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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **SEPTEMBER 2021**

urac ACCREDITED
Pharmacy Benefit Management
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NEWS

DRUG ISSUE	DATE	DETAILS
FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for Janus kinase (JAK) inhibitors that treat certain chronic inflammatory conditions	09/01/2021	The FDA is requiring revisions to the Boxed Warning for Xeljanz™/Xeljanz XR™, Olumiant™ and Rinvoq™ to include information about the risks of serious heart-related events, cancer, blood clots, and death. In a completed FDA review of a large randomized safety clinical trial, the results showed an increased risk of blood clots and death with the lower dose of Xeljanz™. Furthermore, to ensure the benefits of these drugs outweigh the risks in patients who receive them, the FDA is limiting all approved uses to certain patients who have not responded or cannot tolerate one or more TNF blockers. Of note, the other two JAK inhibitors, Jakafi™ and Inrebic™, are not indicated for the treatment of arthritis and other inflammatory conditions, therefore, they are not part of the updates being required to the prescribing information for Xeljanz™, Xeljanz XR™, Olumiant™ and Rinvoq™.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
EXKIVITY™ (MOBOCERTINIB) CAPSULES	TAKEDA PHARMACEUTICAL COMPANY LIMITED	09/15/2021

THERAPEUTIC CLASS
Antineoplastic agents

FDA-APPROVED INDICATION(S)
EXKIVITY™ is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dosage is 160mg orally once daily, with or without food.

DOSAGE FORMS AND STRENGTHS
Capsules: 40mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Boxed Warning: QTc prolongation and *torsades de pointes*
  - Avoid use of concomitant drugs which are known to prolong the QTc interval and use of strong or moderate CYP3A4 inhibitors with EXKIVITY™. Withhold, reduce the dose, or permanently discontinue EXKIVITY™ based on the severity of QTc prolongation.
- Interstitial Lung Disease (ILD)/Pneumonitis: Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold EXKIVITY™ in patients with suspected ILD/pneumonitis and permanently discontinue EXKIVITY™ if ILD/pneumonitis is confirmed.
- Cardiac Toxicity: Monitor cardiac function, including left ventricular ejection fraction, at baseline and during treatment. Withhold, resume at reduced dose or permanently discontinue based on severity.
- Diarrhea: Diarrhea may lead to dehydration or electrolyte imbalance with or without renal impairment. Monitor electrolytes and advise patients to start an antidiarrheal agent at first episode of diarrhea and to increase fluid and electrolyte intake. Withhold, reduce the dose, or permanently discontinue EXKIVITY™ based on the severity.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective non-hormonal contraception.

ADVERSE REACTIONS
- The most common (>20%) adverse reactions are diarrhea, rash, nausea, stomatitis, vomiting, decreased appetite, paronychia, fatigue, dry skin, and musculoskeletal pain.
- The most common (≥2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes, increased amylase, increased lipase, decreased potassium, decreased hemoglobin, increased creatinine, and decreased magnesium.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

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DOSAGE FORMS AND STRENGTHS
Capsules: 40mg

Orphan status: Orphan

SAFETY PROFILE

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid concomitant use of EXKIVITY™ with strong or moderate CYP3A4 inhibitors. If concomitant use of a moderate CYP3A4 inhibitor is unavoidable, reduce the dose of EXKIVITY™.
- CYP3A4 Inducers: Avoid concomitant use of EXKIVITY™ with strong or moderate CYP3A4 inducers.

USE IN SPECIFIC POPUPLATIONS

- Pregnancy: Based on findings from animal studies and its mechanism of action, EXKIVITY™ can cause fetal harm when administered to a pregnant woman.
- Females and Males of Reproductive Potential: Verify pregnancy status in females of reproductive potential prior to initiating EXKIVITY™. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with EXKIVITY™ and for 1 month after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with EXKIVITY™ and for 1 week after the last dose.
- Lactation: Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with EXKIVITY™ and for 1 week after the last dose.
- Pediatric Use: The safety and effectiveness of EXKIVITY™ in pediatric patients have not been established.
- Geriatric Use: Exploratory analysis suggests a higher incidence of Grade 3 and 4 adverse reactions (69% vs 47%) and serious adverse reactions (64% vs 35%) in patients 65 years and older as compared to those younger than 65 years.
- Hepatic Impairment: No dosage adjustment of EXKIVITY™ is recommended for patients with mild or moderate hepatic impairment. The recommended dosage of EXKIVITY™ has not been established for patients with severe hepatic impairment.
- Renal Impairment: No dosage adjustment of EXKIVITY™ is recommended for patients with mild to moderate renal. The recommended dosage of EXKIVITY™ has not been established for patients with severe renal impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TIVDAK™ (TISOTUMAB VEDOTIN-TFTV) FOR INJECTION	SEAGEN INC.	09/20/2021

