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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: FEBRUARY 2021

Date: 03/05/2021

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NEWS

DRUG ISSUE	DATE	DETAILS
Risk of serious heart-related problems and cancer with Xeljanz Xeljanz XR	02/04/2021	The FDA is alerting that preliminary results from a safety clinical trial showed an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to tumor necrosis factor (TNF) inhibitors. The FDA will evaluate the clinical trial results received to date, work with the drug manufacturer to obtain further information, and will communicate final conclusions and recommendations after completing their review or have more information to share. Recommendations for healthcare professionals: • Advise patients that they should not stop taking tofacitinib without first consulting with their healthcare provider, because doing so may worsen their condition. • Advise patients to talk with their healthcare provider if they have any questions or concerns. • Consider the benefits and risks of tofacitinib when deciding whether to initiate or continue patients on the drug. • Continue to follow the recommendations in the tofacitinib prescribing information. • Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.
Emergency use authorization (EUA) for Third COVID-19 Vaccine	02/27/2021	The FDA issued an EUA for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the United States (U.S.). Refer to the following sources for additional important details: • "Letter of authorization"– Includes details regarding the scope of authorization, product description, the specific conditions that must be met, among other important information. • "Fact Sheet for Healthcare Providers Administering Vaccine" – Contains instructions for healthcare providers, dosage and administration details, contraindications, warnings, reported adverse reactions, information to provide to vaccine recipients/caregiver, mandatory requirements for the vaccine administration under EUA, how to report adverse events, information regarding the authority for issuance of the EUA, and the full EUA prescribing information. • "COVID-19 Vaccination Program Operational Guidance" – Serves as an interim playbook for state, territorial, tribal, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions. Additional information can be found at the FDA's COVID-19 Vaccines portal and the Centers for Disease and Control Prevention (CDC) website.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
TEPMETKO (TEPOTINIB) TABLETS	EMD SERONO INC	02/03/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
TEPMETKO is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymalepithelial transition (MET) exon 14 skipping alterations.

DOSAGE AND ADMINISTRATION
The recommended dose is 450 mg orally once daily until disease progression or unacceptable toxicity. Dose adjustments are recommended to manage toxicity.

Patients must be selected on the presence of METex14 skipping.

DOSAGE FORMS AND STRENGTHS
Tablets: 225 mg

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Interstitial lung disease (ILD)/pneumonitis
- Hepatotoxicity
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: edema, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea.

DRUG INTERACTIONS
- Dual strong CYP3A inhibitors and P-gp inhibitors: The effect of strong CYP3A inhibitors or P-gp inhibitors on TEPMETKO has not been studied clinically. However, metabolism and in vitro data suggest concomitant use may increase tepotinib exposure, which may increase the incidence and severity of adverse reactions of TEPMETKO. Avoid concomitant use.
- Strong CYP3A inducers: The effect of strong CYP3A inducers on TEPMETKO has not been studied clinically. However, metabolism and in vitro data suggest concomitant use may decrease tepotinib exposure, which may reduce TEPMETKO efficacy. Avoid concomitant use.

DRUG INTERACTIONS (CONTINUATION)
- Certain P-gp substrates: Tepotinib is a P-gp inhibitor. Concomitant use increases the concentration of P-gp substrates, which may increase the incidence and severity of adverse reactions of these substrates. Avoid co-administration where minimal concentration changes may lead to serious or life-threatening toxicities.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No clinically important differences in safety or efficacy were observed between patients aged 65 years or older and younger patients.
- Renal impairment: No dose adjustment recommended is recommended for mild or moderate renal impairment. The recommended dose has not been established for severe renal impairment.
- Hepatic impairment: No dose adjustment recommended for mild or moderate hepatic impairment. Has not been studied in patients with severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
UKONIQ (UMBRALISIB) TABLETS	TG THERAPEUTICS, INC.	02/05/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
UKONIQ is a kinase inhibitor indicated for the treatment of adult patients with:
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen.
- Relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

DOSAGE AND ADMINISTRATION
The recommended dose is 800 mg orally once daily. Dose adjustments are recommended to manage toxicity.

DOSAGE FORMS AND STRENGTHS
Tablets: 200 mg.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Infections
- Neutropenia
- Diarrhea or non-infectious colitis
- Hepatotoxicity
- Severe cutaneous reactions
- Allergic reactions due to inactive ingredient FD&C yellow no. 5
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: increased creatinine, diarrhea-colitis, fatigue, nausea, neutropenia, transaminase elevation, musculoskeletal pain, anemia, thrombocytopenia, upper respiratory tract infection, vomiting, abdominal pain, decreased appetite, and rash.

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating.

