

## New Drug Approvals

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
12/20/2019	<b>Enhertu®</b>	fam-trastuzumab-deruxtecan-nxki	100 mg/vial	Intravenous Infusion	Breast Cancer	12/26/19
11/20/2019	<b>Givlaari®</b>	givosiran	189 mg/mL	Subcutaneous Injection	Acute Hepatic Porphyria	12/15/19
12/18/2019	<b>Padcev®</b>	enfortumab vedotin-ejfv	20 mg, 30 mg vials	Intravenous Infusion	Bladder Cancer	12/18/19
12/12/19	<b>Vyondys 53®</b>	golodirsen	100 mg/2 mL vial	Intravenous Infusion	Duchenne Muscular Dystrophy	12/16/19

## Newly Available Brand Drugs

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
5/31/18	Consensi®	amlodipine besylate/ celecoxib	2.5 mg/200 mg 5 mg/200 mg 10 mg/200 mg	Tablet	Hypertension and Osteoarthritis	12/18/19

## First Time Generic Approvals

Label Name	Generic Name	Strength	Dosage Form	Use
Carafate®	sucralfate	1 gm/10 mL	Suspension	Stomach Ulcer
Afinitor®	everolimus	2.5 mg, 5 mg, 7.5 mg	Tablet	Kidney, Breast & Brain Cancer

\*Specialty medications are listed in **bold** type

Isordil®	isosorbide dinitrate	40 mg	Tablet	Chest Pain Prevention
Nuvaring®	etonogestrel-ethinyl estradiol vaginal ring	0.120-0.015 mg per 24 hours	Vaginal Ring	Birth Control
Travatan Z®	travaprost	0.004%	Ophthalmic Solution	Glaucoma

## New Uses

Drug Name or Class	Previous Use	New Use
<b>Lynparza® (olaparib)</b>	Ovarian cancer	Certain types of pancreatic cancer
<b>Tecentriq® (atezolizumab)</b>	Bladder cancer	Non-Small Cell Lung Cancer
Vascepa® (cosapent ethyl)	To reduce elevated triglycerides	Add to statins to reduce complications from high triglycerides
<b>Xeljanz XR® (tofacitinib citrate)</b>	Rheumatoid arthritis	Ulcerative colitis
<b>Xtandi® (enzalutamide)</b>	Prostate cancer	Additional form of prostate cancer

## Safety Updates and Recalls

Drug Name or Class	Use	Description	Impact
ranitidine tablets by Glenmark	Reduce stomach acid	Recalled all unexpired lots due to possible presence of N-nitrosodimethylamine (NDMA) impurity	Consumers advised to discontinue use and consult with health care provider about treatment options.
levetiracetam oral solution by Lannett	Prevent seizures	Recalled due to possible contamination with <i>Bacillus subtilis</i> .	Consumers advised to contact their pharmacy to return product.

\*Specialty medications are listed in **bold** type

gabapentin and pregabalin	To prevent seizures and nerve pain	Serious breathing difficulties in patients with respiratory risk factors identified.	Consumers advised to contact their healthcare provider if they develop respiratory problems.
mirtazapine by Aurobindo	Antidepressant	One lot number recalled due to a label error on drug strength.	Consumers advised to contact healthcare provider if they experienced any problems related to this drug product.

References:

1. U.S. Food and Drug Administration. Novel Drug Approvals for 2019. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019>
2. U.S. Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>
3. <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