THERAPEUTIC CLASS
Antineoplastic agents

FDA-APPROVED INDICATION(S)
TIVDAK™ is a tissue factor-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

DOSAGE AND ADMINISTRATION
The recommended dose is 2mg/kg (up to maximum of 200mg) given as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
For injection: 40mg as a lyophilized powder in a single-dose vial for reconstitution.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNINGS AND PRECAUTIONS
- Boxed Warning: Ocular toxicity
  - TIVDAK™ caused changes in the corneal epithelium and conjunctiva resulting in changes in vision, including severe vision loss, and corneal ulceration.
  - Conduct an ophthalmic exam at baseline, prior to each dose, and as clinically indicated.
  - Adhere to premedication and required eye care before, during, and after infusion.
  - Withhold TIVDAK™ until improvement and resume, reduce the dose, or permanently discontinue, based on severity.
- Peripheral Neuropathy: Monitor patients for a new or worsening peripheral neuropathy. Withhold, reduce the dose, or permanently discontinue TIVDAK™ based on severity.
- Hemorrhage: Monitor patients for signs and symptoms of hemorrhage. Withhold, reduce the dose, or permanently discontinue TIVDAK™ based on severity.
- Pneumonitis: Severe, life-threatening or fatal pneumonitis may occur. Withhold TIVDAK™ for persistent or recurrent Grade 2 pneumonitis and consider dose reduction. Permanently discontinue TIVDAK™ for Grade 3 or 4 pneumonitis.
- Embryo-fetal Toxicity: TIVDAK™ can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS
- The most common (≥25%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased, fatigue, lymphocytes decreased, nausea, peripheral neuropathy, alopecia, epistaxis, conjunctival adverse reactions, hemorrhage, leukocytes decreased, creatinine increased, dry eye, prothrombin international normalized ratio increased, activated partial thromboplastin time prolonged, diarrhea, and rash.

DRUG INTERACTIONS
- Strong CYP3A4 Inhibitors: Closely monitor for TIVDAK™ adverse reactions.

USE IN SPECIFIC POPUPLATIONS
- Pregnancy: Based on the mechanism of action and findings in animals, TIVDAK™ can cause fetal harm when administered to a pregnant woman.

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DRUG NAME	MANUFACTURER	APPROVAL DATE
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DOSAGE AND ADMINISTRATION
The recommended dose is 2mg/kg (up to maximum of 200mg) given as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

DOSAGE FORMS AND STRENGTHS
For injection: 40mg as a lyophilized powder in a single-dose vial for reconstitution.

Orphan status: N/A

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Females and Males of Reproductive Potential: TIVDAK™ can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating TIVDAK™ treatment. Advise females of reproductive potential to use effective contraception during treatment with TIVDAK™ and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TIVDAK™ and for 4 months after the last dose. Based on findings from animal studies, TIVDAK™ may impair male fertility.
- Lactation: Because of the potential for serious adverse reactions in a breastfed child, advise lactating women not to breastfeed during treatment with TIVDAK™ and for 3 weeks after the last dose.
- Pediatric use: Safety and effectiveness of TIVDAK™ in pediatric patients have not been established.
- Hepatic impairment: Avoid use of TIVDAK™ in patients with moderate or severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
QULIPTA™ (ATOGEPANT) TABLETS	ABBVIE INC.	09/28/2021

THERAPEUTIC CLASS
Migraine products

FDA-APPROVED INDICATION(S)
QULIPTA™ is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.

DOSAGE AND ADMINISTRATION
The recommended dosage is 10mg, 30mg or 60mg orally once daily with or without food.