USE IN SPECIFIC POPULATIONS (CONTINUATION)
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No overall differences in effectiveness or pharmacokinetics were observed between patients 65 years of age and older and younger patients. There was a higher incidence of infectious serious adverse reactions in patients 65 years of age or older compared to younger patients.
- Renal impairment: No dose adjustment recommended for mild or moderate renal impairment. Has not been studied in patients with severe renal impairment.
- Hepatic impairment: No dose adjustment recommended for mild hepatic impairment. Has not been studied in patients with moderate or severe hepatic impairment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
BREYANZI (LISOCABTAGENE MARALEUCEL) SUSPENSION	BRISTOL-MYERS SQUIBB COMPANY	02/05/2021

THERAPEUTIC CLASS
Antineoplastic agent

FDA-APPROVE INDICATION(S)
BREYANZI is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B

DOSAGE AND ADMINISTRATION
Dosing is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. The dose is 50 to 110 × 10^6 CAR-positive viable T cell.

To be administered in a certified healthcare facility. For autologous and intravenous use only.

DOSAGE FORMS AND STRENGTHS
BREYANZI is a cell suspension for infusion. A single dose contains 50 to 110 × 10^6 CAR-positive viable T cells, with each component supplied separately in one to four single-dose 5 mL vials. Each mL contains 1.5 × 106 to 70 × 10^6 CAR-positive viable T cells.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Boxed warning: Cytokine release syndrome and neurologic toxicities
- BREYANZI REMS
- Hypersensitivity reactions
- Serious infections
- Prolonged cytopenias
- Hypogammaglobulinemia
- Secondary malignancies
- Effects on ability to drive and use machines

ADVERSE REACTIONS
Most common adverse reactions: fatigue, cytokine release syndrome, musculoskeletal pain, nausea, headache, encephalopathy, infections (pathogen unspecified), decreased appetite, diarrhea, hypotension, tachycardia, dizziness, cough, constipation, abdominal pain, vomiting, and edema.

DRUG INTERACTIONS
- Drug-laboratory test interactions: HIV and the lentivirus used to make BREYANZI have limited, short spans of identical genetic material (RNA). Therefore, some commercial HIV nucleic acid tests may yield false-positive results in patients who have received BREYANZI.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Pregnancy status of females with reproductive potential should be verified.
- Pediatric use: Safety and effectiveness have not been established.
- Geriatric use: No clinically important differences in safety or efficacy were observed between patients aged 65 years or older and younger patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
EVKEEZA (EVINACUMAB-DGNB) INJECTION	REGENERON PHARMACEUTICALS, INC.	02/11/2021

THERAPEUTIC CLASS
Antihyperlipidemic

FDA-APPROVE INDICATION(S)
EVKEEZA is an ANGPTL3 (angiopoietin-like 3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

DOSAGE AND ADMINISTRATION
The recommended dose is s 15 mg/kg administered by intravenous infusion once monthly (every 4 weeks).

DOSAGE FORMS AND STRENGTHS
Injection: 345 mg/2.3 mL (150 mg/mL) and 1,200 mg/8 mL (150 mg/mL) solution in single-dose vials.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
- History of serious hypersensitivity reactions to evinacumab-dgnb or to any of the excipients.

WARNINGS AND PRECAUTIONS
- Serious hypersensitivity reactions
- Embryo-fetal toxicity

ADVERSE REACTIONS
Most common adverse reactions: nasopharyngitis, influenza-like illness, dizziness, rhinorrhea, and nausea.

USE IN SPECIFIC POPULATIONS
- Pregnancy: May cause fetal harm. Consider pregnancy testing in patients who may become pregnant prior to starting treatment.
- Females of reproductive potential: Advise females of reproductive potential to use effective contraception.
- Pediatric use: Safety and effectiveness have not been established in pediatric patients with HoFH who are younger than 12 years old.
- Geriatric use: Clinical studies did not include enough patients 65 years of age and older to determine whether they respond differently from younger adult patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
COSELA (TRILACICLIB) FOR INJECTION	G1 THERAPEUTICS, INC.	02/12/2021

THERAPEUTIC CLASS

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FDA-APPROVE INDICATION(S)

COSELA is a kinase inhibitor indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

DOSAGE AND ADMINISTRATION

The recommended dose is 240 mg/m2 as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.

DOSAGE FORMS AND STRENGTHS

For injection: 300 mg of trilaciclib as a lyophilized cake in a single-dose vial.

Orphan status: N/A

SAFETY PROFILE

CONTRAINDICATIONS

- History of serious hypersensitivity reactions to COSELA.

