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PharmNOTES

Summary of New FDA-Approved Products,
New Indications, First-Time Generics,
and WHAT'S IN THE PIPELINE
For: **JULY 2022**

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 8/10/2022

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NEWS

- No drug safety alert published by the FDA in July.

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
BLUDIGO™ (INDIGOTINDISULFONATE SODIUM) INJECTION	PROVEPHARM SAS	7/8/2022

THERAPEUTIC CLASS
Diagnostic product

FDA-APPROVED INDICATION(S)
Bludigo™ is a diagnostic dye indicated for use as a visualization aid in the cystoscopic assessment of the integrity of the ureters in adults following urological and gynecological open, robotic, or endoscopic surgical procedures.

DOSAGE AND ADMINISTRATION
Recommended dose is 5mL given intravenously over 1 minute. Monitor blood pressure and heart rhythm during and after injection.

DOSAGE FORMS AND STRENGTHS
Injection: 40mg/5mL (8mg/mL) indigotindisulfonate sodium in a single-dose ampule

Orphan status: No

SAFETY PROFILE

CONTRAINDICATIONS
- Known hypersensitivity to indigotindisulfonate or any of its components

WARNINGS AND PRECAUTIONS
- Cardiovascular Reactions: Severe or life-threatening cardiovascular reactions including cardiac arrest, arrhythmia, asystole, atrioventricular block second degree, hypotension, elevation in blood pressure, bradycardia, and tachycardia have been reported. Closely monitor blood pressure and cardiac rhythm during and following the Bludigo™ injection. Interrupt administration if reactions are observed.
- Hypersensitivity Reactions: Serious anaphylactic reactions with hypotension, dyspnea, bronchospasm, urticaria, or erythema have been reported. Monitor patients for anaphylactic reactions and have emergency equipment and trained personnel readily available.
- Interference with Oximetry Measurements: Anesthesiologists should be aware of the potential for artifactual reduction in SpO2 when anesthetized patients are administered Bludigo™.

ADVERSE REACTIONS
- Adverse reactions (≥ 1%) are constipation, nausea, vomiting, abdominal pain, pyrexia, ALT increase, and dysuria.

USE IN SPECIFIC POPULATIONS
- Renal impairment: Bludigo™ has not been studied in patients with eGFR < 30 mL/min and is not recommended for use in these patients.

NEW BIOSIMILAR PRODUCTS

- No biosimilar product was approved by the FDA in July.

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	COMMENTS
ZONISADE™ (ZONISAMIDE) ORAL SUSPENION / AZURITY	Anticonvulsants	As adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years of age and older	7/15/2022	The first and only FDA-approved oral liquid formulation of zonisamide. The efficacy and tolerability of zonisamide has been established in 3 double-blind, placebo-controlled, multicenter clinical trials. Orphan: No
KYZATREX™ (TESTOSTERONE UNDECANOATE) CAPSULES / MARIUS PHARMACEUTICALS LLC	Androgens	For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone	7/27/2022	Kyzatrex™ is a proprietary oral softgel capsule that is absorbed primarily via the lymphatic system, avoiding liver toxicity. The oral delivery method eliminates the risk of application site reactions common with intramuscular testosterone injections. Kyzatrex™ mimics the daily rhythm of natural testosterone production since the recommended dosage is recommended to be taken twice daily (morning and evening). Orphan: No
ZORYVE™ (ROFLUMILAST) CREAM / ARCUTIS BIOTHERAPEUTICS INC.	Dermatologicals	For topical treatment of plaque psoriasis, including intertriginous area, in patients 12 years of age and older	7/29/2022	Zoryve™ is the first and only topical phosphodiesterase-4 (PDE4) inhibitor approved for the treatment of plaque psoriasis. It is a once-daily, steroid-free cream and has been shown to rapidly clear plaques and reduce itch across all areas of the body. Orphan: No

NEW FIRST-TIME GENERIC APPROVALS

GENERIC NAME, DOSAGE FORM AND STRENGTH	GENERIC FOR:	THERAPEUTIC CLASS	INDICATIONS	APPROVAL DATE
EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE TABLETS 5MG/500MG, 5MG/1000MG, 12.5MG/500MG AND 12.5MG/1000MG	Synjardy™	Antidiabetics	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	7/7/2022
CITRIC ACID, MAGNESIUM OXIDE AND SODIUM PICOSULFATE FOR ORAL SOLUTION 12GM/3.5GM/10MG PER PACKET	Prepopik™	Laxatives	Bowel preparation	7/18/2022