DOSAGE FORMS AND STRENGTHS
Tablets: 10mg, 30mg and 60mg.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS
- None

ADVERSE REACTIONS
- The most common adverse reactions (at least 4% and greater than placebo) are nausea, constipation, and fatigue.

DRUG INTERACTIONS
- Recommended dosage modifications:
  - Strong CYP3A4 Inhibitors: 10mg once daily
  - Strong and Moderate CYP3A4 Inducers: 30mg or 60mg once daily
  - OATP Inhibitors: 10mg or 30mg once daily

USE IN SPECIFIC POPUPLATIONS
- Pregnancy: There are no adequate data on the developmental risk associated with the use of QULIPTA™ in pregnant women. Based on animal data, may cause fetal harm.
- Lactation: There are no data on the presence of atogepant in human milk, the effects of atogepant on the breastfed infant, or the effects of atogepant on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for QULIPTA™ and any potential adverse effects on the breastfed infant from QULIPTA™ or from the underlying maternal condition.
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric Use: Population pharmacokinetic modeling suggests no clinically significant pharmacokinetic differences between elderly and younger subjects.
- Hepatic Impairment: No dose adjustment of QULIPTA™ is recommended for patients with mild or moderate hepatic impairment. Avoid use of QULIPTA™ in patients with severe hepatic impairment.
- Renal Impairment: The renal route of elimination plays a minor role in the clearance of atogepant. In patients with severe renal impairment and in patients with end-stage renal disease (ESRD), the recommended dosage of QULIPTA™ is 10 mg once daily. For patients with ESRD undergoing intermittent dialysis, QULIPTA™ should preferably be taken after dialysis. No dose adjustment is recommended for patients with mild or moderate renal impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LIVMARLI™ (MARALIXIBAT) ORAL SOLUTION	MIRUM PHARMACEUTICALS INC.	09/29/2021

THERAPEUTIC CLASS
Gastrointestinal agent

FDA-APPROVED INDICATION(S)
LIVMARLI™ is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

DOSAGE AND ADMINISTRATION
The recommended dosage is 380mcg/kg once daily, taken 30 minutes before the first meal of the day.

Starting dose is 190mcg/kg orally once daily and should be increased to 380mcg/kg once daily after one week, as tolerated.

DOSAGE FORMS AND STRENGTHS
Oral solution: 9.5mg of maralixibat per mL.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- None

WARNING AND PRECAUTIONS
- Liver Test Abnormalities: Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption may be considered if abnormalities occur. For persistent or recurrent liver test abnormalities, consider LIVMARLI™ discontinuation.
- Gastrointestinal Adverse Reactions: Consider interrupting LIVMARLI™ treatment if a patient experiences persistent diarrhea, abdominal pain, vomiting, or has diarrhea with bloody stool, vomiting, dehydration requiring treatment, or fever. If diarrhea, abdominal pain, or vomiting persists and no alternate etiology is identified, consider stopping LIVMARLI™ treatment.
- Fat-Soluble Vitamin (FSV) Deficiency: Obtain baseline levels and monitor during treatment. Supplement if deficiency is observed. If FSV deficiency persists or worsens despite FSV supplementation, consider discontinuing LIVMARLI™ treatment.

ADVERSE REACTIONS
- Most common adverse reactions (≥5%) are diarrhea, abdominal pain, vomiting, fat-soluble vitamin deficiency, liver test abnormalities, gastrointestinal bleeding, and bone fractures.

DRUG INTERACTIONS
- Bile Acid Binding Resins: Bile acid binding resins may bind to maralixibat in the gut. Administer bile acid binding resins (e.g., cholestyramine, colesevelam, or colestipol) at least 4 hours before or 4 hours after administration of LIVMARLI™.
- OATP2B1 Subsrates: Maralixibat is an OATP2B1 inhibitor based on in vitro studies. A decrease in the oral absorption of OATP2B1 substrates (e.g., statins) due to OATP2B1 inhibition in the GI tract cannot be ruled out. Consider monitoring the drug effects of OATP2B1 substrates (e.g., statins) as needed.

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NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
LIVMARLI™ (MARALIXIBAT) ORAL SOLUTION	MIRUM PHARMACEUTICALS INC.	09/29/2021

THERAPEUTIC CLASS
Gastrointestinal agent

FDA-APPROVED INDICATION(S)
LIVMARLI™ is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

DOSAGE AND ADMINISTRATION
The recommended dosage is 380mcg/kg once daily, taken 30 minutes before the first meal of the day.

