

## New Drug Approvals

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
11/5/2019	<b>Ziextenzo</b> <sup>®</sup>	pegfilgrastim-bmez	6 mg/0.6 mL	Subcutaneous	Blood Stimulator	11/7/2019
11/8/2019	<b>Reblozyl</b> <sup>®</sup>	luspatercept-aamt	25 mg/75 mg	Subcutaneous	Blood Stimulator	11/13/2019
11/14/2019	<b>Brukinsa</b> <sup>®</sup>	zanubrutinib	80 mg	Capsule	Blood Cancer	11/15/2019
11/15/2019	<b>Adakveo</b> <sup>®</sup>	crizanlizumab-tmca	100 mg/10 mL	IV Solution	Sickle Cell Disease	11/20/2019
11/25/2019	Oxbryta <sup>®</sup>	voxelotor	500 mg	Tablet	Sickle Cell Disease	11/25/2019

## Newly Available Brand Drugs

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
10/21/2019	Biorphen <sup>®</sup>	phenylephrine	0.1mg/ml	injection	Low blood pressure during surgery	11/1/2019
07/03/2019	<b>Xembify</b> <sup>®</sup>	immune globulin subcutaneous human	20%	Subcutaneous injection	Primary Immunodeficiency	11/1/2019
10/29/2019	<b>Vumerity</b> <sup>®</sup>	diroximel fumarate	231 mg	Capsule	Multiple Sclerosis	11/1/2019
08/14/2019	Pretomanid <sup>®</sup>	pretomanid	200 mg	Tablet	Antibiotic	11/7/2019

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

11/28/2018	<b>Truxima®</b>	rituximab-abbs	100 mg/10 mL 500 mg/50 mL	IV Solution	Blood Cancer/ Inflammatory Conditions	11/9/2019
<b>10/4/2019</b>	<b>Bortezomib®</b>	bortezomib	3.5 mg	IV Injection	Blood Cancer	11/14/2019
04/03/2019	<b>Asceniv®</b>	Immune globulin IV [human]-slra	5 GM/50 mL	IV Solution	Immuno-deficiency	10/17/2019
10/21/2019	Amzeeq®	minocycline	4%	Foam	Acne	11/22/2019
12/01/2017	<b>Ogivri®</b>	trastuzumab-dkst	150 mg 420 mg	IV Solution	Breast Cancer	11/29/2019

## First Time Generic Approvals

Label Name	Generic Name	Strength	Dosage Form	Use
Jadenu®	deferasirox	90 mg	Tablet	Chronic Iron Overload
Jadenu®	deferasirox	360 mg	Tablet	Chronic Iron Overload
Apriso®	mesalamine	0.375 gm	Capsule	Ulcerative Colitis

## New Uses

Drug Name or Class	Previous Use	New Use
Calquence® (acalabrutinib)	Mantle cell lymphoma who have received one prior therapy	Chronic lymphocytic leukemia or small lymphocytic lymphoma

## Safety Updates and Recalls

Drug Name or Class	Use	Description	Impact
ranitidine	Stomach acid reducer	Voluntary recall due to potential NDMA amounts above levels established by the FDA	Primarily Over the Counter

### 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>. Updated December 3, 2019. Accessed December 3, 2019.
2. U.S. Food and Drug Administration. Drugs @FDA: FDA Approved Drug Products. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/>. Updated December 3, 2019. Accessed December 3, 2019.