WARNINGS AND PRECAUTIONS

- Injection-site reactions, including phlebitis and thrombophlebitis
- Acute drug hypersensitivity reactions
- Interstitial lung disease (ILD)/pneumonitis
- Embryo-fetal toxicity

ADVERSE REACTIONS

Most common adverse reactions: fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- Certain OCT2, MATE1, and MATE-2K substrates: COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney. Avoid concomitant use with certain OCT2, MATE1, and MATE-2K substrates where minimal concentration changes may lead to serious or life-threatening toxicities. Refer to the full prescribing information for additional details.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Pregnancy testing is recommended for females of reproductive potential prior to initiating.
- Females of reproductive potential: Advise females of reproductive potential to 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 patients 65 years of age and younger patients.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
AMONDYS 45 (CASIMERSEN) INJECTION	SAREPTA THERAPEUTICS	02/25/2021

THERAPEUTIC CLASS
Neurological agent

FDA-APPROVE INDICATION(S)
AMONDYS 45 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.

DOSAGE AND ADMINISTRATION
The recommended dose is 30 mg/kg once weekly, administered as an intravenous infusion.

DOSAGE FORMS AND STRENGTHS
Injection: 100 mg/2 mL in a single-dose vial

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
- Renal toxicity

ADVERSE REACTIONS
Most common adverse reactions: upper respiratory tract infection, cough, pyrexia, headache, arthralgia, and oropharyngeal pain.

USE IN SPECIFIC POPULATIONS
- Geriatric use: DMD is largely a disease of children and young adults; therefore, there is no experience with AMONDYS 45 in geriatric DMD patients.
- Renal impairment: Renal clearance of casimersen is decreased in non-DMD adults with renal impairment based on eGFR. However, because of the effect of reduced skeletal muscle mass on creatinine measurements in DMD patients, no specific dose adjustment can be recommended for DMD patients with renal impairment based on eGFR. Patients with known renal function impairment should be closely monitored during treatment.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
PEPAXTO (MELPHALAN FLUFENAMIDE) INJECTION	ONCOPEPTIDES AB	02/26/2021

THERAPEUTIC CLASS

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FDA-APPROVE INDICATION(S)

PEPAXTO is an alkylating drug indicated in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

DOSAGE AND ADMINISTRATION

The recommended dose is 40 mg intravenously over 30 minutes on Day 1 of each 28-day treatment cycle, in combination with dexamethasone.

DOSAGE FORMS AND STRENGTHS

For injection: 20 mg melphalan flufenamide as a lyophilized powder in single-dose vial for reconstitution and dilution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS

- History of serious hypersensitivity reaction to melphalan flufenamide or melphalan.

WARNINGS AND PRECAUTIONS

- Thrombocytopenia
- Neutropenia
- Anemia
- Infections
- Increased risk of mortality with PEPAXTO at dosages higher than the recommended dosage
- Secondary malignancies
- Embryo-fetal toxicity

ADVERSE REACTIONS

Most common adverse reactions: fatigue, nausea, diarrhea, pyrexia, respiratory tract infection, and the following laboratory abnormalities: leukocytes decrease, platelets decrease, lymphocytes decrease, neutrophils decrease, hemoglobin decrease, and creatinine increase.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating.
- Females and males of reproductive potential: Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception.
- Lactation: Advise not to breastfeed.
- Pediatric use: Safety and effectiveness have not been established.

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
NULIBRY (FOSDENOPTERIN) INJECTION	ORIGIN BIOSCIENCES INC.	02/26/2021

THERAPEUTIC CLASS

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FDA-APPROVE INDICATION(S)

NULIBRY is cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

DOSAGE AND ADMINISTRATION

The recommended dose varies per patient's age and weight. To be administered once daily, by intravenous infusion with non-DEHP tubing, and by a healthcare professional. If deemed appropriate by the healthcare professional, may be administered at home by the patient's caregiver. Refer to full prescribing information for details.

Start if the patient has a diagnosis or presumptive diagnosis of MoCD Type A. In patients with a presumptive diagnosis of MoCD Type A, confirm the diagnosis of MoCD Type A immediately after initiation of treatment. In such patients, discontinue if the MoCD Type A diagnosis is not confirmed by genetic testing.

DOSAGE FORMS AND STRENGTHS

For injection: 9.5 mg of fosdenopterin as a lyophilized powder or cake in a single-dose vial for reconstitution.

Orphan status: Orphan

SAFETY PROFILE

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

- Potential for photosensitivity.

ADVERSE REACTIONS

Most common adverse reactions: catheter-related complications, pyrexia, viral infection, pneumonia, otitis media, vomiting, cough/sneezing, viral upper respiratory infection, gastroenteritis, bacteremia, and diarrhea.