Starting dose is 190mcg/kg orally once daily and should be increased to 380mcg/kg once daily after one week, as tolerated.

DOSAGE FORMS AND STRENGTHS
Oral solution: 9.5mg of maralixibat per mL.

Orphan status: Orphan

SAFETY PROFILE

USE IN SPECIFIC POPULATIONS

- Pregnancy: Maternal use at the recommended clinical dose of LIVMARLI™ is not expected to result in measurable fetal exposure because systemic absorption following oral administration is low.
- Lactation: LIVMARLI™ has low absorption following oral administration, and breastfeeding is not expected to result in exposure of the infant to LIVMARLI™ at the recommended dose.
- Pediatric Use: The safety and effectiveness of LIVMARLI™ for the treatment of cholestatic pruritus in pediatric patients with Alagille syndrome have been established in one study of patients 1 to 15 years of age.
- Geriatric Use: The safety and effectiveness of LIVMARLI™ for the treatment of pruritus in ALGS in adult patients, 65 years of age and older, have not been established.
- Hepatic Impairment: Clinical studies of LIVMARLI™ included ALGS patients with impaired hepatic function at baseline. The efficacy and safety in ALGS patients with clinically significant portal hypertension and in patients with decompensated cirrhosis have not been established.

NEW BIOSMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
BYOOVIZ™ (RANIBIZUMAB-NUNA) INTRAVITREAL INJECTION / SAMSUNG BIOEPIS CO., LTD.	Ophthalmic agents	Treatment of patients with: - Neovascular (Wet) age-related macular degeneration (AMD) - Macular edema following retinal vein occlusion - Myopic choroidal neovascularization (mCNV)	09/18/2021	Byooviz™ is the first ophthalmology biosimilar approved in the United States. Ranibizumab is an anti-vascular endothelial growth factor therapy that prevents vision loss in patients vision loss in patients with retinal vascular disorders which can cause irreversible blindness or visual impairments in adults in the US. This approval represents a great step toward the advancement of a new therapeutic option addressing debilitating disease progression of patients with retinal vascular disorders in the US. Reference product: Lucentis™

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
INVEGA HAFYERA™ (PALIPERIDONE PALMITATE) EXTENDED-RELEASE INJECTABLE SUSPENSION / JANSSEN PHARMACEUTICALS INC.	Antipsychotics/antimanic agents	Treatment of schizophrenia in adults after they have been adequately treated with: - A once-a-month paliperidone palmitate extended-release injectable suspension for at least four months or - An every-three-month paliperidone palmitate extended-release injectable suspension for at least one three-month cycle	09/01/2021	Invega Hafyera™ is the first-and-only twice-yearly injectable for the treatment of schizophrenia in adults. Before transitioning to Invega Hafyera™, patents must be adequately treated with Invega Sustenna™ for at least four months, or Invega Trinza™ for at least one 3-month injection cycle. Orphan status: N/A Controlled substance: No
TRUDHESA™ (DIHYDROERGOTAMINE MESYLATE) NASAL SPRAY / IMPEL NEUROPHARMA INC.	Migraine products	Acute treatment of migraine with or without aura in adults	09/03/2021	Trudhesa™ gently delivers dihydroergotamine mesylate quickly to the bloodstream through vascular-rich upper nasal space. It bypasses the gut and potential absorption issues, offering rapid, sustained, and consistent symptom relief without injection or infusion, even when administered hours after the onset of a migraine attack. Orphan status: N/A Controlled substance: No

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
OPZELURA™ (RUXOLITINIB) CREAM / INCYTE	Antineoplastic agents	Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	09/21/2021	Opzelura™ is the first and only topical formulation of a JAK inhibitor approved in the United States. Research shows dysregulation of the JAK-STAT pathway contributes to key features of atopic dermatitis such as itch, inflammation and skin barrier dysfunction. Orphan status: N/A Controlled substance: No

