PharmNOTES

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

ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

Date: 9/7/2022

TABLE OF CONTENTS

	PAGE
NEWS	3
NEW FDA-APPROVED DRUG PRODUCTS	4-9
NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS	5
• Xenpozyme™ (olipudase alfa-rpcp) for injection	5
NEW BIOSMILAR PRODUCTS	6
NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS	7-8
NEW FIRST-TIME GENERIC APPROVALS	9
NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS	10-13
PIPELINE	14-15
REFERENCES	16

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NEWS

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

NEW FDA-APPROVED DRUG PRODUCTS

NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

DRUG NAME	MANUFACTURER	APPROVAL DATE
XENPOZYME™ (OLIPUDASE ALFA-RPCP) FOR INJECTON	GENZYME CORP	8/31/2022

THERAPEUTIC CLASS
Enzymes

FDA-APPROVED INDICATION(S)
Xenpozyme™ is a hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

DOSAGE AND ADMINISTRATION
The recommended adult and pediatric dosages for the dose escalation and maintenance phases are based on body weight. For adult patients the recommended starting dose is 0.1mg/kg via intravenous infusion every 2 weeks and the maintenance phase is 3mg/kg every 2 weeks, For pediatric patients the recommended starting dosage is 0.03mg/kg via intravenous infusion every 2 weeks and the recommended maintenance dosage is 3mg/kg every 2 weeks.

DOSAGE FORMS AND STRENGTHS
For injection: 20 mg of olipudase alfa-rpcp as a lyophilized powder in a single-dose vial for reconstitution

Orphan status: Yes

SAFETY PROFILE

WARNINGS AND PRECAUTIONS

- **BLACK BOX WARNING: Severe Hypersensitivity Reactions**
  - Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, Xenpozyme™ should be discontinued immediately and appropriate medical treatment should be initiated.
- Infusion-Associated Reactions (IARs): If severe IARs occur, discontinue Xenpozyme™ and initiate appropriate medical treatment.
- Elevated Transaminases: Assess ALT and AST within one month prior to initiation of Xenpozyme™, within 72 hours prior to any infusion during dose escalation, or prior to the next scheduled Xenpozyme™ infusion upon resuming treatment following a missed dose.
- Risk of Fetal Malformations During Dosage Initiation or Escalation in Pregnancy: Xenpozyme™ dosage initiation or escalation, at any time during pregnancy, is not recommended as it may lead to elevated sphingomyelin metabolite levels that may increase the risk of fetal malformations. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Xenpozyme™ is discontinued.

ADVERSE REACTIONS

- Most common adverse reactions in adult patients (incidence ≥10%) are headache, cough, diarrhea, hypotension and ocular hyperemia.
- Most common adverse reactions in pediatric patients (incidence ≥20%) are pyrexia, cough, diarrhea, rhinitis, abdominal pain, vomiting, headache, urticaria, nausea, rash, arthralgia, pruritus, fatigue and pharyngitis.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on findings from animal reproduction studies, Xenpozyme™ may cause embryo-fetal harm when administered to a pregnant female.
- Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Xenpozyme™ and any potential adverse effects on the breastfed infant from Xenpozyme™ or from the underlying maternal condition.
- Females and males with reproductive potential: Verify the pregnancy status in females of reproductive potential prior to initiating Xenpozyme™. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if Xenpozyme™ is discontinued.

NEW BIOSIMILAR PRODUCTS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
CIMERLI™ (RANIBIZUMAB-EQRN) INJECTION / COHERUS BIOSCIENCES INC	Ophthalmic agents	Treatment of patients with: [1] Neovascular (wet) age-related macular degeneration; [2] Macular edema following retinal vein occlusion; [3] Diabetic macular edema; [4] Diabetic retinopathy; [5] Myopic choroidal neovascularization	8/2/2022	Reference product: Lucentis™ (ranibizumab) injection Cimerli™ is the only biosimilar product interchangeable with Lucentis™ for all five indications. Commercial availability is planned for early October 2022. Orphan: No

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
CALQUENCE™ (ACALABRUTINIB MALEATE) TABLETS / ASTRAZENECA	Antineoplastics and adjunctive therapies	Treatment of adult patients with: [1] mantle cell lymphoma who have received at least one prior therapy; [2] chronic lymphocytic leukemia or small lymphocytic lymphoma	8/5/2022	New tablet formulation of Calquence™ has been approved for all current indications. The results from the ELEVATE-PLUS trials showed that the capsule and tablet formulations are bioequivalent, indicating the same efficacy and safety profile can be expected with the same dosing strength and schedule. The tablet can be taken with gastric acid-reducing agents unlike the capsules. Orphan: Yes
MIDAZOLAM HYDROCHLORIDE AUTOINJECTOR FOR INTRAMUSCULAR USE / RAFA LABS LTD.	Hypnotics/sedatives/ sleep disorder agents	Treatment of status epilepticus in adults	8/8/2022	Midazolam autoinjector is recommended to be administered by a trained personnel who have had adequate training in the recognition and treatment of status epilepticus and first aid/basic airway management. Orphan: No
AUVELITY™ (BUPROPION HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE) TABLETS / AXSOME	Antidepressants	Treatment of major depressive disorder (MDD) in adults	8/18/2022	Auvelity™ is a fixed-dose combination of dextromethorphan and bupropion that is given twice daily. It is the second FDA-approved N-methyl-D-aspartate (NMDA) receptor antagonist for the treatment of MDD. Orphan: No

NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	DATE	ADDITIONAL INFORMATION
IMBRUVICA™ (IBRUTINIB) ORAL SUSPENSION / PHARMACYCLICS LLC.	Antineoplastics and adjunctive therapies	Treatment of adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy	8/24/2022	This new formulation of Imbruvica™ allows for the pediatric population to have an approved treatment option for cGVHD, a life-threatening disease. Orphan: Yes
KONVOMEP™ (OMEPRAZOLE AND SODIUM BICARBONATE) ORAL SUSPENSION / AZURITY PHARMACEUTICALS, INC.	Ulcer drugs/antispasmodics/ anticholinergics	Treatment of adult patients with: [1] active benign gastric ulcer; [2] reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients	8/30/2022	Konvomep™ is an oral suspension that provides an alternative for patients with these conditions that are unable to take solid oral dosage forms. Orphan: No

NEW FIRST-TIME GENERIC APPROVALS

GENERIC NAME/DOSAGE FORM/STRENGTH AND MANUFACTURER	GENERIC FOR:	THERAPEUTIC CLASS	INDICATIONS	APPROVAL DATE
ESTRADIOL TRANSDERMAL GEL 0.1% / CHEMO RESEARCH S.L.	Divigel™	Estrogens	Menopausal vasomotor symptoms	8/10/2022
BREXPIPRAZOLE TABLETS 0.25MG, 0.5MG, 1MG, 2MG, 3MG AND 4MG / TEVA PHARMACEUTICALS USA INC.	Rexulti™	Antipsychotics/antimanic agents	Major depressive disorder	8/11/2022
CETRORELIX ACETATE POWDER FOR SUBCUTANEOUS INJECTION 0.25MG BASE/VIAL / AKORN OPERATING COMPANY LLC.	Cetrotide™	Endocrine and metabolic agents	Ovulation induction	8/12/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

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DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
NUBEQA™ (DAROLUTAMIDE) TABLETS / BAYER	Antineoplastics and adjunctive therapies	Treatment of adult patients with non-metastatic castration-resistant prostate cancer (mCRPC)	Treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel	8/5/2022
ENHERTU™ (FAM-TRASTUZUMAB DERUXTECAN-NXKI) INJECTION / ASTRAZENECA AND DAIICHI SANKYO	Antineoplastics and adjunctive therapies	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either: in the metastatic setting, or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy	[1] Treatment of adult patients with unresetectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing chemotherapy; [2] Treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy	8/5/2022, 8/11/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
MYFEMBREE™ (RELUGOLIX, ESTRADIOL AND NORETHINDRONE ACETATE) TABLETS / MYOVANT SCIENCES AND PFIZER INC.	Estrogens	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	Management of moderate to severe pain associated with endometriosis	8/5/2022
XOFLUZA™ (BALOXAVIR MARBOXIL) TABLETS AND SUSPENSION / GENENTECH INC	Antivirals	[1] Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are: otherwise healthy, or at high risk of developing influenza-related complications; [2] Post-exposure prophylaxis of influenza in patients 12 years of age and older following contact with an individual who has influenza	Treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours and who are: otherwise healthy adults and pediatric patients 5 years of age and older	8/11/2022
MIRENA™ (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM) / BAYER	Contraceptives	[1] Prevention of pregnancy for up to 5 years; [2] Treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to 5 years	Prevention of pregnancy for up to 8 years	8/12/2022

NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
IMBRUVICA™ (IBRUTINIB) CAPSULES, TABLETS AND SUSPENSION / PHARMACYCLICS LCC	Antineoplastics and adjunctive therapies	Treatment of mantle cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, Waldenström's macroglobulinemia, marginal zone lymphoma	Treatment of adult and pediatric patients age 1 year and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy	8/24/2022
PEMAZYRE™ (PEMIGATINIB) TABLETS / INCYTE	Antineoplastics and adjunctive therapies	Treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion	Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement	8/26/2022

PIPELINE

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PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	ADDITIONAL INFORMATION	IMPACT
OMIDUBICEL / GAMIDA CELL LTD.	8/1/2022	Treatment of patients with blood cancers in need of an allogeneic hematopoietic stem cell transplant	Omidubicel is a first-in-class, advanced nicotinamide (NAM)-enabled stem cell therapy candidate in development for the treatment of patients with blood cancers in need of bone marrow transplant. The FDA granted Priority Review for the BLA and has set a PDUFA target action date of January 30, 2023. BLA accepted.	High high
MOMELOTINIB / GLAXOSMITHKLINE	8/17/2022	Treatment of myelofibrosis in symptomatic anemic patients previously treated with an approved janus kinase inhibitor (JAK) inhibitor	Momelotinib is a potential new medication with a differentiated mechanism of action with inhibitory ability along 3 key signaling pathways: JAK1, JAK2 and activin A receptor type 1 (ACVR1). The FDA has assigned a PDUFA of June 16, 2023. NDA accepted.	High
FEZOLINETANT / ASTELLAS PHARMA, INC.	8/18/2022	Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause	Fezolinetant is an investigational nonhormonal selective neurokinin 3 (NK3) receptor antagonist. The PDUFA target action date is February 22, 2023. NDA accepted.	Moderate
ROLUPERIDONE / MINERVA NEUROSCIENCES, INC.	8/22/2022	Treatment of negative symptoms in patients with schizophrenia	Currently there is no approved drugs in the United States for the treatment of the negative symptoms of schizophrenia. The roluperidone clinical development program aims to provide effective treatment for a significant unmet medical need. NDA submitted.	Moderate
IPX203 / AMNEAL PHARMACEUTICALS, INC.	8/31/2022	Treatment of Parkinson's disease (PD)	IPX203 is a novel, oral formulation of carbidopa/levodopa extended-release capsules. Based on the RISE-PD clinical trial, IPX203 demonstrated significantly less "off" time and more "good on" time during the day. NDA submitted.	Moderate

REFERENCES

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