USE IN SPECIFIC POPULATIONS

- Pediatric use: Safety and effectiveness for the treatment of MoCD Type A have been established
- in pediatric patients starting from birth.
- Geriatric use: MoCD Type A is largely a disease of pediatric patients. Clinical studies of NULIBRY did not include patients 65 years of age and older.

NEW BIOSMILAR PRODUCTS

- No new biosimilar product approved during February 2021.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
POSIMIR (BUPIVACAINE) SOLUTION / DURECT CORPORATION		In adults for administration into the sub-acromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic sub-acromial decompression	02/01/2021	POSIMIR is a new formulation of bupivacaine that combines the strength of 660mg of bupivacaine base with the innovative SABER® platform technology, enabling continuous sustained delivery of a non-opioid local analgesic over 3 days in adults. POSIMIR contains more bupivacaine than any other approved single-dose sustained-release bupivacaine product. Orphan status: N/A

NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
LINACLOTIDE CAPSULES 145 MCG AND 290 MCG / MYLAN PHARMACEUTICALS INC.	Gastrointestinal agent	• Idiopathic constipation, chronic • Irritable bowel syndrome characterized by constipation	Linzess	02/09/2021
LOTEPREDNOL ETABONATE OPHTHALMIC GEL 0.5% / AKORN OPERATING COMPANY LLC	Ophthalmologic agent; Corticosteroid	Post-operative inflammation and pain following ocular surgery	Lotemax Gel	02/10/2021
APREMILAST TABLETS 10 MG, 20 MG AND 30 MG / UNICHEM LABORATORIES LTD.	Anti-inflammatory agent	Plaque psoriasis	Otezla	02/17/2021
DROXIDOPA CAPSULES 100 MG, 200 MG AND 300 MG / AJANTA PHARMA LIMITED; ALKEM LABORATORIES LIMITED; ANNORA PHARMA PRIVATE LIMITED; AUROBINDO PHARMA LIMITED; HIKMA PHARMACEUTICALS USA INC.; LUNDBECK PHARMACEUTICALS LLC; LUPIN PHARMACEUTICALS, INC.; MSN LABORATORIES PRIVATE LIMITED; SCIEGEN PHARMACEUTICALS, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; TASMAN PHARMA INC.; TEVA PHARMACEUTICALS USA, INC.; ZYDUS PHARMACEUTICALS (USA) INC.	Vasopressor	Neurogenic orthostatic hypotension	Northera	02/18/2021

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

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NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
GOCOVRI (AMANTADINE HYDROCHLORIDE) EXTENDED-RELEASE CAPSULES / ADAMAS PHARMACEUTICALS, INC.	Central nervous system agent; Antiparkinson agent	Treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications	As adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes	02/01/2021
LIBTAYO (CEMIPLIMAB-RWLC) INJECTION / SANOFI	Antineoplastic agent	Treatment of cutaneous squamous cell carcinoma (CSCC)	Treatment of advanced basal cell carcinoma (BCC), previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate	02/09/2020
HUMIRA (ADALIMUMAB) INJECTION / ABBVIE INC.	Tumor Necrosis Factor Inhibitor	Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, crohn's disease, psoriasis, juvenile idiopathic arthritis, ulcerative colitis, hidradenitis suppurativa, and certain types of uveitis	Patient population altered to include treatment of moderately to severely active ulcerative colitis in pediatric patients 5 years of age and older	02/24/2021

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
MARALIXIBAT / MIRUM PHARMACEUTICALS, INC.	02/01/2021	Treatment for: Cholestatic Pruritus in Patients with Alagille Syndrome	Maralixibat is an inhibitor of the apical sodium dependent bile acid transporter (ASBT) in development for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS). NDA submission to FDA completed. FDA granted orphan drug designation to maralixibat.	High High
SPN-812 (viloxazine hydrochloride) / Supernus Pharmaceuticals, Inc.	02/08/2021	Treatment for: Attention Deficit Hyperactivity Disorder (ADHD)	SPN-812 (viloxazine hydrochloride) is a serotonin norepinephrine modulating agent (SNMA) in development as a novel, non-stimulant treatment for attention deficit hyperactivity disorder (ADHD). NDA re-submitted to FDA.	Moderate
Tisotumab vedotin / Genmab A/S and Seagen Inc.	02/10/2021	Treatment for: Cervical Cancer	Tisotumab vedotin is an investigational antibody-drug conjugate (ADC) in development for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. BLA submitted to FDA.	High
AGN-190584 (pilocarpine) Ophthalmic Solution / Allergan	02/25/2021	Treatment for: Presbyopia	AGN-190584 (pilocarpine 1.25%) is an optimized ophthalmic solution formulation of the approved cholinergic muscarinic receptor agonist pilocarpine in development for the treatment of presbyopia. NDA submitted to FDA.	Low

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)