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
KRYSTEXXA™ (PEGLOTICASE) INJECTION / HORIZON THERAPEUTICS PLC	Gout agents	Treatment of chronic gout in adult patients refractory to conventional therapy	Treatment of chronic gout in adult patients refractory to conventional therapy in combination with methotrexate	7/8/2022
COMIRNATY™ (COVID-19 VACCINE, MRNA) INJECTION / PFIZER AND BIONTECH	Vaccines	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older	7/8/2022
XALKORI™ (CRIZOTINIB) CAPSULES / PFIZER LABORATORIES DIV PFIZER INC	Antineoplastics and adjunctive therapies	[1] Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test; [2] Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive	Treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive	7/14/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
OPZELURA™ (RUXOLITINIB) CREAM / INCYTE CORP.	Dermatologicals	Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older	7/18/2022
BENLYSTA™ (BELIMUMAB) INJECTION / GLAXOSMITHKLINE	Systemic lupus erythematosus agents	[1] Treatment of adult patients with active systemic lupus erythematosus (SLE) who are receiving standard therapy; [2] Treatment of adult patients with active lupus nephritis who are receiving standard therapy	[1] Treatment of patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy; [2] Treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy	7/27/2022
STELARA™ (USTEKINUMAB) INJECTION / JANSSEN BIOTECH	Dermatologicals	[1] Treatment of adult patients with: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis; [2] Treatment of pediatric patients 6 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy	[1] Treatment of adult patients with: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis; [2] Treatment of pediatric patients 6 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and active psoriatic arthritis	7/27/2022

PIPELINE

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
NOV03 (PERFLUOROHEXYLOCTANE) / BAUSCH + LOMB CORPORATION AND NOVALIQ GMBH	7/7/2022	Signs and symptoms of dry eye disease (DED) associated with Meibomian gland dysfunction (MGD)	Perfluorohexyloctane is a first-in-class investigational, proprietary, water-free, single-component preservative-free eye drop. NDA submitted.	High
SYD985 ([VIC-] TRASTUZUMAB DUOCARMAZINE) / BYONDIS B.V.	7/12/2022	HER2-positive unresectable locally advanced or metastatic breast cancer	SYD985 is an investigational next generation anti-HER2 antibody-drug conjugate that was granted fast track designation by the FDA in January 2018. The company has been given a Prescription Drug User Fee Act (PDUFA) action date of May 12, 2023. BLA accepted.	High
TROFINETIDE / ACADIA PHARMACEUTICALS INC.	7/18/2022	Treatment of Rett syndrome in adult and pediatric patients two years of age and older	Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome. Trofinetide has been granted Fast Track Status and Orphan Drug Designation for Rett syndrome and has also been granted Rare Pediatric Disease designation by the FDA. NDA submitted.	High high
ACER-001 / ACER THERAPEUTICS INC.	7/18/2022	Treatment of patients with urea cycle disorders (UCDs)	In June 2022 the FDA had issued a Complete Response Letter stating that satisfactory inspection of its third-party contract packaging manufacturer is required before the NDA may be approved. Acer Therapeutics notified the FDA that the packaging manufacturer is ready for inspection. Of note, ACER-001 has been granted orphan drug designation by the FDA. NDA resubmitted.	High high

PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
TREOSULFAN / MEDEXUS PHARMACEUTICALS	7/25/2022	In combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT)	The FDA had sent a CRL stating that the agency cannot approve the NDA in its present form and provided recommendations specific to additional clinical/statistical data and analyses pertaining to the primary and secondary endpoints of the completed pivotal Phase III study. The NDA resubmission includes updates to data files and supporting information in response to the FDA's recommendations. NDA resubmitted.	High
TOFERSEN / BIOGEN INC.	7/26/2022	Superoxide dismutase 1 (SOD1) amyotrophic lateral sclerosis (ALS)	SOD1-ALS is rare genetic form of ALS and, if approved, tofersen would be the first treatment to target a genetic cause of ALS. The application has been granted priority review and given a PDUFA action date of January 25, 2023. NDA accepted.	High high
ZYNQUISTA™ (SOTAGLIFLOZIN) / LEXICON PHARMACEUTICALS INC.	7/27/2022	Heart failure	Sotagliflozin is an oral dual inhibitor of two proteins responsible for glucose regulation known as sodium-glucose co-transporter type 1 and 2 (SGLT1 and SGLT2). The NDA is supported by the results from the Phase 3 SOLOIST-WHF clinical study in patients with type 2 diabetes who had recently been hospitalized for worsening heart failure and the Phase 3 SCORED clinical study in patients with type 2 diabetes, kidney disease and risks for cardiovascular disease. NDA accepted.	Moderate
REZAFUNGIN / CIDARA THERAPEUTICS	7/27/2022	Candidemia and invasive candidiasis	Rezafungin is a novel, once-weekly echinocandin antifungal. The FDA had previously granted Qualified Infectious Disease Product designation to rezafungin which confers priority review. In addition, this indication has orphan designation. NDA submitted.	Moderate

REFERENCES

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