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
PAROXETINE HYDROCHLORIDE ORAL SUSPENSION 10MG/5ML / NOVITIUM PHARMA LLC.	Antidepressants	Treatment of major depressive disorder, panic disorder, obsessive-compulsive disorder, anxiety disorders, post-traumatic stress disorder, premenstrual dysphoric disorder	Paxil™	09/03/2021
ELIGLUSTAT TARTRATE CAPSULES 84MG / AIZANT DRUG RESEARCH SOLUTIONS	Hematopoietic agents	Treatment of type 1 Gaucher disease	Cerdelga™	09/08/2021
VORTIOXETINE HYDROBROMIDE TABLETS 5MG, 10MG AND 20MG / ZYDUS PHARMACEUTICALS USA INC.	Antidepressants	Treatment of major depressive disorder (MDD) in adults	Trintellix™	09/17/2021
CEFTAROLINE FOSAMIL FOR INJECTION 400MG/VIAL AND 600MG/VIAL / APOTEX INC.	Cephalosporins	Treatment of acute bacterial skin and skin structure infections in adult and pediatric patients, community-acquired bacterial pneumonia in adult and pediatric patients 2 months of age and older	Teflaro™	09/21/2021
BRIMONIDINE TARTRATE TOPICAL GEL 0.33% / PADAGIS ISRAEL PHARMACEUTICALS LTD.	Dermatologicals	Topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older	Mirvaso™	09/23/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
BRUKINSA™ (ZANUBRUTINIB) CAPSULES / BEIGENE	Antineoplastic agent	Treatment of mantle cell lymphoma (MCL) who have received at least one prior therapy	(1) Treatment of Waldenström's macroglobulinemia (WM) (2) Treatment of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen	(1) 09/01/2021 (2) 09/14/2021
CABOMETYX™ (CABOZANTINIB) TABLETS / EXELIXIS, INC.	Antineoplastic agent	(1) Treatment of patients with advanced renal cell carcinoma (2) Treatment of patients with advanced renal cell carcinoma as a first-line treatment in combination with nivolumab (3) Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib	Treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible	09/17/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
JAKAFI™ (RUXOLITINIB) TABLETS / INCYTE	Antineoplastic agent	(1) Treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults (2) Treatment of polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea (3) Treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older	Treatment of chronic-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older	09/22/2021
REPATHA™ (EVOLOCUMAB) INJECTION / AMGEN	Antihyperlipidemic agent	(1) Treatment in adults with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction, stroke and coronary revascularization (2) Treatment as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C	(1) Treatment as adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 ears and older with HeHF, to reduce LDL-C (2) Treatment as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C	09/24/2021

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
TORIPALIMAB / COHERUS AND JUNSHI BIOSCIENCES, INC.	09/01/2021	First-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma (NPC) in combination with gemcitabine and cisplatin Second-line treatment of recurrent or metastatic NPC after platinum-containing chemotheray	Toripalimab showed remarkably efficacy in the treatment of advanced NPC, an aggressive tumor with limited treatment options, according to the results from POLARIS-02 and JUPITER-02 studies. BLA submitted.	High
TRIENTINE TETRAHYDROCHLORIDE (TETA 4HCl) / ORPHALAN SA	09/02/2021	First-line treatment of Wilson's Disease	Wilson's Disease is a rare inherited disorder of copper transport primarily affecting the liver and brain, affecting about 1 in every 30,000 people worldwide. TETA 4HCl is proposed as an alternative copper chelating agent to d-Penicillamine as a first-tine treatment. NDA accepted.	High High

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DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
AXS-07 (MELOXICAM AND RIZATRIPTAN) / AXSOME THERAPEUTICS, INC.	09/14/2021	Acute treatment of migraine	AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for migraine. The MOMENTUM and INTERCEPT trials have demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls. NDA accepted.	Moderate
LINZAGOLIX / OBSEVA SA	09/15/2021	Treatment of uterine fibroids	Linzagolix is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist with potential best-in-class efficacy, favorable tolerability profile, and unique and flexible dosing options. If approved, it will be the only GnRH antagonist in uterine fibroids with a low dose non-add-back therapy (ABT) option. NDA submitted.	Moderate

REFERENCES

- U.S. Food and Drug Administration (https://www.fda.gov/)
- Drugs.com (https://www.drugs.com/)
- IBM Micromedex® (https://www.micromedexsolutions.com)
- Pharmacist Letter (https://www.pharmacistletter.com)