongentys™ is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSAGE AND ADMINISTRATION
The recommended dose is 50 mg administered orally once daily at bedtime.

Dose adjustment is recommended for moderate hepatic impairment.

DOSAGE FORMS AND STRENGTHS
Capsules: 25 mg and 50 mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- Concomitant use of non-selective monoamine oxidase (MAO) inhibitors.
- History of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.

WARNINGS AND PRECAUTIONS
- Cardiovascular effects with concomitant use of drugs metabolized by COMT: May cause arrhythmias, increased heart rate, and excessive changes in blood pressure. Monitor patients when treated concomitantly with products metabolized by COMT.
- Falling asleep during activities of daily living: Advise patients prior to treatment.
- Hypotension/Syncope: If occurs, consider discontinuing or adjusting dosage of other medications that can lower blood pressure.
- Dyskinesia: May cause or exacerbate dyskinesia; consider levodopa or dopaminergic medication dose reduction.
- Hallucinations and psychosis: Consider stopping treatment if occurs.
- Impulse control/Compulsive disorders: Consider stopping treatment if occurs.

WARNINGS AND PRECAUTIONS (continuation)
- Withdrawal-emergent hyperpyrexia and confusion: When discontinuing ONGENTYS, monitor patients and consider adjustment of other dopaminergic therapies as needed.

ADVERSE REACTIONS
Most common adverse reactions: dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased.

DRUG INTERACTIONS
- Non-selective MAO inhibitors: Concomitant use may increase the risk of possible arrhythmias, increased heart rate, and excessive changes in blood pressure. Concomitant use with non-selective MAO inhibitors is contraindicated. Selective MAO-B inhibitors can be used concomitantly.

New FDA Approved Products

DRUG NAME	MANUFACTURER	APPROVAL DATE
Ongentys™ (opicapone) Capsules, for oral use	Neurocrine Biosciences, Inc.	04/24/2020

THERAPEUTIC CLASS
Antiparkinsonian

FDA-APPROVE INDICATION(S)
Ongentys™ is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSAGE AND ADMINISTRATION
The recommended dose is 50 mg administered orally once daily at bedtime.

Dose adjustment is recommended for moderate hepatic impairment.

DOSAGE FORMS AND STRENGTHS
Capsules: 25 mg and 50 mg.

Orphan status: N/A

SAFETY PROFILE (continuation)

DRUG INTERACTIONS (continuation)

- Effect on other drugs: Concomitant use with drugs metabolized by COMT may affect the pharmacokinetics of those drugs, which may increase the risk of possible arrhythmias, increased heart rate, and excessive changes in blood pressure. Drugs known to be metabolized by COMT should be administered with caution. Monitor for changes in heart rate, rhythm, and blood pressure in patients concomitantly using drugs metabolized by COMT.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Pediatric use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric use: No overall differences in safety and effectiveness were observed between these patients and younger patients, but greater sensitivity to adverse reactions of some older individuals cannot be ruled out.
- Renal impairment: Avoid use in patients with end-stage renal disease.

USE IN SPECIFIC POPULATIONS (continuation)

- Hepatic impairment: Opicapone exposure is increased in patients with hepatic impairment. Avoid use in patients with severe hepatic impairment. Dose adjustment is recommended for patients with moderate hepatic impairment. No dose adjustment is required in patients with mild hepatic impairment.

(continuation)

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

Drug name / Manufacturer	Therapeutic class	Indication(s)	Date	Comments
Jelmyto™ (mitomycin) Pyelocalyceal Solution / **UroGen Pharma Ltd.**	Antineoplastic agent	Non-surgical treatment of patients with low-grade upper tract urothelial cancer (LG-UTUC)	04/15/2020	Jelmyto™ is a new formulation of mitomycin for pyelocalyceal use. Of note, has been approved for an indication different from the indications of other mitomycin-containing products that were already available in the market. Mitomycin was already available in the market as an intravenous (IV) powder for solution (generic and branded [Mutamycin]), and as an ophthalmic powder for solution (branded [Mitosol]. The IV formulation is indicated for the treatment of gastric cancer and pancreatic cancer. The ophthalmic formulation is indicated as an adjunct to ab externo glaucoma surgery. Orphan status: Orphan
Emerphed™ (ephedrine sulfate) Injection / **Nexus Pharmaceuticals, Inc.**	Adrenergic	Treatment of clinically important hypotension occurring in the setting of anesthesia	04/17/2020	Emerphed™ is a new formulation of ephedrine sulfate for intravenous use in the setting of anesthesia. Orphan status: N/A
Milprosa™ (progesterone) Vaginal System / **Ferring Pharmaceuticals, Inc.**	Progesterone	To support embryo implantation and early pregnancy (up to 10 weeks post-embryo transfer) by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women	04/29/2020	Milprosa™ is a new dosage form of progesterone. Orphan status: N/A

New FDA Approved Indications

Drug name / Manufacturer	Therapeutic class	Previous indication(s)	New indication(s)	Date
Braftovi™ (encorafenib) Capsules / Pfizer Inc.	Antineoplastic agent	In combination with binimetinib (Mektovi™), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	In combination with cetuximab (Erbitux™) for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy	04/08/2020
Imbruvica™ (ibrutinib) Capsules and Tablets / AbbVie Inc.	Antineoplastic agent	Mantle cell lymphoma (MCL); Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL); Waldenström's macroglobulinemia (WM); Marginal zone lymphoma (MZL); Chronic graft versus host disease (cGVHD)	In combination with rituximab for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	04/21/2020
Jublia™ (efinaconazole) Topical Solution / Bausch Health Companies Inc.	Antifungal	Treatment of onychomycosis of the toenails	Patient population altered: To include children 6 years of age and older	04/26/2020
Zejula™ (niraparib) Capsules / GlaxoSmithKline	Antineoplastic agent	Treatment of patients with ovarian, fallopian tube, or primary peritoneal cancer	First-line monotherapy maintenance treatment for women with platinum-responsive advanced ovarian cancer regardless of biomarker status	04/29/2020

New First Time Generic Drug Approval

Drug name / Manufacturer	Therapeutic Class	Date	Generic for:
Albuterol Sulfate Metered Inhalation Aerosol 0.09mg base/inhalation / Cipla USA Inc.	Antiasthma	04/08/2020	Proventil HFA
Clocortolone Pivalate Cream 0.1% / Taro Pharmaceuticals U.S.A., Inc.	Dermatologic agent	04/22/2020	Cloderm

PIPELINE .....

Drug name / Manufacturer	Date	Indication(s)	Comments	Impact
Naxitamab / Y-mAbs Therapeutics, Inc.	04/01/2020	Treatment for: Neuroblastoma	Naxitamab is an anti-GD2 monoclonal antibody in development for the treatment of patients with relapsed/refractory high-risk neuroblastoma. BLA submitted to the FDA.	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)